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WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WHEN: Tuesday, July 12, 2011
9 a.m.–12:30 p.m.

WHERE: Office of the Federal Register
Conference Room, Suite 700
800 North Capitol Street, NW.
Washington, DC 20002

RESERVATIONS: (202) 741–6008

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DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Part 210

RIN 0584–AE11

National School Lunch Program: School Food Service Account Revenue Amendments Related to the Healthy, Hunger-Free Kids Act of 2010

AGENCY: Food and Nutrition Service, USDA.

ACTION: Interim rule.

SUMMARY: This rule amends National School Lunch Program (NSLP) regulations to conform to requirements contained in the Healthy, Hunger-Free Kids Act of 2010 (Pub. L. 111–296) regarding equity in school lunch pricing and revenue from nonprogram foods sold in schools. This rule requires school food authorities (SFAs) participating in the NSLP to provide the same level of financial support for lunches served to students who are not eligible for free or reduced price lunches as is provided for lunches served to students eligible for free lunches. This rule also requires that all food sold in a school and purchased with funds from the nonprofit school food service account, other than meals and supplements reimbursed by the Department of Agriculture, must generate revenue at least equal to the cost of such foods.

DATES: *Effective date:* This rule is effective on July 1, 2011.

Comment dates: Comments on rule provisions: Mailed comments on the provisions in this rule must be postmarked on or before September 15, 2011; e-mailed or faxed comments must be submitted by 11:59 p.m. on September 15, 2011; and hand-delivered comments must be received by 5 p.m. September 15, 2011 to be assured of consideration.

Comments on Paperwork Reduction Act requirements: Comments on the information collection requirements associated with this rule must be received by August 16, 2011.

ADDRESSES: The Food and Nutrition Service (FNS) invites interested persons to submit comments on this interim rule. Comments may be submitted by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the online instructions for submitting comments.
- *Fax:* (703) 305–2879, attention Julie Brewer.
- *Mail:* Julie Brewer, Chief, Policy and Program Development Branch, Child Nutrition Division, Food and Nutrition Service, Department of Agriculture, 3101 Park Center Drive, Room 640, Alexandria, Virginia 22302–1594.
- *Hand Delivery or Courier:* Deliver comments to 3101 Park Center Drive, Room 640, Alexandria, Virginia 22302–1594, during normal business hours of 8:30 a.m.–5 p.m.

All submissions received in response to this interim rule will be included in the record and will be available to the public. Please be advised that the substance of the comments and the identity of the individuals or entities submitting comments will be subject to public disclosure. FNS may also make the comments publicly available by posting a copy of all comments on *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Julie Brewer, Chief, Policy and Program Development Branch, Child Nutrition Division, Food and Nutrition Service, 3101 Park Center Drive, Alexandria, Virginia 22302, or by telephone at (703) 305–2590.

SUPPLEMENTARY INFORMATION:

I. Discussion of Interim Rule

This interim rule promulgates the provisions from sections 205 and 206 of Public Law 111–296, the Healthy, Hunger-Free Kids Act of 2010 (the Act). Section 205 amended section 12 of the Richard B. Russell National School Lunch Act (NSLA) (42 U.S.C. 1760) by adding a new subsection (p), ''Price for a Paid Lunch'' which addresses, for the first time, requirements for SFAs in establishing prices for paid reimbursable lunches (hereinafter called paid lunches). The amendments made by Section 205 provide SFAs with some flexibility in phasing-in any increases in paid lunch prices and in using non-Federal funds to supplement paid lunch revenue to enable them to maintain lower prices for paid lunches. There is also a requirement in section 205 requiring the Department of Agriculture (USDA) to establish procedures to annually collect and publish the paid lunch prices charged by SFAs. These provisions do not apply to the revenue from or prices charged for either afterschool snacks or for school breakfasts offered in 7 CFR part 220.

Section 206 of Public Law 111–296 amended section 12 of the NSLA by adding a paragraph (q), ''Nonprogram Food Sales.'' This provision addresses food sold in schools outside of reimbursable meals and meal supplements, which is purchased with funds from the nonprofit school food service account. Included are foods sold in competition with the reimbursable meal programs as provided in section 10 of the Child Nutrition Act (42 U.S.C. 1779). The law now requires that the proportion of total school food service revenue provided by the sale of nonprogram foods to the total revenue of the school food service account be equal to or greater than the proportion of total food costs associated with obtaining nonprogram foods to the total costs associated with obtaining program and nonprogram foods from the account.

FNS currently has no regulatory requirements regarding pricing of paid lunches, the amount of revenue generated by paid lunches or on the revenue generated by selling nonprogram foods. Following is a discussion of the Act's provisions and the conforming regulatory amendments being made in response. In addition to this interim rule, USDA will issue guidance and provide technical assistance as needed to assist SFAs and State agencies in complying with these new provisions.

Reimbursement Levels

There are three levels of Federal cash reimbursement for lunches, breakfasts, and meal supplements served to children in schools that participate in the NSLP and the School Breakfast Program (SBP). Schools receive the highest amount of reimbursement for meals served to students certified

eligible for free meals, a lesser amount of reimbursement for students certified eligible for reduced price meals, and the lowest reimbursement for meals served to students who are not certified eligible for free or reduced price meals (*i.e.,* paid meals).

Children in families with income at or below 130 percent of the income poverty guidelines prescribed by the U.S. Department of Health and Human Services are eligible for free meals. In addition, children who are categorically eligible because they receive other assistance (for example, receipt of Supplemental Nutrition Assistance Program benefits or enrollment in Head Start) are eligible for free meals. Children in families with income between 130 and 185 percent of the income poverty guidelines are eligible for reduced price meals. The maximum charge for a reduced price lunch is established in section 9(b)(9) of the NSLA and cannot exceed 40 cents. A maximum reduced price charge is also established for afterschool snacks and school breakfasts. Any child not certified for a free or reduced price meal must pay the meal price set by the school food authority.

Revenue From Paid Lunches

The Act defines the term paid lunch as a reimbursable lunch served to students who are not certified to receive free or reduced price meals. NSLP regulations at 7 CFR 210.2 are amended to incorporate this definition.

The Act requires SFAs to evaluate the prices they charge for paid lunches in relation to the Federal paid and free reimbursement rates. For each school year, beginning July 1, 2011, SFAs must annually establish paid meal prices in accordance with the procedures in the Act. Those procedures are contained in a new paragraph (e) added to § 210.14. In addition, § 210.19(a)(2) is amended to require each State agency administering the NSLP to ensure that SFAs comply with the procedures. FNS developed a fact sheet to help schools understand the procedures. The Equity in School Lunch Pricing Fact Sheet can be found at *http://www.fns.usda.gov/cnd/Governance/Legislation/Pricing_Equity_Facts.pdf.* A summary of the procedures follows.

The Act requires SFAs to determine the average price charged for paid lunches in the previous school year (for the school year beginning July 1, 2011, the previous school year is the school year beginning July 1, 2010). The school food authority must determine the average price charged based on the total number of paid lunches claimed at each price in the school food authority for the month of October of the prior school year. October data is used because it conforms to current data collection practices in the NSLP and is representative of the number of days of operation and number of meals served. Choosing a later month in the school year could unnecessarily delay pricing decisions by SFAs.

Calculating the average lunch price based on the number of meals claimed at each price across the school food authority most accurately indicates the revenue generated from paid lunches, which is the intent of Section 205. Requirements for determining the average paid lunch price are in § 210.14(e).

Once this average is determined, the school food authority must calculate the difference between the free lunch per meal reimbursement rate and the paid lunch per meal reimbursement rate in effect for the previous school year (the ''reimbursement difference''). The lunch reimbursement rates used in this calculation must be those received by the school food authority (*e.g.,* taking into account locality (contiguous United States, Alaska or Hawaii) and additional Federal per meal reimbursement when 60 percent of lunches served in the second preceding year were served free or reduced price).

If a school food authority's average price of a paid lunch is equal to or greater than the reimbursement difference, the school food authority is not required to make any adjustments in lunch prices or to add revenue as long as it continues to charge an average price that is not less than the amount of the reimbursement difference. Further, the school food authority has the option to round the average price down to the nearest five cents. A school food authority may reduce its average price of a paid lunch if an equivalent amount of financial support is added from non-Federal sources of funds (other than in-kind contributions). These provisions are added by this rule at § 210.14(e)(2), (e)(4) and (e)(5).

If a school food authority's average price of a paid lunch is less than the reimbursement difference, the school food authority must increase prices for paid lunches, as described in § 210.14(e)(3), or add financial support from non-Federal sources to the school food service account. To determine the price increase, the school food authority must establish an average price for a paid lunch that is not less than the price charged in the previous school year as adjusted by a percentage equal to the sum obtained by adding two percent and the percentage change in the Consumer Price Index for All Urban Consumers (food away from home index) used to increase the Federal reimbursement rate, as set forth in the annual notice announcing adjustments to the national average payments issued by USDA in the **Federal Register** on or about July 1 of each year. SFAs should refer to the **Federal Register** notice from the prior July to obtain the Consumer Price Index. For determining increases required for the school year beginning July 1, 2011, SFAs should use the notice published on July 19, 2010 (75 FR 41796, ''National School Lunch, Special Milk, and School Breakfast Programs, National Average Payments/Maximum Reimbursement Rates'').

Section 205 of the Act amended the NSLA to permit SFAs to round the adjusted average price for a paid lunch down to the nearest five cents following that calculation. Additionally, SFAs are not required to raise prices more than 10 cents annually. SFAs may, at their discretion, increase prices for paid lunches by more than 10 cents. In lieu of increasing prices, a school food authority may reduce the average price of a paid lunch if an equivalent amount of financial support is added from non-Federal sources of funds (other than in-kind contributions). These provisions are found at § 210.14(e)(4) and (e)(5).

If a school food authority chooses to contribute financial support from non-Federal sources in lieu of raising prices for paid lunches, Section 12(p) of the NSLA specifically excludes in-kind contributions and revenue from foods sold in competition with reimbursable meals from qualifying as support from non-Federal sources for this purpose. This rule codifies those prohibitions in § 210.14(e)(5)(ii). In addition, § 210.14(e)(5)(iii) requires that financial support from non-Federal sources must be cash for direct support for paid lunches, including but not limited to per-lunch reimbursements for paid meals provided by States, counties, school districts and others; funds provided by organizations, such as school-related or community groups to support paid lunches; any portion of State revenue matching funds that exceeds the minimum requirement established in 7 CFR 210.17 and is provided for paid lunches; and a proportion attributable to paid lunches from direct payments made from school district funds to support the lunch service. Some examples of unallowable non-Federal support would include any payments, including additional per-meal reimbursements, provided to the school food authority for support of the SBP or other Child Nutrition Program; any payments, including additional per-meal reimbursements, provided

specifically to support free and reduced price meals; and any in-kind contributions converted to direct cash expenditures after July 1, 2011.

In recognition of the short timeframes for implementation, this interim rule allows SFAs to count any non-Federal cash contribution, except for in-kind contributions and revenues from foods sold in competition with reimbursable meals, for School Year 2011–2012 only. This limited allowance is established by this rule in § 210.14(e)(6)(iii). In addition, State agencies should focus their efforts in the initial year of implementation to providing SFAs with technical assistance to ensure compliance.

We also recognize that this rule was published after many SFAs have made pricing decisions for School Year 2011–2012. Therefore, those SFAs that can demonstrate that they raised their prices and met the non-Federal cash contribution allowance described above for School Year 2011–2012, may count any non-Federal cash contribution, except for in-kind contributions and revenues from foods sold in competition with reimbursable meals, toward the revenue requirements for School Year 2012–2013. FNS will issue guidance on how adjustments to the School Year 2012–2013 requirement will be determined in these situations.

If an SFA with an average price lower than the reimbursement difference is not required in any school year to increase its average price, due to low-inflation and rounding rules, the school food authority must use the unrounded average price as the basis for calculations for the next school year. This approach helps ensure that over time the appropriate additional revenues are provided to support paid lunches. Also, if a school food authority has an average price lower than the reimbursement difference and chooses in any school year to increase paid lunch prices more than is required, the amount attributable to the SFAs discretionary additional increase may be carried forward to the next school year(s) to meet the paid lunch pricing requirements. SFAs must keep sufficient records to document and carry forward the average price calculations. These requirements are established by this interim rule in § 210.14(e)(6)(i) and (e)(6)(ii).

As amended by Section 205 of the Act, Section 12(p) of the NSLA also requires that USDA establish procedures to annually collect and publish the paid meal prices charged by SFAs. While the statute refers to the collection of paid meal prices, this interim rule requires that SFAs report only paid lunch prices. This approach minimizes reporting burden on SFAs and State agencies, and is consistent with the other requirements of Section 205, which all pertain to paid lunches. USDA invites commenters to provide input on whether this approach is appropriate, or whether reporting should be expanded to include prices charged for paid breakfasts. The new reporting requirements for SFAs and State agencies, respectively, are contained in amendments to § 210.15(a) and § 210.20(a) made by this rule. This annual report would coincide with other reporting for the month of October.

Revenue From Nonprogram Foods

NSLP regulations are amended by this interim rule to include the new statutory definition of nonprogram food in a new paragraph at § 210.14(f). Section 12(p) of the NSLA as amended by the Act defines nonprogram food as ''food sold in a participating school other than a reimbursable meal provided'' under the NSLA or the Child Nutrition Act of 1966 (42 U.S.C. 1771 *et seq.*) and which is ''purchased using funds from the nonprofit school food service account of the school food authority * * *.'' The definition also specifically identifies as nonprogram food ''food that is sold in competition with a program established under'' the NSLA or the Child Nutrition Act of 1966. Nonprogram beverages are also considered nonprogram food.

Effective July 1, 2011, Section 12(q) of the NSLA, as amended by Section 206 of the Act, requires that the proportion of total school food service revenue provided by the sale of nonprogram foods to the total revenue of the school food service account shall be equal to or greater than the proportion of total food costs associated with obtaining nonprogram foods to the total costs associated with obtaining program and nonprogram foods from the account. The Act also amended the NSLA to require that all revenue from the sale of nonprogram foods accrue to the nonprofit school food service account of a participating SFA. These revenue and accrual requirements are incorporated into NSLP regulations in this interim rule by adding a new paragraph (f) to § 210.14.

Technical Amendments

The definition of ''Nonprofit school food service account'' in § 210.2 is revised by adding references to the new procedures in § 210.14(e) and (f) regarding revenue. In addition, the requirements in § 210.9(b) for the agreement between the State agency and SFAs are amended by adding a reference to these new provisions. Other amendments are made to § 210.15(b) and § 210.20(b) (for SFAs and State agencies, respectively) to provide for the records that must be retained to document compliance with the newly established provisions in § 210.14(e) and (f).

II. Procedural Matters

Issuance of an Interim Rule and Date of Effectiveness

USDA, under the provisions of the Administrative Procedure Act at 5 U.S.C. 553(b)(B), finds for good cause that use of prior notice and comment procedures for issuing this interim rule is impracticable. Sections 205 and 206 of the Healthy, Hunger-Free Kids Act of 2010, Public Law 111–296, enacted on December 13, 2010, requires implementation of those provisions on July 1, 2011. USDA concludes that there is insufficient time to issue a proposed rule prior to the statutory implementation deadline. As a result, this interim rule is necessary to comply with the requirements of Sections 205 and 206 of Public Law 111–296 and ensure that those provisions are implemented and effected by State agencies and SFAs on July 1, 2011.

For the same reason of impracticability due to the statutory implementation deadline, under the provisions of the Congressional Review Act at 5 U.S.C. 808(2), USDA for good cause is issuing this rule with an effective date of July 1, 2011, which is less than the latest of the 60-day delay in effective date prior to, either the submission of a report to Congress, or after publication of the rule in the **Federal Register**, as required under section 801(a)(3)(A) of the Congressional Review Act.

USDA invites public comment on this interim rule. USDA will consider amendments to the rule based on comments submitted during the 90-day comment period. The agency will address comments and affirm or amend the interim rule in a final rule.

Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of

quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This interim rule has been designated an ''economically significant regulatory action'' under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

Regulatory Impact Analysis

As required for all rules that have been designated as significant by the Office of Management and Budget, the following Regulatory Impact Analysis (RIA) was developed for this interim rule: It is included as Appendix A at the end of this document.

Initial Regulatory Impact Analysis

Title: National School Lunch Program: School Food Service Account Revenue Amendments Related to the Healthy, Hunger-Free Kids Act of 2010

Nature of Action: Interim Rule

Need for Action: Codifies provisions of Section 205 and 206 of the Healthy, Hunger-Free Kids Act of 2010 in regulation for the National School Lunch Program (NSLP) and the School Breakfast Program (SBP). These provisions set requirements for student payments or other non-Federal revenues to ensure that the paid meals and à la carte foods generate a level of total revenue for local schools that is comparable to the revenue generated by USDA payments for free meals. In the aggregate, these requirements provide additional revenue to support nutritious and healthful meals for all students.

Affected Parties: Those involved in the operation and administration of the NSLP and SBP, including State education agencies, local school food authorities, schools, students, and the food production, distribution and service industry.

Background

The National School Lunch Program (NSLP) is available to over 50 million children each school day; an average of 31.6 million children per day ate a reimbursable lunch in fiscal year (FY) 2010. The School Breakfast Program (SBP) served an average of 11.6 million children daily. Schools that participate in the NSLP and SBP receive Federal reimbursement and USDA Foods (donated commodities) for lunches and breakfasts that meet program requirements.

The level of Federal support provided varies by the household income of the participating child, with the highest payments for meals provided free to the children with incomes below 130 percent of poverty, a lower amount for meals provided at reduced price to those with incomes between 130 percent and 185 percent of poverty, and a small amount for meals provided to higher-income students (paid meals). Recent data on the number of participating students in each category is presented in Table 1.

TABLE 1—NSLP/SBP AVERAGE DAILY PARTICIPATION, FY 2010

Program	Children (millions) receiving			
	Free meals	Reduced-price meals	Paid meals	Total
NSLP	17.4	3.0	11.1	31.6
SBP	8.7	1.0	1.9	11.6

While USDA subsidizes paid meals to cover part of the cost of production, local communities and State governments cover the remainder of production costs, and have the flexibility to do so from any non-Federal source—student payments, State subsidies, or local funds. Most schools depend on student payments for paid school meals for a part of their revenue. Based on data collected by USDA from a national sample of schools the full price of lunch for school year 2004–05 was $1.60 on average, and the most common (modal) price was $1.50. The full price ranged from $0.65 to $3.00; on average, it was higher in secondary schools than in elementary schools, and higher in large schools than in smaller ones. The full price was also higher in suburban and lower-poverty schools than in schools not in those categories.[1]

However, the revenue received by schools for paid meals is often too low to cover the cost of those meals. An examination of school meal production costs shows that it cost about $2.28 to produce a school lunch in school year 2005–06.[2] While USDA's reimbursement for a free meal ($2.50), including cash and commodity foods, was about 9 percent higher than reported production costs, total revenues from a paid meal—including the price charged to families ($1.60), USDA's cash reimbursement ($0.21), and the commodity entitlement ($0.175)—was 13 percent less. Total revenue from a paid meal represented only 80 percent of the value of Federal support for a free meal. Funding paid meals below the cost of their production effectively shifts Federal subsidies designed for the lowest-income children to others. It can negatively affect all children by limiting the funds available to provide nutritious meals.

Schools are also authorized to prepare and sell non-program foods and meals during the meal period, as long as the revenue is provided to the food service program account. Revenues from non-reimbursable foods fell short of the cost of producing them by an average of about 29 percent in SY 2005–06.[3] Combining reimbursable meals and other foods, reported costs were essentially equal to revenues (101 percent). The average SFA used revenues from reimbursable meals to offset the cost of producing à la carte and other non-reimbursable food items.

The provisions in Section 205 and 206 of the Healthy, Hunger-Free Kids Act of 2010 set requirements for student payments or other non-Federal revenues to ensure that the paid meals and à la carte foods generate a level of total revenue for local schools that is comparable to the revenue generated by USDA payments for free meals. In the aggregate, these requirements provide additional revenue to support nutritious and healthful meals for all students.

I. Summary of Requirements

This interim rule would codify non-discretionary aspects of the following provisions of the Healthy, Hunger-Free Kids Act (Pub. L. 111–296; the Act) under 7 CFR Part 210:

• Section 205 of the Act requires school food authorities (SFAs) participating in the NSLP to establish a price for paid lunches that is on average equal to the difference between free lunch reimbursement and paid lunch reimbursement—the Section 11 reimbursement.[4] An SFA charging less than

[1] U.S. Department of Agriculture, Food and Nutrition Service (2007). *School Nutrition Dietary Assessment Study–III* (multiple volumes), Table II.11. (SNDA–III) Report prepared by Mathematica Policy Research. Available at *www.fns.usda.gov/ora/*.

[2] U.S. Department of Agriculture, Food and Nutrition Service (2008). *School Lunch and Breakfast Cost Study–II* p. ii. (SLBCS–II) Report prepared by Abt Associates, Inc. Available at *www.fns.usda.gov/ora/*.

[3] *School Lunch and Breakfast Cost Study–II.* The conclusion that schools price à la carte foods below their cost may seem counter intuitive. Some school meal providers may see à la carte food sales as a source of additional revenue for relatively little added cost. Many schools attribute overhead and labor costs primarily to reimbursable meal production and do not recognize that such costs support all meal services, and should be allocated in accordance with generally accepted accounting principles. The research cited here allocates the shared cost of overhead and labor that supports both reimbursable and à la carte meal production proportionately across these services.

[4] Federal reimbursement for NSLP lunches is the sum of the values specified in Section 4 and Section 11 of the Richard B. Russell National School Lunch Act (NSLA). A Section 4 reimbursement is distributed to schools for all program lunches. Lunches served to students eligible for free or reduced-price school meals receive both a Section 4 and a Section 11 reimbursement. SFAs must charge students a price equal to the Federal Section 11 rate (or contribute an equivalent sum from State or local sources) for total per meal revenue from

the required amount is required to gradually increase the paid lunch price. The maximum annual average required price increase is limited to not more than 10 cents for any SFA. In lieu of increasing the paid lunch price, an SFA may choose to cover the difference in revenue with non-Federal funds. The Act requires the Secretary to develop regulations to carry out this section, including collecting and publishing the prices that SFAs charge for paid meals annually.

- Section 206 of the Act requires that all food sold in a school and purchased with funds from the nonprofit school food service, other than a reimbursable meal provided under the National School Lunch and School Breakfast Programs, must generate revenue at least equal to the cost of such foods.
- The Act makes these provisions effective on July 1, 2011.

II. Cost/Benefit Assessment

A. Summary of Anticipated Impacts

While the rule will have little or no direct impact on Federal expenditures, it will require the contribution of additional funds to the non-profit school meals program account of participating SFAs:

- For the Section 205 provisions, these funds could be derived from a combination of sources, including program participants who receive paid lunches and State and local governments. State agencies administering the NSLP and SFAs have flexibility to determine which of these sources will contribute revenues to meet the requirements, and in what proportion.
- For the Section 206 provisions, funds will derive from increased prices for à la carte foods and beverages, and thus will all be contributed by the families of school children who choose to purchase these products.
- School food authorities will be required to incur additional administrative costs to implement the rule, reflecting the need to review food costs and revenue records, adjust à la carte prices, and report the prices charged for paid meals.

In addition, we expect that the rule will have Federal budgetary effects as a result of indirect impacts on participation in the school meals programs. To the extent that the Section 205 provisions result in increased prices for paid meals, NSLP participation may be lower than otherwise projected as students choose not to eat, to bring lunch from home, or to acquire it from other sources, resulting in Federal savings in paid reimbursements. To the extent that price increases for à la carte foods result from Section 206 provisions, school children and their families could choose to substitute reimbursable school meals for purchases of à la carte foods, resulting in increased participation and higher Federal meal reimbursements.

Estimates of the overall impacts of the rule, including both changes in SFA revenues and Federal costs, are presented in Table 2. For purposes of this analysis, the rule is assumed to take effect on July 1, 2011, the start of school year (SY) 2011–2012.

TABLE 2—PROJECTED IMPACT OF RULE

[All figures in millions]

	Fiscal year					
	2011	2012	2013	2014	2015	Total
SFA Revenues: [5]						
Section 205	*	$9	$66	$104	$144	$323
Section 206 (non-reimbursable food sales)	175	1,148	1,237	1,320	1,443	5,324
Section 206 (reimbursable meal sales)	64	416	466	484	510	1,939
Administrative Costs	−5	−9	−10	−10	−10	−44
Net SFA Revenues	$234	$1,564	$1,760	$1,898	$2,086	$7,542
Federal Costs:						
Section 205 (NSLP)	*	*	−$3	−$7	−$10	−$20
Section 206 (NSLP)	46	297	338	348	362	1,392
Total Federal Cost	$46	$297	$335	$342	$352	$1,372
Participation Effects:						
Net change in number of lunches served	25	155	151	146	143	620
Net change in number of reimbursable breakfasts served	**	**	**	**	**	**
Baseline Federal Cost of NSLP	$11,521	$12,049	$12,300	$12,415	$12,534	$60,819
Number of lunches	5,387	5,465	5,531	5,586	5,631	27,600
Baseline Federal Cost of SBP	$3,115	$3,338	$3,470	$3,557	$3,629	$17,108
Number of breakfasts	2,091	2,187	2,253	2,298	2,332	11,160

* Equals less than $500,000.
* Small increase.

Note: Entries in tables throughout this analysis may not sum to totals due to rounding.

B. SFA Impacts

1. Revenue from Paid Lunches (Section 205)

Section 205 directs SFAs to take steps to equalize the per meal revenue generated by reimbursable paid lunches and free lunches, thus targeting SFAs whose non-Federal per meal revenue is less than the Section 11 reimbursement for lunches (or $2.46 for school year 2011–12). It permits State and local governments to share, or assume fully, the direct economic impact. Although we cannot anticipate how States, local governments, and SFAs will share the responsibility for raising per-meal receipts for paid lunches, we have estimated the total amount of non-Federal revenue needed to meet the requirements compared to the latest observed levels.

We identified schools whose paid meal prices fell short of the Section 11 reimbursement in school year 2004–2005 using data collected in the third School Nutrition Dietary Assessment Study (SNDA–III).[6] This study collected data from a nationally representative sample of 129 SFAs, 398 schools in those SFAs, and 2,314 children attending those schools (and their parents) in School Year 2004–05. SFA directors provided information on district-wide policies (such as menu-planning

paid meals to match total per meal revenue from free meals. In school year 2010–11, schools earned $2.72 for each free meal, $2.32 for each reduced price meal, and $0.26 for each paid meal.

[5] SFA revenues derive from increases in student payments for paid lunches and à la carte foods, additional contributions to SFA accounts from State or local governments, and higher USDA reimbursements for an expected increase in participation in the reimbursable meals programs.

[6] Because paid lunch price is a school-level variable on the SNDA–III dataset rather than an SFA-level variable, we perform our analysis at the school level. We developed our estimate as though the responsibility for raising paid lunch prices or finding alternate non-federal revenue rests with individual schools. In practice, Section 205 provides SFAs the flexibility to set prices at individual schools however they see fit, as long as the weighted average price across the SFA meets the Section 205 target. For purposes of an aggregate cost estimate, a school-level analysis and a weighted average SFA-level analysis should give comparable results.

systems) and operations (such as food purchasing). As part of the study, school foodservice managers provided information regarding their school's foodservice operations, including paid meal prices, and policies on competitive foods available in or near the foodservice area.

To estimate the number of schools that charge less than the Section 11 reimbursement in FY 2011, we assumed that the schools' paid meal prices kept pace with inflation adjustments in the lunch reimbursement since SY 2004–2005. For this analysis, the schools whose prices fall short of the Section 11 rate today are the schools that would have fallen short of a comparable regulatory target in SY 2004–2005.[7]

• Throughout the forecast period we assume annual increases in the Section 11 rate equal to the projected growth in the Food Away From Home series of the Consumer Price Index.[8] We also assume that baseline paid meal prices would have matched the annual growth in the Section 11 rate. These baseline prices represent what schools would have charged for reimbursable paid meals in the absence of the interim rule.

• The interim rule requires annual price increases (or equivalent non-Federal revenues) of 2 percent above the inflation rate until prices meet the Section 11 target. The rule also allows for annual rounding of adjusted prices to the next lower 5 cents and limits required price increases to no more than 10 cents. SFAs and schools need not round prices down, nor are they prohibited from imposing annual increases above the 10 cent cap. For this estimate, however, we assume that schools take advantage of both provisions: we assume uniform rounding and no optional price increases above 10 cents in any year.

• The interim rule allows SFAs to contribute financial support from non-Federal sources in lieu of part or all of required paid lunch price increases. It requires that financial support from non-Federal sources must be cash for direct support for paid lunches, and may not be in-kind contributions or revenue from foods sold in competition with reimbursable meals. For the first school year of implementation (school year 2011–12), the interim rule allows SFAs to count any non-Federal cash contribution, except for cash revenues from foods sold in outside of reimbursable meals, as an offset for paid lunch price increases. While the most recent analysis of school meals costs and revenues suggests that State and local authorities contribute substantial non-Federal cash revenues to food service accounts, data is not available to determine the extent to which these revenues represent direct support for paid lunches. For the purpose of this analysis, we assume that SFAs will be able to use existing contributions to meet all of the required paid meal revenue increase to meet the rule's requirements for school year 2011–12, and to meet 25 percent of the requirements for subsequent years.

• We assume that increases in paid meal prices above the 2 percent annual inflation rate reduce student consumption of paid meals.[9] We model this reduction with evidence collected in SNDA–III, which showed that over a range of paid meal prices typical of those charged in SY 2004–2005, student participation rate was lower by 0.11 percent for each additional cent in paid lunch prices.[10] In addition to impacts on SFA revenues, this participation effect also implies Federal savings; this is discussed further under Federal Budgetary Impacts, below.

The results of this analysis are presented in Table 3:

TABLE 3—NON-FEDERAL REVENUE REQUIRED TO MEET PAID MEAL REVENUE EQUITY PROVISION

	Fiscal year (millions)					
	2011	2012	2013	2014	2015	Total
Required non-Federal revenue increase based on current estimated paid meal student payments	$8	$56	$87	$138	$192	$481
Existing non-Federal, non-student payment contributions that offset required increase	−8	−47	−21	−35	−48	−158
Net required non-Federal revenue increase	*	9	66	104	144	323

Not all school districts will benefit from this revenue increase. We estimate, based on the distribution of paid lunch prices in SY 2004–05 found in SNDA–III, that about 6,000 of 102,000 schools will not have to increase paid meal prices at all in SY 2011–12 to comply with Section 205 because they already charge prices above the $2.46 target for SY 2011–12. An additional 19,000 schools have prices so low (no greater than $1.59) that the 3.14 percent increase required for SY 2011–12 results in an increase of less than 5 cents, and thus in almost all cases rounds down to zero.[11] Almost all of the remaining schools would have only a 5 cent required increase in SY 2011–12.

Because the provision limits the increase to no more than 10 cents per lunch per year, we anticipate that increases in SFAs with the largest difference between paid lunch prices and the Section 11 rate will continue gradually over many years, with about half of all schools reaching the requirements of the rule in 13 years, and many continuing to work towards paid meal revenue parity for 20 years or more.[12]

SFAs have the option of meeting the revenue requirements by adding funds to the school food service account. However, to the extent that SFAs choose instead to raise paid meal prices, the change will affect students (and their families) whose income exceeds the statutory thresholds for free or reduced price meals. While this spares families with the lowest incomes from the revenue raising objective of the provision, there may be some concern that higher paid meal prices will fall disproportionately on children with incomes relatively close to the upper threshold for reduced price benefits. Table 4 presents a distribution of school-aged children by level of family income:[13]

[7] It is worth noting that the observed relationship between paid lunch and free lunch revenue is relatively stable across the three SNDA studies, which collected data from school years 1991–92, 1998–99, and 2004–05:

• In SY 1991–92, revenue for a paid meal was 79.9 percent of Federal revenue for a free meal.

• In SY 1998–99, revenue for a paid meal was 80.3 percent of Federal revenue for a free meal.

• In SY 2004–05, revenue for a paid meal was 82.2 percent of Federal revenue for a free meal.

[8] The NSLA provides for annual increases in the Section 11 rate equal to growth in the CPI–U's Food Away From Home series. We use projections in the series prepared by OMB for use in the 2012 President's Budget.

[9] We expect that students that no longer consume paid lunches because of price increases will either bring food from home, choose not to eat during school hours, or acquire food from other sources. We do not have data that allows us to estimate the relative frequency of these different responses.

[10] Over the price range examined in SNDA–III, this is an elasticity of −0.30. SNDA–I estimated an elasticity of −0.25 over a range of prices from $1.20 to $1.60 in SY 1991–1992. (Table VII.3, p. 137) U.S. Department of Agriculture, Food and Nutrition Service (1993). *The School Nutrition Dietary Assessment Study.* Report prepared by Mathematica Policy Research. Available at *www.fns.usda.gov/ora/*

[11] These schools would face no required price increase in SY 2011–12 if their SY 2010–11 baseline prices were rounded to an even 5 cent increment. As we note above, this analysis relies on the school-level SNDA–III dataset. Because SNDA–III data indicate that nearly all schools charged prices in 5 cent increments in SY 2004–05, our analysis assumes that all prices in SY 2010–11 are likewise rounded to the nearest 5 cents.

[12] We estimate that the ''revenue gap'' between free reimbursement and paid meal revenue levels would be reduced 28 percent by FY 2015, the end of the accounting period for this analysis. The gap would continue to shrink in future years.

[13] The data in Table 4 reflect special tabulations of Current Population Survey data prepared by Mathematica Policy Research for FNS.

TABLE 4—CHILDREN BY AGE AND FAMILY INCOME, 2008

Family income as a percent of poverty	Children age 5–18 Years (000s)	Percent of total	Percent of total ineligible for free/ reduced meals
≤100%	10,428	18.1	.....
100% to 130%	3,865	6.7	.....
130% to 185%	6,686	11.6	.....
185% to 200%	1,559	2.7	4.3%
200% to 225%	2,638	4.6	7.2
225% to 250%	2,762	4.8	7.6
250% to 300%	4,988	8.7	13.7
>300%	24,571	42.7	67.3
Total	57,496	100.0	100.0

The number of school age children with family incomes just over the limit for school meal benefits is substantial in absolute terms; nearly 1.6 million school age children had family incomes between 185 percent and 200 percent of the Federal poverty threshold in 2008. But this group represents roughly 4 percent of all children whose incomes place them among potential paid meal participants.

2. Revenue From Non-Program Foods (Section 206)

a. Direct Impacts on à la Carte Sales

The interim rule requires that, to the extent that SFA revenues from à la carte foods fall short of the rule's cost-based target, SFAs must take positive action to either raise à la carte prices or invest additional sums in program meals.

Required SFA Revenue Increase

We estimate the SFA-level effects of this provision with data collected as part of an examination of school meal production costs (School Lunch and Breakfast Cost Study–II (SLBCS–II)). The SLBCS–II examined school year 2005–2006 revenue and expense data for a nationally representative sample of 120 school food authorities, and a representative sample of 356 schools within those SFAs. Financial statements, meal production records, recipes, invoices, and other documents were reviewed. Data collected from those SFAs include the revenue generated from program meals, the revenue generated from non-program foods that accrued to the school foodservice account, and the cost of producing those meals and food items, allocated between program and non-program foods using generally-accepted accounting practices. Data from interviews with SFA and school district officials were used to calculate unreported costs and allocate labor costs among SFA activities. Samples of meals taken by students were observed to obtain data on menu items sold in reimbursable and nonreimbursable meals.[14]

We use these data to compute the following two key statistics, specified by the rule, for each of the study's sampled SFAs:

Food cost ratio:

$$\frac{\text{cost of non-program foods}}{(\text{cost of program foods} + \text{cost of non-program foods})}$$

Revenue ratio:

$$\frac{\text{non-program revenue}}{(\text{program revenue} + \text{non-program revenue})}$$

Program foods are the Federally reimbursable lunches, breakfasts, and snacks served in the NSLP and SBP. For purposes of the interim rule, non-program foods are à la carte and other items offered to students other than NSLP or SBP meals.[15] As presented in the estimate, the costs for these foods reflect the allocation of food costs across program meals and non-program foods as required under generally accepted accounting principles, including those ingredients and food components that might be purchased and used to support both reimbursable meal service and à la carte service.

The sum of program revenue and non-program revenue in the second ratio is all revenue in the SFA account. SFA revenue includes Federal subsidies for reimbursable meals, USDA food assistance, student payment for program meals, revenue from à la carte and other non-reimbursable food sales, State and local contributions to the SFA account, and a small amount from other sources such as interest on deposits and the sale of equipment.

The interim rule requires SFAs to generate at least as great a share of total revenue from non-program foods as non-program foods contribute to total food costs. That is, SFAs must ensure that their revenue ratio is at least as great as their food cost ratio. With SLBCS–II data, adjusted for growth in student participation and school food prices, we estimate that à la carte revenues fall short of the amount necessary to balance SFA food cost and revenue ratios as required by the interim rule by almost $2.4 billion for the full 2011 fiscal year.[16]

[14] One limitation of the SLBCS–II for this analysis is that SFAs were not asked to provide separate program and non-program costs. Developing an estimate of the split between program and non-program costs was one of the objectives of the study. Trained observers recorded the foods selected by a sample of students and identified those meals as reimbursable or non-reimbursable. The study then estimated the cost of individual food items based on SFA records of food prices, the value of USDA Foods, school recipe records, and school menus. With this information, the study estimated the share of total food costs attributable to non-program meals. That percentage was applied to non food costs to estimate the overall split between program and non-program costs.

[15] An additional limitation of the SLBCS–II data for this analysis is that financial data for à la carte foods are combined with the data for adult meals, some vending, and catering. Because we cannot isolate à la carte's contribution to these broader measures of cost and revenue we overstate the cost and revenue ratios for some SFAs.

[16] For this analysis we assume that baseline demand for à la carte foods grows at a rate comparable to the growth in student consumption of reimbursable paid lunches. We recognize the limitations of paid meal participation as a proxy for à la carte consumption. Our assumption of comparable growth is intended to reflect changes in

Continued

Impacts of Price Changes on Student Purchase of à la Carte Foods

The revenue increase required to balance SFAs' food and revenue ratios for FY 2011 is about 70 percent above projected baseline à la carte receipts.[17] For years beyond 2011, adjustments are needed not only for price inflation, but for changes in demand for à la carte foods as a result of price increases, absent other action by school or SFA administrators.

• In the absence of a direct measure of student sensitivity to price increases in à la carte foods, we use the same price elasticity estimate that we applied to our Section 205 analysis of paid lunches.[18] For each one cent increase in paid meal prices, SNDA–III estimated a −0.11 percent decrease in participation, a price elasticity of about −0.30.[19]

• Following the initial price adjustment to comply with the rule in 2011, we assume that growth in prices charged for and demand for à la carte foods matches growth in the aggregate Federal reimbursement for paid lunches, using the same assumptions for growth in paid lunch participation and reimbursement rates reflected in the FY 2012 President's Budget.[20]

• It is plausible to image that, over time, the effect of increased prices in reducing demand will decay, as consumers grow accustomed to the higher prices. We have not factored this into our analysis, but to the extent that it occurs, we would expect to see demand increase and overall SFA revenue grow.

Through FY 2015, we estimate that SFA revenues for à la carte foods will increase as a result of the interim rule by the amounts in Table 5.

TABLE 5—INCREASED SFA REVENUE FROM À LA CARTE FOODS[21]

	Fiscal year (millions)					
	2011	2012	2013	2014	2015	Total
Baseline à la carte revenue	$500	$3,279	$3,533	$3,769	$4,119	$15,200
Revenue increase due to price increase	357	2,342	2,524	2,693	2,942	10,858
Revenue decrease due to reduced demand	−182	−1,194	−1,286	−1,372	−1,499	−5,534
Total adjusted à la carte revenue	675	4,427	4,770	5,090	5,561	20,524
Net projected increase in à la carte revenue	175	1,148	1,237	1,320	1,443	5,324

It should be noted that this estimate assumes that the mix of à la carte foods remains equally popular among students relative to price as the foods sold in SY 2004–05 (when the most recent data on à la carte foods was collected), and that schools make no effort to adjust their à la carte offerings to increase their popularity. To the extent that schools make such adjustments, the net revenue increase of the rule would grow.

In addition, the Healthy, Hunger-Free Kids Act of 2010 requires USDA to promulgate nutrition standards for all foods sold in school. Because these standards have not yet been proposed, we did not factor them into this analysis. To the extent that these standards ultimately require schools to eliminate popular items, they could cause a net reduction in demand for à la carte foods, and reduce the revenues generated by this rule.

b. NSLP Participation Impact

We would expect that some portion of the reduced demand for à la carte foods due to price increases would be redirected as additional demand for and participation in the school meals programs.

• We assume that roughly 46 percent of lost demand for à la carte foods due to price increases would be redirected as additional demand for and participation in the school meals programs.[22] For simplicity, and because the consumption of à la carte foods at breakfast is relatively low compared to the consumption of à la carte foods at lunch, we model the shift from à la carte to program foods as one that takes place at lunchtime only.[23] We expect that students that do not choose to participate in school meals or purchase higher-priced à la carte foods will either bring food from home, choose not to eat during school hours, or acquire food from other sources. We do not have data that allows us to estimate the relative frequency of these different responses.

• Data is not available about the income distribution of students who purchase à la carte. We make the assumptions that (1) low-income children are less-frequent consumers of these foods that higher-income children and (2) they are more likely than higher-income children to reduce purchases in response to price increases. We therefore assume that à la carte sales reductions are distributed across school meal eligibility levels in proportion to their share of total program participation.[24]

Our estimate of the increase in SFA revenues that derives from Federal reimbursements and student payments for a larger number of NSLP meals served through FY 2015 as a result of the interim rule is shown in Table 6. This reflects an increase of about 2.9 percent in lunches over the Federal baseline, or about 92 million free lunches, 16 million reduced-price lunches, and 58 million paid lunches in 2015. In

the size of the student population that chooses to consume school foods but is ineligible for free or reduced price meals.

[17] This is the targeted revenue increase prior to a price-induced drop in demand for à la carte foods.

[18] We find the estimated price elasticity for paid lunches from SNDA–III to be a reasonable substitute for this analysis of à la carte consumption given that it measures student response to price increases in a school setting where available substitutes are comparably limited.

[19] For FY 2011, we estimate that SFAs will need to raise prices to generate $357 million in increased revenue for the period July 1—September 30. This would require, on average, a 71 percent increase in à la carte prices. We then apply a 3.0 percent reduction in student purchases of à la carte foods for each 10 percent increase in price, estimating that total revenue from à la carte sales will fall by about 21 percent ($182 million). Net SFA revenues thus will increase $175 million, rather than the $357 million that would be raised under an assumption of constant sales.

[20] This means that we assume SFA prices charged for à la carte foods keep pace with increases in the broader market prices of food and labor reflected in the CPI's ''food away from home'' index.

[21] Reflects a drop in demand following the initial à la carte price increase.

[22] SNDA–III estimates that participation in the reimbursable lunch program is 4.6 percentage points higher in schools that disallow the sale of non-program foods during meal times than in schools that allow non-program food sales (SNDA–III, vol. 2, p. 117). SNDA–I found that 10 percent of students who consumed meals at school purchased their food from à la carte lines, vending machines, or school stores (Table VII.1, p. 131). An overall program participation increase of 4.6 percent from the 10 percent of students who purchase competitive foods implies that 46 percent of students who purchase competitive foods will turn to reimbursable meals if competitive food sales are suspended. For this analysis we assume that the percentage increase in program participation by students who stop purchasing competitive foods due to price is the same as the percentage increase in program participation by students whose competitive food option is eliminated entirely.

[23] SNDA–III found that competitive foods were consumed by 29 percent of NSLP non-participants during the lunch period in SY 2004–2005 (Vol. 2, Table VI.9, p. 196), but that competitive foods were consumed by just 5 percent of SBP non-participants during the breakfast period (SNDA–III, Vol. 2, Table VII.9, p. 264).

[24] We assume that 55 percent of children who stop purchasing à la carte foods in response to higher prices are eligible for free school meals, 10 percent are eligible for reduced price meals, and 35 percent are eligible for paid meals. This is the distribution of NSLP participants in FY 2010. If the children who currently purchase à la carte foods are more likely to be eligible for paid meals, estimated revenues would be less than estimated here, especially in the years before the full effect of Section 205 are realized.

addition to impacts on SFA revenues, this participation effect is reflected in increased Federal costs discussed further under Federal Budgetary Impacts, below. (The amounts shown in Table 6 include the Federal costs shown in Table 10, plus additional amounts derived from student payments or other non-Federal revenue sources for non-free meals.)

TABLE 6—INCREASED SFA REVENUE DUE TO SHIFT FROM À LA CARTE TO NSLP PARTICIPATION

	Fiscal year (millions)					
	2011	2012	2013	2014	2015	Total
Projected increase in SFA revenue from à la carte/NSLP shift	$64	$416	$466	$484	$510	$1,939

3. SFA Administrative Cost

There are no current regulatory requirements regarding pricing of paid lunches, the amount of revenue generated by paid lunches or the revenue generated by selling non-program foods. The interim rule would thus entail new administrative tasks, requiring school food authorities to use information on paid lunch prices, food costs, and revenue records to determine the price changes needed for these meals and à la carte foods.

The rule also requires State agencies and school food authorities to annually provide and report to USDA the paid meal prices charged by school food authorities. We estimate that this will require, in aggregate, roughly 323,000 hours in additional work for States and SFAs each year, increasing administrative costs by about $10 million per year.[25] However, it is important to recognize that, to the extent States and SFAs make use of options to add other non-Federal sources to the school food service account in place of part of all of the price increase, additional administrative costs could result from the need to account for these other revenue sources and amounts. In either case, most additional administrative cost occurs at the SFA level.

Projected administrative costs are shown in Table 7:

TABLE 7—ADMINISTRATIVE COSTS

	Fiscal year (millions)					
	2011	2012	2013	2014	2015	Total
Administrative Costs	$5	$9	$10	$10	$10	$44

C. Federal Budgetary Impacts

We estimate that the interim rule has some impacts on Federal expenditures as well. While no measurable direct Federal costs for the implementation of this provision are anticipated, the impact of the pricing and revenue provisions on participation in the NSLP and SBP will change Federal costs for these programs.

To the extent that the Section 205 provisions result in increased prices for paid meals, NSLP participation may be marginally lower than otherwise projected, resulting in Federal savings in paid reimbursements. We model this reduction with SNDA–III data which suggests that the student participation rate was lower by 0.11 percent for each additional cent in paid lunch prices in SY 2004–05. We anticipate that average daily participation by students receiving paid meals will change as a result of this provision as follows:

TABLE 8—FEWER CHILDREN CONSUMING PAID MEALS DUE TO HIGHER PRICES

	Fiscal year				
	2011	2012	2013	2014	2015
Change in number of children consuming paid meals due to higher prices	*	−7,000	−55,000	−88,000	−124,000

To the extent that price increases for à la carte foods result from Section 206 provisions, this could lead to substitution of NSLP/SBP participation for purchases of these foods, resulting in a marginal participation increase and Federal costs for meal reimbursements. We anticipate that average daily program participation will increase among students switching from à la carte to program meals as a result of this provision as follows:

TABLE 9—MORE CHILDREN CONSUMING PROGRAM MEALS DUE TO HIGHER À LA CARTE PRICES

	Fiscal year				
	2011	2012	2013	2014	2015
Children shifting from à la carte to free meals	76,000	482,000	494,000	499,000	509,000
Children shifting from à la carte to reduced price meals	13,000	83,000	85,000	86,000	88,000
Children shifting from à la carte to paid meals	48,000	306,000	313,000	316,000	322,000
Total newly-participating children	137,000	871,000	892,000	901,000	919,000

[25] Based on estimated recordkeeping and reporting requirements for 57 State agencies and nearly 21,000 SFAs. These requirements are expected to impose a burden of about 15 hours per year per respondent (valued at about $30 per hour). We estimate that just half of a full year's worth of these administrative expenses will be incurred in FY 2011.

The impacts of these effects on Federal expenditures are shown in Table 10.

TABLE 10—FEDERAL BUDGETARY IMPACTS

	Fiscal year (millions)					
	2011	2012	2013	2014	2015	Total
Section 205—NSLP participation	$0	*	−$3	−$7	−$10	−$20
Section 206—NSLP participation	46	$297	338	348	362	1,392
Total	46	297	335	342	352	1,372

* Less than $500,000.

D. Uncertainties

No regulatory requirements currently exist regarding the prices of paid lunches or non-program foods, and limited data are available to estimate the cost and participation impacts of the interim rule's provisions. Therefore, we made several simplifying assumptions in developing this cost estimate, reflecting gaps in available data and evidence. In this section, we describe the impact of several alternative assumptions on the estimate. The effects of these alternatives on our primary estimates are presented in Table 11.

1. More Rapid Increase in Paid Lunch Prices

As noted above, Section 205 directs SFAs charging less than the required paid meal price to gradually increase revenue per paid lunch until the requirement is met, with an annual average increase limited to not more than 10 cents. However, schools may choose to raise prices more rapidly than required, and thus generate additional revenue to support their operations.

While our main estimate assumes that schools make only the increases required by the interim rule, Table 11, Section A shows the estimated impact if schools with low paid meal prices raise prices 5 percent above the rate of inflation each year until the requirement is met. This assumption results in an additional $287 million in revenue over five years relative to the main estimate in Table 3.

2. Alternative Participation Effects Increased Paid Lunch Prices

Our main estimate of the participation impact of paid lunch price increases relies on data from SNDA–III, which suggests that over a 50 cent range in paid meal prices (from $1.50 to $2.00 in SY 2004–05) participation was 0.11 percent lower for each one cent increase in price.

We have modeled two alternative assumptions here:

- Table 11, Section B shows the estimated impact if participation decreases at a higher rate—0.25 percent for each one cent increase in price. This assumption results in a reduction of $160 million in revenue over five years relative to the main estimate in Table 3.
- Table 11, Section C shows the estimated impact if participation decreases at a lower rate—0.05 percent for each one cent increase in price. This would result in $69 million in additional revenue over five years relative to the main estimate in Table 3.

3. Alternative Assumptions for Reductions in à la Carte Food Sales

Our main estimate assumes that a 10 percent increase in prices for à la carte foods will reduce purchase and consumption of those foods by 3.0 percent.

Two alternative assumptions about the price elasticity of demand for à la carte foods are presented here:

- Table 11, Section D shows the estimated impact if a 10 percent increase in prices for à la carte food sales relative to food costs reduces purchase and consumption of those foods by 5.0 percent. This assumption results in a reduction of $3.8 billion in revenue over five years relative to the main estimate from Table 5.
- Table 11, Section E shows the estimated impact if a 10 percent increase in prices for à la carte food sales relative to food costs reduces purchase and consumption of those foods by 1.0 percent. This assumption results in $3.7 billion in additional revenue over five years relative to the main estimate from Table 5.

4. Alternative Levels of NSLP/SBP Participation as a Substitution for à la Carte Sales

Our main estimate assumes that 46 percent of lost demand for à la carte foods due to price increases would be redirected as additional school meals program participation. Two alternative assumptions about this substitution effect are presented:

- Table 11, Section F shows the estimated impact if 20 percent of lost demand was substituted as school meals program participation. This assumption results in a reduction of $787 million in revenue over five years relative to the main estimate in Table 10.
- Table 11, Section G shows the estimated impact if 60 percent of lost demand was substituted as school meals program participation. This assumption results in an increase of $424 million in revenue over five years relative to the main estimate in Table 10.

E. Benefits

The primary social benefits of the statute as implemented by this interim rule are to ensure that school pricing policies and other non-Federal contributions increase the revenue available to local school food service operations to support production of healthful school meals that are consistent with Federal nutrition standards. It does this by eliminating two unintended Federal subsidies—for paid meals and à la carte foods—that are drawn from payments to support free meals for the lowest-income children. The diversion of these funds negatively affects all children by limiting the funds available to provide nutritious meals.

- USDA's research shows that it cost about $2.28 to produce a school lunch in SY 2005–06.[26] While USDA's reimbursement for a free meal ($2.50), including cash and commodity foods, was about 9 percent higher than reported production costs, total revenues from a paid meal—including the price charged to families ($1.60), USDA's cash reimbursement ($0.21), and the commodity entitlement ($0.175)—was 13 percent less. Total revenue from a paid meal was only 80 percent of the value of Federal support for a free meal.
- Research also shows that revenues in SY 2005–06 from non-reimbursable foods fell short of the cost of producing them by an average of about 29 percent.[27] The average SFA used revenues from reimbursable meals to offset the cost of producing à la carte and other non-reimbursable food items.

The provision of additional revenue to the non-profit food service account will provide important financial support to improve the quality of all reimbursable meals. USDA has estimated that the cost of compliance with its proposed rule updating nutrition standards for school meals based on recommendations from the Institute of Medicine (IOM) (RIN 0584–AD59, published January 13, 2011) would increase total costs by roughly 12 percent when fully implemented. The estimated impact of this regulation could increase revenues sufficiently to cover those increased costs,

[26] SLBCS–II, p. ii.

[27] See SLBCS–II.

TABLE 11—COST OF RULE UNDER ALTERNATE ASSUMPTIONS

	Fiscal year					
	2011	2012	2013	2014	2015	Total
Section A. More Rapid Increase in Paid Lunch Prices						
Net required non-Federal revenue increase	$0	$19	$138	$197	$256	$610
Increase Over Primary Estimate	0	10	72	93	112	287
Section B. Greater Sensitivity of Paid Meal Participation to Price						
Net required non-Federal revenue increase	$0	$5	$36	$52	$69	$163
Decrease From Primary Estimate	0	−4	−30	−51	−76	−160
Section C. Lesser Sensitivity of Paid Meal Participation to Price						
Net required non-Federal revenue increase	$0	$11	$79	$126	$177	$392
Increase Over Primary Estimate	0	2	13	22	32	69
Section D. Greater Price Elasticity of Demand for à la Carte Foods						
SFA à la Carte Revenue	$51	$335	$360	$385	$420	$1,551
Decrease From Primary Estimate	−124	−814	−877	−936	−1,022	−3,773
Section E. Lesser Price Elasticity of Demand for à la Carte Foods						
SFA à la Carte Revenue	$296	$1,941	$2,091	$2,231	$2,438	$8,997
Increase Over Primary Estimate	121	792	854	911	995	3,673
Section F. Lesser Substitution of School Meals Participation for à la Carte Sales						
USDA Paid Meal Reimbursements	$20	$129	$147	$151	$158	$605
Decrease From Primary Estimate	−26	−168	−191	−197	−205	−787
Section G. Greater Substitution of School Meals Participation for à la Carte Sales						
USDA Paid Meal Reimbursements	$59	$388	$441	$454	$473	$1,816
Increase Over Primary Estimate	14	91	103	106	110	424

support full consistency with existing standards, and ease the path to rapid and full compliance with strengthened nutrition standards, including (1) increased servings of fruits and vegetables, (2) replacement of refined-grain foods with whole-grain rich foods, and (3) replacement of higher-fat dairy products with low-fat varieties.[28] The increased funding to support these meals could not only improve their nutritional quality, but also their appeal to students, leading to further NSLP–SBP participation increases.[29] This in turn would further increase the impact of the proposed standards described above. (It would also increase the SFA revenue and Federal cost that could result from this rule.)

As documented in the IOM recommendations, the proposed changes in school meals standards correspond to inconsistencies between the typical diets of school-aged children in the United States and the *Dietary Guidelines/MyPyramid* recommendations. In particular, the report cited an analysis of National Health and Nutrition Examination Survey data for 1999–2002 that showed:

- Total vegetable intake was only about 40 percent of the *MyPyramid* levels, with intake of dark green and orange vegetables less than 20 percent of *MyPyramid* levels.
- Total fruit intake was about 80 percent of the *MyPyramid* levels for children ages 5–8, with far lower levels for older children.
- Intake of whole grains was less than one-quarter of *MyPyramid* levels, although total grain intake was at or above *MyPyramid* levels.
- Intake of dairy products varied by age, with the intakes of the youngest children exceeding *MyPyramid* levels, while those of older children were below those levels. However, most dairy consumed contained 2 percent or more milk fat, while the *Dietary Guidelines* recommend fat-free or low-fat dairy products.[30]

The kinds of changes in school meals that this additional revenue will support will promote diets more consistent with the *Guidelines* among program participants. Such diets, in turn, are useful behavioral contributors to health and well-being. As the report of the 2010 Dietary Guidelines Advisory Committee notes, ''evidence is accumulating that selecting diets that comply with the Guidelines reduces the risk of chronic disease and promotes health.'' [31] The report describes and synthesizes the evidence linking diet and different chronic disease

[28] The regulatory impact analysis for 0584–AD59 estimates the cost of reaching full compliance with improved nutrition standards at $6.8 billion over fiscal years 2012–2016.

[29] The IOM report recommending changes to school meals standards identifies factors in their recommendations that may increase and decrease student acceptance, but also points to efforts in a number of localities in which efforts to improve the nutritional quality of school meals have resulted in increased participation. See Institute of Medicine (2010). *School Meals: Building Blocks for Healthy Children.* Washington, DC: The National Academies Press, chapter 9, especially pp. 272–275.

[30] Institute of Medicine (2010). *School Meals: Building Blocks for Healthy Children.* Washington, DC: The National Academies Press, pp. 49–53.

[31] Dietary Guidelines Advisory Committee (2010). *Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010, to the Secretary of Agriculture and the Secretary of Health and Human Services.* U.S. Department of Agriculture, Agriculture Research Service, Washington, DC, p. B1–2.

risks, including cardiovascular disease and blood pressure, as well as the effects of dietary patterns on total mortality.

Children are a subpopulation of particular focus for the Committee; the report emphasizes the increasing common evidence of chronic disease risk factors, such as glucose intolerance and hypertension, among children, and explains that ''[e]vidence documents the importance of optimal nutrition starting during the fetal period through childhood and adolescence because this has a substantial influence on the risk of chronic disease with age.'' [32]

In response, the report notes improvements in food at schools as a critical strategy to prevent obesity, and related health risks, among children. Indeed, the Committee recommends ''[i]mprov[ing] foods sold and served in schools, including school breakfast, lunch, and after-school meals and competitive foods so that they meet the recommendations of the Institute of Medicine and the key findings of the 2010 Dietary Guidelines Advisory Committee. This includes all age groups of children, from preschool through high school.'' [33]

III. Alternatives

Most aspects of the interim rule are non-discretionary, and tie to explicit, specific requirements of Section 205 and 206 of the Act. Because of the mandatory effective date of July 1, 2011, USDA has chosen to use the plain language of the law to the extent possible and focus exclusively on mandatory requirements in this interim rule. However, the Department made several choices to clarify expectations and requirements for program operators. These are described briefly below.

Section 205: Funding From Non-Federal Sources

The law allows SFAs to add ''funding from non-Federal sources'' in lieu of raising paid meal prices. The law explicitly excludes in-kind contributions and revenue from competitive foods from counting toward a non-Federal contribution, but does not otherwise define the parameters of these contributions. USDA considered the following alternatives defining the scope of allowable funding:

• *Apart from in-kind contributions and revenue from competitive foods, allow any other cash funding from a non-Federal source to count.* Because funds contributed to the school food service account are provided for a wide variety of purposes, this broad interpretation could result in few, if any, SFAs receiving additional funds that could support the meal service, potentially undermining the intent of this provision.

• *Count only new sources of contributions after July 1, 2011, the effective date of the provision.* This ''maintenance of effort'' approach would maximize new revenue, but could also penalize SFAs and States that have historically contributed significant non-Federal revenues by requiring them to contribute additional revenue.

• *Allow those non-Federal contributions that provide direct support for paid lunches.* This seemed to cleave most closely to the intent of the law.[34] However, the need to identify and potentially augment such funding sources could be difficult to implement by the July 1 effective date.

The Department chose to allow any non-Federal contribution to the school food service account to count towards the requirement in school Year 2011–12, but for subsequent years to limit contributions to those that are for direct support for paid lunches, in order to balance achieving the intent of the law as soon as possible with enabling implementation in the first year.

Section 205: Calculating the Average Paid Meal Price

To determine the required level of non-Federal revenue, SFAs must calculate the average paid meal price across all paid NSLP lunches served in the district. USDA considered the following alternatives in defining the average price:

• *Average price per lunch:* This method requires SFAs to multiply the number of paid lunches served by the price for each across all schools, add these figures together, and divide by the total number of lunches served in the district for the period. This approach most accurately reflects the total revenue derived from student payments for paid lunches. Because it requires the use of meal counts, it is somewhat more burdensome than the alternative described below.

• *Average price per school):* This would entail SFAs to determine a simple average of prices by school—adding the prices charged at each school and dividing by the total number of schools. This is a simpler calculation, but does not appropriately factor in the number of meals served at each school, or at different price points.

The Department chose the average price per lunch approach, as it most accurately reflects the payments made by families in support of paid lunches, while requiring only limited additional calculation, and no information that is not readily available to schools and SFAs.

IV. Accounting Statement

Table 12 contains the FY 2011 present values of the figures in Table 2 using a 7 percent discount rate. Table 13 contains present values under an alternate 3 percent discount rate. The rightmost columns of Tables 12 and 13 contain the annualized effects of the rule.

TABLE 12—PRESENT VALUE OF SFA REVENUE AND FEDERAL COST: 7 PERCENT DISCOUNT RATE

	Fiscal year						
	2011	2012	2013	2014	2015	Total FY 2011–15	Annualized amount
Transfers (from non-Federal sources to SFA)	$193	$1,193	$1,252	$1,278	$1,331	$5,247	$1,280
Transfers (from Federal Government to SFA)	46	278	293	279	269	1,164	284
Costs	5	9	9	8	8	38	9

TABLE 13—PRESENT VALUE OF SFA REVENUE AND FEDERAL COST: 3 PERCENT DISCOUNT RATE

	Fiscal year						
	2011	2012	2013	2014	2015	Total FY 2011–15	Annualized amount
Transfers (from non-Federal sources to SFA)	$193	$1,239	$1,352	$1,433	$1,550	$5,767	$1,259
Transfers (from Federal Government to SFA)	46	288	316	313	313	1,276	279
Costs	5	9	9	9	9	41	9

[32] Dietary Guidelines Advisory Committee, pp. B1–2, B1–3.

[33] Dietary Guidelines Advisory Committee, p. B3–6.

[34] Senate Report 111–178 on the Healthy Hunger Free Kids Act (page 37) notes: ''School districts that charge at least the difference between the free lunch reimbursement rate and the paid lunch reimbursement rate for paid meals must adjust their prices on an annual basis by the inflation adjustment factor used for federal reimbursement rates. Participating school food authorities may reduce the average price of a paid lunch required under this section if the State agency ensures that sufficient funding from non-Federal sources (other than in-kind contributions) is *added* to the nonprofit school food service account to compensate for the reduction (emphasis added).''

Note: This Analysis will not be codified in the Code of Federal Regulations.

Appendix B to 7 CFR 210 Initial Regulatory Flexibility Analysis

Initial Regulatory Flexibility Analysis Interim Rule: National School Lunch Program: School Food Service Account Revenue Amendments Related to the Health Hunger-Free Kids Act of 2010

[RIN 0584–AE11]

AGENCY: Food and Nutrition Service, USDA

BACKGROUND: The Regulatory Flexibility Act (RFA) requires agencies to consider the impact of their rules on small entities and to evaluate alternatives that would accomplish the objectives of the rules without unduly burdening small entities when the rules impose a significant economic impact on a substantial number of small entities. Inherent in the RFA is Congress' desire to remove barriers to competition and encourage agencies to consider ways of tailoring regulations to the size of regulated entities.

The RFA does not require that agencies necessarily minimize a rule's impact on small entities if there are significant legal, policy, factual, or other reasons for the rule's having such an impact. The RFA requires only that agencies determine, to the extent feasible, the rule's economic impact on small entities, explore regulatory alternatives for reducing any significant economic impact on a substantial number of such entities, and explain the reasons for their regulatory choices.

Reasons That Action Is Being Considered

Sections 205 and 206 of Public Law 111–296, the Healthy, Hunger-Free Kids Act of 2010 (December 13, 2010), amended the Richard B. Russell National School Lunch Act (NSLA) to address revenue from paid lunches and nonprogram foods (foods and beverages sold by schools outside of the reimbursable meals programs). Beginning July 1, 2011, school food authorities (SFAs) that participate in the National School Lunch Program (NSLP) must assess the prices charged for lunches served to students not eligible for free or reduced prices meals (i.e., paid lunches) and ensure sufficient funds are provided to the nonprofit school food service account in relation to the difference between the higher reimbursement that the Federal government provides for free lunches and the lower reimbursement provided for paid lunches. These funds may come in the form of limited increases in paid lunch prices or by providing additional sources of non-Federal funding to support paid lunches. Section 206 requires SFAs to assure that the proportion of total revenue from the sale of nonprogram foods to the total revenue be equal to or greater than the proportion of total food costs associated with obtaining nonprogram foods to the total costs associated with obtaining program and nonprogram foods from the account.

Objectives of, and Legal Basis for, the Interim Rule

Section 12 of the NSLA was amended by adding paragraphs (p) and (q) which, respectively, address the requirements for revenue from paid reimbursable school lunches and from sale of nonprogram foods. These provisions are intended to ensure sufficient funds are provided to the nonprofit school food service account for meals served to students not eligible for free or reduced price meals and for the cost of obtaining nonprogram foods.

Historically, there have been three main sources of funds provided to nonprofit school food service accounts: Federal reimbursements, paid meal revenues, and State and local funding. Research indicates that average prices charged for paid meals—meals served to students not certified to receive free or reduced price meals—are too low to cover the cost of producing those meals. Pricing paid meals below the cost of their production effectively increases federal subsidies for higher income children at the expense of low income children and negatively affects children across all income levels by limiting the funds available to provide nutritious meals. This same rationale applies to the requirement for assuring that the cost of obtaining nonprogram foods. These provisions will ensure that schools have funding available to support serving nutritious meals to all students.

Number of Small Entities to Which the Interim Rule Will Apply

This rule directly regulates the 55 State education agencies and 2 State Departments of Agriculture (SAs) that operate the NSLP and SBP pursuant to agreements with USDA's Food and Nutrition Service (FNS); in turn, its provisions apply to entities that prepare and provide NSLP and SBP meals to students. While SAs are not small entities under the RFA as State populations exceed the 50,000 threshold for a small government jurisdiction, many of the service-providing institutions that work with them to implement the program do meet definitions of small entities:

There are currently about 19,000 School Food Authorities (SFAs) participating in NSLP and SBP. More than 99 percent of these have fewer than 50,000 students.[35] About 26 percent of SFAs with fewer than 50,000 students are private. However, private school SFAs account for only 3 percent of all students in SFAs with enrollments under 50,000.[36]

Nearly 102,000 schools and residential child care institutions participate in the NSLP. These include more than 90,000 public schools, 6,000 private schools, and about 5,000 residential child care institutions (RCCIs).[37] We focus on the impact at the SFA level in this document, rather than the school level, because SFAs are responsible for the administration of the NSLP and the SBP.

Food service management companies (FSMCs) that prepare school meals or menus under contract to SFAs are affected indirectly by the interim rule. Thirteen percent of public school SFAs contracted with FSMCs in school year (SY) 2004–2005.[38] Of the 2,460 firms categorized as ''food service contractors'' under NAICS code 72231, 96 percent employ fewer than 500 workers.[39]

Projected Reporting, Recordkeeping and Other Compliance Requirements

The analysis below covers only those organizations impacted by the interim rule that were determined to be small entities.

School Food Authorities (SFA)/Schools

- Under the interim rule, school food authorities must ensure that schools that participate in the NSLP generate revenue for paid reimbursable lunches that is comparable to Federal free lunch revenue. Schools must evaluate and gradually adjust the price of paid reimbursable lunches or use non-Federal funding to ensure that the school foodservice account receives sufficient revenue to cover this level.

To the extent that schools increase prices rather than use other non-Federal revenues to meet the rule's requirements, and these increases reduce demand for paid lunches, NSLP participation could decrease in these schools. However, USDA estimates that this impact will be small—about 0.11 percent for each additional cent in paid lunch prices.

- Under the interim rule, school food authorities must also ensure that revenue from nonprogram foods cover the cost of obtaining those foods. We estimate that this requirement will result in substantial increases in prices charged for nonprogram foods in some schools, and in turn decrease demand for these foods, leading some students to increase consumption of NSLP/SBP meals, and others to acquire food from other sources. (This is described in more detail in Appendix A.
- Finally, the interim rule will require SFAs to report their paid lunch prices to USDA on an annual basis. We have estimated a small increase in reporting burden for SFAs.

While we recognize that these changes may in some cases increase burden on schools and school food authorities, they are explicit requirements of the Healthy, Hunger Free Kids Act of 2010, and will serve the important intent of that law to ensure that schools have funding available to support serving nutritious meals to all students.

Federal Rules That May Duplicate, Overlap or Conflict With the Interim Rule

FNS is unaware of any such Federal rules or laws.

Significant Alternatives

The law provides for various ways that SFAs can comply with these requirements. The law allows SFAs to limit the increase in the price to a maximum of ten cents annually, although the SFA may choose to

[35] FNS 742 School Food Verification Survey, School Year 2009–2010. This number is approximate, not all SFAs are required to submit the 742 form.

[36] Ibid. RCCIs include but are not limited to juvenile detention centers, orphanages, and medical institutions. We do not have information on the number of children enrolled in these institutions.

[37] FNS program data for FY 2010.

[38] U.S. Department of Agriculture, Food and Nutrition Service, Office of Research, Nutrition and Analysis, School Nutrition Dietary Assessment Study–III, Vol. I, 2007, p. 34 *http://www.fns.usda.gov/ora/MENU/Published/CNP/FILES/SNDAIII-Vol1.pdf*

[39] Ibid.

raise the price higher. Further, in lieu of a price increase, the SFA may add non-Federal funds to the school food service account in the amount of revenue required to meet the requirement. This interim rule allows SFAs to carry-over any increase above the minimum over subsequent school years. This allows the SFA the flexibility to choose to have price increases only periodically, rather than annually. The law also provides flexibility in establishing how to account for adequate revenue for the cost of obtaining foods sold outside of the school meals programs. Once SFAs determine the proportionate revenue needed for nonprogram foods, it may choose to increase the price of certain items to provide the additional revenue, may do an across the board increase or may choose to add funds from sources outside of the school food service account.

Regulatory Flexibility Act

This rule has been reviewed with regard to the requirements of the Regulatory Flexibility Act of 1980 (5 U.S.C. 601–612). It has been certified that this rule will have a significant economic impact on a substantial number of small entities. A Regulatory Flexibility Analysis (RFA) was developed for this interim rule and is included as Appendix B at the end of this document.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Under section 202 of the UMRA, the Department generally must prepare a written statement, including a cost/benefit analysis, for proposed and final rules with Federal mandates that may result in expenditures to State, local, or Tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. When such a statement is needed for a rule, section 205 of the UMRA generally requires the Department to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, more cost-effective or least burdensome alternative that achieves the objectives of the rule. This rule does not contain Federal mandates (under the regulatory provisions of Title II of the UMRA) that impose costs on State, local, or Tribal governments or to the private sector of $100 million or more in any one year. This rule is, therefore, not subject to the requirements of sections 202 and 205 of the UMRA.

Executive Order 12372

The NSLP is listed in the Catalog of Federal Domestic Assistance under No. 10.555. For the reasons set forth in the final rule in 7 CFR part 3015, Subpart V and related notice (48 FR 29115, June 24, 1983), this program is included in the scope of Executive Order 12372, which requires intergovernmental consultation with State and local officials.

Executive Order 13132

Executive Order 13132 requires Federal agencies to consider the impact of their regulatory actions on State and local governments. Where such actions have federalism implications, agencies are directed to provide a statement for inclusion in the preamble to the regulations describing the agency's considerations in terms of the three categories called for under section (6)(b)(2)(B) of Executive Order 13132. USDA has considered the impact of this rule on State and local governments and has determined that this rule does not have federalism implications. This rule does not impose substantial or direct compliance costs on State and local governments. Therefore, under Section 6(b) of the Executive Order, a federalism summary impact statement is not required.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is intended to have preemptive effect with respect to any State or local laws, regulations or policies which conflict with its provisions or which would otherwise impede its full implementation. This rule is not intended to have retroactive effect unless specified in the **DATES** section of the final rule. Prior to any judicial challenge to the provisions of this rule or the application of its provisions, all applicable administrative procedures must be exhausted.

Civil Rights Impact Analysis

FNS has reviewed this rule in accordance with Departmental Regulations 4300–4, ''Civil Rights Impact Analysis'', and 1512–1, ''Regulatory Decision Making Requirements.'' After a careful review of the rule's intent and provisions, FNS has determined that this rule is not intended to limit or reduce in any way the ability of protected classes of individuals to receive benefits on the basis of their race, color, national origin, sex, age or disability nor is it intended to have a differential impact on minority owned or operated business establishments, and woman-owned or operated business establishments that participate in the Child Nutrition Programs.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. Chap. 35; see 5 CFR part 1320), requires that the Office of Management and Budget (OMB) approve all collections of information by a Federal agency from the public before they can be implemented. Respondents are not required to respond to any collection of information unless it displays a current, valid OMB control number. This is a new collection. The new provisions in this rule, which do increase burden hours, affect information collection requirements that will be merged into the NSLP, OMB Control Number #0584–0006, expiration date 5/31/2012. The current collection burden inventory for the NSLP is 12,257,764. These changes are contingent upon OMB approval under the Paperwork Reduction Act of 1995. When the information collection requirements have been approved, FNS will publish a separate action in the **Federal Register** announcing OMB's approval.

Comments on the information collection in this interim rule must be received by August 16, 2011.

Send comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for FNS, Washington, DC 20503. Please also send a copy of your comments to Lynn Rodgers-Kuperman, Program Analysis and Monitoring Branch, Child Nutrition Division, 3101 Park Center Drive, Alexandria, VA 22302. For further information or for copies of the information collection requirements, please contact Lynn Rodgers-Kuperman at the address indicated above. Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the Agency's functions, including whether the information will have practical utility; (2) the accuracy of the Agency's estimate of the proposed information collection burden, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All responses to this request for comments will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Title: National School Lunch Program: School Food Service Account Revenue Amendments Related to the Healthy, Hunger-Free Kids Act of 2010.

OMB Number: 0584–NEW.

Expiration Date: Not Yet Determined.

Type of Request: New Collection.

Abstract: This interim rule promulgates the provisions from sections 205 and 206 of Public Law 111–296, the Healthy, Hunger-Free Kids Act of 2010 (the Act). Section 205 amended section 12 of the Richard B. Russell National School Lunch Act (NSLA) (42 U.S.C. 1760) by adding a new subsection (p), ''Price for a Paid Lunch'' which addresses, for the first time, requirements for SFAs on establishing prices for paid reimbursable lunches (hereinafter called paid lunches). Section 205 provided SFAs with some flexibility in phasing-in any increases in paid lunches and in using non-Federal funds to supplement paid lunch revenue in order to keep the price of a paid lunch lower. These provisions do not apply to the revenue from or prices charged for either afterschool snacks or for school breakfasts offered in 7 CFR part 220. There is also a requirement in section 205 requiring USDA to establish procedures to annually collect and publish the paid lunch prices charged by SFAs.

Section 206 of Public Law 111–296 amended section 12 of the NSLA by adding a paragraph (q), ''Nonprogram Food Sales.'' This provision addresses food in schools outside of the reimbursable meal and meal supplements, which are purchased with funds from the nonprofit school food service account. Included are foods sold in competition with these reimbursable meal programs as provided in section 10 of the Child Nutrition Act (42 U.S.C. 1779). The law now requires that the revenue from the sale of nonprogram foods be proportionate to the total revenue generated by such food.

These changes are effective July 1, 2011.

Those respondents participating in the SBP also participate in the NSLP, thus the burden associated with the SBP will be carried in the NSLP. The average reporting and recordkeeping burden per response and the annual burden hours are explained below and summarized in the charts which follow.

Respondents for this Interim Rule: State Agencies (57) and School Food Authorities (20,858).

Estimated Number of Respondents for this Interim Rule: 20,915.

Estimated Number of Responses per Respondent for this Interim Rule: 3.991824.

Estimated Total Annual Responses: 83,489.

Estimated Total Annual Burden on Respondents for this Interim Rule: 322,827.

ESTIMATED ANNUAL BURDEN FOR 0584–NEW, NATIONAL SCHOOL LUNCH PROGRAM 7 CFR PART 210

	Section	Estimated number of respondents	Frequency of response	Average annual responses	Average burden per response	Annual burden hours
Reporting						
State agency (SA) consolidates paid reimbursable lunch prices reported by SFAs and submits to FNS.	7 CFR 210.14(e)(7).	57	1	57	10	570
SFA reports paid lunch prices for each NSLP school to the SA.	7 CFR 210.14(e)(7).	20,858	1	20,858	0.25	5,215
Total Reporting for Interim Rule	.....	20,915	1	20,915	0.2766	5,785
Total Existing Reporting Burden for 0584–0006, Part 210.	.....	.....	.....	.....	.....	2,981,464
Total Reporting Burden Increase with Interim Rule.	.....	.....	.....	.....	.....	5,785
Total Reporting Burden for 0584–0006, Part 210 with Interim Rule.	.....	.....	.....	.....	.....	2,987,249
Recordkeeping						
SA maintains records of paid reimbursable lunch prices obtained from SFAs.	7 CFR 210.14(e)(7).	57	366	20,858	0.2	4,172
SFA maintains records of its calculation of the average price of paid reimbursable lunches and adjustments.	7 CFR 210.14(e)(1)–(e)(5).	20,858	1	20,858	5	104,290
SFAs maintains records documenting the revenue generated from the sale of nonprogram foods.	7 CFR 210.14(f) ..	20,858	1	20,858	10	208,580
Total Recordkeeping for Interim Rule.	.....	20,915	2.99	62,574	15.1586	317,042
Total Existing Recordkeeping Burden for 0584–0006, Part 210.	.....	.....	.....	.....	.....	9,276,300

ESTIMATED ANNUAL BURDEN FOR 0584–NEW, NATIONAL SCHOOL LUNCH PROGRAM 7 CFR PART 210—Continued

	Section	Estimated number of respondents	Frequency of response	Average annual responses	Average burden per response	Annual burden hours
Total Recordkeeping Burden for 0584–0006, Part 210 with Interim Rule.	.....	.....	.....	.....	.....	9,593,342

SUMMARY OF BURDEN (OMB #0584–NEW)

Total No. Respondents	20,915
Average No. Responses per Respondent	3.991824
Total Annual Responses	83,489
Average Hours per Response	3.8667
Total Burden Hours for Part 210 With Interim Rule	12,580,591
Current OMB Inventory for Part 210	12,257,764
Difference (New Burden Requested With Interim Rule)	322,827

7 CFR 210.15 and 210.20 require that, in order to participate in the NSLP, SFAs and State agencies must maintain records to demonstrate compliance with Program requirements. 7 CFR 210.23 further requires that State agencies and SFAs maintain records for a period of three years.

E-Government Act Compliance

The Food and Nutrition Service is committed to complying with the E-Government Act of 2002, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. In spring 2011, USDA engaged in a series of consultative sessions to obtain input by Tribal officials or their designees concerning the impact of this rule on the Tribe or Indian Tribal governments, or whether this rule may preempt Tribal law. Reports from these consultations will be made part of the USDA annual reporting on Tribal Consultation and Collaboration. USDA will respond in a timely and meaningful manner to all Tribal government requests for consultation concerning this rule and will provide additional venues, such as webinars and teleconferences, to periodically host collaborative conversations with Tribal officials or their designees concerning ways to improve this rule in Indian country.

List of Subjects in 7 CFR Part 210

Grant programs—education; Grant programs—health; Infants and children; Nutrition; Penalties; Reporting and recordkeeping requirements; School breakfast and lunch programs; Surplus agricultural commodities.

Accordingly, 7 CFR part 210 is amended as follows:

PART 210—NATIONAL SCHOOL LUNCH PROGRAM

■ 1. The authority citation for 7 CFR part 210 continues to read as follows:

Authority: 42 U.S.C. 1751–1760, 1779.

■ 2. In § 210.2:
■ a. The definition of ''Nonprofit school food service account'' is amended by adding a sentence at the end;
■ b. The definition of ''Subsidized lunch (paid lunch)'' is removed; and
■ c. The definition of ''Paid lunch'' added.

The additions read as follows:

Subpart A—General

§ 210.2 Definitions.

* * * * *

Nonprofit school food service account * * * This account shall include, as appropriate, non-Federal funds used to support paid lunches as provided in § 210.14(e), and proceeds from nonprogram foods as provided in § 210.14(f).

* * * * *

Paid lunch means a lunch served to children who are either not certified for or elect not to receive the free or reduced price benefits offered under part 245 of this chapter. The Department subsidizes each paid lunch with both general cash assistance and donated foods. The prices for paid lunches in a school food authority shall be determined in accordance with § 210.14(e).

* * * * *

Subpart C—Requirements for School Food Authority Participation

■ 3. In § 210.9, paragraph (b)(1) is revised to read as follows:

§ 210.9 Agreement with State agency.

* * * * *

(b) * * *

(1) Maintain a nonprofit school food service and observe the requirements for and limitations on the use of nonprofit school food service revenues set forth in § 210.14 and the limitations on any competitive school food service as set forth in § 210.11;

* * * * *

■ 4. In § 210.14, new paragraphs (e) and (f) are added to read as follows:

§ 210.14 Resource management.

* * * * *

(e) *Pricing paid lunches.* For each school year beginning July 1, 2011, school food authorities shall establish prices for paid lunches in accordance with this paragraph.

(1) *Calculation procedures.* Each school food authority shall:

(i) Determine the average price of paid lunches. The average shall be determined based on the total number of paid lunches claimed for the month of October in the previous school year, at each different price charged by the school food authority.

(ii) Calculate the difference between the per meal Federal reimbursement for paid and free lunches received by the school food authority in the previous school year (*i.e.,* the reimbursement difference);

(iii) Compare the average price of a paid lunch under paragraph (e)(1)(i) of this section to the difference between reimbursement rates under paragraph (e)(1)(ii) of this section.

(2) *Average paid lunch price is equal to/greater than the reimbursement difference.*

When the average paid lunch price from the prior school year is equal to or

greater than the difference in reimbursement rates as determined in paragraph (e)(1)(iii) of this section, the school food authority shall establish an average paid lunch price for the current school year that is not less than the difference identified in (e)(1)(iii) of this section; except that, the school food authority may use the procedure in paragraph (e)(4)(ii) of this section when establishing prices of paid lunches.

(3) *Average lunch price is lower than the reimbursement difference.* When the average price from the prior school year is lower than the difference in reimbursement rates as determined in paragraph (e)(1)(iii) of this section, the school food authority shall establish an average price for the current school year that is not less than the average price charged in the previous school year as adjusted by a percentage equal to the sum obtained by adding:

(i) 2 percent; and

(ii) The percentage change in the Consumers Price Index for All Urban Consumers used to increase the Federal reimbursement rate under section 11 of the Act for the most recent school year for which data are available. The percentage to be used is found in the annual notice published in the **Federal Register** announcing the national average payment rates, from the prior year.

(4) *Price Adjustments.* (i) *Maximum required price increase.* The maximum annual average price increase required under this paragraph shall not exceed ten cents.

(ii) *Rounding of paid lunch prices.* Any school food authority may round the adjusted price of the paid lunches down to the nearest five cents.

(iii) *Optional price increases.* A school food authority may increase the average price by more than ten cents.

(5) *Reduction in average price for paid lunches.* (i) Any school food authority may reduce the average price of paid lunches as established under this paragraph if the State agency ensures that funds are added to the nonprofit school food service account in accordance with this paragraph.

The minimum that must be added is the product of:

(A) The number of paid lunches claimed by the school food authority in the previous school year multiplied by

(B) The amount required under paragraph (e)(3) of this section, as adjusted under paragraph (e)(4) of this section, minus the average price charged.

(ii) *Prohibitions.* The following shall not be used to reduce the average price charged for paid lunches:

(A) Federal sources of revenue;

(B) Revenue from foods sold in competition with lunches or with breakfasts offered under the School Breakfast Program authorized in 7 CFR part 220. Requirements concerning foods sold in competition with lunches or breakfasts are found in § 210.11 and § 220.12 of this chapter, respectively;

(C) In-kind contributions;

(D) Any in-kind contributions converted to direct cash expenditures after July 1, 2011; and

(E) Per-meal reimbursements (non-Federal) specifically provided for support of programs other than the school lunch program.

(iii) *Allowable non-Federal revenue sources.* Any contribution that is for the direct support of paid lunches that is not prohibited under paragraph (e)(5)(ii) of this section may be used as revenue for this purpose. Such contributions include, but are not limited to:

(A) Per-lunch reimbursements for paid lunches provided by State or local governments;

(B) Funds provided by organizations, such as school-related or community groups, to support paid lunches;

(C) Any portion of State revenue matching funds that exceeds the minimum requirement, as provided in § 210.17, and is provided for paid lunches; and

(D) A proportion attributable to paid lunches from direct payments made from school district funds to support the lunch service.

(6) *Additional considerations.* (i) In any given year, if a school food authority with an average price lower than the reimbursement difference is not required by paragraph (e)(4)(ii) of this section to increase its average price for paid lunches, the school food authority shall use the unrounded average price as the basis for calculations to meet paragraph (e)(3) of this section for the next school year.

(ii) If a school food authority has an average price lower than the reimbursement difference and chooses to increase its average price for paid lunches in any school year more than is required by this section, the amount attributable to the additional voluntary increase may be carried forward to the next school year(s) to meet the requirements of this section.

(iii) For the school year beginning July 1, 2011 only, the limitations for non-Federal contributions in paragraph (e)(5)(iii) of this section do not apply.

(7) *Reporting lunch prices.* In accordance with guidelines provided by FNS:

(i) School food authorities shall report prices charged for paid lunches to the State agency; and

(ii) State agencies shall report these prices to FNS.

(f) *Revenue from nonprogram foods.* Beginning July 1, 2011, school food authorities shall ensure that the revenue generated from the sale of nonprogram foods complies with the requirements in this paragraph.

(1) *Definition of nonprogram foods.* For the purposes of this paragraph, nonprogram foods are those foods and beverages:

(i) Sold in a participating school other than reimbursable meals and meal supplements; and

(ii) Purchased using funds from the nonprofit school food service account.

(2) *Revenue from nonprogram foods.* The proportion of total revenue from the sale of nonprogram foods to total revenue of the school food service account shall be equal to or greater than:

(i) The proportion of total food costs associated with obtaining nonprogram foods to

(ii) The total costs associated with obtaining program and nonprogram foods from the account.

(3) All revenue from the sale of nonprogram foods shall accrue to the nonprofit school food service account of a participating school food authority.

■ 5. In § 210.15:

■ a. Amend paragraph (a)(6) by removing the word ''and'' at the end of paragraph;

■ b. Amend paragraph (a)(7) by removing ''.'' at the end of the paragraph and adding ''; and'' in its place;

■ c. Add a new paragraph (a)(8);

■ d. Amend paragraph (b)(5) by removing ''.'' at the end of the paragraph and adding '';'' in its place;

■ e. Add new paragraphs (b)(6) and (b)(7).

The additions read as follows:

§ 210.15 Reporting and recordkeeping.

(a) * * *

(8) The prices of paid lunches charged by the school food authority.

(b) * * *

(6) Records to document compliance with the requirements in § 210.14(e); and

(7) Records to document compliance with the requirements in § 210.14(f).

■ 6. In § 210.19, paragraph (a)(2) is amended by adding a sentence at the end to read as follows:

Subpart D—Requirements for State Agency Participation

§ 210.19 Additional responsibilities.

(a) * * *

(2) * * * Each State agency shall ensure that school food authorities comply with the requirements for

pricing paid lunches and nonprogram foods as required in § 210.14(e) and § 210.14(f).

* * * * *

■ 7. In § 210. 20:

■ a. Amend paragraph (a)(7) by removing the word ''and'' at the end of paragraph;

■ b. Amend paragraph (a)(8) by removing ''.'' at the end of paragraph and adding ''; and'' in its place;

■ c. Add new paragraph (a)(9);

■ d. Amend paragraph (b)(11) by removing the word ''and'' at the end of paragraph;

■ e. Amend paragraph (b)(12) by removing ''.'' at the end of paragraph and adding '';'' in its place;

■ f. Add new paragraphs (b)(13) and (b)(14).

The additions read as follows:

§ 210.20 Reporting and recordkeeping.

(a) * * *

(9) The prices of paid lunches charged by each school food authority.

(b) * * *

(13) Records showing compliance with the requirements in § 210.14(e)(5) and records supplied annually by school food authorities showing paid meal prices charged as required by § 210.14(e)(6); and

(14) Records to document compliance with the requirements in § 210.14(f).

Dated: June 3, 2011.

Kevin Concannon,

Under Secretary, Food, Nutrition and Consumer Services.

[FR Doc. 2011–14926 Filed 6–16–11; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

National Institute of Food and Agriculture

7 CFR Part 3430

[0524–AA61]

Competitive and Noncompetitive Nonformula Federal Assistance Programs—Administrative Provisions for Biomass Research and Development Initiative

AGENCY: National Institute of Food and Agriculture, USDA.

ACTION: Affirmation of interim rule.

SUMMARY: The National Institute of Food and Agriculture (NIFA) is affirming, without change, an interim rule containing a set of specific administrative requirements for the Biomass Research and Development Initiative (BRDI) to supplement the Competitive and Noncompetitive Non-formula Federal Assistance Programs—General Award Administrative Provisions for this program. The BRDI is authorized under section 9008 of the Farm Security and Rural Investment Act of 2002 (FSRIA), as amended by section 9001 of the Food, Conservation, and Energy Act of 2008 (FCEA).

DATES: This final rule is effective on June 17, 2011.

FOR FURTHER INFORMATION CONTACT: Carmela Bailey, National Program Leader, Division of Bioenergy, National Institute of Food and Agriculture, U.S. Department of Agriculture, STOP 3356, 1400 Independence Avenue, SW., Washington, DC 20250–2299; Voice: 202–401–6443; Fax: 202–401–4888; E-mail: *cbailey@NIFA.usda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background and Summary

Authority

On June 14, 2010 (Volume 75, Number 113), NIFA published an interim rule with a 120-day comment period to provide administrative provisions that are specific to the Federal assistance awards made under section 9008 of the Farm Security and Rural Investment Act of 2002 (FSRIA), Public Law 107–171 (7 U.S.C. 8108), as amended by section 9001 of the Food, Conservation, and Energy Act of 2008 (FCEA), Public Law 110–246, providing authority to the Secretary of Agriculture and the Secretary of Energy, to establish and carry out a joint Biomass Research and Development Initiative (BRDI) under which competitively awarded grants, contracts, and financial assistance are provided to, or entered into with, eligible entities to carry out research on and development and demonstration of biofuels and biobased products; and the methods, practices, and technologies for the production of biofuels and biobased products. No program specific comments were received. NIFA will proceed with the final rule with only minimal changes. Should the Secretaries of USDA and DOE decide to make competitive Federal assistance awards under this authority, the rules contained within subpart K apply. Activities authorized under BRDI are carried out in consultation with the Biomass Research and Development Board, established in section 9008(c) of FSRIA and the Biomass Research and Development Technical Advisory committee established in section 9008(d) of FSRIA. The USDA authority to carry out this program has been delegated to NIFA through the Under Secretary for Research, Education, and Economics.

Purpose

The objectives of BRDI are to develop (a) technologies and processes necessary for abundant commercial production of biofuels at prices competitive with fossil fuels; (b) high-value biobased products (1) To enhance the economic viability of biofuels and power, (2) to serve as substitutes for petroleum-based feedstocks and products, and (3) to enhance the value of coproducts produced using the technologies and processes; and (c) a diversity of economically and environmentally sustainable domestic sources of renewable biomass for conversion to biofuels, bioenergy, and biobased products.

Organization of 7 CFR Part 3430

A primary function of NIFA is the fair, effective, and efficient administration of Federal assistance programs implementing agricultural research, education, and extension programs. As noted above, NIFA has been delegated the authority to administer this program and will be issuing Federal assistance awards for funding made available for this program; and thus, awards made under this authority will be subject to the Agency's assistance regulations at 7 CFR part 3430, Competitive and Noncompetitive Non-formula Federal Assistance Programs—General Award Administrative Provisions. The Agency's development and publication of these regulations for its non-formula Federal assistance programs serve to enhance its accountability and to standardize procedures across the Federal assistance programs it administers while providing transparency to the public. NIFA published 7 CFR part 3430 with subparts A through F as an interim rule on August 1, 2008 [73 FR 44897–44909] and as a final rule on [September 4, 2009] [74 FR 45736–45752]. These regulations apply to all Federal assistance programs administered by NIFA except for the formula grant programs identified in 7 CFR 3430.1(f), the Small Business Innovation Research programs, with implementing regulations at 7 CFR part 3403, and the Veterinary Medicine Loan Repayment Program (VMLRP) authorized under section 1415A of the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (NARETPA).

NIFA organized the regulation as follows: Subparts A through E provide administrative provisions for all competitive and noncompetitive non-formula Federal assistance awards.

Subparts F and thereafter apply to specific NIFA programs.

NIFA is, to the extent practical, using the following subpart template for each program authority: (1) Applicability of regulations, (2) purpose, (3) definitions (those in addition to or different from § 3430.2), (4) eligibility, (5) project types and priorities, (6) funding restrictions (including indirect costs), and (7) matching requirements. Subparts F and thereafter contain the above seven components in this order. Additional sections may be added for a specific program if there are additional requirements or a need for additional rules for the program (*e.g.,* additional reporting requirements). Through this rulemaking, NIFA is adding subpart K for the administrative provisions that are specific to the Federal assistance awards made under the BRDI authority.

II. Administrative Requirements for the Rulemaking

Executive Order 12866

This action has been determined to be not significant for purposes of Executive Order 12866, and therefore, has not been reviewed by the Office of Management and Budget. This final rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; nor will it materially alter the budgetary impact of entitlements, grants, user fees, or loan programs; nor will it have an annual effect on the economy of $100 million or more; nor will it adversely affect the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities in a material way. Furthermore, it does not raise a novel legal or policy issue arising out of legal mandates, the President's priorities or principles set forth in the Executive Order.

Regulatory Flexibility Act of 1980

This final rule has been reviewed in accordance with the Regulatory Flexibility Act of 1980, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 601–612. The Department concluded that the rule will not have a significant economic impact on a substantial number of small entities. The rule does not involve regulatory and informational requirements regarding businesses, organizations, and governmental jurisdictions subject to regulation.

Paperwork Reduction Act (PRA)

The Department certifies that this final rule has been assessed in accordance with the requirements of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* (PRA). The Department concludes that this final rule does not impose any new information requirements; however, the burden estimates will increase for existing approved information collections associated with this rule due to additional applicants. These estimates will be provided to OMB. In addition to the SF–424 form families (*i.e.,* Research and Related and Mandatory), SF–425 Federal Financial Report, Financial Status Reports; NIFA has three currently approved OMB information collections associated with this rulemaking: OMB Information Collection No. 0524–0042, NIFA Current Research Information System (CRIS); No. 0524–0041, NIFA Application Review Process; and No. 0524–0026, Assurance of Compliance with the Department of Agriculture Regulations Assuring Civil Rights Compliance and Organizational Information.

Catalog of Federal Domestic Assistance

This final regulation applies to the Federal assistance program administered by NIFA under the Catalog for Federal Domestic Assistance (CFDA) No.10.312, Biomass Research and Development Initiative.

Unfunded Mandates Reform Act of 1995 and Executive Order 13132

The Department has reviewed this final rule in accordance with the requirements of Executive Order No. 13132 and the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1501 *et seq.,* and has found no potential or substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. As there is no Federal mandate contained herein that could result in increased expenditures by State, local, or Tribal governments, or by the private sector, the Department has not prepared a budgetary impact statement.

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

The Department has reviewed this final rule in accordance with Executive Order 13175, and has determined that it does not have ''Tribal implications.'' The final rule does not ''have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.''

Clarity of This Regulation

Executive Order 12866 and the President's Memorandum of June 1, 1998, require each agency to write all rules in plain language. The Department invites comments on how to make this final rule easier to understand.

List of Subjects in 7 CFR Part 3430

Administrative practice and procedure, Agricultural research, Education, Extension, Federal assistance.

PART 3430—COMPETITIVE AND NONCOMPETITIVE NON–FORMULA FEDERAL ASSISTANCE PROGRAMS—GENERAL AWARD ADMINISTRATIVE PROVSIONS

Accordingly, the interim rule amending 7 CFR part 3430 which was published at 75 FR 33497 on June 14, 2010, is adopted as a final rule without change.

Signed at Washington, DC, on June 10, 2011.

Ralph Otto,

Deputy Director, Food and Community Resources, National Institute of Food and Agriculture.

[FR Doc. 2011–15104 Filed 6–16–11; 8:45 am]

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DEPARTMENT OF AGRICULTURE

National Institute of Food and Agriculture

7 CFR Part 3430

RIN 0524–AA59

Competitive and Noncompetitive Non-Formula Federal Assistance Programs—Specific Administrative Provisions for the Beginning Farmer and Rancher Development Program

AGENCY: National Institute of Food and Agriculture, USDA.

ACTION: Final rule.

SUMMARY: The National Institute of Food and Agriculture (NIFA) is adopting as a final rule, with changes, an interim rule (published at 74 FR 45968 on September 4, 2009) containing a set of specific administrative requirements for the Beginning Farmer and Rancher Development Program (BFRDP) to supplement the Competitive and Noncompetitive Non-Formula Federal Assistance Programs—General Award Administrative Provisions for this

program. The BFRDP is authorized under section 7405 of the Farm Security and Rural Investment Act of 2002, as amended by section 7410 of the Food, Conservation, and Energy Act of 2008.

DATES: This final rule is effective on June 17, 2011.

FOR FURTHER INFORMATION CONTACT: Dr. Siva Sureshwaran, National Program Leader, Institute of Food Production and Sustainability; National Institute of Food and Agriculture, U.S. Department of Agriculture, STOP 2240, 1400 Independence Avenue, SW., Washington, DC 20250–2240; Voice: 202–2720–7536; Fax: 202–401–6070; E-mail: *ssureshwaran@nifa.usda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background and Summary

Authority

Section 7405 of the Farm Security and Rural Investment Act of 2002 (FSRIA), Public Law 107–171 (7 U.S.C. 3319f), as amended by section 7410 of the Food, Conservation, and Energy Act of 2008 (FCEA), Public Law 110–246, authorizes the Secretary of Agriculture (Secretary) to provide training, education, outreach, and technical assistance to beginning farmers or ranchers. The authority to carry out this program has been delegated to the National Institute of Food and Agriculture (NIFA) through the Under Secretary for Research, Education, and Economics.

In carrying out the program, the Secretary is authorized to make competitive grants under section 7405(c) of FSRIA to support new and established local and regional training, education, outreach, and technical assistance initiatives that address the needs of beginning farmers and ranchers. The Secretary may award a BFRDP grant to a collaborative State, Tribal, local, or regionally-based network or partnership of public or private entities, which may include: A State cooperative extension service; a Federal, State, or Tribal agency; a community-based and nongovernmental organization; a college or university (including an institution awarding an associate's degree) or foundation maintained by a college or university; or any other appropriate partner, as determined by the Secretary. BFRDP grants shall be awarded to address needs of beginning farmers and ranchers in the following areas: Mentoring, apprenticeships, and internships; resources and referrals; assisting beginning farmers or ranchers in acquiring land from retiring farmers and ranchers; innovative farm and ranch transfer strategies; entrepreneurship and business training; model land leasing contracts; financial management training; whole farm planning; conservation assistance; risk management education; diversification and marketing strategies; curriculum development; understanding the impact of concentration and globalization; basic livestock and crop farming practices; the acquisition and management of agricultural credit; environmental compliance; information processing; and other similar subject areas of use to beginning farmers or ranchers. Pursuant to FSRIA section 7405(c)(3), these grants shall not have a term of more than 3 years and shall not be in an amount greater than $250,000 per year; however, eligible recipients may receive consecutive grants. These awards also are prohibited by statute from supporting planning, repair, rehabilitation, acquisition, or construction of a building or facility. In addition, not less than 25 percent of these BFRDP grant funds for a fiscal year must be used to support programs and services that address the needs of limited resource beginning farmers or ranchers; socially disadvantaged beginning farmers or ranchers; and farm workers (including immigrant farm workers) desiring to become farmers or ranchers. All BFRDP grant applicants are required to provide funds or in-kind support in an amount that is at least equal to 25 percent of the Federal funds awarded. In making BFRDP grants, priority will be given to partnerships and collaborations that are led by or include nongovernmental and community-based organizations with expertise in new agricultural producer training and outreach. Geographical diversity will be ensured to the maximum extent practicable.

FSRIA section 7405(d) also requires the Secretary to establish beginning farmer and rancher education teams to develop curricula and conduct educational programs and workshops for beginning farmers or ranchers in diverse geographical areas of the United States. The Secretary is required, in promoting the development of curricula and to the maximum extent practicable, to include modules tailored to specific audiences of beginning farmers or ranchers, based on crop or regional diversity. The Secretary is required to cooperate, to the maximum extent practicable, with (1) State cooperative extension services; (2) Federal and State agencies; (3) community-based and nongovernmental organizations; (4) colleges and universities (including an institution awarding an associate's degree) or foundations maintained by a college or university; and other appropriate partners, as determined by the Secretary.

FSRIA section 7405(e) requires the Secretary to establish an online clearinghouse that makes available to beginning farmers or ranchers education curricula and training materials and programs, which may include online courses for direct use by beginning farmers or ranchers.

For fiscal year (FY) 2009, $18 million was made available for the BFRDP, including administrative costs. For FY 2010, $19 million was made available for the BFRDP, including administrative costs. For FY 2011, it is anticipated that $19 million will be made available for the BFRDP, including administrative costs.

Comments on Interim Rule and Development of Final Rule for Subpart J

On September 4, 2009, NIFA published an interim rule [74 FR 45968] to provide administrative provisions that are specific to the BFRDP, as subpart J to 7 CFR part 3430. In the interim rule, NIFA invited comments which were due to the agency by November 3, 2009. We received comments from two professional organizations: Association of Southern Region Extension Directors (ASRED) and National Sustainable Agriculture Coalition (NSAC).

ASRED provided two comments: one on eligibility and the second on the addition of two program types under 7 CFR 3430.604, Project types and priorities. Regarding eligibility, ASRED disagreed with 7 CFR 3430.608(b), Review criteria—Partnership and collaboration, which states: ''In making awards under this subpart, NIFA shall give priority to partnerships and collaborations that are led by or include nongovernmental and community-based organizations with expertise in new agricultural producer training and outreach.'' ASRED commented that it does not support placing priority for awards on non-governmental organizations (NGOs) and community-based organizations (CBOs). ASRED continued their comment as follows: ''NGOs/CBOs certainly can contribute to this program as partner, and in some cases, as lead entities, but we question the idea that, by purpose, structure or outcome, NGOs/CBOs offer any inherent advantage as lead entities.'' ASRED requests that the Cooperative Extension Systems be recognized as equally capable lead agencies given the mission of the Cooperative Extension System, as USDA's outreach arm, in partnership with the land-grant institutions and local governments, to provide informal

education throughout 3,000 counties and parishes across the United States. ASRED's comment includes a discussion of the efficient and effective use of the national extension system and the research being conducted at the land-grant institutions. NIFA is not revising 7 CFR 3430.608(b) as the authorizing program legislation, at 7 U.S.C. 3319f(c)(7), specifically provides that for Standard BFRDP Project grants priority be given to partnerships and collaborations that are led by or include nongovernmental and community-based organizations with expertise in new agricultural producer training and outreach and, as a matter of agency discretion, NIFA is applying the statutory priority requirement to the other two components of the BFRDP as well.

ASRED's other comment recommended that ''tax management, including record keeping and tax form preparation'' and ''basic agricultural law'' be added to the list of BFRDP project focus areas in 7 CFR 3430.604(a), Project types and priorities—Standard BFRDP projects. NIFA agrees with this comment and is revising the regulation to include those subject areas as additional program types under 7 CFR 3430.604(a).

NSAC provided a number of comments on the following sections: 7 CFR 3430.602, Definitions; 7 CFR 3430.605(b), Funding restrictions—Indirect costs; 7 CFR 3430.606(a), Matching requirements—Requirement; 7 CFR 3430.608(a), Review criteria—Evaluation criteria; 7 CFR 3430.608(b), Review criteria—Partnership and collaboration; 7 CFR 3430.609(a), Other considerations—Set aside; 7 CFR 3430.609(c), Other considerations—Duration of awards; and 3430.609(d), Other considerations—Amount of grants. NSAC also provided a recommendation on adopting a regional structure for BFRDP.

7 CFR 3430.602—Definitions

NSAC recommended that NIFA use its statutory discretionary authority to add other criteria to the definition of a ''beginning farmer or rancher'' to include the ''two-fold criteria of the Farm Service Agency (FSA) definition from section 343(11)(D) of the Consolidated Farm and Rural Development Act pertaining to material and substantial participation and day-to-day labor and management.'' NSAC stated that adding these additional criteria will ensure that the program is meeting the needs of the audience for which the program was established. NIFA has not revised the definition of ''beginning farmer or rancher'' because NIFA has chosen to use only criteria identified by Congress in the authorizing legislation.

7 CFR 3430.605(b)—Funding Restrictions—Indirect Costs

NSAC urged NIFA to make BFRDP awards as cooperative agreements and thereby, limit the indirect costs to no more than 10 percent or ''in some fashion put a reasonable and modest cap on indirect costs.'' NSAC feels that this would allow funds to support as many projects and beginning farmers and ranchers as possible. NSAC points to the success of the Sustainable Agriculture Research and Education (SARE) Program which has been successful for over two decades ''despite allowing zero indirect costs.''

NIFA is not revising this section as it cannot use cooperative agreements as a way to limit indirect costs for the standard BFRDP projects. Pursuant to FSRIA § 7405(c)(1) (7 U.S.C. 3319f(c)(1)), and as reflected in 7 CFR 3430.604(a), awards for standard BFRDP projects are required to be made as grants. As with other agricultural research, education, and extension grants, BFRDP grants are subject to the 22 percent cap on indirect costs pursuant to NARETPA § 1462(a) (7 U.S.C. 3310(a)).

For the educational enhancement team projects and online clearinghouse authorized by FSRIA §§ 7405(d) and (e), respectively, 7 CFR 3430.604(b) provides that awards for those components of the BFRDP may be made as either grants or cooperative agreements. Per 7 CFR 3430.2, NIFA defines a grant as ''the award by the Authorized Departmental Officer of funds to an eligible grantee to assist in meeting the costs of conducting for the benefit of the public, an identified project which is intended and designed to accomplish the purpose of the program as identified in the program solicitation or RFA'' and a cooperative agreement as ''the award by the Authorized Departmental Officer of funds to an eligible awardee to assist in meeting the costs of conducting for the benefit of the public, an identified project which is intended and designed to accomplish the purpose of the program as identified in the program solicitation or RFA, and where substantial involvement is expected between NIFA and the awardee when carrying out the activity contemplated in the agreement.'' The award types for those projects will depend on whether substantial involvement is expected.

7 CFR 3430.606(a)—Matching Requirements—Requirement

NSAC urged NIFA ''to clarify in the final rule that for the portion of any match that is cash, it does not require that the cash be in hand, provided the applicant provides sufficient information demonstrating that the funding will be available before the time it is needed for expenditure in the project.'' NSAC commented further that ''requiring that cash be in hand at the time a BFRDP application is submitted is a substantial barrier for smaller community-based and non-profit organizations.'' NIFA is not revising this section as the standards for meeting the matching requirements are found in the USDA uniform assistance regulations (7 CFR parts 3016 and 3019) and in the applicable RFAs.

7 CFR 3430.608(a)—Review Criteria—Evaluation Criteria

NSAC had comments on four of the six evaluation criteria under this section. They had no comments on criterion (2), technical merit, and criterion (3), achievability. Under criterion (1), relevancy, NSAC felt that language should be added ''to the rule that clarifies that 'relevancy' includes due consideration of at least three major factors: (1) Creating the maximum number of enduring beginning farmer and rancher opportunities, (2) ensuring that the enduring opportunities being created are economically viable, environmentally-sound, and help create an enhanced quality of life for the farm family and the community, (3) creating farming opportunities that do not diminish farming opportunities for others.'' NIFA does not concur with this recommendation. NIFA concludes that relevancy addresses critical barriers faced by beginning farmers and ranchers.

Under criterion (4), the expertise and track record of one or more of the applicants, NSAC urged NIFA to ''clarify in the rule that expertise be based on demonstrable and quantifiable factors such as the number of training, assistance, or education activities previously carried out, participants or graduates of the program and success rates, and the number of years a program or activity has been offered.'' NIFA concurred with the recommendation. The recommendation of NSAC was included in the FY 2011 RFA.

Under criterion (5), the adequacy of plans for the participatory evaluation process, outcome-based reporting, and the communication of findings and results beyond the immediate target

audience, NSAC comments that NIFA should help the grantees understand the criterion by providing in the definitions section examples of participatory evaluation, outcome-based reporting, and public communication. NSAC suggests that ''outcome-based reporting be defined as outcomes and impacts rather than activities and inputs'' and that ''communicating findings include the expectation that grantees demonstrate how their communications plans reach beyond the immediate clientele to the larger arena of public stakeholders.'' NIFA concurs with the recommendation regarding ''outcome-based reporting'' and has included the following definition under 7 CFR 3430.602: ''*Outcome-based reporting* means reporting that includes an outcome statement with performance targets, necessary milestones, beneficiary engagement, key individuals, and verification.''

Under criterion (6), other appropriate factors, as determined by the Secretary, NSAC states that proposals should be ''ranked higher if they show the degree and frequency of direct face-to-face work and interaction with actual constituencies served.'' NIFA concurs with the recommendation. The recommendation of NSAC was included in the FY 2011 RFA.

7 CFR 3430.608(b)—Review Criteria—Partnership and Collaboration

To ensure that a real, demonstrable partnership exists, NSAC urges NIFA to require for projects in which the lead grantee is an eligible entity that is not a NGO or CBO, that the NGO or CBO not receive less than 25 percent collectively of the BFRDP funding awarded. NSAC believes that such a provision will ''prevent partnership proposals from becoming partnership in name only.'' NIFA concurs with the recommendation. The recommendation of NSAC has been included in the FY 2011 RFA.

7 CFR 3430.609(a)—Other Considerations—Set Aside

NSAC recommended that NIFA include a recommendation from the Conference Report accompanying the FCEA which encourages the Secretary to ''include immigrant beginning farmers and ranchers in the funding set-aside for socially disadvantaged and limited resource farmers and ranchers.'' NSAC urged NIFA to include this group in this section. NIFA concurs and has revised 7 CFR 3430.609(a) accordingly to include immigrant farm workers planning to become beginning farmers and ranchers.

NSAC had a second comment on this section. NSAC urged NIFA to require groups applying under the 25 percent set aside for limited resource beginning farmers and ranchers, socially disadvantaged beginning farmers and ranchers, and farm workers desiring to become farmers or ranchers, to demonstrate that at least 50.1 percent of the population served by the project be members of one or more of those three groups. NSAC urged NIFA to make this requirement part of the rule. NIFA does not concur with the recommendation from NSAC. NIFA has decided that the target audience need not be a specific group but can be open to all beginning farmers and ranchers so long as the program addresses the needs of one or more of those three groups.

7 CFR 3430.609(c)—Other Considerations—Duration

NSAC urged NIFA to apply the 3-year limit to the educational enhancement team project awards in addition to the standard BFRDP project awards. NIFA concurs with this recommendation and has revised 7 CFR 3430.609(c) accordingly to limit the term of the educational enhancement team project awards to three years.

7 CFR 3430.609(d)—Other Considerations—Amount of Grants

NSAC stated that the BRDFP legislative language clearly limits grants to no more than $250,000 per year and urged NIFA to clarify this in the final rule. In the interim rule, CSREES/NIFA decided to provide the maximum flexibility to the extent of the law for the awards made under the BFRDP authority in not subjecting the educational enhancement team projects to this limitation. However, based on the above comment, NIFA has revised 7 CFR 3430.609(d) to limit the educational enhancement team project awards to no more than $250,000 per year.

Additional Consideration—Regional Program Delivery

NSAC urged NIFA to ''convene a short-duration stakeholder process to determine whether it would be advantageous to adopt a regional structure for BFRDP.'' NSAC felt that a lot could be gained from a regional approach (*i.e.,* ''getting the program close to the ground as possible;'' program would better reflect regional differences and priorities; the structure would allow for more expertise, ownership, and buy-in; and would allow for a more efficient use of resources). NIFA's response to NSAC is that there was not much support for regional program delivery at the first stakeholder meeting. If this program is reauthorized in the next Farm Bill, NIFA would consider revisiting the recommendation. There are a collection of projects that potentially could be strengthened through a regional structure at a later time.

Organization of 7 CFR Part 3430

A primary function of NIFA is the fair, effective, and efficient administration of Federal assistance programs implementing agricultural research, education, and extension programs. As noted above, NIFA has been delegated the authority to administer this program and will be issuing Federal assistance awards for funding made available for this program; and thus, awards made under this authority will be subject to the Agency's assistance regulations at 7 CFR part 3430, Competitive and Noncompetitive Non-formula Federal Assistance Programs—General Award Administrative Provisions. The Agency's development and publication of these regulations for its non-formula Federal assistance programs serve to enhance its accountability and to standardize procedures across the Federal assistance programs it administers while providing transparency to the public. NIFA published 7 CFR part 3430 with subparts A through F as an interim rule on August 1, 2008 [73 FR 44897–44909], and as a final rule on September 4, 2009 [74 FR 45736–45752]. These regulations apply to all Federal assistance programs administered by NIFA except for the formula grant programs identified in 7 CFR 3430.1(f), the Small Business Innovation Research programs with implementing regulations at 7 CFR part 3403 and the Veterinary Medicine Loan Repayment Program (VMLRP), authorized under section 1415A of the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (NARETPA) with implementing regulations at 7 CFR part 3431.

NIFA organized the regulation as follows: Subparts A through E provide administrative provisions for all competitive and noncompetitive non-formula Federal assistance awards. Subparts F and thereafter apply to specific NIFA programs.

NIFA is, to the extent practical, using the following subpart template for each program authority: (1) Applicability of regulations, (2) purpose, (3) definitions (those in addition to or different from § 3430.2), (4) eligibility, (5) project types and priorities, (6) funding restrictions, and (7) matching requirements. Subparts F and thereafter contain the

above seven components in this order. Additional sections may be added for a specific program if there are additional requirements or a need for additional rules for the program (*e.g.,* additional reporting requirements).

Through this rulemaking, NIFA is adding subpart J for the administrative provisions that are specific to the BFRDP.

II. Administrative Requirements for the Final Rulemaking

Executive Order 12866

This action has been determined to be not significant for purposes of Executive Order 12866, and therefore, has not been formally reviewed by the Office of Management and Budget. This final rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; nor will it materially alter the budgetary impact of entitlements, grants, user fees, or loan programs; nor will it have an annual effect on the economy of $100 million or more; nor will it adversely affect the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or Tribal governments or communities in a material way. Furthermore, it does not raise a novel legal or policy issue arising out of legal mandates, the President's priorities or principles set forth in the Executive Order.

Regulatory Flexibility Act of 1980

This final rule has been reviewed in accordance with the Regulatory Flexibility Act of 1980, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 601–612. The Department concluded that the rule will not have a significant economic impact on a substantial number of small entities. The rule does not involve regulatory and informational requirements regarding businesses, organizations, and governmental jurisdictions subject to regulation.

Paperwork Reduction Act (PRA)

The Department certifies that this final rule has been assessed in accordance with the requirements of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* (PRA). The Department concludes that this final rule does not impose any new information requirements; however, the burden estimates will increase for existing approved information collections associated with this rule due to additional applicants.

These estimates have been provided to OMB. In addition to the SF–424 form families (*i.e.,* Research and Related and Mandatory), and SF–425, Federal Financial Reports; NIFA has three currently approved OMB information collections associated with this rulemaking: OMB Information Collection No. 0524–0042, NIFA Current Research Information System (CRIS); No. 0524–0041, NIFA Application Review Process; and No. 0524–0026, Organizational Information.

Catalog of Federal Domestic Assistance

This final regulation applies to the Federal assistance program administered by NIFA under the Catalog of Federal Domestic Assistance (CFDA) No. 10.311, Beginning Farmer and Rancher Development Program.

Unfunded Mandates Reform Act of 1995 and Executive Order 13132

The Department has reviewed this final rule in accordance with the requirements of Executive Order No. 13132 and the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1501 *et seq.,* and has found no potential or substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. As there is no Federal mandate contained herein that could result in increased expenditures by State, local, or Tribal governments, or by the private sector, the Department has not prepared a budgetary impact statement.

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

The Department has reviewed this final rule in accordance with Executive Order 13175, and has determined that it does not have ''Tribal implications''. The final rule does not ''have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes''.

Clarity of This Regulation

Executive Order 12866 and the President's Memorandum of June 1, 1998, require each agency to write all rules in plain language. The Department invites comments on how to make this final rule easier to understand.

List of Subjects in 7 CFR Part 3430

Administrative practice and procedure, Agricultural research, Education, Extension, Federal assistance.

Accordingly, the interim rule amending 7 CFR part 3430 which was published at 74 FR 45968 on September 4, 2009, is adopted as a final rule with the following changes:

PART 3430—COMPETITIVE AND NONCOMPETITIVE NON-FORMULA FEDERAL ASSISTANCE PROGRAMS—GENERAL AWARD ADMINISTRATIVE PROVISIONS

■ 1. The authority citation for part 3430 continues to read as follows:

Authority: 7 U.S.C. 3316; Pub. L. 106–107 (31 U.S.C. 6101 note).

■ 2. Amend § 3430.602 by adding a definition of ''Outcome-based reporting'' to read as follows:

§ 3430.602 Definitions.

* * * * *

Outcome-based reporting means reporting that includes an outcome statement with performance targets, necessary milestones, beneficiary engagement, key individuals, and verification.

■ 3. Amend § 3430.604 as follows:

■ a. Revise paragraph (a)(19); and

■ b. Add new paragraphs (a)(20) and (a)(21), to read as follows:

§ 3430.604 Project types and priorities.

(a) * * *

(19) Tax management, including record keeping and tax form preparation.

(20) Basic agricultural law.

(21) Other similar subject areas of use to beginning farmers or ranchers.

* * * * *

■ 4. Amend § 3430.609 by revising paragraphs (a)(3), (c), and (d), to read as follows:

§ 3430.609 Other considerations.

(a) * * *

(3) Farm workers (including immigrant farm workers) desiring to become farmers or ranchers.

* * * * *

(c) *Duration of awards.* The term of a grant for a standard BFRDP project and an award for an educational enhancement team project under this subpart shall not exceed 3 years. Awards for all other projects under this subpart shall not exceed 5 years. No-cost extensions of time beyond the maximum award terms will not be considered or granted.

(d) *Amount of grants.* A grant for a standard BFRDP project and an award for an educational enhancement team project under this subpart shall not be in an amount that is more than $250,000 for each year.

Signed at Washington, DC, on June 10, 2011.

Ralph Otto,

Deputy Director, Food and Community Resources, National Institute of Food and Agriculture.

[FR Doc. 2011–15105 Filed 6–16–11; 8:45 am]

BILLING CODE 3410–22–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM458; Special Conditions No. 25–431–SC]

Special Conditions: Boeing Model 787 Series Airplanes; Seats With Inflatable Lapbelts

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Boeing Model 787 series airplane. These airplanes will have a novel or unusual design feature(s) associated with seats with inflatable lapbelts. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: The effective date of these special conditions is June 13, 2011. We must receive your comments by July 18, 2011.

ADDRESSES: You must mail two copies of your comments to: Federal Aviation Administration, Transport Airplane Directorate, Attn: Rules Docket (ANM–113), Docket No. NM458, 1601 Lind Avenue, SW., Renton, Washington 98057–3356. You may deliver two copies to the Transport Airplane Directorate at the above address. You must mark your comments: Docket No. NM458. You can inspect comments in the Rules Docket weekdays, except Federal holidays, between 7:30 a.m. and 4 p.m.

FOR FURTHER INFORMATION CONTACT: Jeff Gardlin, FAA, Airframe and Cabin Safety Branch, ANM–115, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–2136; facsimile (425) 227–1149.

SUPPLEMENTARY INFORMATION: The FAA has determined that notice of, and opportunity for prior public comment on, these special conditions, are impracticable because these procedures would significantly delay issuance of the design approval and thus delivery of the affected aircraft. In addition, the substance of these special conditions has been subject to the public comment process in several prior instances with no substantive comments received. The FAA therefore finds that good cause exists for making these special conditions effective upon issuance.

Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data. We ask that you send us two copies of written comments.

We will file in the docket all comments we receive, as well as a report summarizing each substantive public contact with FAA personnel about these special conditions. You can inspect the docket before and after the comment closing date. If you wish to review the docket in person, go to the address in the **ADDRESSES** section of this preamble between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

We will consider all comments we receive by the closing date for comments. We may change these special conditions based on the comments we receive.

If you want us to acknowledge receipt of your comments on these special conditions, include with your comments a self-addressed, stamped postcard on which you have written the docket number. We will stamp the date on the postcard and mail it back to you.

Background

On March 28, 2003, Boeing Commercial Airplanes applied for an FAA type certificate for its new Model 787 series airplane (hereafter referred to as ''787''). Boeing later applied for, and was granted, an extension of time for the type certificate, which changed the effective application date to October 1, 2006. The 787 will be an all-new, twin-engine jet transport airplane with a two-aisle cabin. The maximum takeoff weight will be 476,000 pounds, with a maximum passenger count of 381. These airplanes will have a novel or unusual design feature associated with seats with inflatable lapbelts. The inflatable lapbelt is designed to limit occupant forward excursion in the event of an accident. This will reduce the potential for head injury, thereby reducing the Head Injury Criteria (HIC) measurement. The inflatable lapbelt behaves similarly to an automotive airbag, but in this case the airbag is integrated into the lapbelt, and inflates away from the seated occupant. While airbags are now standard in the automotive industry, the use of an inflatable lapbelt is novel for commercial aviation.

Title 14, Code of Federal Regulations (14 CFR) 25.785 requires that occupants be protected from head injury by either the elimination of any injurious object within the striking radius of the head, or by padding. Traditionally, this has required a set back of 35 inches from any bulkhead or other rigid interior feature or, where not practical, specified types of padding. The relative effectiveness of these means of injury protection was not quantified. With the adoption of Amendment 25–64 to part 25, specifically § 25.562, a new standard that quantifies required head injury protection was created.

Section 25.562 specifies that each seat type design approved for crew or passenger occupancy during takeoff and landing must successfully complete dynamic tests or be shown to be compliant by rational analysis based on dynamic tests of a similar type seat. In particular, the regulations require that persons not suffer serious head injury under the conditions specified in the tests, and that protection must be provided or the seat be designed so that the head impact does not exceed a HIC of 1000 units. While the test conditions described for HIC are detailed and specific, it is the intent of the requirement that an adequate level of head injury protection be provided for passengers in a severe crash.

Because §§ 25.562 and 25.785 and associated guidance do not adequately address seats with inflatable lapbelts, the FAA recognizes that appropriate pass/fail criteria need to be developed that do fully address the safety concerns specific to occupants of these seats.

The inflatable lapbelt has two potential advantages over other means of head impact protection. First, it can provide significantly greater protection than would be expected with energy-absorbing pads, and second, it can provide essentially equivalent protection for occupants of all stature. These are significant advantages from a safety standpoint, since such devices will likely provide a level of safety that exceeds the minimum standards of the Federal aviation regulations. Conversely, inflatable lapbelts in general are active systems and must be relied upon to activate properly when

needed, as opposed to an energy-absorbing pad or upper torso restraint that is passive, and always available. Therefore, the potential advantages must be balanced against this and other potential disadvantages in order to develop standards for this design feature.

The FAA has considered the installation of inflatable lapbelts to have two primary safety concerns: First, that they perform properly under foreseeable operating conditions, and second, that they do not perform in a manner or at such times as would constitute a hazard to the airplane or occupants. This latter point has the potential to be the more rigorous of the requirements, owing to the active nature of the system.

The inflatable lap belt will rely on electronic sensors for signaling and a stored gas canister for inflation. These same devices could be susceptible to inadvertent activation, causing deployment in a potentially unsafe manner. The consequences of inadvertent deployment as well as failure to deploy must be considered in establishing the reliability of the system. Boeing must substantiate that the effects of an inadvertent deployment in flight either would not cause injuries to occupants or that such deployment(s) meet the requirement of § 25.1309(b). The effect of an inadvertent deployment on a passenger or crewmember that might be positioned close to the inflatable lapbelt should also be considered. The person could be either standing or sitting. A minimum reliability level will have to be established for this case, depending upon the consequences, even if the effect on the airplane is negligible.

The potential for an inadvertent deployment could be increased as a result of conditions in service. The installation must take into account wear and tear so that the likelihood of an inadvertent deployment is not increased to an unacceptable level. In this context, an appropriate inspection interval and self-test capability are considered necessary. Other outside influences are lightning and high intensity radiated fields (HIRF). Existing regulations regarding lightning, § 25.1316, and existing HIRF special conditions for the 787–8 airplane, 25–354–SC, are applicable. Finally, the inflatable lapbelt installation should be protected from the effects of fire, so that an additional hazard is not created by, for example, a rupture of the pyrotechnic squib.

In order to be an effective safety system, the inflatable lapbelt must function properly and must not introduce any additional hazards to occupants as a result of its functioning. There are several areas where the inflatable lapbelt differs from traditional occupant protection systems, and requires special conditions to ensure adequate performance.

Because the inflatable lapbelt is essentially a single use device, there is the potential that it could deploy under crash conditions that are not sufficiently severe as to require head injury protection from the inflatable lapbelt. Since an actual crash is frequently composed of a series of impacts before the airplane comes to rest, this could render the inflatable lapbelt useless if a larger impact follows the initial impact. This situation does not exist with energy absorbing pads or upper torso restraints, which tend to provide continuous protection regardless of severity or number of impacts in a crash event. Therefore, the inflatable lapbelt installation should provide protection when it is required, by not expending its protection during a less severe impact. Also, it is possible to have several large impact events during the course of a crash, but there is no requirement for the inflatable lapbelt to provide protection for multiple impacts.

Since each occupant's restraint system provides protection for that occupant only, the installation must address seats that are unoccupied. It will be necessary to show that the required protection is provided for each occupant regardless of the number of occupied seats, and considering that unoccupied seats may have lapbelts that are active.

The inflatable lap belt should be effective for a wide range of occupants. The FAA has historically considered the range from the fifth percentile female to the ninety-fifth percentile male as the range of occupants that must be taken into account. In this case, the FAA is proposing consideration of a broader range of occupants, due to the nature of the lapbelt installation and its close proximity to the occupant. In a similar vein, these persons could have assumed the brace position, for those accidents where an impact is anticipated. Test data indicate that occupants in the brace position do not require supplemental protection, and so it would not be necessary to show that the inflatable lapbelt will enhance the brace position. However, the inflatable lapbelt must not introduce a hazard in that case when deploying into the seated, braced occupant.

Another area of concern is the use of seats, so equipped, by children whether lap-held, in approved child safety seats, or occupying the seat directly. Although specifically prohibited by the FAA operating regulations, the use of the supplementary loop belt (''belly belt'') may be required by other civil aviation authorities, and should also be considered with the end goal of meeting those regulations. Similarly, if the seat is occupied by a pregnant woman, the installation needs to address such usage, either by demonstrating that it will function properly, or by adding appropriate limitation on usage.

Since the inflatable lapbelt will be electrically powered, there is the possibility that the system could fail due to a separation in the fuselage. Since this system is intended as crash/post-crash protection means, failure to deploy due to fuselage separation is not acceptable. As with emergency lighting, the system should function properly if such a separation occurs at any point in the fuselage.

Since the inflatable lapbelt is likely to have a large volume displacement, the inflated bag could potentially impede egress of passengers. Since the bag deflates to absorb energy, it is likely that an inflatable lapbelt would be deflated at the time that persons would be trying to leave their seats. Nonetheless, it is considered appropriate to specify a time interval after which the inflatable lapbelt may not impede rapid egress. Ten seconds has been chosen as a reasonable time since this corresponds to the maximum time allowed for an exit to be openable (§ 25.809). In actuality, it is unlikely that an exit would be prepared by a flight attendant this quickly in an accident severe enough to warrant deployment of the inflatable lapbelt, and the inflatable lapbelt is expected to deflate much quicker than ten seconds.

In addition, during the development of the inflatable lap belt the manufacturer was unable to develop a fabric that would meet the inflation requirements for the bag and the flammability requirements of part I(a)(1)(ii) of appendix F to part 25. The fabrics that were developed that meet the flammability requirement did not produce acceptable deployment characteristics. However, the manufacturer was able to develop a fabric that meets the less stringent flammability requirements of part I(a)(1)(iv) of appendix F to part 25 and has acceptable deployment characteristics.

Part I of appendix F to part 25 specifies the flammability requirements for interior materials and components. There is no reference to inflatable restraint systems in Appendix F, because such devices did not exist at the time the flammability requirements were written. The existing requirements are based on both material types, as well

as use, and have been specified in light of the state-of-the-art of materials available to perform a given function. In the absence of a specific reference, the default requirement would be for the type of material used to construct the inflatable restraint, which is a fabric in this case. However, in writing a special condition, the FAA must also consider the use of the material, and whether the default requirement is appropriate. In this case, the specialized function of the inflatable restraint means that highly specialized materials are needed. The standard normally applied to fabrics is a 12-second vertical ignition test. However, materials that meet this standard do not perform adequately as inflatable restraints. Since the safety benefit of the inflatable restraint is very significant, the flammability standard appropriate for these devices should not screen out suitable materials, thereby effectively eliminating use of inflatable restraints. The FAA will need to establish a balance between the safety benefit of the inflatable restraint and its flammability performance. At this time, the 2.5-inch per minute horizontal test is considered to provide that balance. As the state-of-the-art in materials progresses (which is expected), the FAA may change this standard in subsequent special conditions to account for improved materials.

Finally, it should be noted that the special conditions are applicable to the inflatable lapbelt system as installed. The special conditions are not an installation approval. Therefore, while the special conditions relate to each such system installed, the overall installation approval is a separate finding, and must consider the combined effects of all such systems installed.

Type Certification Basis

Under the provisions of 14 CFR 21.17, Boeing Commercial Airplanes must show that the 787 series airplanes meet the applicable provisions of part 25, as amended by Amendments 25–1 through 25–120, 25–124, 25–125, and 25–128 with the following exceptions: § 25.1301 remains at Amendment 25–119 for cargo fire protection systems.

If the Administrator finds that the applicable airworthiness regulations (i.e., part 25) do not contain adequate or appropriate safety standards for the 787 series airplanes because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, the special conditions would also apply to the other model.

In addition to the applicable airworthiness regulations and special conditions, the 787 series airplanes must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36; and the FAA must issue a finding of regulatory adequacy under § 611 of Public Law 92–574, the ''Noise Control Act of 1972.''.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type certification basis under § 21.17(a)(2).

Novel or Unusual Design Features

The 787 series airplanes will incorporate the following novel or unusual design features: Boeing Commercial Airplanes is proposing to install an inflatable lapbelt on certain seats of 787 series airplanes, in order to reduce the potential for head injury in the event of an accident. The inflatable lapbelt works similar to an automotive airbag, except that the airbag is integrated with the lap belt of the restraint system.

The CFR states the performance criteria for head injury protection in objective terms. However, none of these criteria are adequate to address the specific issues raised concerning seats with inflatable lapbelts. The FAA has therefore determined that, in addition to the requirements of part 25, special conditions are needed to address requirements particular to installation of seats with inflatable lapbelts.

Accordingly, in addition to the passenger injury criteria specified in § 25.785, these special conditions are adopted for the 787 series airplanes equipped with inflatable lapbelts. Other conditions may be developed, as needed, based on further FAA review and discussions with the manufacturer and civil aviation authorities.

Discussion

From the standpoint of a passenger safety system, the inflatable lapbelt is unique in that it is both an active and entirely autonomous device. While the automotive industry has good experience with airbags, the conditions of use and reliance on the inflatable lapbelt as the sole means of injury protection are quite different. In automobile installations, the airbag is a supplemental system and works in conjunction with an upper torso restraint. In addition, the crash event is more definable and of typically shorter duration, which can simplify the activation logic. The airplane operating environment is also quite different from automobiles and includes the potential for greater wear and tear, and unanticipated abuse conditions (due to galley loading, passenger baggage, *etc.*); airplanes also operate where exposure to high intensity electromagnetic fields could affect the activation system.

The following special conditions can be characterized as addressing either the safety performance of the system, or the system's integrity against inadvertent activation. Because a crash requiring use of the inflatable lapbelts is a relatively rare event, and because the consequences of an inadvertent activation are potentially quite severe, these latter requirements are probably the more rigorous from a design standpoint.

Applicability

As discussed above, these special conditions are applicable to the 787 series airplane. Should Boeing Commercial Airplanes apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, the special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on 787 series of airplanes. It is not a rule of general applicability.

The substance of these special conditions has been subjected to the notice and comment period in several prior instances and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. Therefore, because a delay would significantly affect the certification of the airplane, which is imminent, the FAA has determined that prior public notice and comment are unnecessary and impracticable, and good cause exists for adopting these special conditions upon issuance. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Boeing Model 787 series airplanes.

1. Seats with Inflatable Lapbelts. It must be shown that the inflatable lapbelt will deploy and provide protection under crash conditions where it is necessary to prevent serious head injury. The means of protection must take into consideration a range of stature from a two year old child to a ninety-fifth percentile male. The inflatable lapbelt must provide a consistent approach to energy absorption throughout that range of occupants. In addition, the following situations must be considered:

a. The seat occupant is holding an infant.

b. The seat occupant is a child in a child restraint device.

c. The seat occupant is a child not using a child restraint device.

d. The seat occupant is a pregnant woman.

2. The inflatable lapbelt must provide adequate protection for each occupant regardless of the number of occupants of the seat assembly, considering that unoccupied seats may have active seatbelts.

3. The design must prevent the inflatable lapbelt from being either incorrectly buckled or incorrectly installed such that the inflatable lapbelt would not properly deploy. Alternatively, it must be shown that such deployment is not hazardous to the occupant, and will provide the required head injury protection.

4. It must be shown that the inflatable lapbelt system is not susceptible to inadvertent deployment as a result of wear and tear, or inertial loads resulting from in-flight or ground maneuvers (including gusts and hard landings), and other operating and environmental conditions (vibrations, moisture, *etc.*) likely to be experienced in service.

5. Deployment of the inflatable lapbelt must not introduce injury mechanisms to the seated occupant, or result in injuries that could impede rapid egress. This assessment should include an occupant who is in the brace position when it deploys and an occupant whose belt is loosely fastened.

6. It must be shown that inadvertent deployment of the inflatable lapbelt, during the most critical part of the flight, will either not cause a hazard to the airplane or its occupants, or it meets the requirement of § 25.1309(b).

7. It must be shown that the inflatable lapbelt will not impede rapid egress of occupants 10 seconds after its deployment.

8. The system must be protected from lightning and HIRF. The threats specified in the certification basis regarding lightning, § 25.1316, and HIRF (special conditions) for the 787–8 airplane, are incorporated by reference for the purpose of measuring lightning and HIRF protection.

9. Inflatable lap belts, once deployed, must not adversely effect the emergency lighting system (*i.e.,* block proximity lights to the extent that the lights no longer meet their intended function).

10. The inflatable lapbelt must function properly after loss of normal airplane electrical power, and after a transverse separation of the fuselage at the most critical location. A separation at the location of the lapbelt does not have to be considered.

11. It must be shown that the inflatable lapbelt will not release hazardous quantities of gas or particulate matter into the cabin.

12. The inflatable lapbelt installation must be protected from the effects of fire such that no hazard to occupants will result.

13. There must be a means for a crewmember to verify the integrity of the inflatable lapbelt activation system prior to each flight or it must be demonstrated to reliably operate between inspection intervals. The FAA considers the loss of the airbag system deployment function alone (*i.e.,* independent of the conditional event that requires the airbag system deployment) is a major failure condition.

14. The inflatable material may not have an average burn rate of greater than 2.5 inches/minute when tested using the horizontal flammability test as defined in part 25, appendix F, part I, paragraph (b)(5).

Issued in Renton, Washington, on June 13, 2011.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service, ANM–100.

[FR Doc. 2011–15094 Filed 6–16–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2010–0853; Directorate Identifier 2010–NM–116–AD; Amendment 39–16720; AD 2011–12–13]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for the products listed above. This AD requires repetitive testing of the stabilizer takeoff warning switches, and corrective actions if necessary. This AD was prompted by reports that the warning horn did not sound during the takeoff warning system test of the S132 ''nose up stab takeoff warning switch.'' We are issuing this AD to detect and correct a takeoff warning system switch failure, which could reduce the ability of the flightcrew to maintain the safe flight and landing of the airplane.

DATES: This AD is effective July 22, 2011.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in the AD as of July 22, 2011.

ADDRESSES: For service information identified in this AD, contact Boeing Commercial Airplanes, *Attention:* Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, Washington 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; e-mail *me.boecom@boeing.com;* Internet *https://www.myboeingfleet.com.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is

Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Jeffrey W. Palmer, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue, SW., Renton, Washington 98057–3356; *phone:* 425–917–6472; *fax:* 425–917–6590; *e-mail: jeffrey.w.palmer@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an airworthiness directive (AD) that would apply to the specified products. That NPRM published in the **Federal Register** on September 14, 2010 (75 FR 55691). That NPRM proposed to require repetitive testing of the stabilizer takeoff warning switches, and corrective actions if necessary.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the proposal and the FAA's response to each comment.

Support for the NPRM

Continental Airlines, Delta Air Lines, and the Air Line Pilots Association (ALPA), International, support the NPRM.

Requests To Revise Costs of Compliance Section of the NPRM

American Airlines (AA) requested that we revise the Cost of Compliance section of the NPRM to show a more accurate cost to operators. Delta Air Lines noted that the actual cost to operators will be more than what is described in the Costs of Compliance section given in the NPRM.

AA explained that the Costs of Compliance estimate provided in the NPRM specifies 1 work-hour per product at an average labor rate of $85 per hour. However, AA stated that Boeing Service Bulletin 737–27–1289, dated April 7, 2010, estimates 4.25 hours to accomplish the test of the switches and an additional 2.25 hours each to replace the switches. AA asserted that Boeing Service Bulletin 737–27–1289, dated April 7, 2010, estimates a cost to operators of $361.25 to $743.75 per product.

We agree to provide clarification of the Costs of Compliance section in this final rule. Since the issuance of the NPRM, Boeing has issued Service Bulletin Information Notice 737–27–1289 IN 02, dated September 27, 2010, which provides revised work-hours for testing (1 work-hour) and the on-condition replacement (2 work-hours) of the switches. We have revised the Costs of Compliance section of this final rule to reflect the latest cost information provided by the manufacturer.

Request To Add Terminating Action for Repetitive Inspections

ALPA requested that we revise the NPRM to include a terminating action for the repetitive inspections proposed by the NPRM. AA stated that the lack of a terminating action for the repetitive inspections proposed by the NPRM places pressure on the operator because it is required to continue the repetitive inspections at intervals of 750 flight cycles for the affected airplanes.

We disagree to include a terminating action in the final rule. The manufacturer has advised that extensive modifications would be required to eliminate the repetitive inspections. No terminating action is currently available. However, if a modification that addresses the unsafe condition addressed by this AD is developed, approved, and available, operators could request approval of an alternative method of compliance (AMOC) to this AD for doing that modification. No change has been made to the final rule in regard to this issue.

Request To Allow Repair of Switch Before Replacing

AA questioned why operators could not attempt to repair a failed switch before being required to replace the failed switch. AA explained that the NPRM and Boeing Service Bulletin 737–27–1289, dated April 7, 2010, require the switch to be replaced if it fails the test. AA reasoned that the switches are adjustable per ''AMM 31–51–02—Stabilizer Takeoff Warning Switches—Adjustment/Test.''

From these statements, we infer that AA is requesting that we revise the NPRM to allow operators to repair a failed switch. We disagree. The intent of the test specified in paragraph (g) of the final rule is to find and, if necessary, replace switches that fail to electrically open or close properly regardless of adjustment [within the switch's allowable range of adjustment], not switches that are simply out of adjustment. For switches that are out of adjustment, it is acceptable to attempt to adjust a switch that fails the test, prior to replacing the switch. However, the allowable range of adjustment is limited. If the switch continues to fail the test within the switch's allowable range of adjustment, it must be replaced. To preclude test failures due to an out-of-adjustment switch, the manufacturer recommends doing the test with stabilizer trim set at least one unit outside the green band. Doing the test according to the manufacturer's recommendation will ensure that any test failures are due to a malfunctioning switch, not due to a switch that is simply out of adjustment. No change has been made to the final rule in regard to this issue.

Request To Allow Additional Replacement Switch

Delta Air Lines (the commenter) requested that we revise the NPRM to allow switch part number (P/N) 35EN27–4 to be an additional acceptable replacement switch for failed switches. The commenter explained that paragraph (h) of the NPRM specifies that a stabilizer takeoff warning switch which fails the required test must be replaced with a new switch prior to further flight, in accordance with Boeing Service Bulletin 737–27–1289, dated April 7, 2010. The commenter further explained that ''Section 3.B 'Work Instructions' '' of this service information does not specify replacement switches by part number. The commenter also explained that replacement switch part numbers are found in ''Section 2.C.2 'Parts and Materials Supplied by the Operator' of the SB,'' and that this section lists only three part numbers. The commenter expressed that it is aware of an additional switch, which is not listed in Boeing Service Bulletin 737–27–1289, dated April 7, 2010.

We do not agree to allow switch P/N 35EN27–4 to be an additional acceptable replacement switch. This part has not been validated as an acceptable replacement part at this time. The manufacturer is currently assessing the acceptability of this part as a replacement part and might revise the service information at a later time to include this part number. If this part number is found to be acceptable at a later date, its use might be approved as an AMOC to this AD. No change has been made to the final rule in regard to this issue.

Effect of This AD on AD 88–22–09

Paragraph (b) (''Affected ADs'') of this AD has been revised to note that this AD affects AD 88–22–09, Amendment 39–6054 (Docket No. 88–NM–132–AD; 53 FR 41313, October 21, 1988). In addition, we have revised paragraph (g) of this AD to state that accomplishment of the repetitive tests required by this

AD terminates the operational and functional checks of the takeoff configuration warning system required by paragraph A., required item 3 (''Elevator out of Green Band switches'') of AD 88–22–09 for the airplanes affected by this new AD.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting the AD as proposed.

Costs of Compliance

We estimate that this AD would affect 963 airplanes of U.S. registry. We also estimate that it would take about 1 work-hour per product to comply with this AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this AD to the U.S. operators to be $81,855, or $85 per product, per inspection cycle.

We estimate the following costs to do any necessary replacements that would be required based on the results of the proposed inspection. We have no way of determining the number of aircraft that might need this replacement:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
2 work-hours × $85 per hour = $170	Replacement	$0	$170

According to the manufacturer, some of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2011–12–13 The Boeing Company: Amendment 39–16720; Docket No. FAA–2010–0853; Directorate Identifier 2010–NM–116–AD.

Effective Date

(a) This AD is effective July 22, 2011.

Affected ADs

(b) This AD affects AD 88–22–09, Amendment 39–6054 (Docket No. 88–NM–132–AD). This AD does not supersede the requirements of AD 88–22–09.

Applicability

(c) This AD applies to The Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes, certificated in any category; as identified in Boeing Service Bulletin 737–27–1289, dated April 7, 2010.

Subject

(d) Air Transport Association (ATA) of America Code 27: Flight Controls.

Unsafe Condition

(e) This AD was prompted by reports that the warning horn did not sound during the takeoff warning system test of the S132 ''nose up stab takeoff warning switch.'' The Federal Aviation Administration is issuing this AD to detect and correct a takeoff warning system switch failure, which could reduce the ability of the flightcrew to maintain the safe flight and landing of the airplane.

Compliance

(f) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Test

(g) Within 6 months after the effective date of this AD, test the stabilizer takeoff warning switches, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 737–27–1289, dated April 7, 2010. Repeat the test thereafter at intervals not to exceed 750 flight hours. Accomplishment of the repetitive tests required by paragraph (g) of this AD terminates the operational and functional checks of the takeoff configuration warning system required by paragraph A., required item 3 (''Elevator out of Green Band switches'') of AD 88–22–09.

Replacement and Re-test

(h) If any stabilizer takeoff warning switch fails the test required in paragraph (g) or (h) of this AD, replace the stabilizer takeoff warning switch with a new switch and test the new switch before further flight, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 737–27–1289, dated April 7, 2010. Within 750 flight hours after replacement of any switch, test the replaced switch, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 737–27–1289, dated April 7, 2010; and repeat this test on the replaced

switch thereafter at intervals not to exceed 750 flight hours.

Special Flight Permit

(i) Special flight permits, as described in Section 21.197 and Section 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199), are not allowed.

Alternative Methods of Compliance (AMOCs)

(j)(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in the Related Information section of this AD. Information may be e-mailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

Related Information

(k) For more information about this AD, contact Jeffrey W. Palmer, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue, SW., Renton, Washington 98057–3356; *phone:* 425–917–6472; *fax:* 425–917–6590; *e-mail: jeffrey.w.palmer@faa.gov.*

Material Incorporated by Reference

(l) You must use Boeing Service Bulletin 737–27–1289, dated April 7, 2010, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of Boeing Service Bulletin 737–27–1289, dated April 7, 2010, under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, *Attention:* Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, Washington 98124–2207; *phone:* 206–544–5000, extension 1; *fax:* 206–766–5680; *e-mail: me.boecom@boeing.com*; Internet: *https://www.myboeingfleet.com.*

(3) You may review copies of the service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

(4) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at an NARA facility, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on June 3, 2011.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–14344 Filed 6–16–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0588; Directorate Identifier 2010–SW–074–AD; Amendment 39–16717; AD 2011–12–10]

RIN 2120–AA64

Airworthiness Directives; Robinson Helicopter Company Model (Robinson) R22, R22 Alpha, R22 Beta, R22 Mariner, R44, and R44 II Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD) for the specified Robinson model helicopters that currently requires a visual inspection for skin separation along the leading edge of blade skin aft of the skin-to-spar bond line on the lower surface of each main rotor blade (blade) and in the tip cap area. The existing AD also requires a ''tap test'' for detecting a separation or void in both bonded areas and repainting any exposed area of the blades. If any separation or void is detected, the AD requires, before further flight, replacing the blade. Thereafter, before each flight, the existing AD also requires checking for any exposed (bare) metal along the skin-to-spar bond line on the lower surface of each blade near the tip. If any bare metal is found, that AD requires an inspection by a qualified mechanic. This amendment contains the same requirements but expands the applicability to include all serial-numbered model helicopters and limits the applicability to specific blade part numbers. This amendment also requires a repetitive inspection of the blade and any necessary rework. This amendment is prompted by a fatal accident in Israel. We have also included responses to comments objecting to the recording requirements in the current AD relating to the pilot checks before each flight and to comments that the burden of the before-each-flight pilot check exceeds the benefit. We have concluded that a check before the first flight of each day is sufficient for aviation safety. The actions specified by this AD are intended to provide more specific AD actions, to relieve the burdens associated with the before-each-flight check by changing it to a daily check, to detect blade skin debond, and to prevent blade failure and subsequent loss of control of the helicopter.

DATES: Effective July 5, 2011.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 5, 2011.

We must receive comments on this AD by August 16, 2011.

ADDRESSES: Use one of the following addresses to comment on this AD.

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

You may get the service information identified in this AD from Robinson Helicopter Company, 2901 Airport Drive, Torrance, CA 90505, telephone (310) 539–0508, fax (310) 539–5198, or at *http://www.robinsonheli.com/servelib.htm.*

Examining the Docket: You may examine the docket that contains the AD, any comments, and other information on the Internet at *http://www.regulations.gov,* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Operations office (telephone (800) 647–5527) is located in Room W12–140 on the ground floor of the West Building at the street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Eric D. Schrieber, Aviation Safety Engineer, telephone (562) 627–5348, fax (562) 627–5210 (regarding Model R22 helicopters), or Fred Guerin, Aviation Safety Engineer, telephone (562) 627–5232, fax (562) 627–5210 (regarding Model R44 helicopters).

SUPPLEMENTARY INFORMATION: On December 17, 2007, we issued AD 2007–26–12, Amendment 39–15314 (73 FR 397, January 3, 2008). That AD requires a one-time visual inspection for skin

separation along the leading edge of the blade skin aft of the skin-to-spar bond line on the lower surface of each blade and in the tip cap area. That AD also requires a ''tap test'' for detecting a separation or void in both bonded areas. That AD also requires repainting any exposed area of the blades and replacing the blade before further flight if any separation or void occurs. Thereafter, the AD requires, before each flight, checking for any exposed (bare) metal along the skin-to-spar bond line on the lower surface of each blade near the tip. If any bare metal is found, a mechanic must visually inspect the area, perform a ''tap test,'' remove both blade tip covers, and inspect the area. That AD was prompted by 11 reports of blade debond, some occurring in flight and some found during routine maintenance. Blades that develop a debond at the tip may continue to debond causing failure of the blade. This condition most often results from erosion of the protective layer of paint that exposes the edge of the skin, which allows the skin to erode and eventually peel back. In one of the reported incidents, the debond was caused by corrosion from the lower surface of the aluminum tip cap, which is bonded to the inside of the blade tip. The corrosion caused bubbles under the skin but no peeling back of the skin from the spar. The condition was found during inspection and not in flight. The condition, if not corrected, could result in blade failure and subsequent loss of control of the helicopter.

Since issuing AD 2007–26–12, a fatal accident due to blade delamination occurred in Israel. The accident investigation revealed that the operator was in possession of both the United States AD and the service information but apparently failed to follow the United States AD requirements and the service information. However, due to the severity of the unsafe condition, we have determined that modification of the AD requirements is necessary to further aid in correcting the unsafe condition by performing the checks and inspections to prevent further fatalities.

We have reviewed the following Robinson service information:

- Letter titled ''Additional Information Regarding Main Rotor Blade Skin Debonding,'' dated May 25, 2007, discussing blade skin debonding;
- Rotorcraft Flight Manual (RFM) changes to the Normal Procedures Section 4 and Systems Description Section 7, revised April 20, 2007, for each applicable model helicopter containing a ''caution'' about skin-to-spar bond line erosion;
- One Service Letter with two different Nos.: R22 SL–56B and R44 SL–32B, revised April 30, 2010, specifying proper inspection and protection (refinishing) of bonded areas; and
- Service Bulletins SB–103, dated April 30, 2010, for the Model R22, and SB–72, dated April 30, 2010, for the Model R44 helicopters specifying proper inspection and protection (refinishing) of bonded areas for certain affected blades.

Although not required by this AD, Robinson has developed replacement blades, part number C016–7, for the Model R44 helicopter, and part number A016–6 for the Model R22 helicopter. The FAA may require installing these replacement blades in a future AD.

Also, since issuing AD 2007–26–12, we have received various comments from 32 commenters and have given due consideration to each one. We have identified 13 unique issues and addressed those issues as follows:

Twenty-six commenters state that requiring a maintenance logbook entry before each flight to document the blade check for the exposed skin-to-spar bonded area on the lower surface of each blade is unnecessary and burdensome. The commenters also state that the requirement does not add to safety, will require keeping the maintenance logbook in the aircraft, and will ''visually pollute'' the logbook distracting from seeing real maintenance trends.

Upon reconsideration, we agree that making a logbook entry at each preflight check may not be necessary. Therefore, we are replacing the ''before each flight'' check and maintenance logbook entry with a daily ''before the first flight of each day'' check and logbook entry. A ''caution'' to check for paint erosion on the lower surface of the blade along the skin-to-spar bond line will be a part of the pre-flight check section of the revised FAA-approved RFM. We do not agree that maintenance logbook entries ''pollute the logbook'' and distract from seeing real maintenance trends. Operators may make the entries on a separate maintenance record sheet and keep that record sheet as an appendix to the logbook.

Seventeen commenters state that requiring logbook entries during each preflight effectively prohibits student pilots from performing these visual checks and restricts them from flying cross-country flights.

We agree that preflight entries into the logbook will prohibit student pilots from flying solo cross-country flights. Changing the logbook entry requirement from pre-flight to daily will allow the student's flight instructor or a mechanic to make the required logbook entry before the days cross country activity. This will allow the student to fly solo on cross-country flights.

Six commenters state that either the AD is unclear as to whether a pilot or a mechanic should do the checks or that the visual check is difficult without a ladder to see the blade closely.

The FAA agrees that the AD is not specific as to whether a pilot or a mechanic may do the daily check. The ''Daily or Preflight Check'' section of the FAA-Approved RFM is intended to facilitate the paint erosion check by the pilot, and the pilot or a mechanic may perform the check before each flight. The FAA does not agree that a ladder is required to perform this check. When viewing the blade, the requirement is to look at the lower surface of the blade in the area of the bond line for missing paint. This detail should be obvious to any one with normal vision from several feet away.

One commenter states that if this issue is due to a manufacturing problem, the FAA should mandate that Robinson pay to replace the blades.

We do not believe that this blade debond is due to a manufacturing problem. This debond issue appears to be due to the basic design and maintenance, and the actions taken in AD 2007–26–12 have been shown to detect and to prevent the debond problem. However, reliance on continued inspections is an inadequate long term solution. We are considering a subsequent AD to terminate the inspection requirement by mandating the replacement of these rotor blades.

One commenter suggests that Robinson send out kits for abrasion resistant tape to fix the erosion problem.

We do not agree that blade tape will resolve the unsafe condition even though tape is designed to provide longer resistance to erosion than paint. The same unsafe condition exists with both.

Two commenters state this problem was known for 10 months before the AD's release and should not be an immediately adopted rule (IAR). Also, the commenters state more information was made available before issuing the AD to change the requirements.

We agree that we were aware of the safety concern even though the AD had not been issued. We do not agree that the AD should not have been an IAR. As stated in the preamble to the AD, the ''very short time intervals'' required by the AD made notice and the opportunity for prior public comment impracticable and justified issuing the IAR. The AD was issued after considering all known

information pertaining to the safety concern.

Two commenters state that the AD applies to helicopter serial numbers rather than blade serial numbers, which could result in missed initial checks if the blades from helicopters addressed by the AD are reinstalled on helicopters not subject to the AD.

We agree and are revising the ''Applicability'' section to apply to certain part-numbered blades instead of certain serial-numbered helicopters. This will also result in different part-numbered blades not being affected by this AD.

One commenter states that repainting of the blade is difficult, burdensome, expensive, and increases downtime.

We do not consider repainting of the blade costly relative to the safety risk. Inspecting and maintaining the integrity of the spar-to-blade bond line with paint corrects the unsafe condition that could result from erosion of the bond between the spar and the blade skin, which could cause failure of the blade.

Five commenters state the Pilot's Operating Handbook has been updated to include the visual inspections outlined in the AD.

We recognize the preflight check exists in the FAA Approved RFM, and we expect pilots and operators to monitor the erosion on the blades when they make this check before each flight.

One commenter states the AD is not applicable to blades that are not eroded, and many operators can fly 2,200 hours without exposing the bond line. The commenter asks why they are subject to this AD since their blades are not eroded.

We agree that blades that are not eroded will not have this debond condition, and if they continue to be noneroded, many operators can fly 2,200 hours without exposing the bond line. Erosion of the paint is dependent upon the amount of erosive particles in the air and varies widely from one flight environment to another. Since there is no limitation on which environment a helicopter may be operated, checks are necessary to maintain an awareness of the condition of the paint at the bond line. In addition to the environmental concerns, we have determined that some bonded end caps experience corrosion where they contact the lower skin, and with both factors at work, checking all blades is warranted.

One commenter states the order of the inspection should be reversed to do the inspection immediately and then do a check every 10 to 20 hours.

We do not agree that it should be reversed. The 10-hour time before the first inspection is common practice to allow for AD action implementation if there is an acceptably low risk of failure in those 10 hours. Additionally, that time is granted to allow enough time for remotely located helicopters to fly to an appropriate maintenance base. Performing and recording a check before the first flight of each day, instead of every 10 to 20 hours, is a better way to allow the pilot to monitor any erosion trend that may occur. This way, the operator will be aware if the bond line is near exposure and plan accordingly.

One commenter states the AD requires repainting any exposed bare metal on the blade and asks what if the bare metal is elsewhere than the bond line.

We agree that only the exposed area of the bond line needs to be painted. The incorporated Robinson Service Bulletin refers to the Service Letter that specifies the area of inspection and repaint.

The Australian Civil Aviation Safety Authority gave an oral comment to the FAA that instead of using a 1965 or later U.S. quarter dollar coin to perform the tap test, they would like to require alternate tools.

The FAA agrees that an equivalent and appropriate tool other than a 1965 or later U.S. quarter dollar may be used, and we included in the AD a statement that other equivalent and appropriate tools may be used for the inspection.

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require adopting the rule. This AD supersedes AD 2007–26–12 to revise the applicability to include all serial-numbered helicopters and to limit the applicability to specify part-numbered blades and to require the following:

- Before the first flight of each day, visually checking for any bare metal skin-to-spar joint area on the lower surface of each blade. An owner/operator (pilot) holding at least a private pilot certificate may perform this visual check and must enter compliance into the aircraft maintenance records in accordance with 14 CFR 43.11 and 91.417(a)(2)(v).
- If you find any bare metal in the area of the skin-to-spar bond line, before further flight, inspecting the blade by following the requirements of this AD.
- At specified intervals, inspecting each blade for corrosion, a separation, a void, a gap, or a dent.
- Before further flight, refinishing any exposed area of a blade.
- Before further flight, replacing any unairworthy blade with an airworthy blade.

Accomplish the actions by following specified portions of the service bulletins described previously.

The short compliance time involved is required because the previously described critical unsafe condition can adversely affect the controllability and structural integrity of the helicopter. Therefore, visually checking for any bare metal is required before further flight, and this AD must be issued immediately. The 100-hour inspection is required based upon the utilization rate of the helicopters because some operators could fly 100 hours within 30 days. Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

We estimate that this AD will affect 2,690 helicopters on the U.S. registry. We also estimate the following:

- Time to perform the before flight each day is negligible.
- 3 work hours to inspect 2 blades and
- 10 work hours to replace each unairworthy blade, with an estimated 10 blades to be replaced (based on reports of 10 affected blades in the past 2 years) at an average labor rate of $85 per work hour.
- Required parts will cost about $18,130 for a Model R22 blade and about $24,800 for a Model R44 blade.

We estimate an average of 7 recurrent annual or 100-hour inspections before blade retirement. Based on these figures, we estimate the total cost of the AD on U.S. operators to be $5,024,800. This figure includes $4,801,650 to inspect all the blades 7 times; plus $94,900 to replace 5 of the Model R22 blades; plus $128,250 to replace 5 of the Model R44 blades.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not precede it by notice and an opportunity for public comment. We invite you to send any written relevant data, views, or arguments regarding this AD. Send your comments to an address listed under the **ADDRESSES** section. Include the docket number ''FAA–2011–0588; Directorate Identifier 2010–SW–074–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the AD. We will consider all comments received by the closing date and may amend the AD in light of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive concerning this AD. Using the search function of the docket Web site, you can find and read the comments to any of our dockets, including the name of the individual who sent the comment. You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared an economic evaluation of the estimated costs to comply with this AD. See the AD docket to examine the economic evaluation.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in subtitle VII, part A, subpart III, section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2007–26–12, Amendment 39–15314 (73 FR 400; January 3, 2008), Directorate Identifier 2007–SW–04–AD; and by adding a new AD to read as follows:

2011–12–10 Robinson Helicopter Company: Amendment 39–16717; Docket No. FAA–2011–0588, Directorate Identifier 2010–SW–074–AD. Supersedes AD 2007–26–12, Amendment 39–15314, Docket No. FAA–2007–0378, Directorate Identifier 2007–SW–04–AD.

Applicability: Model R22, R22 Alpha, R22 Beta, and R22 Mariner helicopters, with main rotor blade (blade), part number (P/N) A016–4; and Model R44 and R44 II helicopters, with blade, P/N C016–2 or C016–5, certificated in any category.

Compliance: Required as indicated.

To detect blade skin debond and prevent blade failure and subsequent loss of control of the helicopter, do the following:

(a) Before the first flight of each day, visually check for any exposed (bare metal) skin-to-spar joint area on the lower surface of each blade. The actions required by this paragraph may be performed by the owner/operator (pilot) holding at least a private pilot certificate and must be entered into the aircraft records showing compliance with this AD in accordance with 14 CFR 43.9(a)(1)–(4) and 14 CFR 91.417(a)(2)(v). The record must be maintained as required by 14 CFR 91.417, 121.380, or 135.439. This authorization is an exception to our standard maintenance regulations.

(b) If you find any bare metal in the area of the skin-to-spar bond line, before further flight, inspect the blade by following the requirements of paragraph (d) of this AD.

(c) Within 10 hours time-in-service (TIS), unless done previously, and at intervals not to exceed 100 hours TIS or at each annual inspection, whichever occurs first, inspect each blade for corrosion, a separation, a gap, or a dent by following the Compliance Procedure, paragraphs 1 through 6 and 8, of Robinson R22 Service Bulletin SB–103, dated April 30, 2010 (SB103) for the R22 series helicopters, and Robinson R44 Service Bulletin SB–72, dated April 30, 2010 (SB72), for the R44 series helicopters. Although the Robinson service information limits the magnification to 10 ×, a higher magnification is acceptable for this inspection. Also, an appropriate tap test tool which provides similar performance, weight, and consistency of tone may be substituted for the ''1965 or later United States Quarter-dollar coin,'' which is specified in the Compliance Procedure, paragraph 2, of SB–72 and SB–103.

(d) Before further flight, refinish any exposed area of a blade by following the Compliance Procedure, paragraphs 2 through 6, of Robinson R22 Service Letter SL–56B and R44 Service letter SL–32B, dated April 30, 2010, for both the R22 and R44 series helicopters.

(e) Before further flight, replace any unairworthy blade with an airworthy blade.

Note: The Robinson letter titled ''Additional Information Regarding Main Rotor Blade Skin Debonding,'' dated May 25, 2007, which is not incorporated by reference, contains additional information about the subject of this AD. This document is available at *http://www.robinsonheli.com.*

(f) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Send your request to the Manager, Los Angeles Aircraft Certification Office, FAA, Airframe Branch, 3960 Paramount Blvd., Lakewood, California 90712, regarding Model R22 helicopters ATTN: Eric D. Schrieber, Aviation Safety Engineer, telephone (562) 627–5348, fax (562) 627–5210, or regarding Model R44 helicopters *Attn:* Fred Guerin, Aviation Safety Engineer, telephone (562) 627–5232, fax (562) 627–5210.

(g) Special flight permits will not be issued.

(h) The Joint Aircraft System/Component (JASC) Code is: 6210 Main Rotor Blades.

(i) The inspections shall be done following the specified portions of Robinson R22 Service Bulletin SB–103, dated April 30, 2010, or R44 Service Bulletin SB–72, dated April 30, 2010, as appropriate for each model helicopter. Repaint the exposed area of a blade by following Robinson R22 Service letter SL–56B and R44 Service Letter SL–32B (combined in one document), dated April 30, 2010. The Director of the Federal Register approved this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Robinson Helicopter Company, 2901 Airport Drive, Torrance, CA 90505, telephone (310) 539–0508, fax (310) 539–5198, or at *http://www.robinsonheli.com/servelib.htm.* Copies may be inspected at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(j) This amendment becomes effective on July 5, 2011.

Issued in Fort Worth, Texas, on June 2, 2011.

Kim Smith,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2011–14246 Filed 6–16–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0561; Directorate Identifier 2010–SW–001–AD; Amendment 39–16715; AD 2011–12–08]

RIN 2120–AA64

Airworthiness Directives; Bell Helicopter Textron, Inc. Model 205A, 205A–1, 205B, 212, 412, 412CF, and 412EP Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) for the specified Bell Helicopter Textron, Inc. (BHT) model helicopters with tail rotor (T/R) blades with certain serial numbers installed. This action requires a one-time inspection of the T/R blade for corrosion or pitting, and repairing or replacing the T/R blade, if that condition is found during the inspection. This amendment is prompted by a report from the manufacturer that T/R blades with certain serial numbers may have manufacturing anomalies in the spar area. These actions are intended to detect corrosion or pitting in the forward spar area of a T/R blade to prevent a crack in the T/R blade, loss of the T/R blade, and subsequent loss of control of the helicopter.

DATES: Effective July 5, 2011.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 5, 2011.

Comments for inclusion in the Rules Docket must be received on or before August 16, 2011.

ADDRESSES: Use one of the following addresses to submit comments on this AD:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

You may get the service information identified in this AD from Bell Helicopter Textron, Inc., P.O. Box 482, Fort Worth, TX 76101, telephone (817) 280–3391, fax (817) 280–6466, or at *http://www.bellcustomer.com/files/.*

Examining the Docket: You may examine the docket that contains the AD, any comments, and other information on the Internet at *http://www.regulations.gov,* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Operations office (telephone (800) 647–5527) is located in Room W12–140 on the ground floor of the West Building at the street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: DOT/FAA Southwest Region, Michael Kohner, ASW–170, Aviation Safety Engineer, Rotorcraft Directorate, Rotorcraft Certification Office, 2601 Meacham Blvd., Fort Worth, Texas 76137, telephone (817) 222–5447, fax (817) 222–5783.

SUPPLEMENTARY INFORMATION: This amendment adopts a new AD for the specified BHT model helicopters with an installed T/R blade, part number 212–010–750 (all dash numbers), all serial numbers except those with a prefix of ''A'' and the number 17061 or larger. This action requires a one-time inspection of the T/R blade for corrosion or pitting after sanding the paint from the spar area between blade stations 22.5 and 40.0, and repairing or replacing the T/R blade if corrosion, pitting, or damage is discovered. This amendment is prompted by a report from the manufacturer that T/R blades with certain serial numbers may have manufacturing anomalies in the spar area as a result of the chemical milling process. The anomalies may be identified as pits or corrosion on the spar. This corrosion or pitting condition in the forward spar of a T/R blade, if not corrected, could lead to a crack in the T/R blade, loss of the T/R blade, and subsequent loss of control of the helicopter.

We have reviewed the following BHT Alert Service Bulletins, all Revision A, and all dated December 8, 2009, which specify a one-time inspection of the T/R blades for corrosion or pitting, and repairing or replacing the T/R blade if corrosion, pitting, or other damage is discovered:

- Alert Service Bulletin (ASB) No. 205–09–102, for Model 205A and 205A–1 helicopters;
- ASB No. 205B–09–54, for Model 205B helicopters;
- ASB No. 212–09–134, for Model 212 helicopters;
- ASB No. 412CF–09–38, for Model 412CF helicopters; and
- ASB No. 412–09–136, for Model 412 and 412EP helicopters.

This unsafe condition is likely to exist or develop on other helicopters of these same type designs. Therefore, this AD is being issued to require inspecting the T/R blades to detect corrosion or pitting in the forward spar area that could result in a crack, loss of a T/R blade, and subsequent loss of control of the helicopter. Accomplish the actions by following specified portions of the ASBs described previously.

The short compliance time involved is required because the previously described critical unsafe condition can adversely affect the structural integrity and controllability of the helicopter. Therefore, inspecting the T/R blade for corrosion or pitting is required within 25 hours time-in-service (TIS) or 30 days, whichever occurs first. This is a very short compliance time, and this AD must be issued immediately.

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

We estimate that this AD will affect 263 helicopters. Removing, inspecting, refinishing, and re-installing the T/R blade will take about 10 work hours at an average labor rate of $85 per work hour and an approximate labor cost of $850 per helicopter. Replacing the T/R blade with an airworthy blade will take about 6 work hours at an average labor rate of $85 per work hour for an approximate labor cost of $510 per helicopter. Required parts will cost about $17,495 for each T/R blade assembly. Based on these figures, we estimate the total cost impact of the AD on U.S. operators to be $277,565, assuming all affected helicopters are inspected and three T/R blades are replaced.

Comments Invited

This AD is a final rule that involves requirements that affect flight safety and was not preceded by notice and an

opportunity for public comment; however, we invite you to submit any written data, views, or arguments regarding this AD. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2011–0561; Directorate Identifier 2011–SW–001–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the AD. We will consider all comments received by the closing date and may amend the AD in light of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this AD. Using the search function of our docket Web site, you can find and read the comments to any of our dockets, including the name of the individual who sent the comment. You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared an economic evaluation of the estimated costs to comply with this AD. See the AD docket to examine the economic evaluation.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in subtitle VII, part A, subpart III, section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends Part 39 of the Federal Aviation Regulations (14 CFR Part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. Section 39.13 is amended by adding a new airworthiness directive (AD) to read as follows:

2011–12–08 Bell Helicopter Textron, Inc. (BHT): Amendment 39–16715. Docket No. FAA–2011–0561; Directorate Identifier 2010–SW–001–AD.

Applicability: Model 205A, 205A–1, 205B, 212, 412, 412CF, and 412EP helicopters with a tail rotor (T/R) blade, part number 212–010–750 (all dash numbers), all serial numbers (S/Ns) except those S/Ns with a prefix of ''A'' and a number 17061 or larger, installed, certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To detect corrosion or pitting in the forward spar area of a T/R blade to prevent a crack in the T/R blade, loss of the T/R blade, and subsequent loss of control of the helicopter, do the following:

(a) Within 25 hours time-in-service (TIS) or 30 days, whichever occurs first:

(1) Remove the T/R hub and blade assembly from the helicopter and remove the T/R blade from the hub. Remove the paint from the spar area on both sides of the T/R blade by following the Accomplishment Instructions, paragraphs 3. through 5., of the following BHT Alert Service Bulletins, all Revision A, and all dated December 8, 2009: Alert Service Bulletin (ASB) No. 205–09–102 for the Model 205A and 205A–1 helicopters; ASB No. 205B–09–54 for the Model 205B helicopters; ASB No. 212–09–134 for the Model 212 helicopters; ASB No. 412CF–09–38 for the Model 412CF helicopters; and ASB No. 412–09–136 for the Model 412 and 412EP helicopters.

(2) Using a 3-power or higher magnifying glass, visually inspect both sides of the T/R blade for any corrosion or pitting in the spar inspection areas as depicted in Figure 1 of the ASB for your model helicopter.

(b) Before further flight:

(1) If you find any corrosion or pitting that is 0.003 inch deep or less, either replace the unairworthy T/R blade with an airworthy T/R blade or repair the T/R blade.

Note: The maintenance and repair procedures along with the maximum repair damage limitations as referenced in paragraphs (b)(1) and (b)(3) of this AD are contained in the applicable maintenance manual and component repair and overhaul manuals.

(2) If you find any corrosion or pitting that is greater than 0.003 inch deep, replace the T/R blade with an airworthy T/R blade.

(3) If any parent material is removed during the sanding operation required by paragraph (a)(1) of this AD, either replace the T/R blade with an airworthy T/R blade, or repair the T/R blade if the parent material removed is within the maximum repair damage limits.

(4) If there is no corrosion or pitting and no damage greater than 0.003 inch deep, refinish the inspection areas and reinstall each T/R blade onto the T/R hub, install the T/R assembly on the helicopter and track and balance the T/R in accordance with the Accomplishment Instructions, paragraphs 8. through 10., of the ASB for your model helicopter.

(c) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Contact the Manager, Rotorcraft Certification Office, FAA, *Attn:* Michael Kohner, ASW–170, Aviation Safety Engineer, 2601 Meacham Blvd., Fort Worth, Texas 76137, telephone (817) 222–5170, fax (817) 222–5783, for information about previously approved alternative methods of compliance.

(d) Joint Aircraft System/Component (JASC) Code 6410: Tail rotor blades.

(e) Accomplish the instructions in this AD by following the specified portions of the following Bell Helicopter Textron, Inc. Alert Service Bulletin, as applicable to your model helicopter: No. 205–09–102; No. 205B–09–54; No. 212–09–134; No. 412CF–09–38, or No. 412–09–136. Each Alert Service Bulletin is Revision A, and each is dated December 8, 2009. The Director of the Federal Register approved this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. Copies may be obtained from Bell Helicopter Textron, Inc., P.O. Box 482, Fort Worth, TX 76101, telephone (817) 280–3391, fax (817) 280–6466, or at *http://www.bellcustomer.com/files.* Copies may be inspected at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(f) This amendment becomes effective on July 5, 2011.

Issued in Fort Worth, Texas, on May 17, 2011.

Kim Smith,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2011–14247 Filed 6–16–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2010–0957; Directorate Identifier 2010–NM–062–AD; Amendment 39–16718; AD 2011–12–11]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Model 767 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are superseding an existing airworthiness directive (AD) for the products listed above. That AD currently requires, for certain airplanes, reworking the bonding jumper assemblies on the drain tube assemblies of the slat track housing of the wings. For certain other airplanes, the existing AD requires repetitive inspections of the drain tube assemblies of the slat track housing of the wings to find discrepancies, corrective actions if necessary, and terminating action for the repetitive inspections. This new AD also requires replacing the drain tube assemblies. For certain airplanes, this new AD also requires installing an additional electrostatic bond path for the number 5 and 8 inboard slat track drain tube assemblies. For certain other airplanes, this new AD also requires reworking the bonding jumper assembly. This new AD also revises the applicability to include additional airplanes. This AD was prompted by (1) reports of fuel leaks from certain drain locations of the slat track housing near the engine exhaust nozzle, which could result in a fire when the airplane is stationary, or taxiing at low speed; (2) reports of a bonding jumper assembly of certain drain tubes that did not meet bonding specifications and could result in electrostatic discharge and an in-tank ignition source; and (3) reports of fuel leaks onto the main landing gear (MLG) as a result of a cracked drain tube at the number 5 or 8 slat track housing, which could let fuel drain from the main fuel tanks into the dry bay area of the wings and onto hot MLG brakes and result in a fire.

DATES: This AD is effective July 22, 2011.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in the AD as of July 27, 2011.

The Director of the Federal Register approved the incorporation by reference of certain other publications listed in this AD as of August 28, 2001 (66 FR 38350, July 24, 2001).

ADDRESSES: For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P. O. Box 3707, MC 2H–65, Seattle, Washington 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; e-mail *me.boecom@boeing.com*; Internet *https://www.myboeingfleet.com*. You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov*; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (*phone:* 800–647–5527) is Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Rebel Nichols, Aerospace Engineer, Propulsion Branch, ANM–140S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue, SW., Renton, Washington 98057–3356; *phone:* 425–917–6509; *fax:* 425–917–6590; *e-mail: rebel.nichols@faa.gov*.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2001–14–19, amendment 39–12330 (66 FR 38350, July 24, 2001). That AD applies to the specified products. The NPRM was published in the **Federal Register** on October 7, 2010 (75 FR 61999). That NPRM proposed to continue to require, for certain airplanes, reworking the bonding jumper assemblies on the drain tube assemblies of the slat track housing of the wings. That NPRM also proposed to continue to require, for certain other airplanes, repetitive inspections of the drain tube assemblies of the slat track housing of the wings to find discrepancies, corrective actions if necessary, and terminating action for the repetitive inspections. That NPRM also proposed to require replacing the drain tube assemblies, and, for certain airplanes, installing an additional electrostatic bond path for the number 5 and 8 inboard slat track drain tube assemblies. For certain other airplanes, that NPRM also proposed to require reworking the bonding jumper assembly. That NPRM also proposed to revise the applicability to include additional airplanes.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the proposal and the FAA's response to each comment.

Support for the NPRM

Boeing concurs with the contents of the NPRM.

Request To Clarify Service Information

Continental Airlines requested that we revise the NPRM to correct discrepancies in Boeing Service Bulletin 767–57A0094, Revision 2, dated December 17, 2009. (That service bulletin was cited in the NPRM as the appropriate source of service information for the drain tube replacement on Model 767–200, –300, and –300F series airplanes.) In Figure 13 (Sheet 2 of 5) on page 104, and Figure 14 (Sheet 2 of 5) on page 109, the view identified as ''C'' should be identified as ''A.'' These discrepancies were communicated to Boeing and confirmed as discrepancies.

We agree and have revised paragraph (j) in this final rule to specify these corrections.

Request To Clarify Requirements

American Airlines stated that the Relevant Service Information section of the NPRM provides the current requirements (for AD 2001–14–19) but does not provide in detail the new additional requirements for the NPRM. That paragraph, according to the commenter, merely provides information regarding the service bulletins, not the specific proposed requirements. The commenter added that the Relevant Service Information section does not explain whether the new actions are to be done in accordance with the original or revised service information. The commenter

requested that the final rule provide in detail the specific actions that would be required to comply with the new AD.

We agree to provide clarification. The commenter is correct that the Relevant Service Information section describes only the procedures specified in the service information referenced in an AD. When we supersede an existing AD, the Relevant Service Information section highlights the differences in any new service information to provide notice for the public to comment on the new material. New service information includes new service bulletins as well as significant changes in revisions to previously described service bulletins. The proposed requirements are then provided in ''The FAA's Determination and Requirements of the Proposed AD.'' We have not changed the final rule regarding this issue.

Explanation of Change to NPRM

We have revised the Costs of Compliance section in this final rule to provide updated figures for the estimated number of affected airplanes. This change does not significantly affect the fleet cost.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting the AD with the change described previously. We also determined that this change will not increase the economic burden on any operator or increase the scope of the AD.

Costs of Compliance

There are about 920 airplanes of the affected design in the worldwide fleet. The following table provides the estimated costs for U.S. operators to comply with this proposed AD. The average labor rate is $85 per hour.

ESTIMATED COSTS

Action	Work hours	Parts	Cost per airplane	Number of U.S.-registered airplanes	Fleet cost
Inspection (required by AD 2001–14–19).	1	$0	$85 per inspection cycle.	273	$23,205 per inspection cycle.
Drain tube replacement (required by AD 2001–14–19).	12	5,236	$6,256	273	$1,707,888.
Bonding jumper assembly rework (required by AD 2001–14–19).	4	322	$662	48	$31,776.
Drain tube replacement (new action)	Between 7 and 11, depending on configuration.	1,117	Between $1,712 and $2,052.	412	Between $705,344 and $845,424.

We estimate the following costs to rework the drain tube assembly that might be required based on the results of the proposed inspection. We have no way of determining the number of aircraft that might need this rework.

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Drain tube assembly rework	4 work-hours × $85 per hour = $340	Negligible	$340

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in subtitle VII, part A, subpart III, section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing airworthiness directive (AD) 2001–14–19, Amendment 39–12330 (66 FR 38350, July 24, 2001), and adding the following new AD:

2011–12–11 The Boeing Company: Amendment 39–16718; Docket No. FAA–2010–0957; Directorate Identifier 2010–NM–062–AD.

Effective Date

(a) This airworthiness directive (AD) is effective July 22, 2011.

Affected ADs

(b) This AD supersedes AD 2001–14–19, Amendment 39–12330.

Applicability

(c) This AD applies to The Boeing Company airplanes, certificated in any category, identified in paragraphs (c)(1) and (c)(2) of this AD.

(1) Model 767–200, –300, and –300F series airplanes, as identified in Boeing Service Bulletin 767–57A0094, Revision 2, dated December 17, 2009.

(2) Model 767–400ER series airplanes, as identified in Boeing Service Bulletin 767–57A0095, Revision 2, dated December 17, 2009.

Subject

(d) Air Transport Association (ATA) of America Code 57: Wings.

Unsafe Condition

(e) This AD results from (1) reports of fuel leaks from certain drain locations of the slat track housing near the engine exhaust nozzle, which could result in a fire when the airplane is stationary, or taxiing at low speed; (2) reports of a bonding jumper assembly of certain drain tubes that did not meet bonding specifications and could result in electrostatic discharge and an in-tank ignition source; and (3) reports of fuel leaks onto the main landing gear (MLG) as a result of a cracked drain tube at the number 5 or 8 slat track housing, which could let fuel drain from the main fuel tanks into the dry bay area of the wings and onto hot MLG brakes and result in a fire.

Compliance

(f) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Restatement of Requirements of AD 2001–14–19, Amendment 39–12330, With Revised Service Information

Repetitive Inspections/Corrective Action

(g) For airplanes identified in Boeing Service Bulletin 767–57A0060, Revision 1, dated December 31, 1998: Within 500 flight hours after August 28, 2001 (the effective date of AD 2001–14–19), do a general visual inspection of the drain tube assemblies of the slat track housings of the wings to find discrepancies (loose fittings, cracked tubes, fuel leaks), per Part I of the Accomplishment Instructions of Boeing Service Bulletin 767–57A0060, Revision 1, dated December 31, 1998; or Revision 2, dated January 31, 2002. After the effective date of this AD, only Revision 2 may be used.

(1) If any discrepancies are found, before further flight, rework the drain tube assembly per Part II of the Accomplishment Instructions of Boeing Service Bulletin 767–57A0060, Revision 1, dated December 31, 1998; or Revision 2, dated January 31, 2002. After the effective date of this AD, only Revision 2 may be used. Repeat the inspection at intervals not to exceed 500 flight hours until accomplishment of the requirements in paragraph (h) of this AD.

(2) If no discrepancies are found, repeat the inspection thereafter at intervals not to exceed 500 flight hours, until accomplishment of the requirements in paragraph (h) of this AD.

Note 1: For the purposes of this AD, a general visual inspection is defined as: ''A visual examination of an interior or exterior area, installation, or assembly to find obvious damage, failure, or irregularity. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or drop-light and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked.''

Terminating Action for Repetitive Inspections

(h) For airplanes specified in paragraph (g) of this AD: Within 6,000 flight hours or 24 months after August 28, 2001, whichever occurs first, replace the drain tube assemblies of the slat track housings of the wings (including general visual inspection and repair) per Part III of the Accomplishment Instructions of Boeing Service Bulletin 767–57A0060, Revision 1, dated December 31, 1998; or Revision 2, dated January 31, 2002. After the effective date of this AD, only Revision 2 may be used. Any applicable repair must be accomplished prior to further flight. Accomplishment of this paragraph terminates the repetitive inspections required by paragraph (g) of this AD.

Rework of Bonding Jumper Assemblies

(i) For airplanes identified in Boeing Service Bulletin 767–57–0068, dated September 16, 1999: Within 5,000 flight cycles or 22 months after August 28, 2001, whichever occurs first, rework the bonding jumper assembly of the drain tube assemblies of the slat track housing of the wings (including general visual inspection and repair) per the Accomplishment Instructions of Boeing Service Bulletin 767–57–0068, dated September 16, 1999; or Revision 1, dated May 9, 2002. After the effective date of this AD, only Revision 1 may be used. Any applicable repair must be accomplished prior to further flight.

New Requirements of This AD

Drain Tube Replacement

(j) Within 24 months after the effective date of this AD, replace affected drain tube assemblies of the number 5 and number 8 inboard slat track housing, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 767–57A0094 (for Model 767–200, –300, and –300F series airplanes) or 767–57A0095 (for Model 767–400ER series airplanes), both Revision 2, both dated December 17, 2009; except, in Figure 13 (Sheet 2 of 5) on page 104 and Figure 14 (Sheet 2 of 5) on page 109 of Boeing Service Bulletin 767–57A0094, the view identified as ''C'' should be identified as ''A.''

Concurrent Requirements

(k) For airplanes in Groups 1, 2, and 3, as identified in Boeing Service Bulletin 767–57A0094, Revision 2, dated December 17, 2009: The actions specified in paragraphs (k)(1), (k)(2), and (k)(3) of this AD, as applicable, must be done before or concurrently with the requirements of paragraph (j) of this AD.

(1) For Groups 1 and 2: The requirements of paragraph (h) of this AD.

(2) For Group 2 airplanes: Installation of an additional electrostatic bond path for the number 5 and 8 inboard slat track drain tube assemblies, in accordance with Part IV of the Accomplishment Instructions of Boeing Service Bulletin 767–57A0060, Revision 1, dated December 31, 1998; or Revision 2, dated January 31, 2002.

(3) For Group 3 airplanes: The requirements of paragraph (i) of this AD.

(l) For airplanes identified in paragraph (i) of this AD, on which the actions required by paragraph (i) of this AD were done before the effective date of this AD in accordance with Boeing Service Bulletin 767–57–0068, dated September 16, 1999: Prior to or concurrently with the requirements of paragraph (j) of this AD, rework the bonding jumper assembly for the number 5 and 8 inboard slat track housing drain tube installation, in accordance with Part 2 of the Accomplishment Instructions of Boeing Service Bulletin 767–57–0068, Revision 1, dated May 9, 2002.

Credit for Actions Accomplished in Accordance With Previous Service Information

(m) Actions done before the effective date of this AD in accordance with an applicable service bulletin identified in table 1 of this AD are acceptable for compliance with the corresponding requirements of paragraph (j) of this AD.

TABLE 1—CREDIT SERVICE BULLETINS

Affected airplanes	Service Bulletin	Revision level	Date
Model 767–200, –300, and –300F series airplanes	Boeing Service Bulletin 767–57A0094	Original	June 2, 2005.
		1	December 19, 2006.
Model 767–400ER series airplanes	Boeing Service Bulletin 767–57A0095	Original	June 2, 2005.
		1	December 19, 2006.

Alternative Methods of Compliance (AMOCs)

(n)(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in the Related Information section of this AD. Information may be e-mailed to *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov*.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) AMOCs approved previously in accordance with AD 2001–14–19, Amendment 39–12330, are approved as AMOCs for the corresponding provisions of this AD.

Related Information

(o) For information about this AD, contact Rebel Nichols, Aerospace Engineer, Propulsion Branch, ANM–140S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue, SW., Renton, Washington 98057–3356; *phone*: 425–917–6509; *fax*: 425–227–6590; *e-mail*: *rebel.nichols@faa.gov*.

Material Incorporated by Reference

(p) You must use the service information contained in Table 2 of this AD, as applicable, to do the actions required by this AD, unless the AD specifies otherwise.

TABLE 2—ALL MATERIAL INCORPORATED BY REFERENCE

Document	Revision	Date
Boeing Service Bulletin 767–57A0060	1	December 31, 1998.
Boeing Service Bulletin 767–57A0060	2	January 31, 2002.
Boeing Service Bulletin 767–57–0068	Original	September 16, 1999.
Boeing Service Bulletin 767–57–0068	1	May 9, 2002.
Boeing Service Bulletin 767–57A0094	2	December 17, 2009.
Boeing Service Bulletin 767–57A0095	2	December 17, 2009.

(1) The Director of the Federal Register approved the incorporation by reference of the service information contained in Table 3 of this AD under 5 U.S.C. 552(a) and 1 CFR part 51.

TABLE 3—NEW MATERIAL INCORPORATED BY REFERENCE

Document	Revision	Date
Boeing Service Bulletin 767–57A0060	2	January 31, 2002.
Boeing Service Bulletin 767–57–0068	1	May 9, 2002.
Boeing Service Bulletin 767–57A0094	2	December 17, 2009.
Boeing Service Bulletin 767–57A0095	2	December 17, 2009.

(2) The Director of the Federal Register previously approved the incorporation by reference of the service information contained in Table 4 of this AD on August 28, 2001 (66 FR 38350, July 24, 2001).

TABLE 4—MATERIAL PREVIOUSLY INCORPORATED BY REFERENCE

Document	Revision	Date
Boeing Service Bulletin 767–57A0060	1	December 31, 1998.
Boeing Service Bulletin 767–57–0068	Original	September 16, 1999.

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, Washington 98124–2207; telephone: 206–544–5000, extension 1; fax: 206–766–5680; e-mail: *me.boecom@boeing.com*; Internet: *https://www.myboeingfleet.com*.

(4) You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at an NARA facility, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

Issued in Renton, Washington, on May 31, 2011.

Jeffrey E. Duven,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–14337 Filed 6–16–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0220; Directorate Identifier 2010–NM–259–AD; Amendment 39–16721; AD 2011–12–14]

RIN 2120–AA64

Airworthiness Directives; Fokker Services B.V. Model F.28 Mark 0070 and 0100 Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for the products listed above. This AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

* * * The Federal Aviation Administration (FAA) has published Special Federal Aviation Regulation (SFAR) 88, and the Joint Aviation Authorities (JAA) have published Interim Policy INT/POL/25/12. The review, conducted by Fokker Services on the Fokker 100 and Fokker 70 type design in response to these regulations, revealed that the fuel sense line from the overflow valves may touch the adjacent fuel-quantity indication-probe. Under certain conditions, this may result in an ignition source in the wing tank vapour space.

This condition, if not detected and corrected, could result in a wing fuel tank explosion and consequent loss of the aeroplane.

* * * * *

We are issuing this AD to require actions to correct the unsafe condition on these products.

DATES: This AD becomes effective July 22, 2011.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of July 22, 2011.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1137; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on March 15, 2011 (76 FR 13921). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

* * * The Federal Aviation Administration (FAA) has published Special Federal Aviation Regulation (SFAR) 88, and the Joint Aviation Authorities (JAA) have published Interim Policy INT/POL/25/12. The review, conducted by Fokker Services on the Fokker 100 and Fokker 70 type design in response to these regulations, revealed that the fuel sense line from the overflow valves may touch the adjacent fuel-quantity indication-probe. Under certain conditions, this may result in an ignition source in the wing tank vapour space.

This condition, if not detected and corrected, could result in a wing fuel tank explosion and consequent loss of the aeroplane.

For the reasons described above, this AD requires a one-time [general visual] inspection to check the route and clamping of the sense line hose and wiring conduit hose to each wing tank overflow valve and, depending on the findings, the necessary corrective actions.

Corrective actions include installing two brackets next to the overflow valve on the main tank access panel, making a modification to the routing of the hose for the sense line, and installing clamps to keep the hoses in position. Required actions also include revising the maintenance program to include a Critical Design Configuration Control Limitation (CDCCL). You may obtain further information by examining the MCAI in the AD docket.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

We reviewed the available data and determined that air safety and the public interest require adopting the AD as proposed.

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have required different actions in this AD from those in the MCAI in order to follow our FAA policies. Any such differences are highlighted in a NOTE within the AD.

Costs of Compliance

We estimate that this AD will affect 6 products of U.S. registry. We also estimate that it will take about 2 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this AD to the U.S. operators to be $1,020, or $170 per product.

In addition, we estimate that any necessary follow-on actions would take about 4 work-hours and require parts costing $800, for a cost of $1,140 per product. We have no way of determining the number of products that may need these actions.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will

not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this AD:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new AD:

2011–12–14 Fokker Services B.V.: Amendment 39–16721. Docket No. FAA–2011–0220; Directorate Identifier 2010–NM–259–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective July 22, 2011.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all Fokker Services B.V. Model F.28 Mark 0070 and 0100 airplanes, certificated in any category.

Note 1: This AD requires revisions to certain operator maintenance documents to include new actions (e.g., inspections) and/or CDCCLs. Compliance with these actions and/or CDCCLs is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this AD, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance according to paragraph (l) of this AD. The request should include a description of changes to the required actions that will ensure the continued operational safety of the airplane.

Subject

(d) Air Transport Association (ATA) of America Code 28: Fuel.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states: * * * The Federal Aviation Administration (FAA) has published Special Federal Aviation Regulation (SFAR) 88, and the Joint Aviation Authorities (JAA) have published Interim Policy INT/POL/25/12. The review, conducted by Fokker Services on the Fokker 100 and Fokker 70 type design in response to these regulations, revealed that the fuel sense line from the overflow valves may touch the adjacent fuel-quantity indication-probe. Under certain conditions, this may result in an ignition source in the wing tank vapour space.

This condition, if not detected and corrected, could result in a wing fuel tank explosion and consequent loss of the aeroplane.

* * * * *

Compliance

(f) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Actions

(g) At a scheduled opening of the fuel tank, but not later than 84 months after the effective date of this AD, do a general visual inspection of the routing and clamping of the sense line hose and wiring conduit hose to each wing tank overflow valve, in accordance with Part 1 of the Accomplishment Instructions of Fokker Service Bulletin SBF100–28–050, Revision 1, dated July 28, 2010.

(h) If incorrect routing or clamping of the hoses is found during the inspection required by paragraph (g) of this AD, before further flight, install two brackets next to the overflow valve on the main tank access panel, make a modification to the routing of the hose for the sense line, and install clamps to keep the hoses in position, in accordance with Part 2 of the Accomplishment Instructions of Fokker Service Bulletin SBF100–28–050, Revision 1, dated July 28, 2010.

Critical Design Configuration Control Limitations (CDCCL)

(i) Before further flight after determining that the routing and clamping of the sense line hose and wiring conduit hose to each wing tank overflow valve are correct, as required by paragraph (g) of this AD; or before further flight after doing the modification, as required by paragraph (h) of this AD; as applicable: Revise the aircraft maintenance program by incorporating the CDCCL in paragraph 1.L.(1)(c) of Fokker Service Bulletin SBF100–28–050, Revision 1, dated July 28, 2010.

No Alternative Inspections, Inspection Intervals, or CDCCLs

(j) After accomplishing the revision required by paragraph (i) of this AD, no alternative actions (e.g., inspections), intervals, and/or CDCCLs may be used unless the actions, intervals, and/or CDCCLs are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (l) of this AD.

Credit for Actions Accomplished in Accordance With Previous Service Information

(k) Actions done before the effective date of this AD in accordance with Fokker Service Bulletin SBF100–28–050, dated June 3, 2010, are acceptable for compliance with the corresponding requirements of this AD.

FAA AD Differences

Note 2: This AD differs from the MCAI and/or service information as follows: Although European Aviation Safety Agency (EASA) Airworthiness Directive 2010–0159, dated August 3, 2010, specifies revising the maintenance program to include limitations, doing certain repetitive actions (e.g., inspections), and/or maintaining CDCCLs, this AD only requires the revision. Requiring a revision of the maintenance program, rather than requiring individual repetitive actions and/or maintaining CDCCLs, requires operators to record AD compliance only at the time the revision is made. Repetitive actions and/or maintaining CDCCLs specified in the airworthiness limitations must be complied with in accordance with 14 CFR 91.403(c).

Other FAA AD Provisions

(l) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to *Attn:* Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind

Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1137; fax (425) 227–1149. Information may be e-mailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

Related Information

(m) Refer to MCAI EASA Airworthiness Directive 2010–0159, dated August 3, 2010; and Fokker Service Bulletin SBF100–28–050, Revision 1, dated July 28, 2010; for related information.

Material Incorporated by Reference

(n) You must use Fokker Service Bulletin SBF100–28–050, Revision 1, dated July 28, 2010, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Fokker Services B.V., Technical Services Dept., P.O. Box 231, 2150 AE Nieuw-Vennep, the Netherlands; telephone +31 (0)252–627–350; fax +31 (0)252–627–211; e-mail *technicalservices.fokkerservices@stork.com;* Internet *http://www.myfokkerfleet.com.*

(3) You may review copies of the service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

(4) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on June 2, 2011.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–14340 Filed 6–16–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0218; Directorate Identifier 2010–NM–164–AD; Amendment 39–16719; AD 2011–12–12]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Model MD–90–30 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for the products listed above. This AD requires a detailed inspection to detect distress and existing repairs to the leading edge structure of the vertical stabilizer at the splice at Station Zfs=52.267; repetitive inspections for cracking in the front spar cap forward flanges of the vertical stabilizer, and either the aft flanges or side skins; repetitive inspections for loose and missing fasteners; and related investigative and corrective actions if necessary. This AD was prompted by reports of cracked vertical stabilizer skin, a severed front spar cap, elongated fastener holes at the leading edge of the vertical stabilizer, and cracked front spar web and front spar cap bolt holes in the vertical stabilizer. We are issuing this AD to detect and correct such cracking damage, which could result in the structure being unable to support limit load, and could lead to the loss of the vertical stabilizer.

DATES: This AD is effective July 22, 2011.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in the AD as of July 22, 2011.

ADDRESSES: For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, 3855 Lakewood Boulevard, MC D800–0019, Long Beach, California 90846–0001; phone: 206–544–5000, extension 2; fax: 206–766–5683; e-mail: *dse.boecom@boeing.com;* Internet: *https://www.myboeingfleet.com.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Roger Durbin, Aerospace Engineer, Airframe Branch, ANM–120L, Los Angeles ACO, 3960 Paramount Blvd, Lakewood, CA 90712–4137; phone: 562–627–5233; fax: 562–627–5210; e-mail: *Roger.Durbin@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an airworthiness directive (AD) that would apply to the specified products. That NPRM published in the **Federal Register** on March 14, 2011 (76 FR 13546). That NPRM proposed to require a detailed inspection to detect distress in, and existing repairs to, the leading edge structure of the vertical stabilizer at the splice at Station Zfs=52.267, and corrective action if necessary.

Comments

We gave the public the opportunity to participate in developing this AD. We have considered the comment received. The Boeing Company supports the NPRM.

Conclusion

We reviewed the relevant data, considered the comment received, and determined that air safety and the public interest require adopting the AD as proposed.

Costs of Compliance

We estimate that this AD affects 19 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection for existing repairs, distress.	10 work-hours × $85 per hour = $850.	$0	$850	$16,150.
Repetitive inspections for cracking and loose and missing fasteners.	7 work-hours × $85 per hour = $595 per inspection cycle.	0	$595 per inspection cycle	$11,305 per inspection cycle.

We have received no definitive data that would enable us to provide cost estimates for the on-condition action specified in this AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in subtitle VII, part A, subpart III, section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2011–12–12 The Boeing Company: Amendment 39–16719; Docket No. FAA–2011–0218; Directorate Identifier 2010–NM–164–AD.

Effective Date

(a) This AD is effective July 22, 2011.

Affected ADs

(b) None.

Applicability

(c) This AD applies to The Boeing Company Model MD–90–30 airplanes, certificated in any category, as identified in Boeing Alert Service Bulletin MD90–55A014, dated June 24, 2010.

Subject

(d) Joint Aircraft System Component (JASC)/Air Transport Association (ATA) of America Code 55: Stabilizers.

Unsafe Condition

(e) This AD was prompted by reports of cracked vertical stabilizer skin, a severed front spar cap, elongated fastener holes at the leading edge of the vertical stabilizer, and cracked front spar web and front spar cap bolt holes in the vertical stabilizer. We are issuing this AD to detect and correct such cracking damage, which could result in the structure being unable to support limit load, and could lead to the loss of the vertical stabilizer.

Compliance

(f) Comply with this AD within the compliance times specified, unless already done.

Inspections for Distress/Repairs

(g) Within 4,100 flight cycles after the effective date of this AD, do a detailed inspection for distress in and existing repairs to the leading edge structure of the vertical stabilizer at the splice at Station Zfs=52.267, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–55A014, dated June 24, 2010.

Repetitive Inspections for Cracks, and Related Investigative and Corrective Actions

(h) Before further flight after doing the inspection required by paragraph (g) of this AD, inspect for cracks of the left and right vertical stabilizer front spar cap, in accordance with either Option 1 or Option 2 as specified in the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–55A014, dated June 24, 2010. If any crack is found, before further flight, evaluate and verify to confirm all crack indications, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–55A014, dated June 24, 2010.

(1) If any cracking is confirmed, before further flight, repair using a method approved in accordance with the procedures specified in paragraph (l) of this AD.

(2) If no cracking is confirmed, repeat the inspection thereafter at intervals not to exceed the applicable interval specified in paragraph (h)(2)(i) or (h)(2)(ii) of this AD.

(i) If the most recent inspection was done using Option 1, the next inspection must be done within 4,400 flight cycles.

(ii) If the most recent inspection was done using Option 2, the next inspection must be done within 3,000 flight cycles.

Leading Edge Repair

(i) If leading edge distress is found during the detailed inspection required by paragraph (g) of this AD, before further flight and after accomplishing the inspection required by paragraph (h) of this AD, repair the leading edge, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–55A014, dated June 24, 2010.

Inspection for Loose/Missing Fasteners

(j) For airplanes on which no cracking is confirmed during the initial inspection required by paragraph (h) of this AD: At the applicable time specified in paragraph (j)(1) or (j)(2) of this AD, do a detailed inspection for indications of loose and missing fasteners, in accordance with the Accomplishment

Instructions of Boeing Alert Service Bulletin MD90–55A014, dated June 24, 2010. If any loose or missing fastener is found, before further flight, repair the leading edge, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–55A014, dated June 24, 2010.

(1) If the inspection required by paragraph (h) was done using Option 1, do the inspection required by paragraph (j) of this AD within 4,400 flight cycles after accomplishing the inspection required by paragraph (h) of this AD.

(2) If inspection required by paragraph (h) was done using Option 2, do the inspection required by paragraph (j) of this AD within 3,000 flight cycles after accomplishing the inspection required by paragraph (h) of this AD.

(k) For airplanes on which no cracking is confirmed during the most recent inspection required by paragraph (h) of this AD: Repeat the inspection for loose and missing fasteners required by paragraph (j) of this AD thereafter at intervals not to exceed the applicable time specified in paragraph (k)(1) or (k)(2) of this AD.

(1) If the most recent inspection required by paragraph (h) was done using Option 1, the next inspection required by paragraph (j) of this AD must be done within 4,400 flight cycles after accomplishing the most recent inspection required by paragraph (j) of this AD.

(2) If the most recent inspection required by paragraph (h) was done using Option 2, the next inspection required by paragraph (j) of this AD must be done within 3,000 flight cycles after the most recent inspection required by paragraph (j) of this AD.

Alternative Methods of Compliance (AMOCs)

(l)(1) The Manager, Los Angeles Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in the Related Information section of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Los Angeles ACO to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

Related Information

(m) For more information about this AD, contact Roger Durbin, Aerospace Engineer, Airframe Branch, ANM–120L, Los Angeles ACO, 3960 Paramount Blvd., Lakewood, CA 90712–4137; phone: 562–627–5233; fax: 562–627–5210; e-mail: *Roger.Durbin@faa.gov.*

Material Incorporated by Reference

(n) You must use of Boeing Alert Service Bulletin MD90–55A014, dated June 24, 2010, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, 3855 Lakewood Boulevard, MC D800–0019, Long Beach, California 90846–0001; phone: 206–544–5000, extension 2; fax: 206–766–5683; e-mail: *dse.boecom@boeing.com;* Internet: *https://www.myboeingfleet.com.*

(3) You may review copies of the service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

(4) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at an NARA facility, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on May 31, 2011.

Jeffrey E. Duven,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–14339 Filed 6–16–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0326; Directorate Identifier 2011–CE–006–AD; Amendment 39–16725; AD 2011–13–02]

RIN 2120–AA64

Airworthiness Directives; Costruzioni Aeronautiche Tecnam srl Model P2006T Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for the products listed above. This AD results from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

During Landing Gear retraction/extension ground checks performed on the P2006T, a loose Seeger ring was found on the nose landing gear hydraulic actuator cap.

The manufacturer has identified the root cause of this discrepancy in a design deficiency of the hydraulic actuator caps.

This condition, if not corrected, could determine uncommanded and improper extension of the nose or main landing gear.

We are issuing this AD to require actions to correct the unsafe condition on these products.

DATES: This AD becomes effective July 22, 2011.

On July 22, 2011, the Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

For service information identified in this AD, contact Costruzioni Aeronautiche TECNAM Airworthiness Office, Via Maiorise—81043 Capua (CE) Italy; *telephone:* +39 0823 620134; *fax:* +39 0823 622899; *e-mail: m.oliva@tecnam.com, p.violetti@tecnam.com; internet: http:/www.tecnam.com.* You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call 816–329–4148.

FOR FURTHER INFORMATION CONTACT: Albert Mercado, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; *telephone:* (816) 329–4119; *fax:* (816) 329–4090.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on April 6, 2011 (76 FR 18964). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

During Landing Gear retraction/extension ground checks performed on the P2006T, a loose Seeger ring was found on the nose landing gear hydraulic actuator cap.

The manufacturer has identified the root cause of this discrepancy in a design deficiency of the hydraulic actuator caps.

This condition, if not corrected, could determine uncommanded and improper

extension of the nose or main landing gear. To prevent this condition, this AD requires modifying each nose and main landing gear hydraulic actuator by installing security rings.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

We reviewed the available data and determined that air safety and the public interest require adopting the AD as proposed.

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have required different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a Note within the AD.

Costs of Compliance

We estimate that this AD will affect 1 product of U.S. registry. We also estimate that it will take about 2 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour. Required parts will cost about $80 per product.

Based on these figures, we estimate the cost of the AD on U.S. operators to be $250, or $250 per product.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866;

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD Docket.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new AD:

2011–13–02 Costruzioni Aeronautiche Tecnam srl: Amendment 39–16725; Docket No. FAA–2011–0326; Directorate Identifier 2011–CE–006–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective July 22, 2011.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Costruzioni Aeronautiche Tecnam srl P2006T airplanes, serial numbers 01/US through 046/US, 047/US, and 049/US, certificated in any category.

Subject

(d) Air Transport Association of America (ATA) Code 32: Landing Gear.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

During Landing Gear retraction/extension ground checks performed on the P2006T, a loose Seeger ring was found on the nose landing gear hydraulic actuator cap.

The manufacturer has identified the root cause of this discrepancy in a design deficiency of the hydraulic actuator caps.

This condition, if not corrected, could determine uncommanded and improper extension of the nose or main landing gear. To prevent this condition, this AD requires modifying each nose and main landing gear hydraulic actuator by installing security rings.

Actions and Compliance

(f) Unless already done, within 50 hours time-in-service after July 22, 2011 (the effective date of this AD) or within 60 days after July 22, 2011 (the effective date of this AD), whichever occurs first, modify each nose and main landing gear hydraulic actuator in accordance with Costruzioni Aeronautiche Tecnam Service Bulletin No. SB 036–CS, 1st Edition, Rev 1, dated December 15, 2010.

FAA AD Differences

Note: This AD differs from the MCAI and/or service information as follows: The applicability of this AD clarifies the applicability for airplanes in the United States.

Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to *Attn:* Albert Mercado, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; *telephone:* (816) 329–4119; *fax:* (816) 329–4090. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, a federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave., SW., Washington, DC 20591, *Attn:* Information Collection Clearance Officer, AES–200.

Related Information

(h) Refer to MCAI European Aviation Safety Agency (EASA) AD No.: 2011–0042, dated March 11, 2011; and Costruzioni Aeronautiche Tecnam Service Bulletin No. SB 036–CS, 1st Edition, Rev 1, dated December 15, 2010, for related information. For service information related to this AD, contact Costruzioni Aeronautiche TECNAM Airworthiness Office, Via Maiorise—81043 Capua (CE) Italy; *telephone:* +39 0823 620134; *fax:* +39 0823 622899; *e-mail: m.oliva@tecnam.com, p.violetti@tecnam.com; internet: http://www.tecnam.com.* You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call 816–329–4148.

Material Incorporated by Reference

(i) You must use Costruzioni Aeronautiche Tecnam Service Bulletin No. SB 036–CS, 1st Edition, Rev 1, dated December 15, 2010, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Costruzioni Aeronautiche TECNAM Airworthiness Office, Via Maiorise—81043 Capua (CE) Italy; *telephone:* +39 0823 620134; *fax:* +39 0823 622899; *e-mail: m.oliva@tecnam.com, p.violetti@tecnam.com; Internet: http://www.tecnam.com.*

(3) You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

(4) You may also review copies of the service information incorporated by reference for this AD at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Kansas City, Missouri, on June 10, 2011.

Earl Lawrence,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–14937 Filed 6–16–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0551; Directorate Identifier 2009–SW–013–AD; Amendment 39–16714; AD 2011–12–07]

RIN 2120–AA64

Airworthiness Directives; Eurocopter France Model SA–365C, SA–365C1, SA–365C2, SA–365N, SA–365N1, AS–365N2, AS 365 N3, and SA–366G1 Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) for the specified Eurocopter France (Eurocopter) helicopters. This action requires visually inspecting the adhesive bead between the bushing and the Starflex star (Starflex) arm for a crack, a gap, or loss of the adhesive bead, inspecting the Starflex arm ends for delamination, and replacing the Starflex if any of these conditions are found. This amendment is prompted by three cases of deterioration of a Starflex arm. In two of these cases, the deterioration caused high amplitude vibrations in flight, compelling the pilot to make a precautionary landing. The actions specified in this AD are intended to prevent failure of the Starflex, high-amplitude vibrations in flight, and subsequent loss of control of the helicopter.

DATES: Effective July 5, 2011.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 5, 2011.

Comments for inclusion in the Rules Docket must be received on or before August 16, 2011.

ADDRESSES: Use one of the following addresses to submit comments on this AD:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

You may get the service information identified in this AD from American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, TX 75053–4005, telephone (800) 232–0323, fax (972) 641–3710, or at *http://www.eurocopter.com.*

Examining the Docket: You may examine the docket that contains the AD, any comments, and other information on the Internet at *http://www.regulations.gov,* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Operations office (telephone (800) 647–5527) is located in Room W12–140 on the ground floor of the West Building at the street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Jim Grigg, Aerospace Engineer, FAA, Rotorcraft Directorate, Safety Management Group (ASW–112), 2601 Meacham Blvd., Fort Worth, Texas 76137; *telephone:* (817) 222–5126; *fax:* (817) 222–5961.

SUPPLEMENTARY INFORMATION:

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD No. 2008–0165, dated August 28, 2008 (AD No. 2008–0165), which supersedes EASA Emergency AD No. 2006–0321–E, dated October 18, 2006, to correct an unsafe condition for the Eurocopter Model SA–365C, SA–365C1, SA–365C2, SA–365N, SA–365N1, AS–365N2, AS 365 N3, and SA–366G1 helicopters. EASA issued AD No. 2008–0165 as a result of the issuance of Revision 3 of Eurocopter

Emergency Alert Service Bulletin (EASB) Numbers 05.00.51, 05.35, 05.28, and 05.00.21 (military only). EASA advises that their AD was issued following three reported cases of deterioration of a Starflex arm end. They state that in two of these cases, the deterioration caused high amplitude vibrations in flight, compelling the pilot to carry out a precautionary landing. EASA further states that if the Starflex arm end fails, high-amplitude vibrations could make it difficult to control the helicopter.

Related Service Information

Eurocopter has issued one EASB, which applies to four different series helicopters, each with a different EASB number: No. 05.00.51 for the 365N series; No. 05.35 for the 366G1; No. 05.28 for the 365C series; and No. 05.00.21 for non-type certificated military helicopters; all Revision 3, and all dated August 18, 2008. This EASB specifies ''checks of the bushes'' installed on Starflex arm ends and reduces the interval between successive checks ''in order to be able to detect any bush bonding failure or distortion of a Starflex arm end as rapidly as possible.'' EASA classified this EASB as mandatory and issued AD No. 2008–0165 to ensure the continued airworthiness of these helicopters.

FAA's Evaluation and Unsafe Condition Determination

These helicopters have been approved by the aviation authority of member states of the European Union and are approved for operation in the United States. Pursuant to our bilateral agreement with France, EASA, their technical representative, has notified us of the unsafe condition described in their AD. We are issuing this AD because we evaluated all information provided by EASA and determined the unsafe condition exists and is likely to exist or develop on other helicopters of the same type designs. Therefore, this AD is being issued to prevent the failure of the Starflex, high amplitude vibrations in flight, and subsequent loss of control of the helicopter. This AD requires, within 10 hours time-in-service (TIS) and thereafter at intervals not to exceed 10 hours TIS, visually inspecting the adhesive bead between the bushing and the Starflex arm for a crack, a gap, or loss of the adhesive bead, inspecting the Starflex arm ends for delamination, and replacing the Starflex if any of these conditions are found. Accomplish the actions by following specified portions of the EASB described previously.

The short compliance time involved is required because the previously described critical unsafe condition can adversely affect the structural integrity and controllability of the helicopter. Therefore, the actions described previously are required at very short TIS intervals, and this AD must be issued immediately.

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Differences Between This AD and the EASA AD

We have reviewed the EASA AD, and our AD differs from the EASA AD as follows:

- The EASA AD uses the term ''check.'' We instead use the term ''inspect.''
- The EASA AD uses the terms ''bush'' and ''bushes.'' We instead use the terms ''bushing'' and ''bushings.''
- The EASA AD uses the term ''flying hours.'' We instead use the term ''time-in-service.''

Costs of Compliance

We estimate that this AD will affect about 37 helicopters of U.S. registry. We also estimate that it will take about 0.25 work-hour per helicopter to inspect the Starflex arm end, and 10 work-hours to remove and replace the Starflex star, if necessary. The average labor rate is $85 per work-hour. Required parts will cost about $33,794. Based on these figures, we estimate that the total annual cost of this AD on U.S. operators is $50,369, assuming 20 inspections are conducted on each helicopter and assuming one Starflex star is replaced each year.

Comments Invited

This AD is a final rule that involves requirements that affect flight safety and was not preceded by notice and an opportunity for public comment; however, we invite you to submit any written data, views, or arguments regarding this AD. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2011–0551; Directorate Identifier 2009–SW–13–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the AD. We will consider all comments received by the closing date and may amend the AD in light of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this AD. Using the search function of the docket Web site, you can find and read the comments to any of our dockets, including the name of the individual who sent the comment. You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared an economic evaluation of the estimated costs to comply with this AD. See the AD docket to examine the economic evaluation.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in subtitle VII, part A, subpart III, section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends Part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

2011–12–07 Eurocopter France (Eurocopter): Amendment 39–16714; Docket No. FAA–2011–0551; Directorate Identifier 2009–SW–013–AD.

Applicability: Models SA–365C, SA–365C1, SA–365C2, SA–365N, SA–365N1, AS–365N2, AS 365 N3, and SA–366G1 helicopters; certificated in any category.

Compliance: Within 10 hours time-in-service (TIS), and thereafter at intervals not to exceed 10 hours TIS.

To prevent the failure of the Starflex star (Starflex) arm, high amplitude vibrations in flight, and subsequent loss of control of the helicopter, accomplish the following:

(a) Visually inspect the adhesive bead between the bushing and the Starflex arm for a crack, a gap, or loss of the adhesive bead, and inspect the Starflex arm ends for delamination in accordance with the Accomplishment Instructions, paragraph 2.B.1 and 2.B.2 of Eurocopter Emergency Alert Service Bulletin (EASB) No. 05.00.51 for the 365N series helicopters, No. 05.35 for the 366G1 model helicopter, or No. 05.28 for the 365C series helicopters, all Revision 3, and all dated August 18, 2008.

Note 1: The one Eurocopter EASB contains four different service bulletin numbers: No. 05.00.51, No. 05.35; and No. 05.28 for the model helicopters affected by this AD; and No. 05.00.21 for non-type certificated military helicopters.

(b) If there is a crack in the shockproof paint around the entire adhesive bead where the Starflex arm joins the bushing (as shown in Figure 2 of the applicable EASB), a gap between the adhesive bead and the bushing (as shown in Figure 3 of the applicable EASB), delamination of a Starflex arm end (as shown in Figure 4 of the applicable EASB), or loss of adhesive bead (as shown in Figure 5 of the applicable EASB), replace the Starflex before further flight.

(c) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Contact the Manager, Safety Management Group, *Attn:* DOT/FAA Southwest Region, Jim Grigg, ASW–112, Rotorcraft Directorate, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222–5126; *fax:* (817) 222–5961, for information about previously approved alternative methods of compliance.

(d) The Joint Aircraft System/Component (JASC) Code is 6200: Main Rotor System.

(e) The inspection shall be done in accordance with the specified portions of Eurocopter France Emergency Alert Service Bulletins No. 05.00.51, No. 05.35, or No. 05.28. All three of the Alert Service Bulletins are Revision 3 and all are dated August 18, 2008. The Director of the Federal Register approved this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, TX 75053–4005, telephone (800) 232–0323, fax (972) 641–3710, or at *http://www.eurocopter.com.* Copies may be inspected at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

This amendment becomes effective on July 5, 2011.

Note 2: The subject of this AD is addressed in European Aviation Safety Agency AD No. 2008–0165, dated August 28, 2008.

Issued in Fort Worth, Texas, on May 25, 2011.

Kim Smith,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2011–14248 Filed 6–16–11; 8:45 am]

BILLING CODE 4910–13–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 200

[Release No. 34–64649]

Delegation of Authority to the Director of Its Division of Enforcement

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Securities and Exchange Commission (''Commission'') is amending its rules to delegate authority to the Director of the Division of Enforcement (''Division'') to issue witness immunity orders to compel individuals to give testimony or provide other information. This delegation is intended to conserve Commission resources, enhance the Division's ability to detect violations of the Federal securities laws, increase the effectiveness and efficiency of the Division's investigations, and improve the success of the Commission's enforcement actions.

DATES: *Effective Date:* June 17, 2011.

FOR FURTHER INFORMATION CONTACT: Samuel Waldon, Assistant Chief Counsel, (202) 551–4710.

SUPPLEMENTARY INFORMATION: The Commission is amending its rules governing delegations of authority to the Director of the Division of Enforcement. The amendment to Rule 30–4(a)(14) (17 CFR 200.30–4(a)(14)) authorizes the Division Director to issue orders to compel individuals to give testimony or provide other information pursuant to 18 U.S.C. 6002–6004. This delegation follows on the Commission's prior delegation, effective January 19, 2010, of the authority to submit witness immunity requests to the Department of Justice, in connection with judicial proceedings, to compel testimony or the production of other information by witnesses who have provided or have the potential to provide substantial assistance in the Commission's investigations and related enforcement actions. *See* 75 FR 3122 (January 19, 2010). This delegation is intended to further conserve Commission resources, enhance the Division's ability to detect violations of the Federal securities laws, increase the effectiveness and efficiency of the Division's investigations, and improve the success of the Commission's enforcement actions. Notwithstanding anything in the foregoing, in any case in which the Director believes it appropriate, the Director may submit the matter to the Commission. The Commission is adopting this amendment for a period of 18 months, and, at the end of that period, will evaluate whether to extend the delegation to issue immunity orders.

The Commission finds, in accordance with the Administrative Procedure Act (''APA'') (5 U.S.C. 553(b)(3)(A)), that this revision relates solely to agency organization, procedures, or practices. It is therefore not subject to the provisions of the APA requiring notice and opportunity for comment. Accordingly, it is effective June 17, 2011.

List of Subjects in 17 CFR Part 200

Administrative practice and procedure, Authority delegations (Government agencies).

For the reasons set out in the preamble, Title 17, Chapter II of the Code of Federal Regulations is amended as follows:

PART 200—ORGANIZATION; CONDUCT AND ETHICS; AND INFORMATION AND REQUESTS

■ 1. The authority citation for Part 200, Subpart A, continues to read in part as follows:

Authority: 15 U.S.C. 77o, 77s, 77sss, 78d, 78d–1, 78d–2, 78w, 78ll(d), 78mm, 80a–37, 80b–11, and 7202, unless otherwise noted.

* * * * *

■ 2. Section 200.30–4, paragraph (a)(14) is revised to read as follows:

§ 200.30–4 Delegation of authority to Director of Division of Enforcement.

* * * * *

(a) * * *

(14) To submit witness immunity requests to the U.S. Attorney General pursuant to 18 U.S.C. 6002–6004, and, upon approval by the U.S. Attorney General, to seek or, for the period from June 17, 2011 through December 19, 2012, to issue orders compelling an individual to give testimony or provide other information pursuant to subpoenas that may be necessary to the public interest in connection with investigations and related enforcement actions pursuant to section 22(b) of the Securities Act of 1933 (15 U.S.C. 77v(b)), section 21(c) of the Securities Exchange Act of 1934 (15 U.S.C. 78u(c)), section 42(c) of the Investment Company Act of 1940 (15 U.S.C. 80a–41(c)) and section 209(c) of the Investment Advisers Act of 1940 (15 U.S.C. 80b–9(c)).

* * * * *

By the Commission.

Dated: June 13, 2011.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–15030 Filed 6–16–11; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2011–0467]

Drawbridge Operation Regulations; Cheesequake Creek, Morgan, NJ

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Route 35 Bridge, mile 0.0, across Cheesequake Creek at Morgan, New Jersey. The deviation is necessary to perform structural and electrical rehabilitation. This deviation allows the bridge to remain in the closed position for four months.

DATES: This deviation is effective from December 1, 2011 through March 31, 2012.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2011–0467 and are available online at *http://www.regulations.gov,* inserting USCG–2011–0467 in the ''Keyword'' and then clicking ''Search''. They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail Mr. Joe Arca, Project Officer, First Coast Guard District, *joe.m.arca@uscg.mil,* telephone (212) 668–7165. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION: The Route 35 Bridge, across Cheesequake Creek, mile 0.0, at Morgan, New Jersey, has a vertical clearance in the closed position of 25 feet at mean high water and 30 feet at mean low water. The drawbridge operation regulations are listed at 33 CFR 117.709.

The waterway is predominantly used by recreational vessels on a seasonal basis.

The owner of the bridge, the New Jersey Department of Transportation, requested a temporary deviation from the regulations to facilitate structural and electrical rehabilitation of the bridge.

The bridge would not be able to open for vessel traffic for four months during the prosecution of the bridge rehabilitation repairs; however, the repairs will take place during the winter months, December through March, when the bridge normally receives no requests to open.

The Coast Guard published notice of the proposed four month bridge closure in the Local Notice to Mariners on April 7, 2011, with a request for comments. No comments were received.

New Jersey Department of Transportation held a public information meeting with the local marinas and interested parties on March 24, 2011. No objections were received as a result of the public information meeting.

Under this temporary deviation the Route 35 Bridge may remain in the closed position for four months from December 1, 2011 through March 31, 2012. Vessels that can pass under the bridge in the closed position may do so at any time.

In accordance with 33 CFR 117.35(e), the bridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: May 31, 2011.

Gary Kassof,

Bridge Program Manager, First Coast Guard District.

[FR Doc. 2011–15049 Filed 6–16–11; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R5–ES–2011–0035; 92220–1113–0000; ABC Code: C6]

RIN 1018–AX80

Endangered and Threatened Wildlife and Plants; Reinstatement of Listing Protections for the Virginia Northern Flying Squirrel in Compliance With a Court Order

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), are issuing this final rule to comply with a court order that has the effect of reinstating the regulatory protections under the Endangered Species Act of 1973 (ESA), as amended, for the Virginia northern flying squirrel (*Glaucomys sabrinus fuscus*). Pursuant to the District of Columbia District Court order dated March 25, 2011, this rule reinstates the Virginia northern flying squirrel listing as endangered.

DATES: This action is effective June 17, 2011. However, the court order had legal effect immediately upon its filing on March 25, 2011.

ADDRESSES: This final rule is available on the Internet at *http://www.regulations.gov.* It will also be available for inspection, by appointment, during normal business hours at U.S. Fish and Wildlife Service, West Virginia Field Office, 694 Beverly Pike, Elkins, West Virginia 26241. Call (304) 636–6586 to make arrangements.

FOR FURTHER INFORMATION CONTACT: For information contact Deborah Carter, Project Leader, at our West Virginia field office (see **ADDRESSES**) or telephone (304) 636–6586, extension 12. Individuals who are hearing impaired or speech impaired may call the Federal Relay Service at 1–800–877–8337 for TTY assistance.

SUPPLEMENTARY INFORMATION:

Background

On August 26, 2008, we published a final rule to remove ESA protections for the Virginia northern flying squirrel, more commonly known as the West Virginia northern flying squirrel (WVNFS) (73 FR 50226). Additional background information on the WVNFS, including previous Federal actions, can be found in our August 26, 2008, final rule, *http://www.regulations.gov,* or at *http://ecos.fws.gov/speciesProfile/profile/speciesProfile.action?spcode=A09R.*

A lawsuit challenging our final rule was filed in U.S. District Court for the District of Columbia. On March 25, 2011, the U.S. District Court for the District of Columbia vacated and set aside our 2008 delisting rule (*Friends of Blackwater et al.* v. *Salazar et al.,* 1:09–cv–02122–EGS).

The decision reinstates Federal protections that were in place prior to our 2008 delisting. Accordingly, WVNFS is listed as endangered throughout its range (50 FR 26999 27002, July 1, 1985; 50 CFR 17.11(h)). Therefore, take of WVNFS may be authorized only by a permit obtained under section 10 of the ESA, or if exempted by an incidental take statement within a biological opinion issued by the Service pursuant to section 7 of the ESA. We notified all State and Federal partners of the decision and its impact shortly after the order was released. There are no federally recognized Tribes to notify in Virginia or West Virginia. We also took steps to ensure the public was aware of the decision.

This action is independent of any decision by the United States or any interveners in the case to appeal the March 25, 2011, District of Columbia District Court ruling.

Administrative Procedure

This rulemaking is necessary to comply with the March 25, 2011, court order. Therefore, under these circumstances, the Director has determined, pursuant to 5 U.S.C. 553(b)(3)(B), that prior notice and opportunity for public comment are impractical and unnecessary. The Director has further determined, pursuant to 5 U.S.C. 553(d)(3), that the agency has good cause to make this rule effective upon publication.

Effects of the Rule

As of the filing of the court order, delisted WVNFS were again listed as endangered (50 CFR 17.11(h)).

This rule will not affect the status of WVNFS under State laws or suspend any other legal protections provided by State law.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulation Promulgation

In order to comply with the court order discussed above, we amend part 17, subchapter B of chapter I, title 50 of the CFR, as set forth below:

PART 17—[AMENDED]

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

■ 2. Amend § 17.11 by adding an entry in the table at paragraph (h) for ''Squirrel, Virginia northern flying'' under ''MAMMALS'' as follows:

§ 17.11 [Amended]

* * * * *

(h) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
MAMMALS							
*	* *		*	*	*		*
Squirrel, Virginia northern flying.	*Glaucomys sabrinus fuscus*.	U.S.A. (VA, WV).	Entire	E	189	N/A	N/A
*	* *		*	*	*		*

* * * * *

Dated: May 27, 2011.

Rowan W. Gould,

Acting Director, Fish and Wildlife Service.

[FR Doc. 2011–15111 Filed 6–16–11; 8:45 am]

BILLING CODE 4310–55–P

Proposed Rules

Federal Register
Vol. 76, No. 117
Friday, June 17, 2011

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

FEDERAL RESERVE SYSTEM

12 CFR Part 225

[Regulation Y; Docket No. R–1425]

RIN 7100–AD 77

Capital Plans

AGENCY: Board of Governors of the Federal Reserve System (Board).

ACTION: Proposed rule.

SUMMARY: The Board is proposing amendments to Regulation Y to require large bank holding companies to submit capital plans to the Federal Reserve on an annual basis and to require such bank holding companies to provide prior notice to the Federal Reserve under certain circumstances before making a capital distribution.

DATES: Comments must be received by August 5, 2011.

ADDRESSES: You may submit comments, identified by Docket No. R–1425 and RIN No. 7100 AD 77, by any of the following methods:

- *Agency Web Site: http://www.federalreserve.gov.* Follow the instructions for submitting comments at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm.*
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail: regs.comments@federalreserve.gov.* Include the docket number in the subject line of the message.
- *Fax:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Address to Jennifer J. Johnson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, NW., Washington, DC 20551.

All public comments will be made available on the Board's Web site at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm* as submitted, unless modified for technical reasons. Accordingly, comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper in Room MP–500 of the Board's Martin Building (20th and C Streets, NW.) between 9 a.m. and 5 p.m. on weekdays.

FOR FURTHER INFORMATION CONTACT: Benjamin W. McDonough, Counsel, (202) 452–2036, April C. Snyder, Counsel, (202) 452–3099, or Christine E. Graham, Attorney, (202) 452–3005, Legal Division; Timothy P. Clark, Senior Advisor, (202) 452–5264, Michael Foley, Senior Associate Director, (202) 452–6420, or Thomas R. Boemio, Manager, (202) 452–2982, Division of Banking Supervision and Regulation, Board of Governors of the Federal Reserve System, 20th and C Streets, NW., Washington, DC 20551.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

The Board is proposing amendments to Regulation Y (12 CFR part 225) to require large bank holding companies to submit capital plans to the Federal Reserve on an annual basis and to require such bank holding companies to provide prior notice to the Federal Reserve under certain circumstances before making a capital distribution (the proposal or proposed rule).[1] During the years leading up to the recent financial crisis, many bank holding companies made significant distributions of capital, in the form of stock repurchases and dividends, without due consideration of the effects that a prolonged economic downturn could have on their capital adequacy and ability to continue to operate and remain credit intermediaries during times of economic and financial stress. The proposal is intended to address such practices, building upon the Federal Reserve's existing supervisory expectation that large bank holding companies have robust systems and processes that incorporate forward-looking projections of revenue and losses to monitor and maintain their internal capital adequacy.[2]

The Federal Reserve has long held the view that bank holding companies generally should operate with capital positions well above the minimum regulatory capital ratios, with the amount of capital held commensurate with the bank holding company's risk profile.[3] Bank holding companies should have internal processes for assessing their capital adequacy that reflect a full understanding of their risks and ensure that they hold capital corresponding to those risks to maintain overall capital adequacy.[4] Bank holding companies that are subject to the Board's advanced approaches risk-based capital requirements must satisfy specific requirements relating to their internal capital adequacy processes in order to use the advanced approaches to calculate their minimum risk-based capital requirements.[5] Under section 165 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (Dodd-Frank Act), the Board is required to impose enhanced prudential standards on large bank holding companies, including stress testing requirements; enhanced capital, liquidity, and risk management requirements; and a requirement to

[1] The proposed amendments to Regulation Y would be codified at 12 CFR 225.8. As discussed in section V of this preamble, the proposal would also make conforming changes to section 225.4(b) of Regulation Y (12 CFR 225.4(b)).

[2] *See* SR letter 09–4 (Revised March 27, 2009), *available at http://www.federalreserve.gov/boarddocs/srletters/2009/SR0904.htm; see also* Revised Temporary Addendum to SR letter 09–4 (November 17, 2010) (SR 09–04), *available at http://www.federalreserve.gov/newsevents/press/bcreg/bcreg20101117b1.pdf.*

[3] *See* 12 CFR part 225, Appendix A; *see also* SR letter 99–18 (July 1, 1999), *available at http://www.federalreserve.gov/boarddocs/srletters/1999/SR9918.HTM.*

[4] *See* SR letter 09–4 (Revised March 27, 2009), *available at http://www.federalreserve.gov/boarddocs/srletters/2009/SR0904.htm.*

[5] *See* 12 CFR part 225, Appendix G, section 22(a); *see also, Supervisory Guidance: Supervisory Review Process of Capital Adequacy (Pillar 2) Related to the Implementation of the Basel II Advanced Capital Framework,* 73 FR 44620 (July 31, 2008).

establish a risk committee.[6] While the proposal is not mandated by the Dodd-Frank Act, the Board believes that it is appropriate to hold large bank holding companies to an elevated capital planning standard because of the elevated risk posed to the financial system by large bank holding companies and the importance of capital in mitigating these risks.

As part of their fiduciary responsibilities to a bank holding company, the board of directors and senior management bear the primary responsibility for developing, implementing, and monitoring a bank holding company's capital planning strategies and internal capital adequacy processes. The proposal does not diminish that responsibility. Rather, the proposal is intended to (i) Establish minimum supervisory standards for such strategies and processes for certain large bank holding companies; (ii) describe how boards of directors and senior management of these bank holding companies should communicate the strategies and processes, including any material changes thereto, to the Federal Reserve; and (iii) provide the Federal Reserve with an opportunity to review bank holding companies' capital distributions under certain circumstances. The proposal is designed to be flexible enough to accommodate bank holding companies of varying degrees of complexity and to adjust to changing conditions over time.

The proposal is also consistent with the Federal Reserve's recent supervisory practice of requiring capital plans from large, complex bank holding companies. In 2009, the Board conducted the Supervisory Capital Assessment Program (SCAP), a ''stress test'' of 19 large, domestic bank holding companies. The SCAP was focused on identifying whether large bank holding companies had capital sufficient to weather a more-adverse-than-anticipated economic environment while maintaining their capacity to lend. The Federal Reserve required firms identified as having capital shortfalls to raise specific dollar amounts of capital within six months of the release of the SCAP results. The Department of the Treasury established a government backstop available to firms unable to raise the required capital from private markets.[7]

In 2011, the Federal Reserve continued its supervisory evaluation of the resiliency and capital adequacy processes of the same 19 bank holding companies through the Comprehensive Capital Analysis and Review (CCAR). CCAR involved the Federal Reserve's forward-looking evaluation of the internal capital planning processes of the bank holding companies and their anticipated capital actions in 2011, such as increasing dividend payments or repurchasing or redeeming stock.[8] In CCAR, the Federal Reserve evaluated whether these bank holding companies had satisfactory processes for identifying capital needs and held adequate capital to maintain ready access to funding, continue operations and meet their obligations to creditors and counterparties, and continue to serve as credit intermediaries, even under stressful conditions.

As noted above, the Dodd-Frank Act imposes enhanced prudential standards, including stress testing requirements, on large bank holding companies.[9] As the Board implements the Dodd-Frank Act, bank holding companies would be required to incorporate any related requirements into their capital planning strategies and internal capital adequacy processes, including the results of stress tests required by the Dodd-Frank Act.

The Dodd-Frank Act also requires the Board to impose early remediation requirements on large bank holding companies under which a large bank holding company experiencing financial distress must take specific remedial actions in order to minimize the probability that the company will become insolvent and minimize the potential harm of such insolvency to the United States.[10] These early remediation requirements must impose limitations on capital distributions in the initial stages of financial decline and increase in stringency as the financial condition of the company declines.[11] Depending on a bank holding company's financial condition, early remediation requirements imposed under the Dodd-Frank Act may result in additional limitations on a company's capital distributions than the prior notice requirements that would be imposed by the proposed rule.[12]

II. Scope

The proposed rule would apply to every top-tier bank holding company domiciled in the United States that has $50 billion or more in total consolidated assets (large U.S. bank holding companies).[13] This amount would be measured as the average over the previous two calendar quarters, as reflected on the bank holding company's consolidated financial statement for bank holding companies (FR Y–9C). Consistent with the phase-in period for the imposition of minimum risk-based and leverage capital requirements established in section 171 of the Dodd-Frank Act, until July 21, 2015, the proposed rule would not apply to any bank holding company subsidiary of a foreign banking organization that has relied on Supervision and Regulation Letter SR 01–01 issued by the Board of Governors (as in effect on May 19, 2010).[14] The proposed rule also would apply to any institution that the Board has determined, by order, shall be subject in whole or in part to the proposed rule's requirements based on the institution's size, level of complexity, risk profile, scope of operations, or financial condition.

As of March 31, 2011, there were approximately 35 large U.S. bank holding companies. The Board notes that the proposed asset threshold of $50 billion is consistent with the threshold established by section 165 of the Dodd-

[6] *See generally* section 165 of Public Law 111–203, 124 Stat. 1376 (2010) (Dodd-Frank Act); 12 U.S.C. 5365.

[7] *See* Board of Governors of the Federal Reserve System, *The Supervisory Capital Assessment Program: Overview of Results* (May 7, 2009), *available at http://www.federalreserve.gov/bankinforeg/bcreg20090507a1.pdf.*

[8] *See* Board of Governors of the Federal Reserve System, *Comprehensive Capital Analysis and Review: Objectives and Overview* (March 18, 2010), *available at http://www.federalreserve.gov/newsevents/press/bcreg/bcreg20110318a1.pdf.*

[9] Through separate rulemaking or by order, it is expected that the proposal's requirements would be extended to apply to large savings and loan holding companies and nonbank financial companies supervised by the Board pursuant to section 113 of the Dodd-Frank Act.

[10] *See* section 166 of the Dodd-Frank Act; 12 U.S.C. 5366.

[11] *Id.*

[12] The Board notes that Basel III includes a capital conservation buffer designed to ensure that bank holding companies build up capital buffers outside periods of stress that can be drawn down as losses are incurred. Under Basel III, capital distribution constraints would be imposed on a bank holding company when capital levels fall within the capital conservation buffer. *See* Basel Committee on Banking Supervision, *Basel III: A Global Framework for More Resilient Banks and Banking Systems* (December 2010), *available at http://www.bis.org/publ/bcbs189.pdf.*

[13] Thus, the proposal would not apply to a foreign bank or foreign banking organization that was itself a bank holding company or treated as a bank holding company pursuant to section 8(a) of the International Banking Act of 1978 (12 U.S.C. 3106(a)), but generally would apply to any U.S.-domiciled bank holding company subsidiary of the foreign bank or foreign banking organization that meets the proposal's size threshold.

[14] Under Supervision and Regulation Letter SR 01–01, as a general matter, a U.S. bank holding company that is owned and controlled by a foreign bank that is a financial holding company that the Board has determined to be well-capitalized and well-managed is not required to comply with the Board's capital adequacy guidelines. *See* SR letter 01–01 (January 5, 2001), *available at http://www.federalreserve.gov/boarddocs/srletters/2001/sr0101.htm.*

Frank Act relating to enhanced supervision and prudential standards for certain bank holding companies.[15] The proposal generally would apply to large U.S. bank holding companies when any final rule becomes effective.

The Board solicits comment on whether the capital planning and prior notice requirements in the proposed rule should apply, as proposed, to large U.S. bank holding companies. What other asset threshold(s) would be appropriate and why? Are there other measures other than total consolidated assets that should be considered?

In addition, the Board solicits comment on whether the proposed rule should include a transitional period for institutions that did not participate in CCAR. For example, should such institutions have an additional year to come into compliance with the proposed capital planning and prior notice requirements?

III. Capital Plans

A. Annual Capital Planning Requirement

The proposed rule would require a bank holding company to develop and maintain a capital plan. For purposes of the proposal, a capital plan is defined as a written presentation of a company's capital planning strategies and capital adequacy processes that includes (i) An assessment of the expected uses and sources of capital over a nine-quarter forward-looking planning period (beginning with the quarter preceding the quarter in which the bank holding company submits its capital plan) that reflects the bank holding company's size, complexity, risk profile, and scope of operations, assuming both expected and stressful conditions, (ii) a detailed description of the bank holding company's processes for assessing capital adequacy, and (iii) an analysis of the effectiveness of these processes. As described below, the proposed rule specifies certain mandatory elements of a capital plan. The level of detail and analysis expected in a capital plan would vary based on the bank holding company's size, complexity, risk profile, and scope of operations. Thus, for example, a bank holding company with extensive credit exposures to commercial real estate, but very limited trading activities, would be expected to have robust systems in place to identify and monitor its commercial real estate exposures; its systems related to trading activities would not need to be as sophisticated or extensive. In contrast, a bank holding company with extensive exposure to a variety of risk exposures, including both retail and wholesale exposures, as well as significant trading activities and international operations, would be expected to have an integrated system for measuring all these risk exposures and the interactions among them.

The bank holding company's board of directors or a designated committee thereof would be required at least annually to review the effectiveness of the holding company's processes for assessing capital adequacy, ensure that any deficiencies in the firm's processes for assessing capital adequacy are appropriately remediated, and approve the bank holding company's capital plan.[16] After the capital plan is approved by the board of directors, the bank holding company would be required to submit its complete capital plan to the appropriate Reserve Bank and the Board by the 5th of January of each year, or such later date as directed by the appropriate Reserve Bank, after consultation with the Board. A later date may be appropriate if, for example, the bank holding company would need additional time to update its plan to reflect any scenarios that the Federal Reserve has required the bank holding company to evaluate and incorporate in its capital plan as part of its submission.

A bank holding company would be required to update and resubmit its capital plan to the appropriate Reserve Bank and the Board within 30 calendar days after the occurrence of one of the following events:

(i) The bank holding company determines there has been or will be a material change in the bank holding company's risk profile (including a material change in its business strategy or any material risk exposures), financial conditions, or corporate structure since the bank holding company adopted the capital plan; [17] or

(ii) The appropriate Reserve Bank, after consultation with the Board, directs the bank holding company to update its capital plan for reasons described in the proposal.

The appropriate Reserve Bank, after consultation with the Board, could at its sole discretion extend this 30-day period for up to an additional 60 calendar days. Any updated capital plan would be required to satisfy all the requirements of the proposal as if it were the original submission, unless otherwise specified by the appropriate Reserve Bank, after consultation with the Board. However, to the extent that the analysis underlying an initial capital plan were still considered valid, the bank holding company would be able to continue to rely on this analysis for purposes of any revised or updated plan, provided that the analysis was accompanied by an explanation of how the analysis should be considered in the light of any new capital actions or changes in risk profile or strategy.

B. Mandatory Elements of a Capital Plan

Every capital plan would be required to contain at least the following elements:

(i) A discussion of how the bank holding company will, under stressful conditions, maintain capital commensurate with its risks, maintain capital above the minimum regulatory capital ratios, and serve as a source of strength to its depository institution subsidiaries;

(ii) A discussion of how the bank holding company will, under stressful conditions, continue its operations by maintaining ready access to funding, meeting its obligations to creditors and other counterparties, and continuing to serve as a credit intermediary;

(iii) A discussion of the bank holding company's sources and uses of capital over a minimum nine-quarter planning horizon reflecting the risk profile of the firm, including:

(A) Estimates of projected revenues, losses, reserves, and pro forma capital levels, including any minimum regulatory capital ratios (for example, leverage, tier 1 risk-based, and total risk-based) and any additional capital measures deemed relevant by the bank holding company, over the planning horizon under expected conditions and under a range of stressed scenarios, including any scenarios provided by the Federal Reserve and at least one stressed scenario developed by the bank holding company appropriate to its business model and portfolios, and a probabilistic assessment of the likelihood of the bank holding company-developed scenario(s); [18]

[15] *See* section 165(a) of the Dodd-Frank Act; 12 U.S.C. 5365(a). The Dodd-Frank Act provides that the Board may, upon the recommendation of the Financial Stability Oversight Council, increase the $50 billion asset threshold for the application of the resolution plan, concentration limit, and credit exposure report requirements. *See* 12 U.S.C. 5365(a)(2)(B).

[16] As part of this review the board of directors should be made aware of any remaining uncertainties, limitations, and assumptions associated with the bank holding company's capital adequacy processes.

[17] For purposes of determining whether a change in its risk profile was material, a bank holding company would be required to consider a variety of risks, including credit, market, operational, liquidity, and interest rate risks.

[18] With respect to this criterion, for any Federal Reserve-provided stressed scenarios and any related

Continued

(B) A discussion of the results of any stress test required by law or regulation, and an explanation of how the capital plan takes these results into account; and

(C) A description of all planned capital actions over the planning horizon (for example, issuances of debt and equity capital instruments, distributions on capital instruments, and redemptions and repurchases of capital instruments);

(iv) The bank holding company's capital policy;

(v) A discussion of any expected changes to the bank holding company's business plan that are likely to have a material impact on the firm's capital adequacy or liquidity; and

(vi) Until January 1, 2016, a calculation of the pro forma tier 1 common ratio under expected and stressful conditions and discussion of how the company would maintain a pro forma tier 1 common ratio of 5 percent under stressed scenarios.

These proposed mandatory elements of a capital plan are consistent with the Federal Reserve's existing supervisory practice with respect to the information that it expects certain bank holding companies to include in a capital plan for internal planning purposes. As bank holding companies begin to conduct stress tests in accordance with rules to be issued by the Board pursuant to section 165(i)(2) of the Dodd-Frank Act, bank holding companies would be required to incorporate the results of these stress tests into their capital plans.[19] A bank holding company should include in its capital plan other information that it determined was relevant to its capital planning strategies and internal capital adequacy processes.

For purposes of the proposal, a capital action would be defined as any issuance of a debt or equity capital instrument, capital distribution, and any similar action that the Federal Reserve determines could impact a bank holding company's consolidated capital. A capital distribution would be defined as a redemption or repurchase of any debt or equity capital instrument, a payment of common or preferred stock dividends, a payment that may be temporarily or permanently suspended by the issuer on any instrument that is eligible for inclusion in the numerator of any minimum regulatory capital ratio, and any similar transaction that the Federal Reserve determines to be in substance a distribution of capital.[20]

A capital policy would be defined as the bank holding company's written assessment of the principles and guidelines used for capital planning, capital issuance, usage and distributions, including internal capital goals; the quantitative or qualitative guidelines for dividend and stock repurchases; the strategies for addressing potential capital shortfalls; and the internal governance procedures around capital policy principles and guidelines. With respect to a bank holding company's internal capital goals, such goals should apply throughout the planning horizon in the form of capital levels or ratios. The bank holding company should be able to demonstrate that achieving its stated internal capital goals would allow it to continue its operations after the impact of the stressed scenarios included in its capital plan. As part of the continuation of a bank holding company's operations, the Federal Reserve would expect the bank holding company to maintain ready access to funding, meet its obligations to creditors and other counterparties, and continue to serve as a credit intermediary.[21] Similarly, a bank holding company's capital policy should reflect strategies for addressing potential capital shortfalls, such as by reducing or eliminating capital distributions, raising additional capital, or preserving its existing capital, to support circumstances where the bank holding company has underestimated its risks or where its performance has not met its expectations.

As noted above, a bank holding company must include pro forma estimates of its minimum regulatory capital ratios in its capital plan. The proposal would define minimum regulatory capital ratios as any minimum regulatory capital ratio that the Federal Reserve may require of a bank holding company, by regulation or order, including the bank holding company's leverage ratio and tier 1 and total risk-based capital ratios as calculated under Appendices A, D, E, and G to this part 225 (12 CFR part 225 Appendices A, D, E, and G), or any successor regulation. If the Board were to adopt additional or different minimum regulatory capital ratios in the future, a bank holding company would be required to incorporate these minimum capital ratios into its capital plan as they come into effect and reflect them in its planning horizon.

In addition to the requirements discussed above, until January 1, 2016, a bank holding company would be required to calculate its pro forma tier 1 common ratio under expected and stressful conditions and discuss in its capital plan how the bank holding company would maintain a pro forma tier 1 common ratio of 5 percent under those conditions throughout the planning horizon. For purposes of this requirement, a bank holding company's tier 1 common ratio would mean the ratio of a bank holding company's tier 1 common capital to its total risk-weighted assets. Tier 1 common capital would be calculated as tier 1 capital less non-common elements in tier 1 capital, including perpetual preferred stock and related surplus, minority interest in subsidiaries, trust preferred securities and mandatory convertible preferred securities.[22] Tier 1 capital would have the same meaning as under Appendix A to Regulation Y, or any successor regulation, and total risk-weighted assets would have the same meaning as under Appendices A, E, and G of Regulation Y, or any successor regulation.[23]

This definition of tier 1 common capital is consistent with the definition that the Federal Reserve has used for supervisory purposes, including in CCAR. The Basel III framework proposed by the Basel Committee on Bank Supervision includes a different

data requests that would be required to be reflected in the bank holding company's annual capital plan, the Federal Reserve would provide such scenarios and data requests to bank holding companies several weeks before the capital plan due date of January 5. With respect to scenarios designed by the bank holding company, such an exercise will involve robust scenario design and effective translation of scenarios into measures of impact on capital positions. Selection of scenario variables is important for this purpose, as scenarios serve as the link between the overall narrative of the scenario and the tangible capital impact on the firm as a whole. For instance, in aiming to capture the combined capital impact of a severe recession and a financial market downturn, a firm may choose a set of variables that include changes in U.S. Gross Domestic Product, unemployment rate, interest rates, stock market levels, or home price levels.

[19] At this time, the Board does not expect that the results of stress tests conducted under the Dodd-Frank Act alone will be sufficient to address all relevant adverse outcomes that should be covered in a satisfactory capital plan for purposes of this proposed rule.

[20] For example, this definition would include payments on trust preferred securities, but would not include payments on subordinated debt that could not be temporarily or permanently suspended by the issuer.

[21] In addition, each bank holding company would be required to ensure that its internal capital goals reflect any relevant minimum regulatory capital ratio levels, any higher levels of regulatory capital ratios (above regulatory minimums), and any additional capital measures that, when maintained, would allow the bank holding company to continue its operations.

[22] Specifically, non-common elements would include the following items captured in the FR Y–9C: Schedule HC, line item 23 net of Schedule HC–R, line item 5; Schedule HC–R, line items 6a, 6b, and 6c; and Notes to the Balance Sheet—Other as captured in Schedule HC–R, line item 10.

[23] *See* 12 CFR part 225, Appendices A, E, and G.

definition of tier 1 common capital.[24] In recognition of the fact that the Board and the other federal banking agencies continue to work on implementing Basel III in the United States, the Board is proposing to require a bank holding company to demonstrate until January 1, 2016 how it would meet a minimum tier 1 common ratio of 5 percent under stressful conditions under the Board's existing supervisory definition of tier 1 common capital. This level reflects a supervisory assessment of the minimum capital needed to be a going concern on a post-stress basis, based on an analysis of the historical distribution of earnings by large banking organizations.[25]

In connection with its submissions of a capital plan to the Federal Reserve, a bank holding company would be required to provide certain data to the Federal Reserve. To the greatest extent possible, the data templates, and any other data requests, would be designed to minimize burden on the bank holding company and to avoid duplication, particularly in light of potential new reporting requirements arising from the Dodd-Frank Act. Data required by the Federal Reserve would include, but not be limited to, information regarding the bank holding company's financial condition, structure, assets, risk exposure, policies and procedures, liquidity, and management. For example, the Federal Reserve will require the bank holding company to complete data templates that describe in greater detail the bank holding company's assets and potential exposures, whether these reside on balance sheet or not. The frequency of the data collection will depend on the type of data being collected, and certain data may be collected on a quarterly, monthly, weekly, or daily basis. In some cases, the Federal Reserve may require this information to be reported on a loan-level basis.

The Board solicits comment on the proposed mandatory elements of a capital plan. In particular, the Board solicits comment on the requirement that a bank holding company calculate its pro forma tier 1 common ratio under expected and stressful conditions, and the manner in which a bank holding company should include internal capital goals as part of its capital policy.

C. Federal Reserve's Review of Capital Plans

The proposal provides that the Federal Reserve would consider the following factors in reviewing a bank holding company's capital plan:

(i) The reasonableness of the bank holding company's assumptions and analysis underlying the capital plan and its methodologies for reviewing the effectiveness of its capital adequacy processes;

(ii) The comprehensiveness of the capital plan, including the company's capital policy; and

(iii) The bank holding company's ability to maintain capital above each minimum regulatory capital ratio, and, until January 1, 2016, a tier 1 common ratio of 5 percent, on a pro forma basis under stressful conditions throughout the planning horizon.

The Federal Reserve would also consider the following information in reviewing a bank holding company's capital plan:

(i) Relevant supervisory information about the bank holding company and its subsidiaries;

(ii) The bank holding company's regulatory and financial reports, as well as supporting data that would allow for an analysis of a bank holding company's loss, revenue, and reserve projections;

(iii) As applicable, the Federal Reserve's own pro forma estimates of the firm's potential losses, revenues, reserves, and resulting capital adequacy under stressful conditions, as well as the results of any stress tests conducted by the bank holding company or the Federal Reserve; and

(iv) Other information requested or required by the Federal Reserve, as well as any other information relevant, or related, to the bank holding company's capital adequacy.

With respect to the third criterion, the Board expects that, as it develops and conducts supervisory stress testing requirements pursuant to section 165(i)(1) of the Dodd-Frank Act and reviews stress tests submitted by companies pursuant to section 165(i)(2) of the Dodd-Frank Act, the Federal Reserve would consider the results of such stress tests in its evaluation of bank holding companies' capital plans.[26]

D. Federal Reserve Action on a Capital Plan

The proposed rule describes the timeframe under which the Federal Reserve would review and act on a bank holding company's capital plan. Generally, as described in more detail below, the Federal Reserve's review of a capital plan would not delay a bank holding's ability to make capital distributions. Under the proposed rule, a bank holding company would be required to submit a complete annual capital plan by January 5 with respect to that calendar year. The Federal Reserve would object by March 15 to the capital plan, in whole or in part, or provide the bank holding company with a notice of non-objection.

This proposed timeframe is intended to balance the Federal Reserve's interest in having adequate time to review a capital plan with the bank holding company's interest in a process that does not unduly interfere with the ability of its board of directors and senior management to take appropriate capital actions. For example, if a firm submitted a complete annual plan to the Federal Reserve on January 5 of Year 1 with respect to its Year 1 capital plan, the Federal Reserve would provide a response by no later than March 15 of Year 1. The Federal Reserve expects that any non-objection to a capital plan would cover the subsequent four quarters (through the fourth quarter of Year 1). If the firm discussed above submitted a complete capital plan by January 5 of Year 2 with respect to its Year 2 capital plan and had received the Federal Reserve's non-objection to the capital plan provided in Year 1, any fourth-quarter capital distributions in Year 1 would have been covered by non-objection that the Federal Reserve provided in Year 1, and the firm would be notified by March 15 whether or not the Federal Reserve had any objection to dividend payments in the first quarter of Year 2. Thus, for this hypothetical firm, the Federal Reserve's review of its capital plan generally would not delay the bank holding company's ability to pay dividends or take other capital actions while awaiting a response from the Federal Reserve.

In order to adhere to the schedule set forth in the proposed rule, the Federal Reserve would likely require bank holding companies to submit data templates and other required information several weeks before complete capital plans are due.

The proposed rule provides that the Federal Reserve may object to a capital plan, in whole or in part, if (i) The Federal Reserve determines that the

[24] *See* Basel Committee on Banking Supervision, *Basel III: A global framework for more resilient banks and banking systems* (December 2010), *available at http://www.bis.org/publ/bcbs189.pdf.*

[25] As indicated in footnote 21, a bank holding company's internal capital goals must reflect any relevant minimum regulatory capital ratio levels, any higher levels of regulatory capital ratios (above regulatory minimums), and any additional capital measures that, when maintained, would allow the bank holding company to continue its operations. *See* SR 09–04; *see also* Basel Committee on Banking Supervision, Calibrating regulatory minimum capital requirements and capital buffers: A top-down approach (October 2010), *available at http://www.bis.org/publ/bcbs180.htm.*

[26] *See* section 165(i)(1) and (2) of the Dodd-Frank Act; 12 U.S.C. 5365(i)(1) and (2).

bank holding company has material unresolved supervisory issues, including but not limited to issues associated with its capital adequacy processes; (ii) the assumptions and analysis underlying the bank holding company's capital plan, or the bank holding company's methodologies for reviewing the effectiveness of its capital adequacy processes, are not reasonable or appropriate; (iii) the bank holding company has not demonstrated an ability to maintain capital above each minimum regulatory capital ratio, or until January 1, 2016, a tier 1 common ratio of 5 percent, on a pro forma basis under stressful conditions throughout the planning horizon; or (iv) the bank holding company's capital planning processes or proposed capital distributions constitute an unsafe or unsound practice, or would violate any law, regulation, Board order, directive, or any condition imposed by, or written agreement with, the Board.[27]

With respect to the first criterion, material supervisory issues could include inadequate risk management processes, such as the inability to accurately identify and monitor credit risk, market risk, operational risk, liquidity risk or interest rate risk, and any other significant weaknesses in a bank holding company's ability to identify and measure its risk exposures or other potential and material vulnerabilities. The Federal Reserve generally would expect an institution to correct such deficiencies before making any significant capital distributions.

The Federal Reserve would notify the bank holding company in writing of the reasons for a decision to object to a capital plan. Within 5 calendar days of receipt of a notice of objection, the bank holding company could submit a written request for reconsideration of the objection, including an explanation of why reconsideration should be granted. Within 10 calendar days of receipt of the bank holding company's request, the Board would notify the company of its decision to affirm or withdraw the objection to the bank holding company's capital plan.

To the extent that Federal Reserve objected to a capital plan and to the capital actions described therein, and until such time as the Federal Reserve determined that the bank holding company's capital plan satisfies the factors provided in the proposal, the bank holding company generally would not be able to make a capital distribution without providing prior notice to the Federal Reserve under the procedures discussed in section IV of this preamble.

As discussed below in section IV of this preamble, prior notice would not be required in circumstances where the Federal Reserve expressly did not object to specific capital distributions. For example, the Federal Reserve may object to a bank holding company's proposed payments of dividends on common stock, but expressly not object to payments on its preferred stock. In this situation, the bank holding company would not have to provide prior notice in order to make payments on its preferred stock in accordance with its capital plan.

The Board solicits comment on the proposed rule's process for the Federal Reserve's review and action on a capital plan, including the proposed annual deadline for submission of the capital plan of January 5 and the proposed date of March 15 by which the Federal Reserve would object or provide the bank holding company with a notice of non-objection.

E. Resubmission of a Capital Plan

Under the proposal, a bank holding company would be required to revise and resubmit its capital plan if the Federal Reserve objected to the capital plan or the Federal Reserve directed the bank holding company in writing to revise and resubmit its capital plan for any of the following reasons:

(i) The capital plan is incomplete or the capital plan or the bank holding company's internal capital adequacy processes contain weaknesses;

(ii) There has been or will likely be a material change in the bank holding company's risk profile (including a material change in its business strategy or any risk exposure), financial condition, or corporate structure;

(iii) The bank holding company-developed stressed scenario(s) in the capital plan are not sufficiently stressed, or changes in the macro-economic outlook that could have a material impact on a bank holding company's risk profile require the use of updated scenarios; or

(iv) The capital plan or the condition of the bank holding company raise any issues to which the Federal Reserve could object to in its review of a capital plan.

IV. Prior Notice Requirements

The proposal would require a bank holding company to notify the Federal Reserve before making a capital distribution if the Federal Reserve had objected to the bank holding company's capital plan and that objection was still outstanding.[28] Even if the Federal Reserve did not object to the bank holding company's capital plan, the bank holding company *still* would be required to provide prior notice to the Federal Reserve before making capital distributions if:

(i) After giving effect to the capital distribution, the bank holding company would not meet a minimum regulatory capital ratio or, until January 1, 2016, a tier 1 common ratio of 5 percent;

(ii) The Federal Reserve determines that the capital distribution would result in a material adverse change to the organization's capital or liquidity structure or that earnings were materially underperforming projections;[29]

(iii) The dollar amount of the capital distribution would exceed the amount described in the capital plan approved by the Federal Reserve; or

(iv) The capital distribution would occur during a period in which the appropriate Reserve Bank is reviewing the capital plan.

With respect to the third criterion, the Board solicits comments on whether there should be a *de minimis* exception, and if so, how the Board should measure materiality. For example, should the Board exempt a capital distribution from the proposed prior notice requirements if the effect of the distribution, combined with all other capital distributions in the prior 12 months to which the Federal Reserve had not been given prior notice, would reduce the bank holding company's tier 1 risk-based capital ratio by 10 basis points or less?

Under any of these circumstances, notwithstanding a notice of non-objection on its capital plan from the Federal Reserve, the bank holding company would be required to provide the Federal Reserve with 30 calendar days prior notice of the proposed capital distribution. A bank holding company would be required to file its notice of a proposed capital distribution with the appropriate Reserve Bank. Such a notice would be required to contain the following information:

[27] In determining whether a capital plan or proposed capital distributions would constitute an unsafe or unsound practice, the appropriate Reserve Bank would consider whether the bank holding company is and would remain in sound financial condition after giving effect to the capital plan and all proposed capital distributions.

[28] For purposes of the proposed prior notice requirements, the Federal Reserve would treat a bank holding company that became subject to the proposed rule after January 5 of a calendar year as if it had received the Federal Reserve's non-objection to its capital plan. Accordingly, it would not be subject to this aspect of the proposed prior notice requirements. *See* proposed sections 225.8(f)(1)(i),(iv).

[29] A bank holding company would be notified in advance if any of the circumstances in the second criterion applied or were likely to apply.

(i) The bank holding company's previously approved capital plan or an attestation that there have been no changes to its capital plan;

(ii) The purpose of the transaction;

(iii) A description of the capital distribution, including for redemptions or repurchases of securities, the gross consideration to be paid and the terms and sources of funding for the transaction, and for dividends, the amount of the dividend(s); and

(iv) Any additional information requested by the appropriate Reserve Bank or Board.

In most circumstances, within 15 calendar days of receipt of a notice, the appropriate Reserve Bank would either approve the proposed transaction or capital distribution or refer the notice to the Board for decision. If the notice were referred to the Board for decision, the Board would be required act on the notice within 30 calendar days after the Reserve Bank receives the notice. The appropriate Reserve Bank, after consultation with the Board, may, at its sole discretion, shorten the 30-day prior notice period.

With respect to notices provided for capital distributions that would occur during the period that the appropriate Reserve Bank is reviewing the company's capital plan, a bank holding company would not be permitted to consummate the proposed capital distribution until the appropriate Reserve Bank provides the bank holding company with a notice of non-objection to the capital plan.

The Board could deny the proposed capital distribution under circumstances that parallel those under which the Board may object to a bank holding company's capital plan.

The proposal provides that the Board would notify the bank holding company in writing of the reasons for a decision to disapprove any proposed capital distribution. Within 10 calendar days of receipt of a notice of disapproval by the Board, the bank holding company could submit a written request for a hearing.

If the bank holding company requested a hearing, the Board would order a hearing within 10 calendar days of receipt of the request if it finds that material facts are in dispute, or if it otherwise appears appropriate. Any hearing conducted would be held in accordance with the Board's Rules of Practice for Formal Hearings (12 CFR part 263). At the conclusion of any hearing, the Board would by order approve or disapprove the proposed capital action on the basis of the record of the hearing.

The Board solicits comments on the proposed prior notice requirements. Are there any circumstances that may arise under which bank holding companies may need additional flexibility with respect to capital distributions? If so, please describe those circumstances and indicate how the Board could assure that any added flexibility would not be used to circumvent the proposal's prior notice requirements.

V. Conforming Amendments to Section 225.4(b) of Regulation Y

In addition to the capital planning and prior notice requirements discussed above, the Board is proposing to make conforming changes to section 225.4(b) of Regulation Y, which currently requires prior notice to the Federal Reserve of certain purchases and redemptions of a bank holding company's equity securities.[30] Because such prior notice would be separately required in the proposed rule at section 225.8 of Regulation Y, the Board is proposing an amendment to section 225.4(b) to provide that section 225.4(b) shall not apply to any bank holding company that is subject to section 225.8.

The Board solicits comments on this proposed amendment to section 225.4(b) of Regulation Y and on all other aspects of the proposal.

VI. Administrative Law Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.,* generally requires that an agency prepare and make available for public comment an initial regulatory flexibility analysis in connection with a notice of proposed rulemaking. Under regulations issued by the Small Business Administration, a small entity includes a bank holding company with assets of $175 million or less (small bank holding company).[31] As of December 31, 2010, there were approximately 4,493 small bank holding companies.

As discussed in the Supplementary Information, the proposed rule applies to every top-tier bank holding company domiciled in the United States with $50 billion or more in total consolidated assets. Bank holding companies that are subject to the proposed rule therefore substantially exceed the $175 million asset threshold at which a banking entity would qualify as a small bank holding company.

Because the proposed rule is not likely to apply to any bank holding company with assets of $175 million or less, if adopted in final form, it is not expected to apply to any small bank holding company for purposes of the RFA. The Board does not believe that the proposed rule duplicates, overlaps, or conflicts with any other Federal rules. In light of the foregoing, the Board does not believe that the proposed rule, if adopted in final form, would have a significant economic impact on a substantial number of small entities. Nonetheless, the Board seeks comment on whether the proposed rule would impose undue burdens on, or have unintended consequences for, small organizations, and whether there are ways such potential burdens or consequences could be minimized in a manner consistent with the purpose of the proposed rule.

B. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3506; 5 CFR part 1320, Appendix A.1), the Board reviewed the proposed rule under the authority delegated to the Board by Office of Management and Budget (OMB). The Board may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid OMB control number. The OMB control number will be assigned.

The proposed rule contains requirements subject to the PRA. The collection of information that would be required by this proposed rule is found in new section 225.8 of Regulation Y (12 CFR part 225). The Board is proposing to require certain bank holding companies to submit capital plans to the Federal Reserve on an annual basis and to require such holding companies to provide prior notice to the Federal Reserve under certain circumstances before making a capital distribution.

Section 225.8(d)(1)(i) would require a bank holding company to develop and maintain an initial capital plan. The level of detail and analysis expected in a capital plan would vary based on the bank holding company's size, complexity, risk profile, scope of operations, and the effectiveness of its processes for assessing capital adequacy. Section 225.8(d)(2) provides a list of the mandatory elements to be included in the capital plan.

Sections 225.8(d)(1)(ii) would require a bank holding company to submit its complete capital plan to the appropriate Reserve Bank and the Board each year by the 5th of January, or such later date as directed by the appropriate Reserve Bank after consultation with the Board.

Section 225.8(d)(1)(iii) would require the bank holding company's board of directors or a designated committee to review and approve the bank holding company's capital plan prior to its

[30] *See* 12 CFR 225.4(b).

[31] 13 CFR 121.201.

submission to the appropriate Federal Reserve Bank under section 225.8(d)(1)(ii). In addition, section 225.8(d)(1)(iv) would require the bank holding company to update and re-submit its capital plan within 30 days of the occurrence of certain events.

Within 5 calendar days of receipt of a notice of objection by the Board of the bank holding company's capital plan, pursuant to section 225.8(e)(3), the banking holding company may submit a written request for reconsideration.

In certain circumstances, large bank holding companies would be required, pursuant to section 225.8(f)(1), to provide prior notice to the Federal Reserve before making capital distributions. As listed in section 225.8(f)(2), such a notice would be required to contain the following information: The bank holding company's current capital plan or an attestation that there have been no changes to its current capital plan; the purpose of the transaction; a description of the capital action, including for redemptions or repurchases of securities, the gross consideration to be paid, and for dividends, the amount of the dividend(s); the terms and sources of funding for the transaction; and any additional information requested by the appropriate Reserve Bank or Board.

Under section 225.8(f)(8)(i), if the Federal Reserve disapproves of a bank holding company's capital plan, the bank holding company within 10 calendar days of receipt of a notice of disapproval by the Board may submit a written request for a hearing.

In connection with submissions of capital plans to the Federal Reserve, bank holding companies would be required pursuant to section 225.8(d)(3) to provide certain data to the Federal Reserve. Data request templates, would be designed to minimize burden on the bank holding company and to avoid duplication. Data required by the Federal Reserve could include, but would not be limited to, information regarding the bank holding company's financial condition, structure, assets, risk exposure, policies and procedures, liquidity, and management.

The proposed rule would apply to every top-tier bank holding company domiciled in the United States with $50 billion or more in average total consolidated assets. Currently, 35 bank holding companies would be required to comply with the proposed information collection.

The Federal Reserve estimates that each of the bank holding companies would take, on average, 12,000 hours to comply with the section 225.8(d)(1)(i) recordkeeping requirement to develop and maintain the initial capital plan and with the section 225.8(d)(1)(ii) reporting requirement to submit the initial capital plan. The one-time implementation burden for these requirements is estimated to be 420,000 hours.

The Federal Reserve estimates that each of the bank holding companies would take, on average, 100 hours annually to comply with the section 225.8(d)(1)(iii) recordkeeping requirement to review and revise its capital plan. The annual burden for this recordkeeping requirement is estimated to be 3,500 hours.

Upon written request from the Federal Reserve, each bank holding company would be required to revise and resubmit its capital plan to the Federal Reserve. It is estimated that 10 bank holding companies would be requested to provide revised capital plans. The Federal Reserve estimates that it would take this subset of bank holding companies, on average, 100 hours to comply with the section 225.8(d)(1)(iv) recordkeeping requirement to revise and resubmit their capital plans.

Of the 10 bank holding companies, it is estimated that 2 would provide written request for a hearing regarding the disapproval of its capital plan. These bank holding companies would take, on average, 16 hours to comply with the section 225.8(e)(3) reporting requirement. The annual burden for these requirements is estimated to be 1,832 hours.

The Federal Reserve estimates that approximately 10 bank holding companies would be required to provide prior notice before giving capital distributions. The 10 bank holding companies would take, on average, 16 hours to comply with the section 225.8(f)(1) reporting requirement. Of the 10 bank holding companies, it is estimated that 2 would provide written request for a hearing regarding the disapproval of its prior notice. The 2 bank holding companies would take, on average, 16 hours to comply with the section 225.8(f)(8)(i) reporting requirement. The annual burden for these reporting requirements is estimated to be 192 hours.

The Federal Reserve estimates that bank holding companies would take, on average, 1,042 hours monthly to comply with the section 225.8(d)(3) reporting requirement to provide additional data to the Federal Reserve in connection with the submission of capital plans. The annual burden for this reporting requirement is estimated to be 437,640 hours.

The total annual burden for this proposed information collection is estimated to be 862,364 hours.

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the Board's functions; including whether the information has practical utility; (2) the accuracy of the Board's estimate of the burden of the proposed information collection, including the cost of compliance; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology. Comments on the collection of information should be sent to Cynthia Ayouch, Acting Federal Reserve Clearance Officer, Division of Research and Statistics, Mail Stop 95–A, Board of Governors of the Federal Reserve System, Washington, DC 20551, with copies of such comments sent to the Office of Management and Budget, Paperwork Reduction Project (7100–to be assigned), Washington, DC 20503.

C. Solicitation of Comments on Use of Plain Language

Section 722 of the Gramm-Leach-Bliley Act, Public Law 106–102, requires the Federal banking agencies to use plain language in all proposed and final rules published after January 1, 2000. The Board invites comment on how to make the interim final rule easier to understand. For example:

- Have we organized the material to suit your needs? If not, how could the rule be more clearly stated?
- Are the requirements in the rule clearly stated? If not, how could the rule be more clearly stated?
- Do the regulations contain technical language or jargon that is not clear? If so, which language requires clarification?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the regulation easier to understand? If so, what changes would make the regulation easier to understand?
- Would more, but shorter, sections be better? If so, which sections should be changed?
- What else could we do to make the regulation easier to understand?

List of Subjects in 12 CFR Part 225

Administrative practice and procedure, Banks, Banking, Federal Reserve System, Holding companies, Reporting and recordkeeping requirements, Securities.

12 CFR Chapter II

Authority and Issuance

For the reasons stated in the preamble, the Board of Governors of the Federal Reserve System proposed to amend subpart A of Regulation Y, 12 CFR part 225 as follows:

PART 225—BANK HOLDING COMPANIES AND CHANGE IN BANK CONTROL (REGULATION Y)

1. The authority citation for part 225 continues to read as follows:

Authority: 12 U.S.C. 1817(j)(13), 1818, 1828(o), 1831i, 1831p–1, 1843(c)(8), 1844(b), 1972(1), 3106, 3108, 3310, 3331–3351, 3906, 3907, and 3909; 15 U.S.C. 1681s, 1681w, 6801 and 6805.

Subpart A—General Provisions

2. Section 225.4 is amended by adding paragraph (b)(7):

§ 225.4 Corporate practices.

* * * * *

(b) * * *

(7) *Exception for certain bank holding companies.* This section 225.4(b) shall not apply to any bank holding company that is subject to § 225.8 of Regulation Y (12 CFR 225.8).

* * * * *

2. Add § 225.8 to read as follows:

§ 225.8 Capital planning.

(a) *Purpose.* This section establishes capital planning and prior notice requirements for capital distributions by certain bank holding companies.

(b) *Scope and Effective Date.*

(1) This section applies to every top-tier bank holding company domiciled in the United States:

(i) With total consolidated assets greater than or equal to $50 billion computed on the basis of the average of the company's total consolidated assets over the course of the previous two calendar quarters, as reflected on the bank holding company's consolidated financial statement for bank holding companies (FR Y–9C); provided that until July 21, 2015, this section will not apply to any bank holding company subsidiary of a foreign banking organization that has relied on Supervision and Regulation Letter SR 01–01 issued by the Board of Governors (as in effect on May 19, 2010); or

(ii) That is subject to this section, in whole or in part, by order of the Board based on the institution's size, level of complexity, risk profile, scope of operations, or financial condition.

(2) On or after January 1, 2012, the provisions this section shall apply to any bank holding company that becomes subject to this section under paragraph (b)(1) beginning on the date the company becomes subject to this section, except that, for purposes of the requirements described in paragraph (f), a bank holding company that becomes subject to this section pursuant to paragraph (b)(1)(i) after the 5th of January of a calendar year will be deemed to have received a notice of non-objection from the Federal Reserve on its capital plan for capital distributions made within that calendar year.

(3) Nothing in this section shall be read to limit the authority of the Federal Reserve to issue a capital directive or take any other supervisory or enforcement action, including action to address unsafe or unsound practices or conditions or violations of law.

(c) *Definitions.* For purposes of this section, the following definitions apply:

(1) *Capital action* means any issuance of a debt or equity capital instrument, any capital distribution, and any similar action that the Federal Reserve determines could impact a bank holding company's consolidated capital.

(2) *Capital distribution* means a redemption or repurchase of any debt or equity capital instrument, a payment of common or preferred stock dividends, a payment that may be temporarily or permanently suspended by the issuer on any instrument that is eligible for inclusion in the numerator of any minimum regulatory capital ratio, and any similar transaction that the Federal Reserve determines to be in substance a distribution of capital.

(3) *Capital plan* means a written presentation of a bank holding company's capital planning strategies and capital adequacy processes that includes—

(i) an assessment of the expected uses and sources of capital over a nine-quarter forward-looking planning period (beginning with the quarter preceding the quarter in which the bank holding company submits its capital plan) that reflects the bank holding company's size, complexity, risk profile, and scope of operations, assuming both expected and stressful conditions,

(ii) a detailed description of the bank holding company's processes for assessing capital adequacy, and

(iii) an analysis of the effectiveness of these processes.

(4) *Capital policy* means a bank holding company's written assessment of the principles and guidelines used for capital planning, capital issuance, usage and distributions, including internal capital goals; the quantitative or qualitative guidelines for dividend and stock repurchases; the strategies for addressing potential capital shortfalls; and the internal governance procedures around capital policy principles and guidelines.

(5) *Minimum regulatory capital ratio* means any minimum regulatory capital ratio that the Federal Reserve may require of a bank holding company, by regulation or order, including the bank holding company's leverage ratio and tier 1 and total risk-based capital ratios as calculated under Appendices A, D, E, and G to this part (12 CFR part 225), or any successor regulation.

(6) *Tier 1 capital* has the same meaning as under Appendix A to this part or any successor regulation.

(7) *Tier 1 common capital* means tier 1 capital less the non-common elements of tier 1 capital, including perpetual preferred stock and related surplus, minority interest in subsidiaries, trust preferred securities and mandatory convertible preferred securities.

(8) *Tier 1 common ratio* means the ratio of a bank holding company's tier 1 common capital to total risk-weighted assets.

(9) *Total risk-weighted assets* has the same meaning as under Appendices A, E, and G to this part, or any successor regulation.

(d) *General requirements.*

(1) *Annual capital planning.*

(i) A bank holding company must develop and maintain a capital plan.

(ii) A bank holding company must submit its complete capital plan to the appropriate Reserve Bank and the Board each year by the 5th of January, or such later date as directed by the appropriate Reserve Bank after consultation with the Board.

(iii) The bank holding company's board of directors or a designated committee thereof must at least annually and prior to submission of the capital plan under paragraph (d)(1)(ii):

(A) Review the effectiveness of its processes for assessing capital adequacy,

(B) Ensure that any deficiencies in its processes for assessing capital adequacy are appropriately remediated; and

(C) Approve the bank holding company's capital plan.

(iv) The bank holding company must update and re-submit its capital plan to the appropriate Reserve Bank within 30 calendar days of the occurrence of one of the following events:

(A) The bank holding company determines there has been or will be a material change in the bank holding company's risk profile, financial condition, or corporate structure since the bank holding company adopted the capital plan; or

(B) The appropriate Reserve Bank, after consultation with the Board,

directs the bank holding company to revise and re-submit its capital plan under paragraph (e)(4).

(v) The appropriate Reserve Bank, after consultation with the Board, may at its sole discretion extend the 30-day period in paragraph (d)(1)(iv) for up to an additional 60 calendar days.

(vi) Any updated capital plan must satisfy all the requirements of this section, including the requirements set forth in paragraphs (d)(1), (d)(2), and (e)(4), unless otherwise specified by the appropriate Reserve Bank, after consultation with the Board.

(2) *Mandatory elements of capital plan.* Every capital plan must contain at least the following elements:

(i) A discussion of how the bank holding company will, under stressful conditions, maintain capital commensurate with its risks, maintain capital above the minimum regulatory capital ratios, and serve as a source of strength to its depository institution subsidiaries;

(ii) A discussion of how the bank holding company will, under stressful conditions, continue its operations by maintaining ready access to funding, meeting its obligations to creditors and other counterparties, and continuing to serve as a credit intermediary;

(iii) A discussion of the bank holding company's sources and uses of capital reflecting the risk profile of the firm over a minimum nine-quarter planning horizon, including:

(A) Estimates of projected revenues, losses, reserves, and pro forma capital levels, including any minimum regulatory capital ratios (for example, leverage, tier 1 risk-based, and total risk-based capital ratios) and any additional capital measures deemed relevant by the bank holding company, over the planning horizon under expected conditions and under a range of stressed scenarios, including any scenarios provided by the Federal Reserve and at least one stressed scenario developed by the bank holding company appropriate to its business model and portfolios, and a probabilistic assessment of the likelihood of the bank holding company developed scenario(s);

(B) A discussion of the results of any stress test required by law or regulation, and an explanation of how the capital plan takes these results into account; and

(C) A description of all planned capital actions over the planning horizon;

(iv) The bank holding company's capital policy;

(v) A discussion of any expected changes to the bank holding company's business plan that are likely to have a material impact on the firm's capital adequacy or liquidity; and

(vi) Until January 1, 2016, a calculation of the pro forma tier 1 common ratio under expected and stressful conditions and discussion of how the company will maintain a pro forma tier 1 common ratio of 5 percent under the stressed scenarios required under paragraph (d)(2)(iii).

(3) *Data collection.* Upon the request of the appropriate Reserve Bank or the Board, the bank holding company shall provide the appropriate Reserve Bank with information regarding—

(i) the bank holding company's financial condition, including its capital;

(ii) the bank holding company's structure;

(iii) amount and risk characteristics of the bank holding company's on- and off-balance sheet exposures, including exposures within the bank holding company's trading portfolio, other trading-related exposures (such as counterparty-credit risk exposures) or other items sensitive to changes in market factors, including, as appropriate, information about the sensitivity of positions in the trading portfolio to changes in market rates and prices;

(iv) the bank holding company's relevant policies and procedures, including risk management policies and procedures;

(v) the bank holding company's liquidity profile and management; and

(vi) any other relevant qualitative or quantitative information requested by the appropriate Reserve Bank or the Board to facilitate review of the bank holding company's capital plan under this section.

(e) *Review of capital plans by the Federal Reserve.*

(1) *Considerations and inputs.*

(i) The appropriate Reserve Bank, after consultation with the Board, will consider the following factors in reviewing a bank holding company's capital plan:

(A) The reasonableness of the bank holding company's assumptions and analysis underlying the capital plan and its methodologies for reviewing the effectiveness of its capital adequacy processes;

(B) The comprehensiveness of the capital plan, including the company's capital policy; and

(C) The bank holding company's ability to maintain capital above each minimum regulatory capital ratio, and until January 1, 2016, a tier 1 common ratio of 5 percent, on a pro forma basis under expected and stressful conditions throughout the planning horizon.

(ii) The appropriate Reserve Bank, after consultation with the Board, will also consider the following information in reviewing a bank holding company's capital plan:

(A) Relevant supervisory information about the bank holding company and its subsidiaries;

(B) The bank holding company's regulatory and financial reports, as well as supporting data that would allow for an analysis of a bank holding company's loss, revenue, and reserve projections;

(C) As applicable, the Federal Reserve's own pro forma estimates of the firm's potential losses, revenues, reserves, and resulting capital adequacy under stressful conditions, as well as the results of any stress tests conducted by the bank holding company or the Federal Reserve; and

(D) Other information requested or required by the appropriate Reserve Bank or the Board, as well as any other information relevant, or related, to the bank holding company's capital adequacy.

(2) *Federal Reserve action on a capital plan.*

(i) By March 15 of the calendar year in which a capital plan was submitted, the appropriate Reserve Bank, after consultation with the Board, will object, in whole or in part, to the capital plan or provide the bank holding company with a notice of non-objection to the capital plan.

(ii) The appropriate Reserve Bank, after consultation with the Board, may object to a capital plan if it determines that:

(A) The bank holding company has material unresolved supervisory issues, including but not limited to issues associated with its capital adequacy processes;

(B) The assumptions and analysis underlying the bank holding company's capital plan, or the bank holding company's methodologies for reviewing the effectiveness of its capital adequacy processes, are not reasonable or appropriate;

(C) The bank holding company has not demonstrated an ability to maintain capital above each minimum regulatory capital ratio, or, until January 1, 2016, a tier 1 common ratio of 5 percent, on a pro forma basis under stressful conditions throughout the planning horizon; or

(D) The bank holding company's capital planning processes or proposed capital distributions constitute an unsafe or unsound practice, or would violate any law, regulation, Board order, directive, or any condition imposed by, or written agreement with, the Board. In determining whether a capital plan or

any proposed capital distribution would constitute an unsafe or unsound practice, the appropriate Reserve Bank would consider whether the bank holding company is and would remain in sound financial condition after giving effect to the capital plan and all proposed capital distributions.

(iii) The appropriate Reserve Bank, after consultation with the Board, will notify the bank holding company in writing of the reasons for a decision to object to a capital plan.

(iv) If the appropriate Reserve Bank, after consultation with the Board, objects to a capital plan and until such time as the appropriate Reserve Bank, after consultation with the Board, determines that the bank holding company's capital plan does not give rise to a condition described under paragraph (e)(2)(ii), the bank holding company may not make any capital distribution, other than those capital distributions with respect to which the appropriate Reserve Bank has indicated its non-objection, without providing prior notice to the appropriate Reserve Bank under the procedures set forth in paragraph (f).

(3) *Request for reconsideration.*

(i) Within 5 calendar days of receipt of a notice of objection by the appropriate Reserve Bank, the bank holding company may submit a written request to the Board requesting reconsideration of the objection, including an explanation of why reconsideration should be granted.

(ii) Within 10 calendar days of receipt of the bank holding company's request under paragraph (i), the Board would notify the company of its decision to affirm or withdraw the objection to the bank holding company's capital plan.

(4) *Re-submission of a capital plan.* A bank holding company must revise and resubmit its capital plan pursuant to paragraph (d)(1)(iv)(B) if:

(i) The appropriate Reserve Bank objects to the capital plan; or

(ii) The appropriate Reserve Bank, after consultation with the Board, directs the bank holding company in writing to revise and resubmit its capital plan for any of the following reasons:

(A) The capital plan is incomplete or the capital plan or the bank holding company's internal capital adequacy processes contain weaknesses;

(B) There has been or will likely be a material change in the bank holding company's risk profile (including a material change in its business strategy or any risk exposure), financial condition, or corporate structure;

(C) The bank holding company-developed stressed scenario(s) in the capital plan are not sufficiently stressed, or changes in the macro-economic outlook that could have a material impact on a bank holding company's risk profile require the use of updated scenarios; or

(D) The capital plan or the condition of the bank holding company raise any of the issues described in paragraph (e)(2)(ii).

(f) *Prior notice requirements.*

(1) *Circumstances requiring prior notice.* Except as provided in paragraph (f)(2)(iv), notwithstanding a notice of non-objection under paragraph (e)(2)(i), a bank holding company must provide the appropriate Reserve Bank with 30 calendar days prior notice of a capital distribution under the following circumstances:

(i) The appropriate Reserve Bank, after consultation with the Board, has objected to the bank holding company's capital plan;

(ii) After giving effect to the capital distribution, the bank holding company would not meet a minimum regulatory capital ratio, or, until January 1, 2016, a tier 1 common ratio of 5 percent;

(iii) The Federal Reserve determines that the capital distribution would result in a material adverse change to the organization's capital or liquidity structure or that earnings were materially underperforming projections;

(iv) The dollar amount of the capital distribution would exceed the amount described in the capital plan approved under this section; or

(v) The capital distribution would occur during the period that the appropriate Reserve Bank is reviewing the company's capital plan under paragraph (e).

(2) *Contents of notice.* Any notice of a capital distribution under this section shall be filed with the appropriate Reserve Bank and the Board and shall contain the following information:

(i) The bank holding company's previously approved capital plan or an attestation that there have been no changes to its capital plan;

(ii) The purpose of the transaction;

(iii) A description of the capital distribution, including for redemptions or repurchases of securities, the gross consideration to be paid and the terms and sources of funding for the transaction, and for dividends, the amount of the dividend(s); and

(iv) Any additional information requested by the appropriate Reserve Bank or Board.

(3) *Shortening the notice period.* The appropriate Reserve Bank, after consultation with the Board, may, at its sole discretion, shorten the prior notice period described in paragraph (f)(1).

(4) *Acting on notice.* Within 15 calendar days of receipt of a notice under this section, the appropriate Reserve Bank, after consultation with the Board, will either approve the transaction proposed in the notice or refer the notice to the Board for decision. If the notice is referred to the Board for decision, the Board will act on the notice within 30 calendar days after the Reserve Bank receives the notice.

(5) Notwithstanding any other provision in paragraph (f), with respect to a prior notice provided under paragraph (f)(1)(v), a bank holding company may not consummate the proposed capital distribution until the appropriate Reserve Bank provides the bank holding company with a notice of non-objection to the capital plan pursuant to paragraph (e)(2).

(6) *Factors considered in acting on notice.* The Board may disapprove a proposed capital distribution for any of the reasons described in paragraph (e)(2)(ii).

(7) *Disapproval and hearing.*

(i) The Board will notify the bank holding company in writing of the reasons for a decision to disapprove any proposed capital distribution. Within 10 calendar days of receipt of a notice of disapproval by the Board, the bank holding company may submit a written request for a hearing.

(ii) The Board will order a hearing within 10 calendar days of receipt of the request if it finds that material facts are in dispute, or if it otherwise appears appropriate. Any hearing conducted under this paragraph shall be held in accordance with the Board's Rules of Practice for Formal Hearings (12 CFR part 263).

(iii) At the conclusion of the hearing, the Board will by order approve or disapprove the proposed capital distribution on the basis of the record of the hearing.

By order of the Board of Governors of the Federal Reserve System, June 10, 2011.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 2011–14831 Filed 6–16–11; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2011–0536; Airspace Docket No. 11–ANM–13]

Proposed Amendment of Class E Airspace; Shelby, MT

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify Class E airspace at Shelby, MT. Controlled airspace is necessary to accommodate aircraft using Area Navigation (RNAV) Global Positioning System (GPS) standard instrument approach procedures at Shelby Airport. The FAA is proposing this action to enhance the safety and management of aircraft operations at the airport.

DATES: Comments must be received on or before August 1, 2011.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590; telephone (202) 366–9826. You must identify FAA Docket No. FAA–2011–0536; Airspace Docket No. 11–ANM–13, at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Eldon Taylor, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue, SW., Renton, WA 98057; telephone (425) 203–4537.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2011–0536 and Airspace Docket No. 11–ANM–13) and be submitted in triplicate to the Docket Management System (see **ADDRESSES** section for address and phone number). You may also submit comments through the Internet at *http://www.regulations.gov*.

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2011–0536 and Airspace Docket No. 11–ANM–13''. The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace_amendments/*.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue, SW., Renton, WA 98057.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267–9677, for a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by creating additional Class E airspace extending upward from 700 feet above the surface at Shelby Airport, Shelby MT. Controlled airspace is necessary to accommodate aircraft using the RNAV (GPS) standard instrument approach procedures at the airport, and would enhance the safety and management of aircraft operations. Adjustments to the geographic coordinates of the airport also would be made.

Class E airspace designations are published in paragraph 6005, of FAA Order 7400.9U, dated August 18, 2010, and effective September 15, 2010, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in this Order.

The FAA has determined this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation; (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, section 106, describes the authority for the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in subtitle VII, part A, subpart I, section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would create additional controlled airspace at Shelby Airport, Shelby, MT.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9U, Airspace Designations and Reporting Points, dated August 18, 2010, and effective September 15, 2010 is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ANM MT E5 Shelby, MT [Modified]

Shelby Airport, MT
(Lat. 48°32′26″ N., long. 111°52′16″ W.)

That airspace extending upward from 700 feet above the surface within a 6.7-mile radius of Shelby Airport, and within 2.7 miles each side of the 043° bearing from Shelby Airport extending from the 6.7-mile radius to 7.4 miles northeast of the airport; that airspace extending upward from 1,200 feet above the surface within an area bounded by lat. 48°50′00″ N., long. 111°45′00″ W.; to lat. 48°49′00″ N., long. 111°22′00″ W.; to lat. 48°38′00″ N., long. 111°17′00″ W.; to lat. 48°21′00″ N., long. 111°36′00″ W.; to lat. 48°18′00″ N., long. 112°01′00″ W.; to lat. 48°28′00″ N., long. 112°12′00″ W.; to lat. 48°38′00″ N., long. 112°11′00″ W.; to lat. 48°38′00″ N., long. 112°03′00″ W., thence to the point of beginning.

Issued in Seattle, Washington, on June 9, 2011.

John Warner,

Manager, Operations Support Group, Western Service Center.

[FR Doc. 2011–15024 Filed 6–16–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2011–0232; Airspace Docket No. 11–AWA–3]

RIN 2120–AA66

Proposed Amendment to Class B Airspace; Seattle, WA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify Class B airspace in Seattle, WA to contain aircraft conducting Instrument Flight Rules (IFR) approach procedures to Seattle-Tacoma International Airport (SEA). This action would further support the FAA's national airspace redesign goal of optimizing terminal and en route airspace areas to enhance safety, improving the flow of air traffic, and reducing the potential for near midair collision in the terminal area.

DATES: Comments must be received on or before August 16, 2011.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M–30, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001; telephone: (202) 366–9826. You must identify FAA Docket No. FAA–2011–0232 and Airspace Docket No. 11–AWA–3 at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Ken McElroy, Airspace, Regulations and ATC Procedures Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2011–0232 and Airspace Docket No. 11–AWA–3) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the Internet at *http://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Nos. FAA–2011–0232 and Airspace Docket No. 11–AWA–3.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov/regulations_policies/rulemaking/recently_published/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Western Service Center, Federal Aviation Administration, 1601 Lind Ave., SW., Renton, WA 98057.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267–9677, for a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

Background

In 1974, the FAA issued a final rule establishing the Seattle-Tacoma, WA, Terminal Control Area (38 FR 17250). As a result of the Airspace Reclassification final rule (56 FR 65638), which became effective in 1993, the terms ''terminal control area'' and ''airport radar service area'' were replaced by ''Class B airspace area'' and ''Class C airspace area,'' respectively. The primary purpose of a Class B airspace area is to reduce the potential for midair collisions in the airspace surrounding airports with high density air traffic operations by providing an area, in which all aircraft are subject to certain operating rules and equipment requirements.

In recent years, Seattle has completed construction projects that modernized the airport and added capacity at SEA.

These projects included the construction of a new Runway 16 L/R and 34 L/R, which increased the lateral distance between runways and allows simultaneous arrival and departure operations under visual flight rules (VFR) and simultaneous approaches during IFR conditions. Operationally, using parallel dependent ILS approaches results in higher airport arrival acceptance rates during IFR minimums, but requires aircraft to be established on the final approach courses not less than 17 miles from the airport. During periods of moderate air traffic, this requirement quickly extends the final approach course to a distance greater than 22 miles from the airport, which places the aircraft on the approaches outside the confines of the current Seattle Class B airspace.

Since the Seattle Class B airspace area was established in 1974, SEA has experienced increased traffic levels, a considerably different fleet mix, and airport infrastructure improvements enabling simultaneous instrument approach procedures. For calendar year 2009, SEA documented 316,136 total operations and was rated number 16 among all Commercial Service Airports with 15,273,092 passenger enplanements. Under the current Class B airspace configuration, aircraft routinely enter, exit, and then reenter Class B airspace while flying published instrument approach procedures, which is contrary to FAA Order 7400.2, Procedures for Handling Airspace Matters. In addition, SEA now utilizes parallel dependent ILS approaches, which requires aircraft to be established on final at least 17 miles from the airport. This results in aircraft exceeding the lateral boundaries of the current Class B airspace by up to 5 to 10 miles during moderate levels of air traffic. FAA modeling of existing traffic flows has shown that expanded Class B airspace extensions would enhance safety by containing all instrument approach procedures and associated traffic patterns within the confines of Class B airspace, and better segregate IFR aircraft arriving/departing SEA and VFR aircraft operating in the vicinity of Seattle Class B airspace. The proposed Class B airspace modifications described in this NPRM are intended to address these issues.

Pre-NPRM Public Input

In 2010, the FAA initiated action to form an Ad Hoc Committee to provide comments and recommendations regarding the planned modifications to the Seattle Class B airspace area. The Washington State Department of Transportation chaired the Ad Hoc Committee; participants included representatives of air carrier, Aircraft Owners and Pilot Association, general aviation, corporate, helicopter, government agencies with aviation interests, military and law enforcement airspace users. The Ad Hoc Committee responded in July 2010 and provided a proposed modification of the Seattle Class B airspace area to the FAA Seattle Terminal Radar Approach Control Facility (TRACON).

In addition, and as announced in the **Federal Register** (75 FR 60352), three informal airspace meetings were held on December 9, 2010, at the Snohomish County Auditorium, Everett, WA; December 14, 2010, at the Highline Performing Arts Center, Burien, WA; and December 16, 2010, at the Theater at Auburn Mountainview, Auburn, WA.

These meetings provided interested airspace users with an opportunity to present their views and offer suggestions regarding the planned modification of the Seattle Class B airspace. All comments received as a result of the informal airspace meetings, along with the recommendations made by the Ad Hoc Committee, were considered in developing this proposal.

Ad Hoc Committee and Other Recommendations

The Ad Hoc Committee recommended a design with two ceilings: 7,000 feet MSL in the outer areas and 10,000 feet MSL for the inner areas. The FAA analyzed the recommendation and found that due to local terrain the recommendation had merit. Maintaining a classic Class B design similar to the current one would make the design more complex and use more airspace than necessary to protect SEA arrivals and departures.

In reaching this recommendation, the Ad Hoc Committee considered non-participating aircraft possibly crossing the ends of the airspace at 7,500 feet, but the presence of nonparticipating aircraft in close proximity to Class B airspace is not unique to SEA. Also, the committee discussed whether a non-traditional design might be confusing or difficult to navigate around, and concluded that it was not.

After the Ad Hoc Committee's report was submitted to the TRACON, Seattle TRACON recommended adding to the original proposal by expanding Area F from 2,000 feet to 10,000 feet to the northwest to cover Puget Sound west of Elliott Bay and the residential area over Magnolia Bluff. This would encompass the Boeing Field/King County International Airport (BFI) Instrument Landing System runway 13R final approach course in the Class B airspace. Numerous Traffic Alert and Collision Avoidance System (TCAS) events with large and heavy jet aircraft have been reported in this area.

Since BFI traffic is in close proximity to SEA traffic in a south flow, such TCAS events have immediate repercussions on SEA traffic, particularly if the aircraft responding to a TCAS Resolution Advisory climbs into the path of traffic on the SEA final. This situation impacts SEA traffic, and expanding the Class B airspace in this area may be a potential solution.

In the current Class B airspace configuration, the area over the water west of the northwest corner of Area D and Magnolia Bluff itself is beneath a 3,000 foot to 10,000 foot shelf. This proposal would lower the floor of Class B to 2,000 feet on either side of the BFI runway 13R final approach course. Area D over BFI would remain exactly the same as in the current airspace configuration.

Ninety-six comments were received during the public meetings requesting the elimination of the 2,000 foot proposal over Magnolia due to increased noise and air pollution. These comments also disagreed with the need to change airspace, argued the inconvenience of public meeting location, and contended that the airspace changes would increase aircraft noise disturbance to nesting birds. A petition from the Magnolia community was submitted with 862 signatures attached.

Based on the public comments received, the FAA concedes that effective alternatives exist for achieving the increased safety that was the objective of lowering the airspace floor. Therefore, the FAA intends to examine alternative, nonregulatory (procedural) means to reducing the TCAS events. The FAA will stress efforts toward increased enforcement and pilot education, and improved procedures, and, only if appropriate, pursue a regulatory solution in the Seattle Magnolia area.

Informal Airspace Meeting Comments

Several comments were received indicating a preference to retain the classic VOR radial/DME description methods for the Seattle Class B airspace area.

Initially, the FAA considered a classic description method but it would result in a design that used more airspace than necessary to contain SEA traffic. The primary description methodology is using geographic coordinates (latitude and longitude). Wherever possible, however, the airspace corners, intersections and more central, lower

altitude pieces are described in multiple ways, including the VOR radial/DME method.

Three commenters requested a reduction in the Class B airspace around the Enumclaw glider area/Bergseth Airport (private).

The FAA agrees that the proposed airspace would cause a hardship for glider flights returning to the Bergseth Airport. The final proposed airspace has been adjusted to mitigate the impact.

Two commenters stated the proposed airspace design will ''squeeze'' or ''trap'' VFR aircraft on the edges of the Class B.

The FAA agrees with these comments, and the two areas specified—on the northeast and southeast corners of the proposed airspace—have been reshaped to mitigate this concern.

Two commenters believed the VFR corridors must be retained and usable.

The proposed design will require a slight modification to the VFR flyways.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 to modify the SEA Class B airspace area. This action (depicted on the attached chart) proposes to revise the Class B airspace while maintaining some existing features familiar to local users. Overall, it reduces the size of the Seattle Class B airspace by approximately 194 square miles. Containing two different ceiling altitudes, the Class B proposal expands the eastern boundary to ensure containment of turbojet aircraft, but eliminates excessive outer (arrival route) wings that currently extend to 30 nautical miles (NM). Where possible, this proposal also aligns certain Class B boundaries with existing Very High Frequency Omnidirectional Range Navigational Aids and geographical features resulting in improved boundary definition. This would make navigation around and through the airspace easier for a variety of aviation interests, even though it consists of primary boundary portrayal using latitude and longitude points (GPS waypoints). The following are the proposed revisions for each area of the SEA Class B airspace:

Area A. 2 NM arc northeast of SEA would be straightened and realigned with the border of Class D airspace. The area just south of SEA would be moved slightly to the west to better contain arrivals to SEA runway 34L/departures from 16R. This runway 34L/16R was recently constructed and commissioned in 2008. Its extended centerline to the south is just barely contained within the current Class B airspace. There is no other traffic in this area except SEA traffic.

Area B. No change.

Area C. Southeast corner would be moved to the west, and floor of airspace would be raised from 1,600 feet to 1,800 feet.

Area D. No change.

Area E. Southeast border of airspace would be moved slightly to the west.

Area F. No change.

Area G. 2 NM arc northeast of SEA would be straightened and realigned with the border of Class D airspace.

Area H. Entire airspace would be moved east slightly. Northern and southern boundaries are depicted as angles instead of curves.

Area I. Floor would be lowered to 4,000 feet. Area would be narrowed and described with straight lines instead of curved lines.

Area J. New area would join existing areas that had floors of 5,000 feet.

Area K. New area with floor of 5,000 feet.

Area L. Area would be narrowed and described with straight lines instead of curved lines.

Area M. Area would be expanded slightly on the northeast and southeast corners and described with straight lines instead of curved lines.

Area N. New area floor would be raised from 3,000 feet to 4,000 feet in part of area, and lowered from 5,000 feet to 4,000 feet in part of area. Boundary would be described by straight lines.

Area O. Area would be considerably smaller. Floor would be lowered from 6,000 feet to 5,000 feet in part of the area, and raised from 3,000 feet to 5,000 feet in part of area. Ceiling would be lowered from 10,000 feet to 7,000 feet.

Area P. Area would be considerably smaller. Floor would be lowered from 6,000 feet to 5,000 feet in part of the area and raised from 3,000 feet to 5,000 feet in part of area. Ceiling would be lowered from 10,000 feet to 7,000 feet.

Area Q. Area would be reshaped with straight lines instead of curved lines. Floor would be lowered from 6,000 feet and 8,000 feet to 5,000 feet. Ceiling would be lowered from 10,000 feet to 7,000 feet.

Area R. Size of area would be significantly reduced and described by straight lines instead of curved lines.

Area S. Area would be reshaped with straight lines instead of curved lines.

Area T. Area would be reshaped with straight lines instead of curved lines. Ceiling would be lowered from 10,000 feet to 7,000 feet. These changes are being proposed to ensure the containment of IFR aircraft within Class B airspace as required by FAA directives.

All radials listed in the SEA Class B airspace description in this NPRM are stated in degrees relative to both True North and Magnetic North.

Class B airspace areas are published in paragraph 3000 of FAA Order 7400.9U, dated August 18, 2010, and effective September 15, 2010, and incorporated by reference in 14 CFR 71.1. The Class B airspace area proposed in this document would be published subsequently in the Order.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. We have determined that there is no new information collection requirement associated with this proposed rule.

Regulatory Evaluation Summary

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96–39) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, the Trade Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or Tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation with base year of 1995). This portion of the preamble summarizes the FAA's analysis of the economic impacts of this proposed rule.

Department of Transportation Order DOT 2100.5 prescribes policies and procedures for simplification, analysis, and review of regulations. If the expected cost impact is so minimal that a proposed or final rule does not warrant a full evaluation, this order permits that a statement to that effect and the basis for it be included in the preamble if a full regulatory evaluation of the cost and benefits is not prepared. Such a determination has been made for

this proposed rule. The reasoning for this determination follows.

After consultation with a diverse cross-section of stakeholders that participated in the Ad Hoc Committee to develop the recommendations contained in this proposal, and a review of the recommendations and comments, the FAA expects that this proposed rule would result in minimal cost. This proposed rule would enhance safety by containing all instrument approach procedures, and associated traffic patterns, within the confines of Class B airspace and better segregate IFR aircraft arriving/departing SEA and VFR aircraft operating in the vicinity of the Seattle Class B airspace.

This NPRM would enhance safety, reduce the potential for a midair collision in the Seattle area and would improve the flow of air traffic. As such, we estimate a minimal impact with substantial positive net benefits. The FAA requests comments with supporting justification about the FAA determination of minimal impact. The FAA has, therefore, determined that this proposed rule is not a ''significant regulatory action'' as defined in section 3(f) of Executive Order 12866, and is not ''significant'' as defined in DOT's Regulatory Policies and Procedures.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (Pub. L. 96–354) (RFA) establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration.'' The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA.

However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

The FAA believes the proposal would not have a significant economic impact on a substantial number of small entities as the economic impact is expected to be minimal. We request comments from the potentially affected small businesses.

Therefore, the FAA certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities.

International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. The FAA has assessed the potential effect of this proposed rule and determined that it would enhance safety and is not considered an unnecessary obstacle to trade.

Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (in 1995 dollars) in any one year by State, local, and Tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.'' The FAA currently uses an inflation-adjusted value of $143.1 million in lieu of $100 million. This proposed rule does not contain such a mandate; therefore, the requirements of Title II of the Act do not apply.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9U, Airspace Designations and Reporting Points, dated August 18, 2010, and effective September 15, 2010, is amended as follows:

Paragraph 3000 Subpart B—Class B airspace.

* * * * *

ANM WA B Seattle, WA [Modified]

Seattle-Tacoma International Airport
(Primary Airport)
(Lat. 47°27′00″ N., long. 122°18′42″ W.)
Seattle VORTAC (SEA)
(Lat. 47°26′07″ N., long. 122°18′35″ W.)

Boundaries

Area A. That airspace extending upward from the surface to and including 10,000 feet MSL within an area bounded by a line beginning at the 3.6-mile DME on the SEA 007°(T)/348°(M) radial to a point on the 4-mile arc of the sea 007°(T)/348°(M) radial, then counterclockwise along the 4-mile arc to the sea 326°(T)/306°(M) radial to the Puget Sound shoreline, then south along the Puget Sound shoreline to the 2-mile arc of the SEA VORTAC, then counterclockwise along the 2-mile arc of the SEA VORTAC to the sea 202°(T)/183°(M) radial extending to the 4-mile DME on the SEA 197°(T)/178°(M) radial, then extending to the 6-mile DME on the sea 192°(T)/173°(M) radial, then counterclockwise along the 6-mile arc of the SEA VORTAC to the SEA 163°(T)/144°(M) radial extending to the 4-mile DME on the SEA VORTAC 159°(T)/140°(M) radial, extending to the 2-mile arc of the SEA VORTAC 146°(T)/127°(M) radial, then counterclockwise along the 2-mile arc of SEA VORTAC to the SEA VORTAC 069°(T)/050°(M) radial to the point of beginning.

Area B. That airspace extending upward from 1,100 feet MSL to and including 10,000 feet MSL within an area bounded by a line beginning at the 4-mile DME point on the SEA 007°(T)/348°(M) radial extending to the 6-mile arc of the sea 007°(T)/348°(M) radial, then counterclockwise along the 6-mile arc of the SEA VORTAC to the SEA 342°(T)/323°(M) radial to the 4-mile arc of the SEA 342°(T)323°(M) radial, then clockwise along the 4-mile arc of the SEA VORTAC to the point of beginning.

Area C. That airspace extending upward from 1,800 feet MSL to and including 10,000 feet MSL within an area bounded by a line beginning at the 6-mile DME on the SEA 192°(T)/173°(M) radial to the 12-mile arc of the SEA 192°(T)/173°(M) radial, then counterclockwise along the 12-mile arc of the SEA VORTAC to the SEA 166°(T)/147°(M) radial extending to the 8-mile DME on the SEA 163°(T)/144°(M) radial to a point on the 6-mile arc of the SEA 163°(T)/144°(M) radial, then clockwise along the 6-mile arc of the SEA VORTAC to the point of beginning.

Area D. That airspace extending upward from 1,800 feet MSL to and including 10,000 feet MSL within an area bounded by a line beginning at the 6-mile arc of the SEA 007°(T)/348°(M) radial, then counterclockwise along the 6-mile arc of the SEA VORTAC to the SEA 342°(T)/323°(M) radial, then to the 12-mile arc of the SEA 342°(T)/323°(M) radial, then clockwise along the 12-mile arc of the SEA VORTAC to the SEA 007°(T)/348°(M) radial to the point of beginning.

Area E. That airspace extending upward from 2,000 feet MSL to and including 10,000 feet MSL within an area bounded by a line beginning at the 4-mile arc of the SEA 197°(T)/178°(M) radial, then clockwise along the 40-mile arc of the SEA VORTAC to the SEA 326°(T)/307°(M) radial, then south along the Puget Sound shoreline to the 2-mile arc of the SEA VORTAC then counterclockwise along the 2-mile arc of the SEA VORTAC to the SEA 202°(T)/183°(M) radial to the point of beginning.

Area F. That airspace extending upward from 2,000 feet MSL to and including 10,000 feet MSL within an area bounded by a line beginning at the 4-mile DME on the SEA 342°(T)/323°(M) radial extending north on the SEA 342°(T)/323°(M) radial to the Puget Sound shoreline, then south along the Puget Sound shoreline to the 4-mile DME on the SEA VORTAC 326°(T)/307°(M) radial, then clockwise along the 4-mile arc of SEA VORTAC to the point of beginning.

Area G. That airspace extending upward from 2,000 feet MSL to and including 10,000 feet MSL within an area bounded by a line beginning at the 3.6 DME on the SEA 007°(T)/348°(M) radial extending to the 12-DME on the SEA 007°(T)/348°(M) radial, then clockwise along the 12-mile arc of the SEA VORTAC to the SEA 022°(T)/003°(M) radial to the 4-mile arc of the SEA VORTAC, then clockwise along the 4-mile arc of the SEA VORTAC to the SEA 159°(T)/140°(M) radial to the 2-mile DME on the SEA VORTAC 146°(T)/127°(M) radial, then counterclockwise along the 2-mile arc to the SEA VORTAC 069°(T)/050°(M) radial to the point of beginning.

Area H. That airspace extending upward from 3,000 feet MSL to and including 10,000 feet MSL within an area bounded by a line beginning at the 20-mile DME on the SEA VORTAC 338°(T)/319°(M) radial east to the 20-mile DME on the SEA VORTAC 023°(T)/004°(M) radial, then southeast along the 16-mile DME on the SEA VORTAC 032°(T)/013°(M) radial south to the 12-mile DME on the SEA VORTAC 135°(T)/116°(M) radial, then southwest to the 18.3 mile DME on the SEA VORTAC 157°(T)/138°(M) west to the 18-mile DME on the SEA VORTAC 200°(T)/181°(M) radial, then northwest to the 15-mile DME on the SEA VORTAC 212°(T)/193°(M) radial north to the 18-mile DME on the SEA VORTAC 335°(T)/316°(M) radial to the point of beginning, excluding that airspace in the areas A through G.

Area I. That airspace extending upward from 4,000 feet MSL to and including 10,000 feet MSL within an area bounded by a point 47°48′13″/122°27′59″ (SEA 344°(T)/325°(M) at 23NM), clockwise to a point 47°47′59″/122°08′02″ (SEA 018°(T)/359°(M) radial at 23NM), to a point 47°44′31″/122°07′00″ (SEA 023°(T)/004°(M) radial at 20NM), to a point 47°44′39″/122°29′41″ (SEA 338°(T)/319°(M) radial at 20NM) to the point of beginning.

Area J. That airspace extending upward from 5,000 feet MSL to and including 10,000 feet MSL within an area bounded by a point 47°39′31″/122°05′41″ (SEA 033°(T)/014°(M) at 16NM), clockwise to a point 47°37′49″/121°59′59″ (SEA 047°(T)/028°(M) radial at 17.2NM), to a point 47°17′36″/122°00′04″ (124°(T)/105°(M) radial at 15.2NM), to a point 47°17′38″/122°06′07″ (SEA 135°(T)/116°(M) radial at 12NM) to the point of beginning.

Area K. That airspace extending upward from 5,000 feet MSL to and including 10,000 feet MSL within an area bounded by: a point 47°38′53″/122°36′14″ (SEA 317°(T)/298°(M) radial at 17.5NM), to a point 47°13′24″/122°30′14″ (SEA 212°(T)/193°(M) radial at 15NM), to a point 47°16′09″/122°36′01″ (SEA 230°(T)/211°(M) radial at 15.5NM) to the point of beginning.

Area L. That airspace extending upward from 6,000 feet MSL to and including 10,000 feet MSL within an area bounded by a point 47°39′00″/122°43′03″ (SEA 308°(T)/289°(M) radial at 21NM), clockwise to a point 47°38′53″/122°36′14″ (SEA 317°(T)/298°(M) radial at 17.5NM), to a point 47°16′09″/122°36′01″ (SEA 230°(T)/211°(M) radial at 15.5NM), to a point 47°18′46″/122°42′45″ (SEA 246°(T)/227°(M) radial at 18NM) to the point of beginning.

Area M. That airspace extending upward from 6,000 feet MSL to and including 10,000 feet MSL within an area bounded by a point 47°37′49″/121°59′59″ (SEA 047°(T)/028°(M) radial at 17.2NM), clockwise to a point 47°36′45″/121°56′03″ (SEA 055°(T)/036°(M) radial at 18.6NM), to a point 47°35′39″/121°51′58″ (SEA 062°(T)/043°(M) radial at 20.4NM), to a point 47°18′18″/121°51′40″ (SEA 113°(T)/094°(M) radial at 19.9NM), to a point 47°17′28″/121°55′42″ (SEA 119°(T)/100°(M) radial at 17.8NM), to a point 47°17′36″/122°00′04″ (SEA 124°(T)/105°(M) radial at 15.2NM) to the point of beginning.

Area N. That airspace extending upward from 4,000 feet MSL to and including 10,000 feet MSL within an area bounded by: a point 47°09′13″/122°27′36″ (SEA 200°(T)/181°(M) radial at 18NM), clockwise to a point 47°09′17″/122°08′06″ (SEA 157°(T)/138°(M) radial at 18.3NM), to a point 47′06′16″/122°08′34″ (SEA 161°(T)/142°(M) radial at 21NM), to a point 47°06′20″/122°26′21″ (SEA 195°(T)/176°(M) radial at 20.5NM to the point of beginning.

Area O. That airspace extending upward from 5,000 feet MSL to and including 7000 feet MSL within an area bounded by a point 47°18′46″/122°42′45″ (SEA 246°(T)/227°(M) radial at 18NM), clockwise to a point 47°16′09″/122°36′01″ (SEA 230°(T)/211°(M) radial at 15.5NM), to a point 47°13′24″/122°30′14″ (SEA 212°(T)/193°(M) radial at 15NM), to a point 47°09′13″/122°27′36″ (SEA 200°(T)/181°(M) radial at 18NM), to a point 47°06′20″/122°26′21″ (SEA 195°(T)/176°(M) radial at 20.5NM), to a point 47°02′35″/122°30′26″ (SEA 199°(T)/180°(M) radial at 24.9NM), to a point 47°10′55″/122°40′04″ (SEA 224°(T)/205°(M) radial at 21.1NM) to the point of beginning.

Area P. That airspace extending upward from 5,000 feet MSL to and including 7000 feet MSL within an area bounded by: a point 47°17′38″/122°06′07″ (SEA 135°(T)/116°(M) radial at 12NM), clockwise to a point 47°17′36″/122°00′04″ (SEA 124°(T)/105°(M) radial at 15.2NM), to a point 47°17′28″/121°55′42″ (SEA 119°(T)/100°(M) radial at 17.8NM), to a point 47°14′03″/121°58′57″ (SEA 132°(T)/113°(M) degree radial at 18NM), to a point 47°11′46″/121°58′59″ (SEA 137°(T)/118°(M) radial at 19.6NM), to a point 47°02′38″/122°06′04″ (SEA 160°(T)/141°(M) radial at 25NM), to a point 47°06′16″/122°08′34″ (SEA 161°(T)/142°(M) radial at 21NM), to a point 47°09′17″/122°08′06″ (SEA 157°(T)/138°(M) degree radial at 18.3NM) to the point of beginning.

Area Q. That airspace extending upward from 5,000 feet MSL to and including 7,000 feet MSL within an area bounded by: a point 47°51′15″/122°30′00″ (SEA 343°(T)/324°(M) radial at 26.3NM), clockwise to a point 47°51′09″/122°05′46″ (SEA 019°(T)/360°(M) radial at 26.5NM), to a point 47°41′54′/121°55′57″ (SEA 044°(T)/025°(M) radial at 22NM), to a point 47°36′45″/121°56′03″ (SEA 055°(T)/036°(M) radial at 18.6NM), to a point 47°37′49″/121°59′59″ (SEA 047°(T)/028°(M) radial at 17.2NM), to a point 47°39′31″/122°05′41″ (SEA 033°(T)/014°(M) radial at 16NM), to a point 47°44′31″/122°07′00″ (SEA 023°(T)/004°(M) radial at 20NM), to a point 47°47′59″/122°08′02″ (SEA 018°(T)/359°(M) radial at 23NM) to a point 47°48′13″/122°27′59″ (SEA 344°(T)/325°(M) radial at 23NM), to a point 47°44′39″/122°29′41″ (SEA 338°(T)/319°(M) radial at 20NM), to a point 47°42′25″/122°29′50″ (SEA 335°(T)/316°(M) radial at 18NM), to a point 47°38′53″/122°36′14″ (SEA 317°(T)/298°(M) radial at 17.5NM), to a point 47°39′00″/122°43′03″ (SEA 308°(T)/289°(M) radial at 21NM) to the point of beginning.

Area R. That airspace extending upward from 6,000 feet MSL to and including 7,000 feet MSL within an area bounded by a point 47°55′27″/122°27′04″ (SEA 349°(T)/330°(M) radial 29.9NM), clockwise to a point 47°55′31″/122°08′29″ (SEA 013°(T)/354°(M) radial at 30.2NM), to a point 47°51′09″/122°05′46″ (SEA 019°(T)/360°(M) radial at 26.5NM), to a point 47°51′15″/122°30′00″ (SEA 343°(T)/324°(M) radial at 26.3NM) to the point of beginning.

Area S. That airspace extending upward from 5,000 feet MSL to and including 10,000 feet MSL within an area bounded by a point 47°06′20″/122°26′21″ (SEA 195°(T)/176°(M) radial at 20.5NM), clockwise to a point 47°06′16″/122°08′34″ (SEA 161°(T)/142°(M) radial at 21NM), to a point 47°02′38″/122°06′04″ (SEA 160°(T)/141°(M) radial at 25NM), to a point 47°02′35″/122°30′26″ (SEA 199°(T)/180°(M) radial at 24.9NM) to the point of beginning.

Area T. That airspace extending upward from 6,000 feet MSL to and including 7,000 feet MSL within an area bounded by a point 47°02′35″/122°30′26″ (SEA 199°(T)/180°(M) radial at 24.9NM), clockwise to a point 47°02′38″/122°06′04″ (SEA 160°(T)/141°(M) radial at 25NM), to a point 46°57′13″/122°08′03″ (SEA 166°(T)/147°(M) radial at 29.8NM), to a point

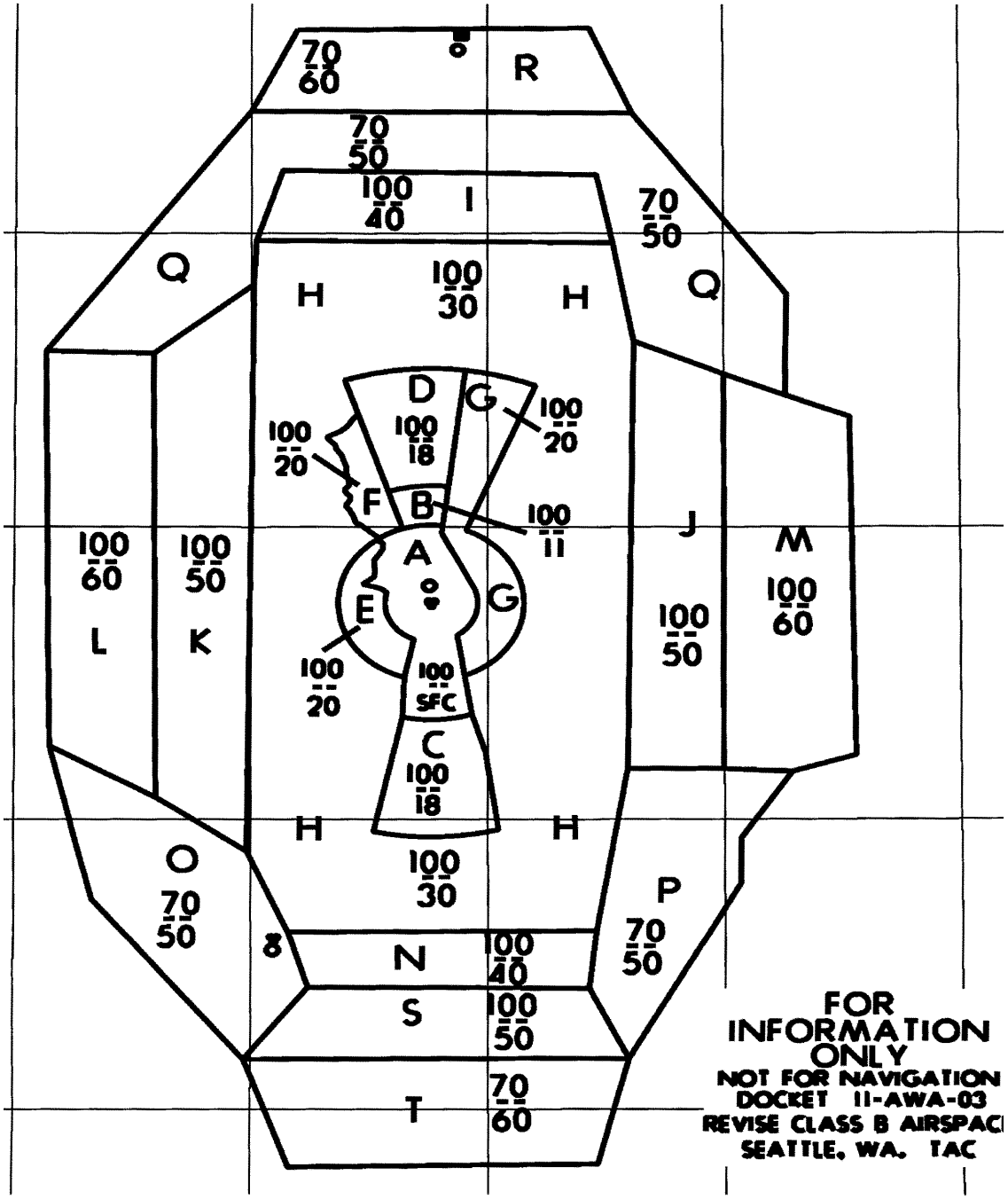
46°57′05″/122°27′35″ (SEA 192°(T)/173°(M) radial at 29.7NM) to the point of beginning.

Issued in Washington, DC, on June 13, 2011.

Gary Norek,

Acting Manager, Airspace, Regulations and ATC Procedures Group.

BILLING CODE 4910–13–P



[FR Doc. 2011–15120 Filed 6–16–11; 8:45 am]
BILLING CODE 4910–13–C

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2011–0496; Airspace Docket No. 11–AWP–6]

Proposed Establishment of Class D and Amendment of Class E Airspace; Los Angeles, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class D airspace at Los Angeles International Airport, Los Angeles, CA. Controlled airspace is necessary to contain potential missed approaches at Los Angeles International Airport. The FAA is proposing this action to enhance the safety and management of aircraft operations at the airport. This action also would edit Class E airspace by adding the geographic coordinates and the airport name to the airspace designation.

DATES: Comments must be received on or August 1, 2011.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590; telephone (202) 366–9826. You must identify FAA Docket No. FAA–2011–0496; Airspace Docket No. 11–AWP–6, at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Eldon Taylor, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue, SW., Renton, WA 98057; telephone (425) 203–4537.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA 2011–0496 and Airspace Docket No. 11–AWP–6) and be submitted in triplicate to the Docket Management System (see **ADDRESSES** section for address and phone number). You may also submit comments through the Internet at *http://www.regulations.gov*.

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2011–0496 and Airspace Docket No. 11–AWP–6''. The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at *http://www.regulations.gov*. Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace_amendments/*.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue, SW., Renton, WA 98057.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267–9677, for a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by establishing Class D airspace at Los Angeles International Airport, Los Angeles, CA for containment of potential missed approaches at Los Angeles International Airport. This action is based on the results of a study conducted by the Los Angeles VFR Task Force, and the Los Angeles Class B Workgroup. This action would further enhance the safety and management of aircraft operations at the airport. This action also would edit Class E airspace extending upward from 700 feet above the surface by adding ''Los Angeles International Airport, CA'' and ''lat. 33°56′33″ N., long. 118°24′26″ W.'' to the airspace designation.

Class D and Class E airspace designations are published in paragraph 5000 and 6005, respectively, of FAA Order 7400.9U, dated August 18, 2010, and effective September 15, 2010, which is incorporated by reference in 14 CFR 71.1. The Class D and Class E airspace designation listed in this document will be published subsequently in this Order.

The FAA has determined this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, section 106, describes the authority for the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in subtitle VII, part A, subpart I, section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of

airspace. This regulation is within the scope of that authority as it establishes additional controlled airspace at Los Angeles International Airport, Los Angeles, CA.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9U, Airspace Designations and Reporting Points, dated August 18, 2010, and effective September 15, 2010 is amended as follows:

Paragraph 5000 Class D airspace.

* * * * *

AWP CA D Los Angeles, CA [New]

Los Angeles International Airport, CA
(Lat. 33°56′33″ N., long. 118°24′26″ W.)
Santa Monica Municipal Airport, CA
(Lat. 34°00′57″ N., long. 118°27′05″ W.)

That airspace extending upward from the surface to and including 2,700 feet MSL bounded by a line beginning at lat. 33°57′42″ N., long. 118°27′23″ W.; to lat. 33°58′18″ N., long. 118°26′24″ W.; then via the 2.7-mile radius of the Santa Monica Municipal Airport counterclockwise to lat. 34°00′00″ N., long. 118°24′02″ W.; to lat. 34°00′00″ N., long. 118°22′58″ W.; to lat. 33°57′42″ N., long. 118°22′10″ W., thence to the point of beginning. That airspace extending upward from the surface to and including 2,500 feet MSL bounded by a line beginning at lat. 33°55′50″ N., long. 118°22′06″ W.; to lat. 33°54′16″ N., long. 118°24′17″ W.; to lat. 33°52′47″ N., long. 118°26′22″ W.; to lat. 33°55′51″ N., long. 118°26′05″ W., thence to the point of beginning. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the Earth.

* * * * *

AWP CA E5 Los Angeles, CA [Amended]

Los Angeles International Airport, CA
(Lat. 33°56′33″ N., long. 118°24′26″ W.)

That airspace extending upward from 700 feet above the surface bounded by a line beginning at lat. 34°05′00″ N., long. 118°33′03″ W.; to lat. 34°05′00″ N., long. 118°15′03″ W.; to lat. 34°00′00″ N., long. 118°15′03″ W.; to lat. 34°00′00″ N., long. 118°07′03″ W.; to lat. 33°56′00″ N., long. 118°07′03″ W.; to lat. 33°56′00″ N., long. 117°53′03″ W.; to lat. 33°46′00″ N., long. 117°45′03″ W.; to lat. 33°39′00″ N., long. 117°30′03″ W.; to lat. 33°30′00″ N., long. 117°30′03″ W.; to lat. 33°30′00″ N., long. 117°45′03″ W.; to lat. 33°42′00″ N., long. 118°09′03″ W.; to lat. 33°42′00″ N., long. 118°26′03″ W.; to lat. 33°48′00″ N., long. 118°26′03″ W.; to lat. 33°53′00″ N., long. 118°33′03″ W., thence to the point of beginning. That airspace extending upward from 1,200 feet above the surface bounded by a line beginning at lat. 34°00′00″ N., long. 119°05′03″ W.; to lat. 34°00′00″ N., long. 118°33′03″ W.; to lat. 34°05′00″ N., long. 118°33′03″ W.; to lat. 34°05′00″ N., long. 117°59′03″ W.; to lat. 33°56′00″ N., long. 117°59′03″ W.; to lat. 33°56′00″ N., long. 117°53′03″ W.; to lat. 33°46′00″ N., long. 117°45′03″ W.; to lat. 33°39′00″ N., long. 117°30′03″ W.; to lat. 33°30′00″ N., long. 117°30′03″ W.; to lat. 33°30′00″ N., long. 118°34′03″ W.; to lat. 33°28′30″ N., long. 118°34′03″ W.; to lat. 33°28′30″ N., long. 119°07′03″ W.; to lat. 33°52′03″ N., long. 119°07′02″ W., thence to the point of beginning.

Issued in Seattle, Washington, on June 8, 2011.

John Warner,

Manager, Operations Support Group, Western Service Center.

[FR Doc. 2011–15023 Filed 6–16–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2011–0402; Airspace Docket No. 11–ASO–18]

Proposed Establishment of Class E Airspace; Copperhill, TN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E Airspace at Copperhill, TN, to accommodate new Area Navigation (RNAV) Global Positioning System (GPS) Standard Instrument Approach Procedures at Martin Campbell Field Airport. This action would enhance the safety and airspace management of Instrument Flight Rules (IFR) operations at the airport.

DATES: Comments must be received on or before August 1, 2011.

ADDRESSES: Send comments on this rule to: U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001; Telephone: 1–800–647–5527; Fax: 202–493–2251. You must identify the Docket Number FAA–2011–0402; Airspace Docket No. 11–ASO–18, at the beginning of your comments. You may also submit and review received comments through the Internet at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to comment on this rule by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2011–0402; Airspace Docket No. 11–ASO–18) and be submitted in triplicate to the Docket Management System (see **ADDRESSES** section for address and phone number). You may also submit comments through the Internet at *http://www.regulations.gov*.

Annotators wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2011–0402; Airspace Docket No. 11–ASO–18.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded from and comments submitted through *http://www.regulations.gov*. Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace_amendments/*.

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays. An informal docket may also be examined during normal business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Avenue, College Park, Georgia 30337.

Persons interested in being placed on a mailing list for future NPRM's should contact the FAA's Office of Rulemaking, (202) 267–9677, to request a copy of Advisory circular No. 11–2A, Notice of Proposed Rulemaking distribution System, which describes the application procedure.

The Proposal

The FAA is considering an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 to establish Class E airspace at Copperhill, TN, providing the controlled airspace required to support the new RNAV GPS standard instrument approach procedures for Martin Campbell Field Airport. Controlled airspace extending upward from 700 feet above the surface would be established for the safety and management of IFR operations at the airport.

Class E airspace designations are published in Paragraph 6005 of FAA order 7400.9U, dated August 18, 2010, and effective September 15, 2010, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This proposed rulemaking is promulgated under the authority described in subtitle VII, part A, subpart I, section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This proposed regulation is within the scope of that authority as it would establish Class E airspace at Martin Campbell Field Airport, Copperhill, TN.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9U, Airspace Designations and Reporting Points, dated August 18, 2010, effective September 15, 2010, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ASO TN E5 Copperhill, TN [New]

Martin Campbell Field Airport
(Lat. 35°0′57″ N., long. 84°20′49″ W.)

That airspace extending upward from 700 feet above the surface within an 8.1-mile radius of Martin Campbell Field Airport.

Issued in College Park, Georgia, on June 1, 2011.

Mark D. Ward,

Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2011–15114 Filed 6–16–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

Proposed Modification of the Las Vegas, NV, Class B Airspace Area; Public Meetings

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of meetings.

SUMMARY: This notice announces three fact-finding informal airspace meetings to solicit information from airspace users and others, concerning a proposal to modify Class B airspace at Las Vegas, NV. The purpose of these meetings is to provide interested parties an opportunity to present views, recommendations, and comments on the proposal. All comments received during these meetings will be considered prior to any issuance of a notice of proposed rulemaking.

DATES: The informal airspace meetings will be held on Thursday, August 18, 2011; Tuesday August 23, 2011; and Thursday, August 25, 2011. All meetings will run from 6:30 p.m. until 9 p.m. Comments must be received on or before October 10, 2011.

ADDRESSES: (1) The meeting on Thursday, August 18, 2011, will be held at Centennial High School, 10200 Centennial Parkway, Las Vegas, NV 89149; (2) The meeting on Tuesday, August 23, 2011, will be held at Coronado High School, 10 1 Coronado Center Drive, Henderson, NV 89052; (3) The meeting on Thursday, August 25, 2011, will be held at Shadow Ridge High School, 5050 Brent Lane, Las Vegas, NV 89131.

Comments: Send comments on the proposal, in triplicate, to: John Warner, Manager, Operations Support Group, Western Service Center, Air Traffic Organization, Federal Aviation Administration, 1601 Lind Ave., SW., Renton, WA 98057.

FOR FURTHER INFORMATION CONTACT: John Gough, Manager, Airspace and Procedures, and Bill Ruggiero, Support Manager Las Vegas, TRACON, 699 Wright Brothers Lane, Las Vegas, NV 89119; telephone: (702) 597–5910.

SUPPLEMENTARY INFORMATION:

Meeting Procedures

(a) The meetings will be informal in nature and will be conducted by one or more representatives of the FAA Western Service Area. A representative from the FAA will present a briefing on the planned Class B airspace area modification. Each participant will be given an opportunity to deliver comments or make a presentation, although a time limit may be imposed. Only comments concerning the plan to modify the Las Vegas Class B airspace will be accepted.

(b) The meetings will be open to all persons on a space-available basis. There will be no admission fee or other charge to attend and participate.

(c) Any person wishing to make a presentation to the FAA panel will be asked to sign in and estimate the amount of time needed for such presentation. This will permit the panel to allocate an appropriate amount of time for each presenter. These meetings will not be adjourned until everyone on the list has had an opportunity to address the panel.

(d) Position papers or other handout material relating to the substance of these meetings will be accepted. Participants wishing to submit handout material should present an original and two copies (3 copies total) to the presiding officer. There should be additional copies of each handout available for other attendees.

(e) These meetings will not be formally recorded. However, a summary of comments made at the meetings will be filed in the docket.

Agenda for the Meetings

—Sign-in.
—Presentation of Meeting Procedures.
—Informal Presentation of the planned Class B Airspace area modification.
—Public Presentations and Discussions.
—Closing Comments.

Issued in Washington, DC, on June 13, 2011.

Gary A. Norek,

Acting Manager, Airspace, Regulations and ATC Procedures Group.

[FR Doc. 2011–15107 Filed 6–16–11; 8:45 am]

BILLING CODE 4910–13–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Chapter 1

Effective Date for Swap Regulation

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of proposed order and request for comment.

SUMMARY: Pursuant to section 754 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (''Dodd-Frank Act''), the general effective date for certain provisions of subtitle A of title VII of the Dodd-Frank Act (''Title VII'') that do not require a rulemaking is 360 days after enactment, or July 16, 2011, unless another effective date is specifically provided. Following the general effective date, market participants may be subject to certain Commodity Exchange Act (''CEA'' or ''Act'') requirements but not others. To provide greater clarity regarding the applicability of various statutory and regulatory requirements, the Commodity Futures Trading Commission (''CFTC'' or the ''Commission'') is proposing to grant, pursuant to its section 4(c) exemptive authority, temporary relief in two parts with respect to various requirements of the CEA that apply or may apply to certain agreements, contracts, and transactions. In part one, the Commission is proposing to temporarily exempt persons or entities with respect to provisions of the CEA added or amended by the Dodd-Frank Act that reference one or more terms regarding entities or instruments that Title VII requires be ''further defined,'' such as the terms ''swap,'' ''swap dealer,'' ''major swap participant,'' or ''eligible contract participant,'' to the extent that requirements or portions of such provisions specifically relate to such referenced terms. In part two, the Commission is proposing to grant relief from certain provisions of the CEA that will or may apply to certain agreements, contracts, and transactions in exempt or excluded commodities as a result of the repeal of various CEA exemptions and exclusions as of July 16, 2011.

DATES: Comments must be received on or before July 1, 2011.

ADDRESSES: Comments may be submitted, referenced as ''Effective Dates,'' by any of the following methods:

- *Agency Web site, via its Comments Online process: http://comments.cftc.gov.* Follow the instructions for submitting comments through the Web site.
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Send to David A. Stawick, Secretary, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.
- *Courier:* Same as mail above.

Please submit your comments using only one method. ''Effective Dates'' must be in the subject field of responses submitted via e-mail, and clearly indicated on written submissions. All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov.* You should submit only information that you wish to make available publicly. If you wish the CFTC to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in section 145.9 of the CFTC's regulations.[1]

The CFTC reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *http://www.cftc.gov* that it may deem to be inappropriate for publication, including obscene language. All submissions that have been redacted or removed that contain comments on the merits of this action will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

FOR FURTHER INFORMATION CONTACT: Terry Arbit, Deputy General Counsel, 202–418–5120, *tarbit@cftc.gov,* or Harold Hardman, Deputy General Counsel, 202–418–5120, *hhardman@cftc.gov,* Office of the General Counsel, or Steven Kane, Consultant, 202–418–5911, *skane@cftc.gov,* Office of the Chief Economist, Commodity Futures Trading Commission, Three Lafayette Centre, 1151 21st Street, NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Introduction

On July 21, 2010, President Obama signed the Dodd-Frank Act.[2] Title VII of the Dodd-Frank Act amends the CEA [3] to establish a comprehensive new regulatory framework for swaps. The legislation was enacted to reduce risk, increase transparency, and promote market integrity within the financial system by, among other things: (1) Providing for the registration and comprehensive regulation of swap dealers and major swap participants; (2) imposing clearing and trade execution

[1] 17 CFR 145.9.

[2] *See* Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010).

[3] 7 U.S.C. 1 *et seq.*

requirements on standardized derivative products; (3) creating robust recordkeeping and real-time reporting regimes; and (4) enhancing the rulemaking and enforcement authorities of the Commission with respect to, among others, all registered entities and intermediaries subject to the Commission's oversight. Title VII also includes amendments to the Federal securities laws to establish a similar regulatory framework for security-based swaps under the authority of the Securities and Exchange Commission (''SEC'').

Section 754 of the Dodd-Frank Act provides that, unless otherwise provided, the provisions of subtitle A of Title VII[4] ''shall take effect on the later of 360 days after the date of the enactment of this subtitle or, to the extent a provision of this subtitle requires a rulemaking, not less than 60 days after publication of the final rule or regulation implementing such provisions of this subtitle.'' The date 360 days after the date of enactment is July 16, 2011.

To implement the Dodd-Frank Act, the Commission has to-date issued 53 advance notices of proposed rulemaking or notices of proposed rulemaking, two interim final rules, one final rule, and one proposed interpretive order. The regulatory requirements that have been proposed by the Commission present a substantially complete mosaic of the Commission's proposed regulatory framework under Title VII. In light of this substantially complete mosaic, the Commission reopened or extended the comment period of many of its proposed rulemakings in order to provide the public with an additional opportunity to comment on the proposed new regulatory framework for swaps, either in part or as a whole.[5] The extended comment period closed on June 3, 2011. The Commission also has solicited public comments on phasing of rule implementation (*i.e.,* identifying which requirements can be met sooner and which ones will take more time).[6]

[4] Subtitle A of Title VII contains two parts. Part I, entitled ''Regulatory Authority,'' consists of sections 711–720; part II, entitled ''Regulation of Swap Markets,'' consists of sections 721–754. Subtitle B of Title VII is entitled ''Regulation of Security-Based Swap Markets,'' and consists of sections 761–774. References to ''Title VII'' in this Release shall include only subtitle A of Title VII.

[5] *See* Reopening and Extension of Comment Periods for Rulemakings Implementing the Dodd-Frank Wall Street Reform and Consumer Protection Act, 76 FR 25274, May 4, 2011.

[6] The Commission has noted its ability to phase in implementation of the new requirements based on factors such as: The type of swap, including by asset class; the type of market participants that engage in such trades; the speed with which market infrastructures can meet the new requirements; and whether registered market infrastructures or participants might be required to have policies and procedures in place ahead of compliance with such policies and procedures by non-registrants. *http://www.cftc.gov/ucm/groups/public/@newsroom/documents/file/staffconcepts050211.pdf.*

II. Background and Discussion

Section 712(d)(1) of the Dodd-Frank Act requires the Commission and the SEC to further define certain terms used in Title VII, including the terms ''swap,'' ''swap dealer,'' ''major swap participant,'' and ''eligible contract participant.''[7] Section 721(c) requires the Commission to adopt a rule to further define the terms ''swap,'' ''swap dealer,'' ''major swap participant,'' and ''eligible contract participant'' to prevent evasion of statutory and regulatory obligations.[8] The Commission has issued two notices of proposed rulemaking that address these definitions.[9]

The Commission's final rulemakings further defining the terms in sections 712(d) and 721(c) will not be in place as of July 16, 2011. Consequently, concerns have been raised about effects upon the swaps market during the period between July 16, 2011 and prior to the date(s) that those rulemakings have been completed. The Commission is proposing this relief to address these concerns and provide clarity to market participants upon the general effective date of the Dodd-Frank Act. The Commission reiterates its intent to ''strive to ensure that current practices will not be unduly disrupted during the transition to the new regulatory regime.''[10]

[7] Section 712(d) provides: ''Notwithstanding any other provision of this title and subsections (b) and (c), the Commodity Futures Trading Commission and the Securities and Exchange Commission, in consultation with the Board of Governors [of the Federal Reserve System], shall further define the terms 'swap', 'security-based swap', 'swap dealer', 'security-based swap dealer', 'major swap participant', 'major security-based swap participant', and 'security-based swap agreement' in section 1a(47)(A)(v) of the Commodity Exchange Act (7 U.S.C. 1a(47)(A)(v)) and section 3(a)(78) of the Securities Exchange Act of 1934 (15 U.S.C. 78c(a)(78)).''

[8] Section 721(c) provides: ''To include transactions and entities that have been structured to evade this subtitle (or an amendment made by this subtitle), the Commodity Futures Trading Commission shall adopt a rule to further define the terms 'swap', 'swap dealer', 'major swap participant', and 'eligible contract participant'.''

[9] *See* Further Definition of ''Swap Dealer,'' ''Security-Based Swap Dealer,'' ''Major Swap Participant,'' ''Major Security-Based Swap Participant'' and ''Eligible Contract Participant,'' 75 FR 80174, Dec. 21, 2010 (''Entity Definitions'') and Further Definition of ''Swap,'' ''Security-Based Swap,'' and ''Security-Based Swap Agreement''; Mixed Swaps; Security-Based Swap Agreement Recordkeeping, 76 FR 29818, May 23, 2011.

[10] *See* Notice Regarding the Treatment of Petitions Seeking Grandfather Relief for Trading Activity Done in Reliance Upon Section 2(h)(1)–(2) of the Commodity Exchange Act, 75 FR 56512, 56513, Sept. 16, 2010 (''Grandfather Notice'').

Section 712(f) of the Dodd-Frank Act authorizes the Commission to ''promulgate rules, regulations, or orders permitted by this [Dodd-Frank] Act,'' conduct studies and prepare reports, register persons, and ''exempt persons, agreements, contracts, or transactions from the provisions of the Act, under the terms contained in this Act,'' in order to prepare for the effective dates of the provisions of Title VII. Section 4(c) of the CEA, as amended by the Dodd-Frank Act, provides the Commission with authority to exempt certain agreements, contracts, and transactions that may otherwise be subject to the CEA from various provisions of the CEA.[11]

The provisions of Title VII can be grouped into 4 major categories: (1) Provisions that require a rulemaking (for which relief is not being proposed); (2) self-effectuating provisions that reference terms that require further definition; (3) self-effectuating provisions that do not reference terms that require further definition and that repeal provisions of current law; and (4) self-effectuating provisions for which relief is not being proposed.

Section 754 specifies that unless otherwise provided in Title VII, provisions requiring a rulemaking become effective ''not less than 60 days after publication of the final rule'' (but not before July 16, 2011). Category 1 provisions, therefore, are not self-effectuating. A significant number of the Title VII provisions fall into this category. Examples of such provisions in Category 1 include new CEA section 4s(a) (governing registration of swap dealers and major swap participants), new CEA section 4s(e) (governing capital and margin requirements for swap dealers and major swap participants), and new CEA section 4s(h) (external business conduct standards for swap dealers and major swap participants).[12] The requirements in these provisions of the CEA will not become effective, at a minimum, until 60 days after publication of a final Commission rule (and not before July 16, 2011).

Because these provisions are not self-effectuating as of July 16, 2011, it is not necessary to provide relief with respect to Category 1 provisions as of July 16, and they are outside the scope of the proposed order. Similarly, Category 4 provisions also are outside the scope of the proposed order, and will go into

[11] 7 U.S.C. 6(c).

[12] 7 U.S.C. 6s(a), 6s(e) and 6s(h), respectively.

effect on July 16, 2011.[13] Lists of Category 1 and Category 4 provisions prepared by Commission staff will be published on the Commission's Web site.

The proposed relief discussed herein is considered in two parts, each addressing one of the remaining Categories noted above: (1) Category 2—provisions that are self-effectuating (*i.e.,* do not require rulemaking) and reference terms that require further definition (*i.e.,* ''swap,'' ''swap dealer,'' ''major swap participant,'' or ''eligible contract participant''); and (2) Category 3—provisions that are self-effectuating (*i.e.,* do not require rulemaking) and repeal provisions of current law, but that do not reference terms that require further definition. These parts are discussed, in turn, in the sections that follow.

A. Part One: Category 2—Self-Effectuating Provisions Referencing Terms That Require Further Definition

Some provisions of Title VII that do not require a rulemaking and thus, under section 754, become effective on July 16, 2011, specifically reference the terms ''swap,'' ''swap dealer,'' ''major swap participant,'' or ''eligible contract participant'' (or other entities or instruments) which themselves are the subject of rulemakings for further definition under sections 712(d) and 721(c) of the Dodd-Frank Act. As discussed above, the final rulemakings on these further definitions will not be in place by July 16, 2011.

In response to requests from market participants for greater clarity regarding the applicability of various regulatory requirements to certain agreements, contracts, and transactions (referred to hereafter collectively as ''transactions'') following the general effective date,[14] the Commission is proposing this temporary exemptive order pursuant to section 4(c) of the CEA. Specifically, for the Category 2 provisions described above, the Commission proposes to exempt persons and entities from the provisions of the CEA, as added or amended by the Dodd-Frank Act, that reference one or more of the terms regarding entities or instruments subject to further definition under sections 712(d) and 721(c) of the Dodd-Frank Act, including the terms ''swap,'' ''swap dealer,'' ''major swap participant,'' or ''eligible contract participant.'' [15] The proposed exemptive relief from such provisions would apply only with respect to those requirements or portions of such provisions that specifically relate to such referenced terms.

This proposed relief would not in any way limit the Commission's authority with respect to any person, entity, or transaction pursuant to CEA sections 2(a)(1)(B), 4b, 4o, 6(c), 6(d), 6c, 8(a), 9(a)(2), or 13, or the regulations of the Commission promulgated pursuant to such authorities, including CEA section 4c(b) proscribing fraud.[16] This relief would not apply to any provisions of Title VII and the CEA that have become effective prior to July 16, 2011 [17] or Commission regulations already issued. Further, this relief would not affect any effective date set out in any specific Dodd-Frank Act rulemaking by the Commission. In addition, the proposed order would not limit the Commission's authority under section 712(f) of the Dodd-Frank Act to issue rules, orders, or exemptions prior to the effective date of any provision, in order to prepare for the effective date of such provision, provided that such rule, order, or exemption shall not become effective prior to the effective date of the provision. Finally, this proposed order would not affect the applicability of any provision of the CEA to futures contracts or options on futures contracts.[18]

The proposed temporary exemptive relief would expire upon the earlier of: (1) The effective date of the applicable final rule further defining the relevant term; or (2) December 31, 2011. The

[13] Examples of Category 4 provisions include new CEA section 5b(c)(2), 7 U.S.C. 7a–1(c)(2) (core principles for derivatives clearing organizations (''DCOs'')); new CEA section 5(d), 7 U.S.C. 7(d) (core principles for designated contract markets); and new CEA sections 4c(a)(5)–(6), 7 U.S.C. 6c(a)(5)–(6) (certain anti-disruptive practices authority). To the extent that the Commission has issued proposed rulemakings to implement any Category 4 provisions, any requirements or guidance in such rulemakings will not become effective until the effective date of a final rulemaking.

In two cases, a Category 4 provision that amends the CEA references a term that requires further definition, but nevertheless, the Commission does not believe that it is appropriate to include the provision in the proposed order. These provisions are new CEA section 5b(g), 7 U.S.C. 7a–1(g) (depository institutions and SEC-registered clearing agencies clearing swaps prior to enactment are ''deemed to be registered'' as DCOs); and amended CEA section 22(a), 7 U.S.C. 25(a) (private right of action with respect to swaps).

There also are provisions in Category 4 that reference a term that requires further definition, but that do not amend the CEA and thus are outside the scope of the Commission's exemptive authority under CEA Section 4(c). Such provisions in Title VII include, for example: (1) Section 711 and much of section 712 (provisions regarding certain definitions and regulatory authority of CFTC and SEC); and (2) sections 724(b) and 725(g) (amending the Bankruptcy Code and the Legal Certainty for Bank Products Act of 2000, respectively).

[14] *See, e.g.,* Futures Industry Association, Petition for Exemption Pursuant to Section 4(c) of the Commodity Exchange Act (June 1, 2011) (requesting that the Commission ''adopt an order pursuant to section 4(c) of the [CEA] exempting such Clearing Members from the requirements of section 4d(f) of the CEA, as added by section 724 of [the Dodd-Frank Act], for a period of not less than 30 calendar days, beginning July 16, 2011, the effective date of many provisions of the Dodd-Frank Act, and ending not before August 15, 2011'') (footnote omitted). New CEA section 4d(f), 7 U.S.C. 7d(f), falls within Category 2 discussed above.

See also (1) Futures Industry Association, Institute of International Bankers, International Swaps and Derivatives Association, Investment Company Institute, Securities Industry and Financial Markets Association, and U.S. Chamber of Commerce, Request for Clarification and Relief Under Sections 754 and 739 of the Dodd-Frank Wall Street Reform and Consumer Protection Act; Petition for Exemption Pursuant to Section 4(c) of the Commodity Exchange Act, (June 10, 2011); (2) The Financial Services Roundtable, Letter re. Automatically Effective Provisions under Title VII of the Dodd-Frank Act, Application for Exemption Pursuant to Section 4(c) of the Commodity Exchange Act and Section 712(f) Pending Effectiveness of Final Rulemaking (June 10, 2011); (3) National Grain and Feed Association, Letter re. Status of Options on Agricultural Commodities Entered Into After July 16, 2011 (June 7, 2011); and (4) Paul Pantano on behalf of Commodity Options and Agricultural Swaps Working Group, Letter re. Transition Exemption for Options on Agricultural Commodities Entered Into After July 15, 2011 (June 6, 2011).

[15] The Commission's authority to provide exemptive relief under CEA section 4(c), as amended by section 721(d) of the Dodd-Frank Act, may not extend to certain Category 2 provisions of the Dodd-Frank Act and the CEA. These provisions include: new CEA section 4s(l), 7 U.S.C. 6s(l) (providing for swap dealer segregation requirements with respect to uncleared swaps); amended CEA section 5b(a), 7 U.S.C. 7a–1(a) (prohibiting a DCO from performing the functions of a DCO with respect to swaps unless the DCO is registered with the Commission); and new CEA section 4s(k), 7 U.S.C. 6s(k) (providing for the duties and designation of a chief compliance officer for swap dealers and major swap participants). As such, these provisions will take effect on July 16, 2011, and may not be subject to the exemptive relief noted above granted by the Commission. The Commission staff has informed the Commission that it is separately considering whether to issue a no-action letter in which the staff would state that it would not recommend that the Commission commence an enforcement action against markets or market participants for failure to comply with the above-referenced provisions over a similar time period.

[16] The Dodd-Frank Act amended the CEA's anti-fraud and anti-manipulation provisions, including CEA section 4b, to cover ''swaps.'' Although these provisions therefore would, under the proposed relief, not apply to ''swaps'' under the Dodd-Frank Act because that term is subject to further definition, nevertheless, they will apply to all transactions other than ''swaps'' (including, but not limited to, futures contracts, options on futures contracts, transactions with retail customers in foreign currency or other commodities pursuant to CEA section 2(c)(2) (7 U.S.C. 2(c)(2)), and transactions subject to exemptive relief pursuant to part two of the proposed order).

[17] *See, e.g.,* section 737(d) of the Dodd-Frank Act (amendments regarding position limits effective on the date of enactment). Similarly, this relief would not affect the effective date of any provision that may become effective after July 16, 2011, such as section 716 of the Dodd-Frank Act.

[18] Accordingly and by way of non-exclusive example, where a provision references both swaps and futures, this relief does not affect in any way the application of the provision (and any implementing Commission regulations thereunder) insofar as it refers to futures.

Commission is proposing to limit this proposed relief to no more than a fixed period—*i.e.* December 31, 2011—for several reasons.

First, the Commission believes it appropriate and prudent to periodically review the extent and scope of any relief provided from the CEA, as amended by the Dodd-Frank Act. The Commission anticipates that additional rulemakings to implement the Dodd-Frank Act will be completed during this period of transitional relief. During this period the Commission also will be considering the appropriate phase-in of the various regulatory requirements under the Dodd-Frank rulemakings. Accordingly, the Commission believes it would be appropriate to periodically re-examine the scope and extent of the proposed exemptive relief in order to ensure that the scope of relief is appropriately tailored to the schedule of implementation of the Dodd-Frank Act requirements.[19]

Second, the limitation of this exemptive relief to no more than a fixed period of time is consistent with similar limitations on transitional relief provided by the Congress elsewhere in Title VII. Section 723(c) of the Dodd-Frank Act allows persons to submit petitions to the Commission ''to remain subject to section 2(h) of the [CEA].'' [20] In acting upon such petitions, the Commission may allow persons to ''continue operating subject to section 2(h) [of the CEA] for not longer than a 1-year period.'' Similarly, section 734 authorizes the Commission to grant petitions for persons to remain subject to the provisions of section 5d of the CEA governing the operation of exempt boards of trade (''EBOTs'') ''for up to 1 year after the effective date of this subtitle.'' [21] In light of these provisions authorizing the Commission to provide transitional relief for no longer than a fixed period of time, the Commission believes it would be appropriate to provide transitional relief consistent with section 712(f) of the Dodd-Frank Act and CEA section 4(c) under this proposed order for no longer than a fixed time period.

The Commission nonetheless reiterates its intent that existing practices should not be unduly disrupted during any transition period. Moreover, the Commission reiterates its intent to deliberatively and efficiently proceed to complete the rulemakings to implement the Dodd-Frank Act. In the event that a further definitions rulemaking is completed prior to December 31, 2011, the Commission will at that time address the appropriate phase-in and implementation dates of the resulting regulatory requirements. Alternatively, should the proposed order expire at the end of the fixed time period—December 31, 2011—such expiration will not affect the Commission's ability to provide further relief, as appropriate, to avoid undue disruption or costs to market participants.

B. Part Two: Category 3—Provisions That are Self-Effectuating and Repeal Provisions of Current Law But That Do Not Reference Terms That Require Further Definition

Currently, the CEA includes provisions that exclude or exempt, in whole or in part, certain transactions from Commission oversight under the CEA. These are as follows:

i. Section 2(d)(1),[22] transactions in excluded commodities [23] between eligible contract participants and not executed or traded on a trading facility;

ii. Section 2(d)(2),[24] principal-to-principal transactions in excluded commodities between certain eligible contract participants and executed or traded on an electronic trading facility;

iii. Section 2(g),[25] transactions subject to individual negotiation between eligible contract participants in commodities other than agricultural commodities and not executed or traded on a trading facility;

iv. Sections 2(h)(1)–(2),[26] transactions in exempt commodities [27] between eligible contract participants and not entered into on a trading facility;

v. Sections 2(h)(3)–(7),[28] principal-to-principal transactions in exempt commodities between eligible commercial entities (''ECEs'') [29] and executed or traded on an electronic trading facility (called exempt commercial markets, or ''ECMs'');

vi. Section 5d,[30] transactions in commodities, among other things, having a nearly inexhaustible deliverable supply or no cash market, between eligible contract participants and traded on an EBOT; and

vii. Section 2(e),[31] which generally provides that nothing in the CEA governs or is applicable to an electronic trading facility that limits transactions authorized to be conducted on its facilities to those satisfying the requirements of sections 2(d)(2), 2(g) or 2(h)(3).

Under the Dodd-Frank Act, these provisions all will be removed from the CEA as of July 16, 2011. However, part 35 of the Commission's regulations will continue to be available with respect to transactions that meet the conditions therein, until such time as it may be withdrawn, amended, or replaced by the Commission.

Part 35 originally was promulgated in 1993 pursuant to the Commission's general exemptive authority in CEA section 4(c), and provides a broad-based exemption from the CEA for ''swap agreements'' in any commodity. Specifically, part 35 exempts ''swap agreements,'' as defined therein, from most of the provisions of the CEA if: (1) They are entered into by ''eligible swap participants'' (''ESPs''); [32] (2) they are not part of a fungible class of agreements standardized as to their material economic terms; [33] (3) the creditworthiness of any party having an actual or potential obligation under the swap agreement would be a material consideration in entering into or determining the terms of the swap agreement, including pricing, cost, or credit enhancement terms; [34] and (4)

[19] The Commission adopted a similar approach in not granting ''grandfather'' relief with respect to transactions being conducted under CEA sections 2(h)(1) and (2), 7 U.S.C, 2(h)(1) and (2): ''Until the contents and timing of the Commission's regulations affecting bilateral swaps are better known, however, the Commission has determined not to grant grandfather relief as it is impossible to know at this time whether such relief will be necessary.'' *See* Grandfather Notice, 75 FR at 56513.

[20] 7 U.S.C. 2(h).

[21] 7 U.S.C. 7a–3.

[22] 7 U.S.C. 2(d)(1).

[23] The term ''excluded commodity'' is defined in CEA section 1a(13), 7 U.S.C. 1a(13), to include, among other things, financial instruments such as a currency, interest rate, or exchange rate, or any economic or commercial index based on prices, rates, values, or levels that are not within the control of any party to the transaction.

[24] 7 U.S.C. 2(d)(2).

[25] 7 U.S.C. 2(g).

[26] 7 U.S.C. 2(h)(1)–(2).

[27] The term ''exempt commodity'' is defined in CEA section 1a(14), 7 U.S.C. 1a(14), as a commodity other than an excluded or agricultural commodity, and includes energy and metals commodities.

[28] 7 U.S.C. 2(h)(3)–(7).

[29] The term ''eligible commercial entity'' is defined in CEA section 1a (11), 7 U.S.C. 1a(11).

[30] 7 U.S.C. 7a–3.

[31] 7 U.S.C. 2(e).

[32] The parties covered under the ESP definition, while very broad, are not coextensive with those covered by the terms ''ECE'' or ''eligible contract participant.'' Therefore, it is possible that a small segment of persons or entities that are currently relying on one or more of the CEA exclusions or exemptions cited above might not qualify as an ESP and consequently would not be eligible for exemptive relief under part 35.

[33] This condition was designed so that the exemption would not establish ''a market in swap agreements, the terms of which are fixed and are not subject to negotiation that functions essentially in the same manner as an exchange but for the bilateral execution of transactions.'' *See* Exemption for Certain Swap Agreements, 58 FR 5587, at 5590, Jan. 22, 1993.

[34] By this condition, the exemption does not extend to transactions that are subject to a clearing system where the credit risk of individual members of the system to each other in a transaction to which each is a counterparty is effectively eliminated and

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they are not entered into or traded on a multilateral transaction execution facility.[35] Accordingly, transactions that fully meet the conditions of part 35 are outside the scope of the proposed order.[36]

However, because part 35 covers essentially non-standardized, non-cleared, non-exchange traded transactions, certain persons or entities that currently rely on the CEA exclusions or exemptions cited above may not qualify for part 35. In response to requests from market participants for greater clarity regarding the applicability of various statutory and regulatory requirements to certain transactions following the general effective date, the Commission, pursuant to its authority under section 4(c) of the CEA, is proposing to grant relief for those transactions that satisfy the conditions specified below.

Specifically, the Commission is proposing to temporarily exempt a transaction in exempt or excluded commodities (and any person or entity offering or entering into such transaction) from the CEA (other than the anti-fraud and anti-manipulation enforcement provisions identified below) following the general effective date if the transaction otherwise would comply with part 35, notwithstanding that: (1) The transaction may be executed on a multilateral transaction execution facility; (2) the transaction may be cleared; (3) persons offering or entering into the transaction may be eligible contract participants as defined in the CEA (prior to July 16, 2011); (4) the transaction may be part of a fungible class of agreements that are standardized as to their material economic terms; and/or (5) no more than one of the parties to the transaction is entering into the transaction in conjunction with its line of business, but is neither an eligible contract participant nor an ESP, and the transaction was not and is not marketed to the public (the ''line of business provision'').[37]

As noted above, this proposed temporary exemptive relief would not affect the availability of either part 35 or part 32 with respect to transactions that fully meet the conditions therein.[38] For transactions that fall outside of existing part 35 or part 32, this relief would only be available to the extent those transactions (and persons offering or entering into such transactions) fall within the scope of any of the existing CEA sections 2(d), 2(e), 2(g), 2(h), and 5d as in effect prior to July 16, 2011 [39] or the line of business provision.

With respect to any transaction within the scope of the proposed order, the proposed exemptive relief would not in any way limit the Commission's authority with respect to any person, entity, or transaction pursuant to CEA sections 2(a)(1)(B), 4b, 4o, 6(c), 6(d), 6c, 8(a), 9(a)(2) or 13, or the regulations of the Commission promulgated pursuant to such authorities, including CEA section 4c(b) proscribing fraud.[40] Additionally, this proposed relief would not affect any Dodd-Frank Act implementing regulations (and any implementation period contained therein) that the Commission promulgates and applies to the subject transactions, market participants, or markets.[41] This proposed temporary exemptive relief would expire upon the earlier of: (1) December 31, 2011; or (2) the repeal or replacement of part 35 or part 32, as applicable. The Commission is proposing to provide this exemptive relief in part two of the proposed order for no longer than a fixed period of time for the same reasons as described above with respect to part one of the proposed order.

III. Section 4(c) of the Commodity Exchange Act

Section 4(c)(1) of the CEA [42] authorizes the CFTC to exempt any transaction or class of transactions (including any person or class of persons offering, entering into, rendering advice or rendering other services with respect to, the transaction) from any of the provisions of the CEA (subject to certain exceptions). Pursuant to section 4(c)(2), the Commission must determine that: (1) The exemption is appropriate for the transactions and consistent with the public interest; (2) the exemption is consistent with the purposes of the CEA; (3) the transaction will be entered into solely between ''appropriate persons;'' [43] and (4) the exemption will not have a material adverse effect on the ability of the Commission or any contract market to discharge its regulatory or self-regulatory responsibilities under the

replaced by a system of mutualized risk of loss that binds members generally whether or not they are counterparties to the original transaction. *Id.* at 5591.

[35] In this context, a multilateral transaction execution facility is a physical or electronic facility in which all market makers and other participants that are members simultaneously have the ability to execute transactions and bind both parties by accepting offers which are made by one member and open to all members of the facility. *Id.*

[36] Similarly, part 32 of the Commission's regulations will continue to be available with respect to commodity option transactions that meet the conditions therein, until such time as part 32 may be withdrawn, amended, or replaced by the Commission. *See* Commodity Options and Agricultural Swaps, 76 FR 6095, Feb 3, 2011.

[37] Commenters responding to the Commission's proposed Entity Definitions have suggested that the Commission should exercise its authority to further define the term ''eligible contract participant'' to encompass the ''line of business'' provision that was a part of the Commission's Policy Statement Concerning Swap Transactions, 54 FR 30694, 30696–30697, July 21, 1989. The staff is evaluating these comments in the context of the Commission's rulemaking to further define the term ''eligible contract participant.''

[38] In September 2010, the Commission published an order in the **Federal Register** providing that it would extend grandfather relief to ECMs and EBOTs provided that certain conditions are met. *See* Order Regarding the Treatment of Petitions Seeking Grandfather Relief for Exempt Commercial Markets and Exempt Boards of Trade, 75 FR 56513, Sept. 16, 2010. Nothing in this proposed order is intended to impact the availability of this grandfather relief.

[39] This exemptive relief would not be available to an electronic trading facility that, as of July 15, 2011, is not already operating as an ECM pursuant to CEA sections 2h(3)–(7), or to an EBOT that, as of July 15, 2011, is not already operating pursuant to CEA section 5d, or not compliant with the conditions set forth in such provisions.

[40] As discussed above, the addition of the term ''swap'' to some of these provisions would not in any way affect the applicability of these anti-fraud and anti-manipulation enforcement provisions to transactions subject to relief pursuant to part two of the proposed order.

[41] Further, the proposed order would not affect any Commission rulemaking authority over agreements, contracts, or transactions that may not depend on the terms subject to further definition under sections 712(d) or 721(c) of the Dodd-Frank Act. This relief also would not affect any provisions of the Dodd-Frank Act or the CEA that have become effective prior to July 16, 2011 or regulations already issued.

[42] Section 4(c)(1) of the CEA, 7 U.S.C. 6(c)(1), provides in full that:

In order to promote responsible economic or financial innovation and fair competition, the Commission by rule, regulation, or order, after notice and opportunity for hearing, may (on its own initiative or on application of any person, including any board of trade designated or registered as a contract market or derivatives transaction execution facility for transactions for future delivery in any commodity under section 5 of this Act) exempt any agreement, contract, or transaction (or class thereof) that is otherwise subject to subsection (a) (including any person or class of persons offering, entering into, rendering advice or rendering other services with respect to, the agreement, contract, or transaction), either unconditionally or on stated terms or conditions or for stated periods and either retroactively or prospectively, or both, from any of the requirements of subsection (a) of this section, or from any other provision of this chapter (except subparagraphs (C)(ii) and (D) of section 2(a)(1), except that the Commission and the Securities and Exchange Commission may by rule, regulation, or order jointly exclude any agreement, contract, or transaction from section 2(a)(1)(D)), if the Commission determines that the exemption would be consistent with the public interest.

[43] CEA Section 4(c)(3), 7 U.S.C. 6(c)(3), includes within the term ''appropriate persons'' a number of specified categories of persons deemed appropriate under the CEA for entering into transactions exempted by the Commission under section 4(c). This includes persons the Commission determines to be appropriate in light of their financial or other qualifications, or the applicability of appropriate regulatory protections.

CEA.[44] The Commission may grant such an exemption by rule, regulation or order, after notice and opportunity for hearing, and may do so on application of any person or on its own initiative. Further, the Commission may grant such an exemption either conditionally or unconditionally, or for stated periods within the Commission's discretion. Finally, section 712(f) of the Dodd-Frank Act authorizes the Commission to ''exempt persons, agreements, contracts, or transactions from the provisions of the [Dodd-Frank] Act, under the terms contained in'' the Dodd-Frank Act, in order to prepare for the effective dates of the provisions of Title VII.

In enacting section 4(c), Congress noted that the goal of the provision ''is to give the Commission a means of providing certainty and stability to existing and emerging markets so that financial innovation and market development can proceed in an effective and competitive manner.'' [45] The proposed relief is intended to provide clarity and stability to the markets and market participants concerning the applicability of the provisions of the CEA, as added or amended by the Dodd-Frank Act (in part one), and the current provisions of the CEA as repealed by the Dodd-Frank Act (in part two), upon the general effective date of the Dodd-Frank Act, thereby avoiding or minimizing undue and unwarranted disruptions to the markets.

The Commission notes that the proposed order is temporary in scope and reserves the Commission's anti-fraud and anti-manipulation enforcement authority. As such, the Commission believes that the proposed order would be consistent with the public interest and purposes of the CEA. The Commission also believes the order to be limited to appropriate persons, including persons in current registration categories for which the Dodd-Frank Act expanded the definition to include activities relating to swaps (*e.g.,* introducing brokers, commodity pool operators, commodity trading advisors, and associated persons thereof).[46] The proposed order will not have a material adverse effect on the ability of the Commission or any contract market to discharge its regulatory or self-regulatory duties under the CEA.

The Commission seeks comment on whether the proposed temporary exemptions are consistent with the public interest and other requirements of CEA section 4(c).

IV. Request for Comment

The Commission requests comment on all aspects of this proposed temporary exemptive order.

V. Related Matters

A. Paperwork Reduction Act

The Paperwork Reduction Act (''PRA'') [47] imposes certain requirements on Federal agencies (including the Commission) in connection with conducting or sponsoring any collection of information as defined by the PRA. This proposed temporary exemptive order, if approved, would not require a new collection of information from any persons or entities that would be subject to the proposed order.

B. Cost-Benefit Analysis

Section 15(a) of the CEA [48] requires the Commission to consider the costs and benefits of its action before issuing an order under the CEA. By its terms, section 15(a) does not require the Commission to quantify the costs and benefits of an order or to determine whether the benefits of the order outweigh its costs. Rather, section 15(a) simply requires the Commission to ''consider the costs and benefits'' of its action.

Section 15(a) of the CEA further specifies that costs and benefits shall be evaluated in light of five broad areas of market and public concern: (1) Protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of futures markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations. The Commission may in its discretion give greater weight to any one of the five enumerated areas and could in its discretion determine that, notwithstanding its costs, a particular order is necessary or appropriate to protect the public interest or to effectuate any of the provisions or to accomplish any of the purposes of the CEA.

1. Protection of Market Participants and the Public

As discussed above, the Commission is proposing that the scope of this temporary exemptive relief be limited to persons who are ''appropriate persons'' as set forth in section 4(c) of the Act. Further, this proposal does not affect the Commission's existing and future anti-fraud and anti-manipulation authorities, including CEA sections 2(a)(1)(B), 4b, 4o, 6(c), 6(d), 6c, 8(a), 9(a)(2), or 13, or the regulations of the Commission promulgated pursuant to such authorities, including section 4c(b) proscribing fraud. The Commission believes that market participants and the public will benefit from the clarity offered by the proposed temporary exemptive relief, while maintaining the Commission's authorities regarding the prevention and deterrence of fraud and manipulation. With respect to costs, the Commission believes that the exemptive relief imposes no affirmative duties or obligations on market participants and the public. The temporary exemptive relief does not contain any requirement to create, retain, submit, or disclose any information. Furthermore, the exemptive relief imposes no recordkeeping or related data retention or disclosure requirements on any person, including small businesses. Consequently, the Commission finds it unlikely that the exemptive relief will impose any additional costs beyond the existing costs associated with ongoing operations, including those that ensure that behavior and statements are not fraudulent or manipulative.

2. Efficiency, Competition, and Financial Integrity

Although the Dodd-Frank Act establishes a comprehensive new regulatory framework for swaps, the Commission's work to implement that framework will not be complete as of July 16, 2011. Accordingly, this relief offers the benefit of greater clarity in the swaps market that is in the interest of both the markets and the public. Accordingly, the Commission believes that this temporary exemptive relief is an appropriate measure to facilitate a transition to the comprehensive new regulatory framework for swaps set out in Title VII of the Dodd-Frank Act. Such an orderly transition will promote

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[44] CEA Section 4(c)(2), 7 U.S.C. 6(c)(2), provides in full that:

The Commission shall not grant any exemption under paragraph (1) from any of the requirements of subsection (a) of this section unless the Commission determines that—

(A) The requirement should not be applied to the agreement, contract, or transaction for which the exemption is sought and that the exemption would be consistent with the public interest and the purposes of this Act; and

(B) the agreement, contract, or transaction—

(i) Will be entered into solely between appropriate persons; and

(ii) Will not have a material adverse effect on the ability of the Commission or any contract market or derivatives transaction execution facility to discharge its regulatory or self-regulatory duties under this Act.

[45] House Conf. Report No. 102–978, 1992 U.S.C.C.A.N. 3179, 3213.

[46] *See* CEA section 4(c)(3)(K), 7 U.S.C. 6(c)(3)(K) (appropriate persons may include such ''other persons that the Commission determines to be appropriate in light of their financial or other qualifications, or the applicability of appropriate regulatory protections'').

[47] 44 U.S.C. 3507(d).

[48] 7 U.S.C. 19(a).

market efficiency, competition, and financial integrity.

3. Price Discovery

As stated above, the temporary relief proposed here is designed to maintain the functioning of the markets until such time as the comprehensive new regulatory framework for swaps set forth in the Dodd-Frank Act is in place. With the clarity offered by the proposed exemptive relief, markets would function better as venues for price discovery.

4. Sound Risk Management Practices

Appropriate persons covered by this proposal would be subject to the Commission's full array of existing anti-fraud and anti-market manipulation provisions and certain new authorities provided under the Dodd-Frank Act. Market participants and the public will benefit substantially from the continuing protection through the prevention and deterrence of fraud and manipulation. Markets protected from fraud and manipulation function better as venues for price discovery and risk management.

5. Other Public Interest Considerations

The proposed exemptive order is temporary and limited. It would not affect the applicability of any provision of the CEA to futures contracts, options on futures contracts, or transactions with retail customers in foreign currency or other commodities pursuant to CEA section 2(c)(2). Further, it would expire at an appropriate date, as discussed above. The expiration provision would permit the Commission to ensure that the scope and extent of exemptive relief is appropriately tailored to the schedule of implementation of the Dodd-Frank Act requirements.

After considering these factors, the Commission has determined to seek comment on the proposed temporary exemptive order, as discussed above. The Commission seeks comment on all aspects of the foregoing proposed application of the cost-benefit considerations set forth in CEA section 15(a). Commenters also are invited to submit any data or other information that they may have quantifying or qualifying the costs and benefits of the proposal with their comment letters.

Issued in Washington, DC, on June 14, 2011 by the Commission.

David A. Stawick,

Secretary of the Commission.

Appendices to Effective Date for Swap Regulation—Commission Voting Summary and Statements of Commissioners

Note: The following appendices will not appear in the Code of Federal Regulations.

Appendix 1—Commission Voting Summary

On this matter, Chairman Gensler and Commissioners Dunn, Sommers, Chilton and O'Malia voted in the affirmative; no Commissioner voted in the negative.

Appendix 2—Statement of Chairman Gary Gensler

I support the proposed order regarding the effective dates of certain Dodd-Frank Act provisions.

The Dodd-Frank Act has a deadline of 360 days after enactment for completion of the bulk of our rulemakings—July 16, 2011. Both the Dodd-Frank Act and the Commodity Exchange Act (CEA) give the CFTC the flexibility and authority to address the issues relating to the effective dates of Title VII. We have coordinated closely with the SEC on these issues.

Section 754 of the Dodd-Frank Act states that Subtitle A of Title VII—the Subtitle that provides for the regulation of swaps—''shall take effect on the later of 360 days after the date of the enactment of this subtitle or, to the extent a provision of this subtitle requires a rulemaking, not less than 60 days after publication of the final rule or regulation implementing such provisions of this subtitle.''

Thus, those provisions that require rulemakings will not go into effect until the CFTC finalizes the respective rules. This is a substantial portion of the derivatives provisions under Dodd-Frank. Furthermore, they will only go into effect based on the phased implementation dates included in the final rules. Today we are releasing a list of the provisions of the swaps subtitle that require rulemakings.

There are other provisions of Title VII that do not require rulemaking and will take effect on July 16. The proposed order that we are considering today would provide relief until December 31, 2011, or when the definitional rulemakings become effective, whichever is sooner, from certain provisions that would otherwise apply to swaps or swap dealers on July 16. This includes provisions that do not directly rely on a rule to be promulgated, but do refer to terms that must be further defined by the CFTC and SEC, such as ''swap'' and ''swap dealer.''

The proposed order also would provide relief through no later than December 31, 2011, from certain CEA requirements that may result from the repeal, effective on July 16, 2011, of some of sections 2(d), 2(e), 2(g), 2(h) and 5d.

There have been suggestions to delay implementation of the derivatives reforms included in the Dodd-Frank Act. That is not what today's proposed order is. Instead, it provides the time necessary for the Commission to complete the rulemaking process to implement the Dodd-Frank Act.

Some might ask: Why six months? Six months will provide the Commission with the opportunity to re-examine the status of final rulemaking in light of the changed regulatory landscape at the time. It would allow us, if appropriate at the time, to tailor relief from certain provisions of the Dodd-Frank Act at the end of the year.

It is important to note, however, that until the CFTC completes its rule-writing process and implements and enforces those new rules, the public remains unprotected.

Appendix 3—Statement of Commissioner Bart Chilton

I concur with the Commission's decision today to provide needed relief with regard to provisions of the Wall Street Reform and Consumer Protection Act that go into effect on July 16, 2011. I believe, however, that the precise nature of this relief must be developed utilizing an iterative process with affected parties to ensure that essential legal certainty is provided to the markets and to market participants. I will not support any final rule on this issue that does not provide clear and unequivocal guidance regarding the legality of transactions and the required responsibilities under the Act. In addition, this relief must be issued promptly, in order to ensure that there is no gap in the effective date of the Act's provisions and the common understanding of the effectiveness of those dates.

[FR Doc. 2011–15195 Filed 6–15–11; 4:15 pm]

BILLING CODE 6351–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 175 and 183

[Docket No. USCG–2009–0206]

RIN 1825–AB34

Installation and Use of Engine Cut-Off Switches on Recreational Vehicles

Correction

Proposed Rule document 2011–14140 was inadvertently published in the Rules section of the issue of June 8, 2011, beginning on page 33161. It should have appeared in the Proposed Rules section.

[FR Doc. 2011–15122 Filed 6–16–11; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 334

Archers Creek, Ribbon Creek, and Broad River; U.S. Marine Corps Recruit Depot, Parris Island, SC; Danger Zone

AGENCY: United States Army Corps of Engineers, Department of Defense.

ACTION: Notice of proposed rulemaking and request for comments.

SUMMARY: The U.S. Army Corps of Engineers (Corps) is proposing to amend its regulations for two existing danger zones that are located adjacent to the rifle range and pistol range at the U.S. Marine Corps Recruit Depot Parris Island in Beaufort County, South Carolina. These danger zones were established in the 1960s. The proposed amendments include reformatting the existing regulations for clarity, modifying the boundaries of the danger zones, and modifying the hours of range operations from 6:30 a.m. to 5 p.m. to 6 a.m. to 5 p.m. Monday through Friday. These amendments will enhance the ability of the U.S. Marine Corps to provide for the safe operation of the existing rifle and pistol ranges.

DATES: Written comments must be received on or before July 18, 2011.

ADDRESSES: You may submit comments, identified by docket number COE–2011–0010, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

E-mail: david.b.olson@usace.army.mil. Include the docket number, COE–2011–0010, in the subject line of the message.

Mail: U.S. Army Corps of Engineers, Attn: CECW–CO–R (David B. Olson), 441 G Street, NW., Washington, DC 20314–1000.

Hand Delivery/Courier: Due to security requirements, we cannot receive comments by hand delivery or courier.

Instructions: Direct your comments to docket number COE–2011–0010. All comments received will be included in the public docket without change and may be made available on-line at *http://www.regulations.gov,* including any personal information provided, unless the commenter indicates that the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI, or otherwise protected, through regulations.gov or e-mail. The regulations.gov Web site is an anonymous access system, which means we will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail directly to the Corps without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, we recommend that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If we cannot read your comment because of technical difficulties and cannot contact you for clarification, we may not be able to consider your comment. Electronic comments should avoid the use of any special characters, any form of encryption, and be free of any defects or viruses.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.* All documents in the docket are listed. Although listed in the index, some information is not publicly available, such as CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form.

FOR FURTHER INFORMATION CONTACT: Mr. David B. Olson, Headquarters, Operations and Regulatory Community of Practice, Washington, DC at 202–761–4922 or Mr. Nathaniel I. Ball, U.S. Army Corps of Engineers, Charleston District, Regulatory Division, at 843–329–8047.

SUPPLEMENTARY INFORMATION: Pursuant to its authorities in Section 7 of the Rivers and Harbors Act of 1917 (40 Stat 266; 33 U.S.C. 1) and Chapter XIX of the Army Appropriations Act of 1919 (40 Stat 892; 33 U.S.C. 3) the Corps is proposing to amend the regulations in 33 CFR part 334 by modifying the regulations for existing danger zones that are located immediately adjacent to the U.S. Marine Corps Recruit Depot at Parris Island, South Carolina. The proposed modifications to the regulations are described below.

The proposed modifications include reformatting the existing regulations to describe the areas, the regulations, and enforcement. The proposed format is consistent with other danger zone regulations and provides greater clarity. The boundaries of both areas have been modified to incorporate modern methods of measuring ballistic footprints and design criteria for range construction. Since the proposed changes to the boundaries of the areas are relatively minor, the existing live fire warning signs will continue to be used to ensure safe navigation in the vicinity of the rifle and pistol ranges.

The proposed regulations allow the Commanding General, U.S. Marine Corps Recruit Depot, Parris Island South Carolina Director, to restrict passage of persons, vessels and other watercraft in navigable waters adjacent to the existing rifle range and pistol range between the hours of 6 a.m. and 5 p.m. Monday through Friday, and from 6 a.m. to 12 p.m. on Saturdays, National holidays excepted, and at other times as designated and properly published by the Commanding General, U.S. Marine Corps Recruit Depot Parris Island.

The proposed regulations would result in an increase in the hours of operation from 6:30 a.m. to 5 p.m., to 6 a.m. to 5 p.m. Monday through Friday. Existing procedures for publishing any temporary changes in the hours of operation include sending a notice to local news sources, marinas, and fishing shops. The public will continue to be able to use these portions of Archers Creek, Ribbon Creek, and the Broad River when the rifle and pistol ranges are not in use.

Procedural Requirements

a. *Review Under Executive Order 12866.* This proposed rule is issued with respect to a military function of the Department of Defense and the provisions of Executive Order 12866 do not apply.

b. *Review Under the Regulatory Flexibility Act.* The proposed rule has been reviewed under the Regulatory Flexibility Act (Pub. L. 96–354) which requires the preparation of a regulatory flexibility analysis for any regulation that will have a significant economic impact on a substantial number of small entities (i.e., small businesses and small governments). The Corps determined that this regulation would have little or no economic impact on the public nor would it result in any anticipated navigational hazard or interference with existing waterway traffic. This regulation will have no significant economic impact on small entities.

c. *Review Under the National Environmental Policy Act.* Due to the administrative nature of this action and because there is no intended change in the use of the area, the Corps expects that this regulation, if adopted, will not have a significant impact to the quality of the human environment and,

therefore, preparation of an environmental impact statement will not be required. An environmental assessment will be prepared after the public notice period is closed and all comments have been received and considered. It will be available from the District office listed at the end of **FOR FURTHER INFORMATION CONTACT,** above.

d. *Unfunded Mandates Act.* This proposed rule does not impose an enforceable duty among the private sector and, therefore, is not a Federal private sector mandate and is not subject to the requirements of Section 202 or 205 of the Unfunded Mandates Reform Act (Pub. L. 104–4, 109 Stat. 48, 2 U.S.C. 1501 *et seq.*). We have also found under Section 203 of the Act, that small governments will not be significantly or uniquely affected by this regulation.

List of Subjects in 33 CFR Part 334

Danger zones, Navigation (water), Restricted areas, Waterways.

For the reasons set out in the preamble, the Corps proposes to amend 33 CFR part 334 as follows:

PART 334—DANGER ZONE AND RESTRICTED AREA REGULATIONS

1. The authority citation for part 334 continues to read as follows:

Authority: 40 Stat. 266 (33 U.S.C. 1) and 40 Stat. 892 (33 U.S.C. 3).

2. Revise § 334.480 to read as follows:

§ 334.480 Archers Creek, Ribbon Creek, and Broad River; U.S. Marine Corps Recruit Depot, Parris Island, South Carolina; danger zones.

(a) *The areas.* (1) The danger zone on Archers Creek (between the Broad River and Beaufort River), Ribbon Creek, and the Broad River shall encompass all navigable waters of the United States, as defined at 33 CFR part 329, adjacent to the existing rifle range. This area is bounded by a line connecting the following coordinates: Commencing from the shoreline at the southernmost portion of the area, at latitude 32°19′59″ N, longitude 80°42′54″ W, thence to a point at latitude 32°20′05″ N, longitude 80°43′16″ W, thence to a point at latitude 32°21′40″ N, longitude 80°44′54″ W, thence to a point at latitude 32°22′20″ N, longitude 80°43′52″ W, thence to a point on the shoreline at latitude 32°21′34″ N, longitude 80°42′48″ W, thence follow the mean high water line southwesterly around Horse Island approximately 2.3 nautical miles to a point at latitude to latitude 32°21′22″ N, longitude 80°42′30″ W, thence to a point on the shoreline at latitude 32°20′56″ N, longitude 80°41′50″ W, thence follow the mean high water line southwesterly approximately 2.2 nautical miles to terminate at the southernmost portion of the area.

(2) The danger zone on the Broad River shall encompass all navigable waters of the United States, as defined at 33 CFR part 329, adjacent to the existing pistol range. This area is bounded by a line connecting the following coordinates: Commencing from the shoreline at the easternmost portion of the area, at latitude 32°19′36″ N, longitude 80°42′34″ W, thence to a point at latitude 32°19′23″ N, longitude 80°42′50″ W, thence to a point at latitude 32°19′06″ N, longitude 80°43′31″ W, thence to a point at latitude 32°19′28″ N, longitude 80°43′54″ W, thence to a point at latitude 32°19′59″ N, longitude 80°43′28″ W, thence to a point on the shoreline at latitude 32°20′10″ N, longitude 80°43′10″ W, and thence follow the mean high water line southeasterly approximately 0.75 nautical miles to terminate at the easternmost portion of the area.

(b) *The regulations.* (1) All persons, vessels, or other watercraft are prohibited from entering, transiting, anchoring, or drifting within the danger zones described in paragraph (a) of this section when the adjacent rifle or pistol ranges on Parris Island are in use.

(2) Firing over these ranges will normally take place between the hours of 6 a.m. and 5 p.m., Monday through Friday, and from 6 a.m. to 12 p.m. on Saturday, National holidays excepted, and at other times as designated and properly published by the Commanding General, U.S. Marine Corps Recruit Depot Parris Island.

(3) Warning signs indicating the periods when the rifle range is in use will be posted by the entrances to Archers Creek and Ribbon Creek. In addition, warning signs will be placed along the shoreline on the Broad River near the upstream and downstream boundaries of both the rifle range and the pistol range.

(4) Warning flags shall be flown from the top of the lookout tower and on the rifle range and pistol range during actual firing. In addition, a sentry lookout will be on duty during actual firing and a patrol boat will be accessible for clearing the area and warning all approaching vessels of the danger zone and the schedule of firing.

(5) During storms or similar emergencies these areas shall be opened to vessels to reach safety without undue delay for the preservation of life and property.

(c) *Enforcement.* The regulations in this section shall be enforced by the Commanding General, U.S. Marine Corps Recruit Depot Parris Island and/or such persons or agencies as he/she may designate.

Dated: June 10, 2011.

Michael G. Ensch,

Chief, Operations and Regulatory, Directorate of Civil Works.

[FR Doc. 2011–15091 Filed 6–16–11; 8:45 am]

BILLING CODE 3720–58–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2010–1024; FRL–9320–4]

Approval and Promulgation of Air Quality Implementation Plans; Indiana; Prevention of Significant Deterioration Greenhouse Gas Tailoring Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a draft revision to the Indiana State Implementation Plan (SIP), submitted by the Indiana Department of Environmental Management (IDEM) to EPA on December 3, 2010, for parallel processing. The proposed SIP revision modifies Indiana's Prevention of Significant Deterioration (PSD) program to establish appropriate emission thresholds for determining which new stationary sources and modification projects become subject to Indiana's PSD permitting requirements for their greenhouse gas (GHG) emissions. EPA is proposing approval of Indiana's December 3, 2010, SIP revision because the Agency has made the preliminary determination that this SIP revision is in accordance with the Clean Air Act (CAA) and EPA regulations regarding PSD permitting for GHGs.

DATES: Comments must be received on or before July 18, 2011.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2010–1024, by one of the following methods:

1. *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.

2. *E-mail: blakley.pamela@epa.gov.*

3. *Fax:* (312) 692–2450.

4. *Mail:* Pamela Blakley, Chief, Air Permits Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

5. *Hand Delivery:* Pamela Blakley, Chief, Air Permits Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R05–OAR–2010–1024. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional instructions on submitting comments, go to Section I of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. We recommend that you telephone Sam Portanova, Environmental Engineer, at (312) 886–3189 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Sam Portanova, Environmental Engineer, Air Permits Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–3189, *portanova.sam@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. This supplementary information section is arranged as follows:

I. What should I consider as I prepare my comments for EPA?

When submitting comments, remember to:

1. Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).

2. Follow directions—EPA may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

3. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

4. Describe any assumptions and provide any technical information and/or data that you used.

5. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

6. Provide specific examples to illustrate your concerns, and suggest alternatives.

7. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

8. Make sure to submit your comments by the comment period deadline identified.

II. Indiana's Submittal for Parallel Processing

On December 3, 2010, IDEM submitted a draft SIP revision request to EPA to establish appropriate emission thresholds for determining which new or modified stationary sources become subject to Indiana's PSD permitting requirements for GHG emissions. Final approval of this SIP revision request will be consistent with the provisions of EPA's Tailoring Rule,[1] which established appropriate GHG emission thresholds for determining the applicability of PSD requirements to GHG-emitting sources, ensuring that smaller GHG sources emitting less than these thresholds are not subject to permitting requirements. Pursuant to section 110 of the CAA, EPA is proposing to approve this revision into the Indiana SIP.

Because this draft SIP revision is not yet state-effective, Indiana requested that EPA ''parallel process'' the SIP revision. Under this procedure, the EPA Regional Office works closely with the state while developing new or revised regulations. Generally, the state submits a copy of the proposed regulation or other revisions to EPA before concluding its rulemaking process. EPA reviews this proposed state action and prepares a proposed rulemaking action. EPA publishes this proposed rulemaking in the **Federal Register** and solicits public comment in approximately the same timeframe during which the state finalizes its rulemaking process.

After Indiana submits the formal state-effective SIP revision request, EPA will prepare a final rulemaking action for the SIP revision. If changes are made to the SIP revision after EPA's proposed rulemaking, such changes must be acknowledged in EPA's final rulemaking action. If the changes are significant, then EPA may be obliged to repropose the action.

III. What is the background for this proposed action?

This section briefly summarizes EPA's recent GHG-related actions that provide the background for this proposed action. More detailed discussion of the background is found in the preambles for those actions. In particular, the background is contained in what we call the GHG PSD SIP Narrowing Rule,[2] and in the preambles to the actions it cites.

[1] ''Prevention of Significant Deterioration and Title V Greenhouse Gas Tailoring Rule; Final Rule.'' 75 FR 31514 (June 3, 2010).

[2] ''Limitation of Approval of Prevention of Significant Deterioration Provisions Concerning

Continued

A. GHG-Related Actions

EPA has recently undertaken a series of actions pertaining to the regulation of GHGs that, although for the most part distinct from one another, establish the overall framework for this proposed action on the Indiana SIP. Four of these actions include, as they are commonly called, the ''Endangerment Finding'' and ''Cause or Contribute Finding,'' which EPA issued in a single final action,[3] the ''Johnson Memo Reconsideration,'' [4] the ''Light-Duty Vehicle Rule,'' [5] and the ''Tailoring Rule.'' Taken together and in conjunction with the CAA, these actions established regulatory requirements for GHGs emitted from new motor vehicles and new motor vehicle engines; determined that such regulations, when they took effect on January 2, 2011, subjected GHGs emitted from stationary sources to PSD requirements; and limited the applicability of PSD requirements to GHG sources on a phased-in basis. EPA took this last action in the Tailoring Rule, which, more specifically, established appropriate GHG emission thresholds for determining the applicability of PSD requirements to GHG-emitting sources.

PSD is implemented through the SIP system, and so in December 2010, EPA promulgated several rules to implement the new GHG PSD SIP program. Recognizing that some states had approved SIP PSD programs that did not apply PSD to GHGs, EPA issued a SIP call and, for some of these states, a Federal Implementation Plan (FIP).[6] Recognizing that other states had approved SIP PSD programs that do apply PSD to GHGs, but that do so for sources that emit as little as 100 or 250 tons per year (tpy) of GHG, and that do not limit PSD applicability to GHGs to the higher thresholds in the Tailoring Rule, EPA issued the GHG PSD SIP Narrowing Rule. Under that rule, EPA withdrew its approval of the affected SIPs to the extent those SIPs covered GHG-emitting sources below the Tailoring Rule thresholds. EPA based its action primarily on the ''error correction'' provisions of CAA section 110(k)(6).

B. Indiana's Actions

On July 23, 2010, Indiana provided a letter to EPA, in accordance with a request to all states from EPA in the Tailoring Rule, with confirmation that the state has the authority to regulate GHGs in its PSD program. The letter also confirmed that current Indiana rules require regulating GHGs at the existing 100/250 tpy threshold, rather than at the higher thresholds set in the Tailoring Rule. See the docket for this proposed rulemaking for a copy of Indiana's letter.

In the SIP Narrowing Rule, published on December 30, 2010, EPA withdrew its approval of Indiana's SIP, among other SIPs, to the extent that SIP applies PSD permitting requirements to GHG emissions from sources emitting at levels below those set in the Tailoring Rule.[7] As a result, Indiana's current approved SIP provides the state with authority to regulate GHGs, but only at and above the Tailoring Rule thresholds; and Federally requires new and modified sources to receive a PSD permit based on GHG emissions only if they emit at or above the Tailoring Rule thresholds.

Indiana is currently in the process of amending its state regulations to also incorporate the Tailoring Rule thresholds, and has submitted its draft regulations to EPA for parallel processing. Indiana is seeking to revise its SIP to incorporate expected state regulatory changes adopted at the local level into the Federally-approved SIP. Doing so will clarify the applicable thresholds in the Indiana SIP.

The basis for this SIP revision is that limiting PSD applicability to GHG sources to the higher thresholds in the Tailoring Rule is consistent with the SIP provisions that provide required assurances of adequate resources, and thereby addresses the flaw in the SIP that led to the SIP Narrowing Rule. Specifically, CAA section 110(a)(2)(E) includes as a requirement for SIP approval that states provide ''necessary assurances that the State * * * will have adequate personnel [and] funding * * * to carry out such [SIP].'' In the Tailoring Rule, EPA established higher thresholds for PSD applicability to GHG-emitting sources on grounds that the states generally did not have adequate resources to apply PSD to GHG-emitting sources below the Tailoring Rule thresholds,[8] and no state, including Indiana, asserted that it did have adequate resources to do so.[9]

In the SIP Narrowing Rule, EPA found that the affected states, including Indiana, had a flaw in their SIPs at the time they submitted their PSD programs, which was that the applicability of the PSD programs was potentially broader than the resources available to them under their SIP.[10] Accordingly, for each affected state, including Indiana, EPA concluded that EPA's action in approving the SIP was in error, under CAA section 110(k)(6), and EPA rescinded its approval to the extent the PSD program applies to GHG-emitting sources below the Tailoring Rule thresholds.[11] EPA recommended that states adopt a SIP revision to incorporate the Tailoring Rule thresholds, thereby (i) assuring that under state law, only sources at or above the Tailoring Rule thresholds would be subject to PSD; and (ii) avoiding confusion under the Federally-approved SIP by clarifying that the SIP applies to only sources at or above the Tailoring Rule thresholds.[12]

IV. What is EPA's analysis of Indiana's proposed SIP revision?

The regulatory revisions that IDEM submitted for parallel processing on December 3, 2010, establish thresholds for determining which stationary sources and modifications become subject to permitting requirements for GHG emissions under Indiana's PSD program. Specifically, the submittal includes changes to Indiana's PSD

Greenhouse Gas Emitting-Sources in State Implementation Plans; Final Rule.'' 75 FR 82536 (December 30, 2010).

[3] ''Endangerment and Cause or Contribute Findings for Greenhouse Gases Under Section 202(a) of the Clean Air Act.'' 74 FR 66496 (December 15, 2009).

[4] ''Interpretation of Regulations that Determine Pollutants Covered by Clean Air Act Permitting Programs.'' 75 FR 17004 (April 2, 2010).

[5] ''Light-Duty Vehicle Greenhouse Gas Emission Standards and Corporate Average Fuel Economy Standards; Final Rule.'' 75 FR 25324 (May 7, 2010).

[6] Specifically, by notice dated December 13, 2010, EPA finalized a ''SIP Call'' that would require those states with SIPs that have approved PSD programs but do not authorize PSD permitting for GHGs to submit a SIP revision providing such authority. ''Action To Ensure Authority To Issue Permits Under the Prevention of Significant Deterioration Program to Sources of Greenhouse Gas Emissions: Finding of Substantial Inadequacy and SIP Call,'' 75 FR 77698 (Dec. 13, 2010). EPA has begun making findings of failure to submit that would apply in any state unable to submit the required SIP revision by its deadline, and finalizing FIPs for such states. *See, e.g.,* ''Action To Ensure Authority To Issue Permits Under the Prevention of Significant Deterioration Program to Sources of Greenhouse Gas Emissions: Finding of Failure To Submit State Implementation Plan Revisions Required for Greenhouse Gases,'' 75 FR 81874 (December 29, 2010); ''Action To Ensure Authority To Issue Permits Under the Prevention of Significant Deterioration Program to Sources of Greenhouse Gas Emissions: Federal Implementation Plan,'' 75 FR 82246 (December 30, 2010). Because Indiana's SIP already authorizes Indiana to regulate GHGs once GHGs become subject to PSD requirements on January 2, 2011, Indiana is not subject to the proposed SIP Call or FIP.

[7] ''Limitation of Approval of Prevention of Significant Deterioration Provisions Concerning Greenhouse Gas Emitting-Sources in State Implementation Plans; Final Rule.'' 75 FR 82536 (December 30, 2010).

[8] Tailoring Rule, 75 FR 31,517/1.

[9] SIP Narrowing Rule, 75 FR 82,540/2.

[10] *Id.* at 82,542/3.

[11] *Id.* at 82,544/1.

[12] *Id.* at 82,540/2.

regulations at 326 Indiana Administrative Code (IAC) 2–2–1 and 326 IAC 2–2–4.[13]

Indiana is currently a SIP-approved state for the PSD program, and has incorporated EPA's 2002 NSR reform revisions (67 FR 80186) for PSD into its SIP (72 FR 33395). In a letter provided to EPA on July 23, 2010, Indiana notified EPA of its interpretation that the state currently has the authority to regulate GHGs under its 326 IAC 2–2 PSD regulations. The current Indiana program (adopted prior to the promulgation of EPA's Tailoring Rule) applies to major stationary sources (having the potential to emit at least 100 tpy or 250 tpy or more of a regulated NSR pollutant, depending on the type of source) or modifications undertaken in areas designated attainment or unclassifiable with respect to the NAAQS.

Indiana has revised 326 IAC 2–2–1 to add GHG-related language to the definitions of ''regulated NSR pollutant'' and ''significant'' and to add a new definition for ''subject to regulation.'' We find these revisions to be consistent with the Tailoring Rule.

In 326 IAC 2–2–4, Indiana has added language that says the air quality analysis requirements of this section shall not apply with respect to GHGs. This does not affect the air quality-related requirements elsewhere in the PSD rule, including requirements for source information (326 IAC 2–2–10), additional impact analysis (326 IAC 2–2–7), or additional requirements for sources impacting Federal Class I areas (326 IAC 2–2–14). We find this revision to be approvable.

V. What action is EPA taking?

EPA is proposing to approve Indiana's December 3, 2010, SIP submittal, relating to PSD requirements for GHG-emitting sources in 326 IAC 2–2–1 and 326 IAC 2–2–4. Specifically, Indiana's December 3, 2010, proposed SIP revision establishes appropriate emissions thresholds for determining PSD applicability to new and modified GHG-emitting sources in accordance with EPA's Tailoring Rule. EPA has made the preliminary determination that this SIP submittal is approvable because it is in accordance with the CAA and EPA regulations regarding PSD permitting for GHGs.

[13] Attachment A to the December 3, 2010, submittal includes revisions to 326 IAC 2–7 to add GHG provisions to Indiana's Title V regulations. However, these regulations are not part of the SIP and IDEM has not included 326 IAC 2–7 in the December 3, 2010, request for SIP approval. IDEM intends to make a separate submittal requesting approval of the 326 IAC 2–7 regulatory revisions.

If EPA does approve Indiana's changes to its air quality regulations to incorporate the appropriate thresholds for GHG permitting applicability into Indiana's SIP, then 40 CFR 52.773(k), as included in EPA's SIP Narrowing Rule, which codifies EPA's limiting its approval of Indiana's PSD SIP to not cover the applicability of PSD to GHG-emitting sources below the Tailoring Rule thresholds, is no longer necessary. In this proposed action, EPA is also proposing to amend 40 CFR 52.773 to remove this unnecessary regulatory language.

VI. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have Tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on Tribal governments or preempt Tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, and Reporting and recordkeeping requirements.

Dated: June 9, 2011.

Susan Hedman,

Regional Administrator, Region 5.

[FR Doc. 2011–15102 Filed 6–16–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Chapter I

[EPA–HQ–OPP–2010–0197; FRL–8877–9]

RIN 2070–ZA11

Pesticides; Policies Concerning Products Containing Nanoscale Materials; Opportunity for Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed policy statement.

SUMMARY: EPA seeks comment on several possible approaches for obtaining information about what nanoscale materials are present in registered pesticide products. Under one approach, EPA would use section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to obtain information regarding what nanoscale material is present in a registered pesticide product and its potential effects on humans or the environment. If EPA adopts this approach, 40 CFR 152.50(f)(3) would also require the inclusion of such information with any application for registration of a pesticide product that contains a nanoscale material. Under an alternative approach, EPA would obtain such information using Data Call-In notices (DCIs) under FIFRA section 3(c)(2)(B). If EPA adopts this alternate approach, EPA would also

need to require the inclusion of this information with any application for registration of a pesticide product that contains a nanoscale material. It is EPA's view that FIFRA section 6(a)(2) is the most efficient and expedient administrative approach to obtaining information about nanoscale materials in pesticides and EPA would prefer to use this approach. EPA is also proposing a new approach for how EPA will determine on a case-by-case basis whether a nanoscale active or inert ingredient is a ''new'' active or inert ingredient for purposes of FIFRA and the Pesticide Registration Improvement Act (PRIA), even when an identical, non-nanoscale form of the nanoscale ingredient is already registered.

DATES: Comments must be received on or before July 18, 2011.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2010–0197, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2010–0197. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Jed Costanza, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 347–0204; fax number: (703) 308–8005; e-mail address: *costanza.jed@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. What is this document about?

This document describes several possible approaches for obtaining certain additional information on the composition of pesticide products. The notice focuses particularly on information about what nanoscale materials are present in registered pesticide products. In connection with this document, EPA describes ''nanoscale material'' as an active or inert ingredient and any component parts thereof intentionally produced to have at least one dimension that measures between approximately 1 and 100 nanometers (nm).

Under one approach, EPA would use section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to obtain information regarding what nanoscale material is present in a registered pesticide product and its potential effects on humans or the environment. If EPA adopts this approach, 40 CFR 152.50(f)(3) would also require the inclusion of such information with any application for registration of a pesticide product that contains a nanoscale material.

Under an alternative approach, EPA would obtain such information using Data Call-In notices (DCIs) under FIFRA section 3(c)(2)(B). If EPA adopts this alternate approach, EPA would also need to require the inclusion of this information with any application for registration of a pesticide product that contains a nanoscale material. EPA is reviewing whether this could be done under existing regulations or whether EPA would need to amend existing regulations to clarify that the information is required with any application for registration.

It is EPA's view that FIFRA section 6(a)(2) is the most efficient and expedient administrative approach to obtaining information about nanoscale materials in pesticides and EPA would prefer to use this approach.

This document also proposes a new approach for how EPA will determine on a case-by-case basis whether a nanoscale active or inert ingredient is a ''new'' active or inert ingredient for purposes of FIFRA and the Pesticide Registration Improvement Act (PRIA), even when an identical, non-nanoscale form of the nanoscale ingredient is already registered.

After considering any public comments on the use of FIFRA section 6(a)(2) or DCIs under FIFRA section 3(c)(2)(B), as well as public comments submitted in response to other questions posed in this document, EPA plans to issue a subsequent document in the **Federal Register** announcing its approach to gather this information. EPA is also asking for specific input on the proposed approach for determining whether a nanoscale material is ''new'' under FIFRA and PRIA.

B. Does this action apply to me?

This action is directed to those persons who manufacture, distribute, sell, apply, or regulate pesticide products, including agricultural, commercial, and residential products (NAICS codes 32532 and 32561). This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not

listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

C. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Applicable Statutory and Regulatory Requirements

As a general matter, pesticides may not be sold or distributed in the United States unless they are registered with EPA. FIFRA section 3(a) (7 U.S.C. 136a(a)). In order to obtain a pesticide registration, an applicant must provide EPA with data (or cite existing data) demonstrating that the proposed registration complies with the requirement for registration. FIFRA section 3(c)(1)(F) (7 U.S.C. 136a(c)(1)(F)). FIFRA contains two provisions under which EPA may register pesticides: Section 3(c)(5) for ''unconditional'' registration and section 3(c)(7) for ''conditional'' registration (7 U.S.C. 136a(c)(5) and 7 U.S.C. 136a(c)(7)). Importantly, EPA must make statutorily required findings for each and every pesticide product for which registration is sought, regardless of whether another pesticide product with the same or similar composition and use patterns is already registered.

The standard for determining whether an application should be granted unconditionally is found in FIFRA section 3(c)(5). This section provides that, in order to grant a registration, EPA must find that a product's composition warrants the proposed claims for it; that the product's labeling and other material required to be submitted comply with FIFRA; that the product will perform its intended function without causing unreasonable adverse effects on the environment; and that, when used in accordance with widespread and commonly recognized practice, the product will not cause unreasonable adverse effects on the environment.

FIFRA defines ''unreasonable adverse effects on the environment'' as including ''any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.'' FIFRA section 2(bb) (7 U.S.C. 136(bb)). Thus, a critical aspect of determining whether or not a pesticide product should be granted a registration is an evaluation of whether the benefits associated with the use of a pesticide outweigh the risks associated with such use. The burden of demonstrating that a product meets the standards for registration rests at all times on the registrant or applicant for registration. See, *e.g., Industrial Union Dept.* v. *American Petroleum Institute,* 448 U.S. 607, 653 n. 61 (1980); *Environmental Defense Fund* v. *EPA,* 510 F.2d 1292, 1297, 1302 (DC Cir. 1975).

The Agency has promulgated regulations in 40 CFR parts 158 and 161 which identify the types of data EPA expects an applicant to provide to support an application for registration of a pesticide product. The Agency requires a wide variety of studies in order to evaluate whether a pesticide will cause unreasonable adverse effects on the environment. These required studies include both toxicity tests and data to characterize exposure to a pesticide, including extensive information on a product's composition, and its fate in the environment and within the human body. For certain pesticides EPA also requires data on product efficacy.

If an applicant cannot provide necessary data for EPA to make the determinations required to register a product unconditionally under FIFRA section 3(c)(5), EPA may still be able to register the product ''conditionally'' under FIFRA section 3(c)(7). FIFRA section 3(c)(7) authorizes EPA to register a pesticide product on the condition that the applicant provides additional data necessary to support a finding that the product meets the statutory standards in FIFRA section 3(c)(5). FIFRA section 3(c)(7) authorizes conditional registration in three circumstances. First, the Agency may conditionally register a product if EPA determines, among other things, that the product is identical or substantially similar to a currently registered pesticide or differs only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and that approving the registration in the manner proposed would not significantly increase the risk of any unreasonable adverse effect on the environment. FIFRA section 3(c)(7)(A) (7 U.S.C. 136a(c)(7)(A)). Products approved under this authority are commonly called ''me-too registrations.'' Second, EPA may register a pesticide for an additional use, if the applicant provides data to evaluate the safety of the new use, and use of the product would not significantly increase the risk of unreasonable adverse effects on the environment compared to products already registered. FIFRA section 3(c)(7)(B) (7 U.S.C. 136a(c)(7)(B)). These product approvals are referred to as ''new use'' registrations. Finally, EPA may conditionally register a pesticide product that contains an active ingredient not present in any currently registered pesticide product, if the Administrator determines that:

1. The applicant has provided all data necessary to evaluate the safety of the pesticide, with the exception of any data which are lacking because the applicant has not had enough time to generate the data since learning of the requirement;

2. Use of the pesticide during the time period needed to develop the additional data will not cause unreasonable adverse effects on the environment; and

3. Use of the pesticide is in the public interest.

FIFRA section 3(c)(7)(C) (7 U.S.C. 136a(c)(7)(C)).

As with applications for unconditional registrations, applicants for conditional registration bear the burden at all times of demonstrating that the statutory standards are met.

The Agency's interest in data to evaluate the risks and benefits of a pesticide does not necessarily end once EPA has registered a pesticide product. Accordingly, other provisions of FIFRA allow the Agency to require pesticide registrants to develop and submit information the Agency believes it needs in order to maintain the registration of pesticide products.

A. DCI

Under FIFRA section 3(c)(2)(B), EPA may send a DCI notice to a registrant requiring the registrant to provide additional data or other information, which the registrant may need to generate or compile. Specifically, ''if the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide, the Administrator shall notify all existing registrants of the pesticide to which the determination relates and provide a list of such registrants to any interested person.'' Failure to respond to the DCI can serve as the basis for suspending the registration of the product, thereby making it unlawful for the registrant to sell or distribute the pesticide.

Generally, EPA's determination that additional data are needed is contemplated to occur for one of the following five reasons:

1. *The Re-registration Program.* Section 4 of FIFRA requires EPA to re-assess the health and safety data for all pesticide active ingredients registered before November 1, 1984, to determine whether these ''older'' pesticides meet the criteria for registration that would be expected of a pesticide being registered today for the first time. Section 4 of FIFRA directs EPA to use section 3(c)(2)(B) authority to obtain the required data.

2. *The Registration Review Program.* Section 3(g) of FIFRA contains provisions to help achieve the goal of reviewing each pesticide every 15 years to assure that the pesticide continues to pose no risk of unreasonable adverse effects on human health or the environment. Section 3(g) instructs EPA to use the section 3(c)(2)(B) authority to obtain the required data.

3. *Anticipated Residue/Percent Crop Treated Information.* Under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), before a pesticide may be used on food or feed crops, the Agency must establish a tolerance for the pesticide residues on that crop or establish an exemption from the requirement to have a tolerance. Section 408(b)(2)(E) and (F) of FFDCA authorize the use of anticipated or actual residue (AR) data and percent crop treated (PCT) data to establish, modify, maintain, or revoke a tolerance for a pesticide. FFDCA requires that if AR data are used, data must be reviewed 5 years after a tolerance is initially established.

4. *The Special Review Program.* EPA may conduct a Special Review if EPA believes that a pesticide poses risks of unreasonable adverse effects on human health or the environment. In the Special Review Program, EPA focuses on specific hazards or uses of a pesticide. Special Reviews are not intended to be comprehensive evaluations of the pesticide; instead the Special Review DCIs are to address the specific hazard or exposure concerns that are at issue.

5. *Enforcement and Unanticipated Circumstances.* The need for a DCI may arise from the discovery of deficiencies in previously submitted data, or from the discovery of specific attributes of the pesticide or its ingredients. This may lead the Agency to determine that additional information is necessary to reassess whether the pesticide will cause unreasonable adverse effects on the environment. This type of DCI is needed because the concern and therefore the need for data arise not from a mandated review program like Re-registration or Registration Review described above, but from unanticipated circumstances. Section 3(c)(2)(B) of FIFRA provides a means of obtaining any needed data.

B. FIFRA Section 6(a)(2)

FIFRA section 6(a)(2) provides that registrants must inform the Agency of relevant information relating to their products, even though it was not specifically requested by EPA. Specifically, FIFRA section 6(a)(2) requires that, ''[i]f at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator.'' (7 U.S.C. 136d(a)(2)). For over 30 years, EPA has interpreted this provision expansively to include not only information relating directly to adverse effects caused by pesticides, but also to other types of information and studies that EPA would typically use in assessing whether a pesticide meets the statutory standard for registration (*i.e.,* the ''unreasonable adverse effects on the environment'' risk/benefit standard). See 43 FR 37611 (August 23, 1978).

In 1997, EPA promulgated a final rule at 40 CFR part 159, subpart D in the **Federal Register** issue of September 19, 1997 (62 FR 49370) (FRL–5739–1), setting forth EPA's interpretation and enforcement policy regarding FIFRA section 6(a)(2). The rule explains, among other things, what information EPA regards as ''additional'' and ''factual,'' as well as how quickly and to whom such information must be reported. The regulation specifies many kinds of information, from varied scientific disciplines, that EPA requires registrants to submit pursuant to FIFRA section 6(a)(2). The types of information reflect the variety of scientific data used by EPA in making the statutorily required determinations—whether pesticides cause unreasonable adverse effects on the environment. Thus, for example, the regulations generally require registrants to report studies indicating that a pesticide causes new or a higher incidence of toxic effects than previously identified (see 40 CFR 159.165) and to report incidents involving injury to humans, pets, or wildlife resulting from exposure to a pesticide (40 CFR 159.184). But, EPA uses other types of information that do not directly demonstrate adverse effects in its risk assessments, and new factual information of this kind is also reportable under the regulation. For example, registrants must report studies that identify new metabolites, degradates, impurities, or contaminants of pesticides (40 CFR 159.179); certain information on the detection of pesticide residues in water, food, and feed (40 CFR 159.178); and new studies of human exposure (40 CFR 159.170). In sum, EPA's regulation requires reporting of many types of information relevant to EPA's assessment of the safety of a pesticide product—in the words of section 6(a)(2) ''information regarding unreasonable adverse effects on the environment of the pesticide''—not merely information that directly concerns adverse effects.

In promulgating that regulation, however, EPA also recognized it was impossible to establish rules addressing every type of factual information that might become relevant in the future to judging whether a registered pesticide product continued to meet the FIFRA statutory standards. Accordingly, 40 CFR 159.195(a) provides:

The registrant shall submit to the Administrator information other than that described in §§ 159.165 through 159.188 if the registrant knows, or reasonably should know, that if the information should prove to be correct, EPA might regard the information alone or in conjunction with other information about the pesticide as raising concerns about the continued registration of a product or about the appropriate terms and conditions of registration of a product.

In addition, 40 CFR 159.195(c) provides that:

[t]he registrant shall submit * * * information other than that described in §§ 159.165 through 159.188 if the registrant has been informed by EPA that such additional information has the potential to raise questions about the continued registration of a product or about the appropriate terms and conditions of registration of a product.

Thus, once the Agency has informed registrants that EPA considers a particular type of information relevant to determining whether a pesticide has the potential to cause unreasonable adverse effects on the environment, that type of information becomes reportable under FIFRA section 6(a)(2).

Finally, EPA promulgated a regulation at 40 CFR part 152 addressing the submission of applications for registration (53 FR 15952, May 4, 1988) (FRL–3266–9b). That rule specifies, among other things, certain types of information that an application for registration of a pesticide product must contain. The rule provides that the applicant must ''furnish with his application any factual information of which he is aware regarding unreasonable adverse effects of the pesticide on man or the environment, which would be required to be reported under FIFRA section 6(a)(2), if the product were registered.'' 40 CFR 152.50(f)(3).

Registrants' compliance with FIFRA section 6(a)(2) and EPA's implementing regulations in 40 CFR parts 152 and 159 ensures that EPA has access to any additional factual information that could be important for determining whether a previous Agency decision to register a pesticide remains a correct one, and whether a registered pesticide can in fact be used without posing unreasonable adverse effects to human health and the environment. This provision of FIFRA recognizes that registrants may come into the possession of important new information that was not anticipated by the Agency or of information the importance of which was not previously known, and that in the absence of registrants submitting such information, EPA might well remain unaware of the information. Failures to report required information, or delays in reporting, are regarded by EPA as violations of FIFRA section 6(a)(2), which in turn makes them actionable under FIFRA sections 12(a)(2)(B)(ii) and 12(a)(2)(N) (7 U.S.C. 136j(a)(2)(B)(ii) and 7 U.S.C. 136j(a)(2)(N)).

III. EPA's Interest in Nanoscale Materials as Pesticide Ingredients

EPA believes that certain information concerning pesticide ingredients, which applicants and registrants have not routinely provided previously, is relevant to the Agency's statutory obligation to determine whether the registration of a pesticide may cause unreasonable adverse effects on the environment. For the reasons discussed below, EPA is particularly interested in nanoscale materials in this context. Accordingly, EPA is considering how to collect information about what nanoscale materials are in pesticide products and is therefore soliciting public comment on two possible approaches. It is important to first clarify how the term ''nanoscale material'' is being used for purposes of this document.

A. Nanoscale Material

To date, EPA has not developed formal definitions for the terms ''nanotechnology'' or ''nanoscale materials'' or any similar terms for regulatory purposes under any statute administered by the Agency. Broad definitions for the terms ''nanotechnology'' or ''nanoscale materials'' and discussions of nanotechnology generally reflect the same common elements, namely:

1. The material's particle size measures typically between approximately 1 and 100 nm in at least one dimension;

2. The material exhibits unique or novel properties compared to larger particles of the same material; and

3. Rather than occurring naturally, the material has been manufactured or engineered at the nanoscale to take advantage of these unique properties. See, for example, the definition from the National Nanotechnology Initiative at: *http://www.nano.gov/html/facts/whatIsNano.html.*

These elements do not readily work in a regulatory context because of the high degree of subjectivity involved with interpreting such phrases as ''unique or novel properties'' or ''manufactured or engineered to take advantage of these properties.'' Moreover, the contribution of these subjective elements to risk has not been established.

Instead, OPP will focus on more objective criteria in describing when information about a ''nanoscale material'' in a pesticide product may be relevant to determining whether the product has an unreasonable adverse environmental effect. Specifically, such information may be relevant in this context when the active or inert ingredient and any component parts thereof is intentionally produced to have at least one dimension that measures between approximately 1 and 100 nanometers, regardless of the aggregation or agglomeration state of the final material.

In determining whether an ingredient meets this description, EPA may review particle size data and, among other things, the manufacturing process to determine whether it employs processes specifically to create or enhance the proportion of nanoscale materials in the product, as compared with other processes used to produce similar products. The Agency generally expects that these ingredients may comprise, but are not limited to, metal-based (*e.g.,* silver) and carbon-based (*e.g.,* carbon nanotubes) nanoscale materials. The Agency does not, however, intend this description to cover biological materials (*e.g.,* DNA, RNA, proteins) or materials in their natural state (*e.g.,* clays). To the extent that the application of this description to a particular product or ingredient is unclear, EPA would review information provided by a registrant or applicant concerning the composition of the pesticide product and to provide an Agency view on whether the product did (or did not) contain a nanoscale material for purposes of this policy.

B. Potential of Nanoscale Materials To Affect Human Health and the Environment

There is a growing body of scientific evidence showing that differences can exist between nanoscale material(s) and their non-nanoscale counterpart(s) (Ref. 1). Nanoscale materials may have different or enhanced properties—for example, electrical, chemical, magnetic, mechanical, thermal, or optical properties—or features, such as improved hardness or strength, that are highly desirable for applications in commercial, medical, military, and environmental sectors (Ref. 2). These properties are a direct consequence of small size, which results in a larger surface area per unit of volume and/or quantum effects that occur at the nanometer scale (*i.e.,* 1×0^{-9} meters). Small size itself is also a desirable property of nanoscale materials that is exploited for miniaturization of applications/processes and/or

stabilization or delivery of payloads to diverse environments or incorporation into diverse products.

Nanoscale materials have a range of potentially beneficial public and commercial applications, including medicine and public health, clean energy through more efficient solar panels, pollution reduction and environmental cleanup, and improved products such as stronger, lighter, and more durable or conductive materials. These benefits arise from the distinctive properties of nanoscale materials, in that they are potentially more interactive or durable than other chemicals as a result of their size and composition. EPA sees the emergence of nanoscale materials as offering potential benefits for society in many different fields, including pest control products. The use of nanoscale materials in pesticide products and treated articles may allow for more effective targeting of pests, use of smaller quantities of a pesticide, and minimizing the frequency of spray-applied surface disinfection. These could contribute to improved human and environmental safety and could lower pest control costs. For example, as a materials preservative, nanosilver should maintain its efficacy longer and require smaller quantities than other silver preservatives due to an expected gradual and controlled release of silver as opposed to the rapid release of for example, silver from a zeolite structure or the immediate dissolution of a silver salt. Therefore EPA seeks to encourage innovative work in developing nanoscale materials to realize these benefits.

However, a number of organizations have considered whether the small size of nanoscale materials or the unique or enhanced properties of nanoscale materials may, under specific conditions, pose new or increased hazards to humans and the environment. Government, academic, and private sector scientists in multiple countries are performing research into the human health effects of diverse nanoscale materials, resulting in a substantial and rapidly growing body of scientific evidence. Recently, governmental and expert peer review organizations have reviewed and summarized this evidence and offered views about the implications of this evidence for environmental and human health and safety.

For instance, in 2009, the National Institute of Occupational Safety and Health (NIOSH) issued a report, ''Approaches to Safe Nanotechnology: Managing the Health and Safety Concerns Associated with Engineered Nanomaterials,'' which summarized the available scientific information about nanoscale materials and identified the following potential health and safety properties:

- Nanomaterials have the greatest potential to enter the body through the respiratory system if they are airborne and in the form of respirable-sized particles (nanoparticles). They may also come into contact with the skin or be ingested.
- Based on results from human and animal studies, airborne nanoparticles can be inhaled and deposit in the respiratory tract; and based on animal studies, nanoparticles can enter the bloodstream, and translocate to other organs.
- Experimental studies in rats have shown that equivalent mass doses of insoluble incidental nanoparticles are more potent than large particles of similar composition in causing pulmonary inflammation and lung tumors. Results from *in vitro* cell culture studies with similar materials are generally supportive of the biological responses observed in animals.
- Experimental studies in animals, cell cultures, and cell-free systems have shown that changes in the chemical composition, crystal structure, and size of particles can influence their oxidant generation properties and cytotoxicity.
- Studies in workers exposed to aerosols of some manufactured or incidental microscopic (fine) and nanoscale (ultrafine) particles have reported adverse lung effects including lung function decrements and obstructive and fibrotic lung diseases. The implications of these studies to engineered nanoparticles, which may have different particle properties, are uncertain.
- Some nanomaterials may initiate catalytic reactions depending on their composition and structure that would not otherwise be anticipated based on their chemical composition. (Ref. 3).

Earlier the same year, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), an independent scientific committee advising the European Commission's Health and Consumer Directorate, issued a report, ''Risk assessment of products of nanotechnologies.'' The SCENIHR report identified properties similar to those identified in the NIOSH report:

> Some specific hazards, discussed in the context of risk for human health, have been identified. These include the possibility of some nanoparticles to induce protein fibrillation, the possible pathological effects caused by specific types of carbon nanotubes, the induction of genotoxicity, and size effects in terms of biodistribution.

and:

> For some nanomaterials, toxic effects on environmental organisms have been demonstrated, as well as the potential to transfer across environmental species, indicating a potential for bioaccumulation in species at the end of that part of the food chain.

(Ref. 4).

In another recent survey of scientific research on nanoscale materials, the authors reported:

> Many studies have examined the pro-inflammatory effects of manufactured NPs [nanoparticles], on the basis that their ability to cause inflammation is a major predictor of potential hazard in such particles. The first important finding was that NPs have a more pronounced effect on inflammation, cell damage and cell stimulation than an equal mass of particles of the same material of greater size [* * *]. This appears to hold true for materials as varied as carbon black, titanium dioxide, various metals and polystyrene [* * *]. Surface area is the metric driving the pro-inflammatory effects and this is evident both *in vitro* [* * *] and *in vivo* [* * *], particles of various sizes producing inflammatory effects that are directly related to the surface area dose.

(Ref. 5 [reference numbers in the original were omitted]).

Other reports in the scientific literature have indicated that some nanoscale materials may cross the placental barrier (Ref. 6) or translocate to diverse organs following oral exposure (Ref. 7). Once in these diverse sites and organs, the large surface area of nanoscale materials may facilitate increased reactivity and/or an inflammatory response, resulting in toxic effects.

Two recent literature surveys describe a broad range of effects in non-mammalian species following exposure to nanoscale materials (Refs. 8 and 9). These include, for example, increased ventilation rates, mucus production, and pathologies, and related alteration of enzyme activities and indicators of oxidative stress in rainbow trout, *Oncorhyncus mykiss* (Refs. 10 and 11), and ingestion and accumulation of nanoscale material in the digestive tract, as well as mortality, increased heart rates, and reduced fecundity in *Daphnia magna* (Refs. 12, 13, and 14). Translocation of nano-scale materials from gill and gut surface to blood and other organs in exposed Medaka, *Oryzius latipes,* has also been reported (Ref. 15) and carbon nanotubes, although unable to cross the egg surface, have been shown to delay hatching in zebrafish, *Danio rerio* (Ref. 16). A recent review of lethal effects and concentrations determined for a wide variety of species showed that some nanoscale materials, including nano-titanium, nano-zinc oxide, nano-silver, nano-copper oxide, C60, and single- and multi-walled carbon nanotubes, would be classified as harmful to extremely toxic to non-mammalian species (Ref. 17).

While the reports and articles cited previously have focused primarily on

differences between nanoscale material and conventionally sized material of the same substances, EPA has also consulted with the FIFRA Scientific Advisory Panel (SAP) on the extent to which different types of nanoscale materials may display different properties. (The SAP is a Federal advisory committee consisting of external, independent, expert, scientific peer reviewers who provide advice to EPA on scientific issues involved in the regulation of pesticides.) In response to EPA questions on how size and other properties of nanoscale materials potentially affect risk and how to assess such risks, the SAP said: ''Existing data clearly indicate that many properties of particles change with size, including rate of release of ionic forms of metal, reactivity or catalytic efficiency, Plasmon resonance, and quantum effects. * * * The effect of particle size on biological responses to particle exposure is less well defined.'' (Ref. 18). The SAP also noted that ''[o]ther physicochemical properties, such as shape, charge and surface coating, are also likely to impact biological response and environmental fate [of nanoscale materials]. * * * The lack of a clear understanding of how particle size and other physical properties affect hazard profiles led most Panel members to be unsupportive of bridging among silver-based materials with different properties.'' (Ref. 18).

It is important to emphasize that, while the conclusions described previously apply to the specific material(s) and or context in which the study was conducted, any individual type of nanoscale material may not display all or even any of the characteristics observed and reported for other nanoscale materials. In other words, some nanoscale materials may have properties which, for purposes of assessing the risk of a pesticide, are essentially identical to larger sized materials (or particles) of the same substance. Furthermore, nanoscale materials may also have properties that make them less risky, or more beneficial in some other way, than larger sized materials (or particles) of the same substance. So, it appears increasingly likely that there are few, if any, universal ''nanoscale'' effects, and the distinctive effects seen at nanoscale are specific to the properties of each material type under specific exposure scenarios. Thus, EPA does not regard the fact that an ingredient meets our description of a nanoscale material as evidence that a pesticide containing the ingredient would cause unreasonable adverse effects on the environment and thus would no longer meet the statutory standards for registration. Rather, the presence of a nanoscale material in a pesticide is grounds for EPA to consider the possible need for data to characterize the potential of the ingredient to pose risks. However, the registration status of a product would not change merely as a result of providing information to EPA about the presence of a previously-unreported nanoscale material. If, based on a science based assessment of the risks of the specific pesticide ingredients involved, EPA were to determine that the pesticide no longer met the criteria for registration, or that some change was needed in the conditions of use, EPA would conduct a separate action to notify the manufacturer of that determination, consistent with current FIFRA regulations.

Finally, scientifically speaking, there currently is no bright line with respect to a size below (or above) which nanoscale materials do (or do not) exhibit properties that might be of interest in assessing whether a pesticide product has the potential to cause unreasonable adverse effects on the environment. Therefore, the precise size range in nanometers addressed by the policies proposed in this document might be revised in the future as new information becomes available.

C. Nanoscale Materials and Pesticides

The Agency has information indicating that the use of nanotechnology has started to expand into pesticide products, as it already has in many other fields. For instance, a number of companies have contacted EPA expressing an interest in obtaining registrations for pesticide products containing ingredients identified as nanosilver or nanosilver composite structures (jointly referred to as ''nanosilver''), and several companies have submitted applications to register pesticides containing nanosilver. In addition, EPA now has information suggesting that there are other pesticide products currently registered and in the marketplace that contain nanosilver as an active ingredient.

In order for EPA to fulfill its responsibilities to regulate pesticides under FIFRA, it needs to determine whether pesticidal products meet the statutory standards for registration. As summarized previously, EPA believes that what intentionally produced nanoscale materials are in a pesticide product, whether as an active or inert ingredient, is relevant to that determination. Accordingly, EPA is considering how to collect information not only about what nanoscale materials are in pesticide products, but also other information that may be relevant to the assessment of the potential of such pesticide products to cause unreasonable adverse effects on the environment. Such information may be important for EPA to determine whether EPA should continue the registration of a product, or amend, as appropriate, the terms and conditions of registration of a product. EPA is therefore soliciting public comment on two possible approaches for obtaining this information, as discussed in this document.

IV. Information Relevant To Assessing the Presence of Nanoscale Materials in a Pesticide

In light of the foregoing and in consideration of the potential for nanoscale material to cause different effects and to behave differently in the environment and within organisms from larger particles of the same substance, as well as from nanoscale materials with different characteristics (see Unit III.B.), EPA believes that any of the following types of information are relevant to assessing the potential of a pesticide to cause unreasonable adverse effects on the environment:

- Any information concerning what nanoscale materials are present in pesticides, whether as an active ingredient or as an inert ingredient;
- For any pesticide product that contains nanoscale material, whether active or inert, any existing information that characterizes the size and size distribution of the nanoscale material as measured in nanometers;
- For any pesticide product that contains nanoscale materials, whether active or inert, any existing information that describes the manufacturing process used to produce the nanoscale material in whatever size range it is produced;
- For any pesticide product that contains nanoscale materials, whether active or inert, and that also is or will be used for an end-use formulation that contain(s) a composite (*e.g.,* the active ingredient is a matrix complex comprised of the nanoscale material(s) in combination with a carrier, such as silica or sulfur), any existing information that characterizes the size and size distribution of the composite; and
- For any pesticide product that contains nanoscale materials, whether active or inert, any existing information that shows adverse effects at any level of exposure to the nanoscale material on humans or nontarget species, and/or that shows the levels or nature (*e.g.* routes, frequency, or life stage) of

potential human and environmental exposure.

Importantly, the foregoing is not intended to be an exclusive list. To the extent that a registrant has a pesticide product that contains a nanoscale material, and in addition has any other existing information not captured in the previous list that pertains to, concerns, or otherwise relates to the nanoscale material and has the potential to raise questions about the continued registration of a product or the appropriate terms and conditions of a product registration, EPA is also considering whether this too should be submitted to the Agency.

EPA will review information submitted concerning what nanoscale materials are present, including any existing information not previously provided to the Agency on size and size distribution, manufacturing process, and adverse effects. EPA will use this and product use information to determine if it raises any issues, not previously considered, regarding the product's potential to cause unreasonable adverse effects on the environment. In some cases, EPA may determine that additional information is needed to assess such potential; in this case, additional data may be required including data on physical and chemical properties, rate of nanoscale material release, and acute, subchronic, and chronic toxicity to human and ecological receptors.

V. Reporting the Presence of Nanoscale Materials in Pesticide Products

As discussed in Units III. and IV. of this document, EPA believes that information about what nanoscale materials are in pesticide products is important to its assessment of whether pesticides meet the statutory standard for registration. EPA may require such information under either FIFRA section 6(a)(2) or section 3(c)(2)(B). The Agency believes that announcing the applicability of FIFRA section 6(a)(2) to this type of information would be the most efficient and expedient administrative approach to obtaining existing information about nanoscale materials in pesticides, in which case any registrants with this type of information would be required to report it to EPA. The Agency is considering, however, an alternative approach under which it would issue DCIs under FIFRA section 3(c)(2)(B) to obtain this information, in which case registrants that received the DCI would be required to respond. This unit of the document discusses the two possible approaches and related procedures for obtaining information concerning nanoscale materials in pesticides.

A. FIFRA Section 6(a)(2)

As mentioned previously, FIFRA section 6(a)(2) and implementing regulations in 40 CFR part 159 require pesticide registrants to report certain information if that information:

1. Is additional;
2. Is factual; and
3. Regards unreasonable adverse effects on the environment of the pesticide.

Per 40 CFR 159.195, this includes information that, if correct, a registrant knows, or reasonably should know, would be regarded by EPA, either alone or in conjunction with other information about the pesticide, as raising concerns about the continued registration of a product or about the appropriate terms and conditions of registration of a product.

Announcing the applicability of FIFRA section 6(a)(2) to information about nanoscale materials in pesticides would not mean that EPA is expanding its interpretation of FIFRA section 6(a)(2) or changing its regulations. Rather, consistent with EPA's section 6(a)(2) regulations, EPA would be merely identifying a set of information that adds to the subset of reportable section 6(a)(2) data explicitly identified at present under the section 6(a)(2) regulations.

Further, the Agency notes that the identification of information as reportable under FIFRA section 6(a)(2) does not mean that any particular pesticide or group of pesticides, to which such information pertains, poses a risk. Rather, the requirement merely indicates that EPA has determined that a particular type of information is relevant to, and may improve the Agency's ability to assess, whether the pesticide would cause an unreasonable adverse environmental effect.

As part of this approach, EPA would also require that any such information be reported in connection with any application to register a pesticide product containing any nanoscale material (40 CFR 152.50(f)(3)). As with the reporting obligation under FIFRA section 6(a)(2), EPA would consider the failure to provide these types of information with an application for a product containing nanoscale material to be a violation of FIFRA sections 12(a)(2)(B)(ii) and 12(a)(2)(N).

Agency regulations implementing FIFRA section 6(a)(2) provide that a registrant must submit information to EPA that is reportable under section 6(a)(2) no later than the 30th calendar day after the registrant first possesses or becomes aware of the information (40 CFR 159.155). In addition, a registrant is required to submit to EPA any section 6(a)(2) information not explicitly covered under the section 6(a)(2) regulations if EPA has informed the registrant that such additional information has the potential to raise questions about the continued registration of a product or the appropriate terms and conditions of registration of a product (40 CFR 159.195).

After learning that EPA was considering relying on FIFRA 6(a)(2) to require reporting, some stakeholders raised questions about the use of FIFRA section 6(a)(2) to obtain this information. Even though, as stated above, EPA is not making a judgment that the presence of any particular nanoscale material poses a risk, it has been argued that use of the ''adverse effects'' reporting authority in FIFRA section 6(a)(2) could create a ''stigma'' for the nanotechnology industry.

EPA does not believe that using FIFRA section 6(a)(2) to gather information on the presence of nanoscale materials in pesticide products would create a stigma for the nanotechnology industry. EPA's longstanding interpretation of section 6(a)(2) is that it is not limited to requiring reporting only of actual ''adverse effects'' of pesticides, and its use does not imply that ''adverse effects'' actually have occurred, or even could occur, in connection with the pesticide or pesticide ingredient on which the information is being obtained. FIFRA section 6(a)(2) requires reporting of ''additional factual information regarding unreasonable adverse effects on the environment,'' where ''unreasonable adverse effects on the environment'' is specifically defined as a risk/benefit standard. EPA's implementing regulations require reporting of a wide range of data, which—like information on nanoscale materials—are relevant to EPA's risk/benefit evaluations, but which do not indicate the pesticide causes any adverse effects. Any suggestion that this information gathering proposal implied an EPA position on the adverse effects of pesticides containing nanoscale materials would be a misinterpretation of EPA's intent.

It is further EPA's position that merely filing an additional report under FIFRA section 6(a)(2) does not stigmatize pesticides and would not stigmatize any nanomaterials in pesticides, since filing such reports is quite common. On average, EPA receives 200 studies and 56,000 incident reports per year under this authority. In

fact, over the last 10 years, pesticide registrants have filed section 6(a)(2) reports on more than two-thirds of all pesticide active ingredients.

Use of FIFRA section 6(a)(2) also would have only a minimal overall administrative burden for both EPA and industry. Under section 6(a)(2), only registrants who know that their products contain nanoscale materials would be required to report to EPA. Further, they would be required to report only the information they know about. Section 6(a)(2) does not require a registrant to generate new data or to seek out additional information. Further, registrants and applicants whose products do not contain nanoscale materials (or who do not know that their products contain nanoscale materials) would have no reporting obligation under FIFRA section 6(a)(2). Under this approach, EPA would be required to keep track of each response received under 6(a)(2), but would not otherwise need to prepare or track individual requests for the information.

B. DCIs Under FIFRA Section 3(c)(2)(B)

As an alternative to relying on FIFRA section 6(a)(2) to obtain information concerning nanoscale materials in pesticides, EPA is also considering issuing DCIs under FIFRA section 3(c)(2)(B). The Agency has authority under FIFRA section 3(c)(2)(B) to issue a DCI notice to a pesticide registrant directing them to provide data ''required to maintain in effect an existing registration of a pesticide * * *'' The DCI notice is addressed to an individual registrant, specifically identifies the information or data that the registrant must provide, prescribes an initial response deadline of 90 days, and, if data are to be generated, it may prescribe a timeframe for generating and providing that data. Under FIFRA, EPA can suspend the registration of a pesticide if the registrant fails to respond to a DCI.

As part of this alternate approach, EPA would also need to require the inclusion of this information with any application for registration of a pesticide product that contains a nanoscale material. EPA is reviewing whether this could be done under existing regulations or whether EPA would need to amend existing regulations to clarify that this information is required with any application for registration. As with the reporting obligation under FIFRA section 6(a)(2), EPA would consider the failure to provide these types of information with an application for a product containing nanoscale material to be a violation of FIFRA sections 12(a)(2)(B)(ii) and 12(a)(2)(N).

Since EPA's goal is to identify what nanoscale materials are contained in products (and the products that contain them) and to gather existing information not previously provided to assess their safety, the DCI would need to require the kinds of information specified in Unit IV. of this document. Because such a request is not consistent with the Re-registration or Registration Review programs, the Agency would use the Enforcement and Unanticipated Circumstances category available in the currently approved Information Collection Request (73 FR 55072, September 24, 2008) (FRL–8719–3).

Unless a registrant has already disclosed the presence of nanoscale material in all of its products, there currently is no way to identify with certainty what nanoscale materials are in products (and the products that contain them). Therefore, in order to identify what nanoscale materials are in products, EPA could initially send an individual Enforcement and Unanticipated Circumstances DCI order to each of the 1,716 currently registered pesticide producers. Under this approach each of these pesticide registrants would then be required to respond within 90 days by either providing the requested information about the nanoscale materials in their product(s) or certifying that their product(s) do not contain nanoscale materials. In addition to keeping track of each response like under FIFRA section 6(a)(2), the approach under FIFRA section 3(c)(2)(B) could require EPA to also prepare and track the issuance of individual DCIs for each pesticide registrant, as well as determine and take any necessary enforcement actions for non-responders. EPA notes that only pesticide registrants receive DCIs; EPA would need to employ additional administrative procedures to ensure that applicants also provided such information.

A variation on this approach would be for EPA to craft a DCI that would be more targeted and place less burden on industry and the Agency, possibly by not requiring a response from recipients of the DCI who do not have (or who do not know that they have) nanoscale material in their registered pesticide products. The Agency has not used such an approach with any DCI in the past; however, and a number of issues, including enforcement, would need to be addressed if it were to seek to do so here. EPA could also focus its initial data gathering on certain classes of pesticides that might be most likely to contain a nanoscale material that EPA would be interested in knowing about. EPA is interested in receiving comments on these variations.

It is useful to note that while FIFRA section 6(a)(2) can be used to obtain existing information, the DCI approach under FIFRA section 3(c)(2)(B) allows the Agency to request that data be generated. If EPA uses FIFRA section 6(a)(2) authority and the Agency learns, for instance, the identity of a nanoscale material present in a product, and subsequently determines that sufficient data are not available to support the continued registration of the pesticide, EPA could then use the DCI approach under FIFRA section 3(c)(2)(B) to gather such information. EPA must use the DCI approach if EPA intends to require a registrant to provide information which the registrant does not already possess.

It is anticipated that some registrants will request that EPA review information to determine if their product contains nanoscale materials. To the extent that the description of nanoscale material to a particular product or ingredient is unclear, EPA will review information concerning the composition and manufacturing process of the pesticide product and, based on that information, the Agency will determine whether the product does (or does not) contain nanoscale material.

It has been suggested that the use of a 3(c)(2)(B) approach would result in submission of information that only reflected the composition of registrants' products at the time of their responses, but that EPA would need periodically to issue DCIs to ensure that registrants did not alter the composition of the products to add nanoscale materials after submitting their responses. EPA is interested in receiving comments on options whereby it can ensure registrants report what nanoscale materials are in products, regardless of when they are added to the pesticide.

Under either the 6(a)(2) or the 3(c)(2)(B) approach, DCIs targeted to individual pesticide products that contain specific nanoscale materials would likely be used in the future to collect more specific information or data about particular products. EPA would consider doing so on a case-by-case basis and would tailor any request for information accordingly.

C. Amending the Pesticide Data Requirement Regulations

Some stakeholders have suggested, as an alternative to relying on either FIFRA section 6(a)(2) or 3(c)(2)(B) DCIs to obtain information concerning nanoscale materials in pesticides, that EPA instead promulgate a regulation amending the data requirements in 40

CFR parts 158 and 161. The Agency could amend the data requirements to include disclosure of what nanoscale materials are present as part of the pesticide registration process. However, completing this action would not provide information on currently registered pesticide products.

The Agency sees such proposed rulemaking with a broader scope in that it would address not only the basic information such as identifying what nanoscale materials are in products, but also many other types of data required for making safety evaluations. The Agency is currently making data need decisions on a case-by-case basis, and EPA is trying to tailor data requirements to the particular characteristics of each product. The Agency does not yet have the knowledge base typically gained through the registration process to support the development of specific data requirements that would be imposed broadly for the registration of pesticides containing nanoscale materials across all the application and use scenarios, as required for such a rulemaking.

Although it could take considerable time to finalize and implement a rule establishing standard data requirements for pesticides containing nanoscale materials, and the Agency thus believes that this approach by itself would not generate information on nanoscale ingredients in pesticides in a timely manner, EPA also seeks comment on this approach.

VI. Proposed Policy Regarding Classification of Applications Under FIFRA and PRIA for Products Containing Nanoscale Active and Inert Ingredients

As discussed in more detail earlier in this document, under FIFRA, all pesticides must meet stringent statutory and regulatory standards before they are registered by the Agency and allowed to be marketed and sold. Pesticides containing nanoscale materials, whether as active or inert ingredients, must meet the same safety standards as other pesticides. Because of the large and increasing body of data described in Unit III.B. of this document demonstrating that size can alter the manner in which materials behave and, in turn, the potential risk to human health and the environment associated with such materials, EPA proposes to apply an initial presumption that active and inert ingredients, which are the nanoscale versions of non-nanoscale active and inert ingredients already present in registered pesticide products, are potentially different from those conventionally sized counterparts. Because the size, shape, and other characteristics of nanoscale ingredients are likely to vary widely, EPA also proposes to apply an initial presumption that nanoscale active and inert ingredients are potentially different even from other, already-registered nanoscale versions of the same ingredients. As explained later in this document, however, applicants can overcome this presumption on a case-by-case basis.

Historically, EPA has evaluated an application for registration of a pesticide product that claims to have the same composition and uses as a currently registered pesticide—a so-called ''me-too application''—under either the ''conditional'' registration or ''unconditional'' registration authorities in FIFRA section 3(c)(7) and section 3(c)(5), respectively. In making the statutory determinations under section 3(c)(7)(A)—whether the applicant's product is identical or substantially similar to a currently registered pesticide or differs only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and that approving the registration in the manner proposed would not significantly increase the risk of any unreasonable adverse effect on the environment—EPA has focused on whether the use patterns of the products are identical or similar and whether the ingredients present in the products have the same chemical structure and are present in about the same percentages. Until recently, EPA generally has not focused on the size of an ingredient as an attribute relevant to making the determinations under section 3(c)(7)(A).

As noted previously, however, once the size of an ingredient is reduced below approximately 100 nm, a substance can exhibit different properties, and therefore it may also have different potential environmental health and safety properties. Accordingly, for a product containing an ingredient that is a nanoscale version of a conventionally sized active or inert ingredient contained in an already-registered product, EPA may require additional data in order to determine that the nanoscale material differs only in ways that do not significantly increase the risk of unreasonable adverse effects on the environment and that approving the registration in the manner proposed would not significantly increase the risk of any unreasonable adverse effect on the environment, and/or require different terms and conditions for the registration. EPA is thus proposing that it not make the requisite findings absent specific information on the nanoscale material included in a pesticide product when the application relies on a comparison to a currently registered pesticide product containing either a non-nanoscale version of the same ingredient or another nanoscale version of the ingredient that has different characteristics. Under this approach, the Agency would follow the same thinking in making the statutorily required determinations under FIFRA section 3(c)(7)(B) and 3(c)(7)(C), as well as FIFRA section 3(c)(5).

For purposes of registration under FIFRA section 3(c)(5) or 3(c)(7), therefore, EPA would initially classify any application for registration of a pesticide product containing an active or inert ingredient that is a nanoscale material as an application for a ''new'' active or inert ingredient, even when another registered pesticide product contains a non-nanoscale form of the ingredient or a nanoscale form of the ingredient with different size dimensions or other properties. This initial presumption, however, could be rebutted on a case-by-case basis through the submission of, among other possibilities, bridging data or other information demonstrating to EPA's satisfaction that the nanoscale material's properties, which are relevant to assessing the potential risks to human health and the environment, are substantially similar to the properties of the already-registered non-nanoscale or already-registered nanoscale form of the material, or that the nanoscale material differs only in ways that do not significantly increase the risk of unreasonable adverse effects on the environment, and that approving the registration in the manner proposed would not significantly increase the risk of any unreasonable adverse effect on the environment.

If an applicant could make this showing to EPA's satisfaction, then the application would be processed as a ''me-too'' application within the timeframes prescribed for such applications. However, if an applicant could not make this showing to EPA's satisfaction, then EPA would process such products as new active ingredients or new inert ingredients and would complete its review within the timeframes prescribed for such applications. In those circumstances, the Agency would likely require the applicant to provide the types of data typically required for an assessment of the potential hazards and exposure to a new active or inert ingredient. Under this proposed policy, it would also follow that if a registrant wished to change the composition of its product to include a nanoscale version of a

material that EPA had previously approved in non-nanoscale form, the registrant would need to notify EPA and obtain EPA approval before making such a change in the composition of its product. However, as noted earlier, the registration status of a product would not change merely as a result of providing information to EPA about the presence of a previously-unreported nanoscale material. If EPA made an affirmative finding that a change in status or conditions of use was necessary, EPA would notify the registrant in accordance with applicable regulations and procedures.

VII. Does this document contain binding requirements?

This document seeks comments on how the Agency could use FIFRA section 6(a)(2) or FIFRA section 3(c)(2)(B) to gain information on what nanoscale materials are in pesticides. Given that the Agency is seeking comment before determining its approach to obtaining information on what nanoscale materials are in pesticides, there are no binding requirements in this document.

Once this document is finalized, the Agency's policy for determining whether a nanoscale material is a new active or inert ingredient for purposes of both FIFRA and PRIA would be intended only as guidance to EPA personnel and decision-makers and to pesticide applicants. While the requirements in the statute and Agency regulations are binding on EPA and the applicants, the proposed policy described in this document would not be binding on EPA personnel, pesticide applicants, or the public. Accordingly, EPA may depart from the policy proposed herein if and when circumstances warrant. Likewise, pesticide applicants may assert that the proposed policy is not applicable to a specific pesticide or situation in which EPA may be expected to apply it.

VIII. Questions for Comment

The Agency is seeking public comment on several questions, including whether it should use the FIFRA section 6(a)(2) reporting obligation to obtain information on what nanoscale materials are in pesticide products or use FIFRA section 3(c)(2)(B) as described in this document to obtain such information.

With respect to the scope of reportable information, EPA specifically invites comments on the following issues:

1. In view of the Agency's goal of identifying what nanoscale materials are in products so that EPA can determine whether it needs additional data to evaluate the products' safety under FIFRA, should EPA change the description of a ''nanoscale material''? For example, should the size range remain ''between approximately 1 and 100 nm in one dimension''? Are there other characteristics that EPA should consider, *e.g.,* morphology, including shape and crystal structure; surface chemistry and reactivity; specific surface area, charge; solubility; conductive, magnetic, and optical properties?

2. Should the reporting requirement apply only to nanoscale material that is ''intentionally produced to have at least one dimension that measures between approximately 1 and 100 nanometers,'' or should it also apply to naturally occurring materials? Why?

3. Is the meaning of ''intentionally produced'' sufficiently clear? If not, in what circumstances would the term be unclear and how might it be clarified? Would offering a consultation procedure—by which a registrant or applicant describes to EPA the production process that results in the presence of a material in the nanoscale size range, and EPA responds with a determination regarding whether reporting is required—be an acceptable approach to providing clarity?

4. Should the reporting requirement apply to ingredients in pesticides that contain any amount of a nanoscale material, or should the requirement apply only if an ingredient contains more than a specified percentage (*e.g.,* 10%) of nanoscale material? If the latter, what should the specified percentage be and why?

5. How should the reporting requirement apply to a pesticide manufacturer who purchases ingredients that may contain nanoscale material?

6. Are there ways in which the description of ''nanoscale materials'' can be refined and clarified, including ways in which agglomeration and aggregation could be considered as well as suggestions for ways in which more subjective criteria, such as ''unique or novel properties'' can be incorporated into the screening criteria?

7. Is EPA's description of ''nanoscale material'' inconsistent with other definitions of nanoscale material or similar terms? If so, please comment on whether such differences create any regulatory issues. In particular, does the focus on ''intentionally produced'' materials create any such inconsistency with other definitions of nanoscale materials or similar terms?

8. If a pesticide is identified as containing a particular nanoscale material, what would be the most useful next steps to inform EPA's understanding of potential risks associated with the pesticide? Are there tests that could provide useful information toward an understanding of risk that would be common to all nanoscale materials, or should the data requirements necessarily be compound- and situation-specific? How should bioavailability be considered in determining testing requirements (*e.g.,* are nano-particles respirable or bound to other components)?

With respect to the proposed approaches, EPA is seeking comment on how to implement them to ensure efficient, effective, and timely review of applications. EPA specifically invites comments on the following issues:

1. Is there a way to determine, in advance of receiving an application for registration of a product containing a nanoscale material, whether a particular kind of nanoscale material has properties that, for purposes of risk assessment, are essentially the same as larger sized materials of the same substance? If so, how would such determinations be made and on what would they be based?

2. What kinds of information should EPA accept as demonstrating that a pesticide product containing a nanoscale ingredient is identical or substantially similar to a currently registered pesticide or differs only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and that approving the registration in the manner proposed would not significantly increase the risk of any unreasonable adverse effect on the environment?

3. Can you suggest any alternative(s) to the proposed approaches that would be equally or even more effective in addressing the status of nanoscale materials as new active or inert ingredients for purposes of both FIFRA and PRIA, keeping in mind the data showing that size, especially when reduced below approximately 100 nm, may alter the manner in which materials behave and, in turn, the potential risk to human health and the environment associated with such materials?

With respect to the potential alternative ways of obtaining the needed information on what nanoscale materials are in pesticide products, EPA specifically invites comments on the following issues:

1. Has EPA appropriately characterized in this document the current scientific understanding of the potential risks of nanoscale materials? If not, please comment on how to

characterize the potential risks of nanoscale materials. How would the perception of the risks of nanoscale materials differ depending on the approach used by EPA to require needed data on nanoscale materials in pesticides? How could EPA lessen the possibility that issuance of a final requirement to report what nanoscale materials are in pesticides will result in a public misunderstanding of the potential risks of nanotechnology more generally?

2. Do commenters believe that identification of the nanoscale materials in pesticide products is relevant to EPA's statutory determination regarding the potential for unreasonable adverse effects on the environment? Please provide the scientific or legal basis for your view.

3. Has EPA characterized the alternative approaches with respect to which they would: (a) result in a misunderstanding of the potential risks posed by nanoscale materials; (b) result in the timely submission of needed information; and (c) impose burdens on pesticide companies, those whose products do, and do not, contain nanoscale materials? If not, please comment on those issues.

4. If EPA uses FIFRA section 6(a)(2) to obtain the needed information on nanoscale materials in pesticides, how could the Agency ensure that its action is not mischaracterized or misunderstood as a determination that the mere fact that a pesticide contains nanoscale materials causes unreasonable adverse environmental effects?

5. If EPA were to use DCIs to obtain the needed information on nanoscale materials in pesticides, how could EPA reduce both the burdens on registrants and on EPA, as well as the time required to complete such a process? For example, is it possible to reduce the burdens on registrants by targeting only certain types of products? If so, how would EPA determine which products should receive DCIs?

6. What are the advantages and disadvantages of requesting information on nanoscale materials specifically versus requesting information on size distribution generally? (Note that either type of information could be collected under either the 6(a)(2) or the 3(c)(2)(B) approach, except that 6(a)(2) cannot be used to require the production of new information that does not already exist, while a collection under 3(c)(2)(B) must be directed to an individual registrant and requires a response.) Is identifying what nanoscale materials are in products a useful first step, or should EPA move towards immediate collection of more specific information, such as particle size distribution, on products that might contain nanoscale materials? Are there other physical and/or chemical properties that might be equally or more important for assessing the potential of a pesticide to cause unreasonable adverse effects on the environment (*e.g.,* morphology, including shape and crystal structure; surface chemistry and reactivity; specific surface area, charge; solubility; conductive, magnetic, and optical properties)? Should information on these properties be separately requested? What would be the value and burden of obtaining such information?

1. If EPA were to use rulemaking to establish data requirements for pesticides containing nanoscale materials, what types of information should EPA use to determine appropriate data requirements? What types of studies should EPA require to evaluate a nanoscale material?

2. When choosing an approach for obtaining needed data, how should EPA weigh considerations relating to the need to update its safety evaluations of currently marketed pesticides in a timely manner, the goal of ensuring marketplace equity, and the interest in minimizing the burdens on regulated entities?

IX. References

As indicated under **ADDRESSES**, a docket has been established for this document under docket ID number EPA–HQ–OPP–2010–0197. The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical contact person listed under **FOR FURTHER INFORMATION CONTACT**.

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2. National Nanotechnology Initiative. 2011. Strategic Plan. *http://www.nano.gov/nnistrategicplan211.pdf.*
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4. SCENIHR. 2009. Risk Assessment of Products of Nanotechnologies. European Commission. Directorate-General for Health and Consumers. Scientific Committee on Emerging and Newly Identified Risks, Brussels: 28th Plenary Meeting. January 19, 2009. *http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_s_01.pdf.*
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7. Kim, Y.S. *et al.* 2008. Twenty-Eight Day Oral Toxicity, Genotoxicity, and Gender-Related Tissue Distribution of Silver Nanoparticles in Sprague-Dawley Rats. Inhalation Toxicology. 20 (6):575–583.
8. Handy *et al.* 2008. The ecotoxicology and chemistry of manufactured nanoparticles. Ecotoxicology 17:287–314.
9. Klaine *et al.* 2008. Nanomaterials in the Environment: Behavior, Fate, Bioavailability, and Effects. Environ. Toxicol. Chem. 27: 1825–1851.
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12. Lovern and Klaper. 2006. Daphnia magna mortality when exposed to titanium nanoparticles and fullerene (C60) nanoparticles. Environ. Toxicol. Chem. 25:1132–1137.
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14. Roberts *et al.* 2007. *In vivo* biomodification of lipidcoated carbon nanotubes by *Daphnia magna.* Environ. Sci. Technol. 41:3025–3029
15. Kashiwada *et al.* 2006. Distribution of nanoparticles in the see-through Medaka (*Oryzias latipes*). Environ. Health Perspect. 114:1697–1702.
16. Cheng *et al.* 2007. Effect of carbon nanotubes on developing zebrafish (*Danio rerio*) embryos. Environ. Toxicol. Chem. 26:708–716.
17. Kahru and Dubourguier. 2010. Review: From ecotoxicology to nanoecotoxicology. Toxicology 269:105–119.
18. FIFRA Science Advisory Panel (SAP). 2010. ''Evaluation of Hazard and Exposure Associated with Nanosilver and Other Nanometal Pesticide

Products.'' Report from the FIFRA Scientific Advisory Panel Meeting of November 2009. *http://www.epa.gov/scipoly/sap/meetings/2009/november/110309ameetingminutes.pdf.*

X. Applicable Statutory and Executive Order Reviews

EPA submitted this document to the Office of Management and Budget (OMB) for review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Any changes made in response to OMB recommendations have been documented in the docket for this action as required by section 6(a)(3)(E) of the Executive Order.

The information collection requirements associated with reporting under FIFRA section 6(a)(2) as prescribed in 40 CFR part 159, subpart D are approved under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.* The approval is identified under OMB Control No. 2070–0039 and EPA ICR No. 1204. The information collection requirements associated with DCIs is approved under OMB Control No. 2070–0174 and identified by EPA ICR No. 2288. If EPA were to finalize a policy that required additional reporting of information not currently collected, or that substantively changed the burden for such reporting (for example if it resulted in a larger number of such reports than covered in current burden estimates), EPA would submit a request for revised PRA approval to OMB.

The various other statutory and Executive Order review requirements that apply to a regulatory action do not apply to this action because this document is not a regulatory action and does not otherwise impose new requirements. As indicated previously, this document requests comment on several approaches for applying existing requirements in order to obtain information on nanoscale materials in pesticide products and presents the Agency's proposed policy for determining whether a nanoscale material is a new active or inert ingredient for purposes of both FIFRA and PRIA.

List of Subjects

Environmental protection, Administrative practice and procedure, Nanotechnology, Pesticides and pests.

Dated: June 8, 2011.

Stephen A. Owens,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2011–14943 Filed 6–16–11; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register
Vol. 76, No. 117
Friday, June 17, 2011

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

AGENCY FOR INTERNATIONAL DEVELOPMENT

Notice of Public Information Collection, Request for Comment on the Continued Use of the Partner Information Form (0412–0577) in Compliance With the Paperwork Reduction Act of 1995

ACTION: Notice.

SUMMARY: The US Agency for International Development invites the general public and other Federal agencies to take this opportunity to comment on the following continuing information collections, as required by the Paperwork Reduction Act of 1995. This information collection was first approved by OMB in 2008, and the Partner Information Form has been used successfully in screening programs in West Bank/Gaza and elsewhere since the OMB approval.

Comments are requested concerning: (a) Whether the continuing collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Submit comments on or before August 16, 2011.

ADDRESSES: Send comments via:

E-mail: regulatorypolicy@usaid.gov

Mail: George Higginbotham, Management Policy Analyst, USAID, RRB, 1300 Pennsylvania Avenue, NW., Washington, DC 20523; (202) 712–1948.

SUPPLEMENTARY INFORMATION:

OMB Number: 200705–0412–003.

Form Number: 0412–0577.

USAID Internal Form Number: AID 500–13.

Title: Partner Information Form.

Type of review: Extension of Information Collection.

Purpose: The United States Agency for International Development intends to continue collection of information from individuals and/or officers of for-profit and non-profit non-governmental organizations (NGOs) who apply for USAID contracts, grants, cooperative agreements, other funding from USAID, or who apply for registration with USAID as Private and Voluntary Organizations. The collection of this information will be used to conduct screening to ensure that neither USAID funds nor USAID-funded activities inadvertently provide support to entities or individuals associated with terrorism. Screening programs are being conducted in West Bank/Gaza and other critical priority countries and will be conducted under the Congressionally authorized pilot Partner Vetting System program.

Annual Reporting Burden:

Respondents: 40,000 individuals, 4,000 organizations.

Total Annual Responses: 44,000.

Total Annual Hours Requested: 11,000.

Dated: June 1, 2011.

Lynn Winston,

Division Chief, Information and Records Division, Office of Management Services, Bureau for Management.

George Higginbotham,

Management Policy Analyst.

[FR Doc. 2011–14786 Filed 6–16–11; 8:45 am]

BILLING CODE 6116–01–P

DEPARTMENT OF AGRICULTURE

Agricultural Research Service

Notice of Intent To Reestablish the National Genetic Resources Advisory Council, and Request for Nominations

AGENCY: Agricultural Research Service, USDA.

ACTION: Notice of Intent and Request for Nominations.

SUMMARY: The notice announced USD intent to reestablish the National Genetic Resources Advisory Council. The notice was published in the **Federal Register** on May 16, 2011.

FOR FURTHER INFORMATION CONTACT: J. Robert Burk, 202–720–3684.

Correction

In the **Federal Register** of May 14, 2011, in FR Doc. 2011–11926, on pages 28209–28210 in the **SUPPLEMENTARY INFORMATION** section, correct to read as follows:

The biographical information and clearance forms must be completed and returned to USDA within 10 working days of notification, to expedite the clearance process that is required before selection of Council members by the Secretary of Agriculture. Equal opportunity practices will be followed in all appointments to the Council in accordance with USDA policies. To ensure that the recommendations of the Council have taken into account the needs of the diverse groups served by USDA, membership shall include, to the extent practicable, individuals with demonstrated ability to represent all racial and ethnic groups, women and men, persons with disabilities, and limited resource agriculture producers.

Yvette Anderson,

Federal Register Liaison Officer for Agriculture Research Service.

[FR Doc. 2011–15092 Filed 6–16–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Forest Service

Black Hills National Forest, Mystic Ranger District, South Dakota, Section 30 Limestone Mining Project

AGENCY: Forest Service, USDA.

ACTION: Corrected Notice of intent to prepare an environmental impact statement.

SUMMARY: A Plan of Operation has been submitted by Pete Lien and Sons, Inc., for the purpose of mining for chemical grade limestone within mining claims on National Forest System land. The proposal is to mine within Pennington County, South Dakota, totaling approximately 100 acres about one mile north of the northwest boundary of Rapid City, South Dakota. The original Notice of Intent for this project was published in **Federal Register** (71FR62989) on Friday, October 27, 2006. A Corrected Notice of Intent to prepare an EIS was published in the **Federal Register** (74FR51550) on Wednesday, October 7, 2009. That first Corrected Notice of Intent was republished due to time lapse between the estimated schedule in the original

Notice of Intent and the revised estimated Draft and Final EIS publication dates. A Notice of Availability for the Section 30 Limestone Mining Project Draft EIS was published in the **Federal Register** (76FR14968) on Friday, March 18, 2011. This second Corrected Notice of Intent is being republished due to time lapse between the schedule in the first Corrected Notice of Intent and the new estimated Final EIS publication date.

DATES: The final environmental impact statement is expected to be completed by September of 2011.

FOR FURTHER INFORMATION CONTACT: Dave Slepnikoff, Project Coordinator, Black Hills National Forest, Mystic Ranger District, at above address, phone (605) 343–1567.

SUPPLEMENTARY INFORMATION:

Purpose and Need for Action

The Purpose and Need for this project is authorization of Pete Lien and Sons, Inc., proposal to exercise their rights under U.S. mining laws while protecting the environment in accordance with Forest Service regulations for locatable minerals. The Purpose and Need has several components. Pete Lien and Sons, Inc. has a statutory right to extract locatable minerals (chemical grade limestone) as proposed in accordance with the General Mining Law of 1872, as amended (30 U.S.C. 21–54). The Forest Service has the responsibility to protect surface resources of National Forest System lands to the extent practicable. Forest Service mining regulations state that, ''operations shall be conducted so as, where feasible, to minimize adverse impacts on National Forest System surface resources (36 CFR 228.8).''

Proposed Action

The proposed action is to approve the Plan of Operation (PoO) submitted by Pete Lien and Sons, Inc. to mine approximately 100 acres of National Forest System lands on the PLS 30–1 through PLS 30–10 Lode Mining Claims, SDMMC #209097. The Plan of Operations was developed by Pete Lien and Sons, Inc. It was submitted to the Forest Service in accordance with the General Mining Law of 1872, as amended and Forest Service mining regulations at 36 CFR 228 Subpart A. The Project is located between Rapid City and Black Hawk, South Dakota. Legal description is; T.2N., R.7E., NE ¼ Section 30, BHM.

The Plan of Operation is summarized as follows:

- It is estimated that the operation will process approximately 10 million tons of limestone. The life of the proposed mine is estimated at 10 years, not including final reclamation.
- Remove vegetation, stockpile topsoil for future reclamation, drill and blast rock to remove an approximate 20 foot bed of limestone rock resulting in an open pit with approximately 20 foot high walls.
- Blasted rock may be crushed on site to reduce size for hauling. Raw materials will be hauled to the east of Highway 79 for processing into chemical grade limestone products.
- Concurrent reclamation is planned. Therefore approximately 60 acres will be disturbed at any one time. Reclamation will result in a depression on the existing hillside. High walls will be reduced, site graded, topsoil applied, and vegetation planted once mineral extraction is complete.
- The Mine Safety and Health Administration (MSHA) will be responsible for enforcing mine safety regulations. The mine site will be enclosed by fences and gates as required by MSHA and other regulatory guidance.

Pete Lien and Sons, Inc. will secure permits for all mining and reclamation activities as required by law. Several permits have been obtained or will be obtained pending the NEPA analysis and decision. Notable permit requirements include:

- Clean Water Act—Apply for construction/mining activity permit with National Pollutant Discharge Elimination System (NPDES).
- Clean Air Act—Permit or permits will be obtained to ensure that equipment and dust control measures comply with the Clean Air Act.
- South Dakota Mining License—Pete Lien and Sons, Inc. currently has a mining license inclusive of the relevant portion of Section 30. The proposed mine may be exempt from further state permitting per a statutory exemption for the extraction of cement precursors.
- Pennington County Construction (Mining) Permit—Pete Lien and Sons, Inc. will notify the County of its schedule and plans to initiate mining on Section 30. Construction permit CP 01–05 specifies the scope of the County's further review of road impacts, drainage, and other matters related to mining on Section 30.

Responsible Official

Craig Bobzien, Forest Supervisor, Black Hills National Forest, 1019 North 5th Street, Custer, South Dakota 57730–7239.

Nature of Decision To Be Made

The Forest Supervisor will decide whether the proposed action will proceed as proposed or as modified by an alternative. Also, the Supervisor will decide which recommended mitigation measures and monitoring requirements will be applied, and whether a Forest Plan Amendment is required.

Scoping Process

The Forest Service advertised the proposal in the Rapid City Journal, newspaper of record on Friday, October 27, 2006. The project is listed in the Black Hills National Forest Quarterly NEPA calendar. Adjacent landowners, known interested parties, and government agencies received letters describing the project and identifying the project timeframe. Scoping comments were recieved by November 27, 2006. An informational and public meeting was held on November 14, 2006, at 7 p.m. in the Black Hawk Elementary School Gymnasium regarding this project proposal.

Preliminary Issues

At this time, project planners are aware of issues related to cultural (heritage) resources and scenic quality. Through the Scoping process, we will use comments obtained about the proposed action to determine the breadth of issues to be addressed in the analysis.

The potential for adverse affects to heritage resources has been identified as an issue for this proposed undertaking. A number of archaeological sites have been identified and recorded in the project area as a result of heritage resource surveys. Five of these sites have been evaluated as eligible for nomination to the National Register of Historic Places. Through consultation with Indian tribes, use of this area for religious activities has also been documented. Pursuant to the National Historic Preservation Act (NHPA), the Forest is in consultation with Indian tribes and the South Dakota State Historic Preservation Office to develop measures of avoidance and/or mitigation for significant cultural and archaeological values by the proposed undertaking. Successful completion of consultation pursuant to the NHPA would result in a Memorandum of Agreement that will implement avoidance or mitigation of significant heritage resources in the Area of Potential Affect.

The existing vegetation will be removed prior to mining. The current scenic view will be altered from visible vantage points.

Comment Requested

This notice of intent corrects information in the original NOI. The original NOI initiated the scoping process which guides the development of the environmental impact statement. The Forest Service sought information that planners may not have been aware of, or comments and/or concerns regarding potential effects of the proposal to authorize mining on the Section 30 PLS Lode Mining Claims. Early Notice of Importance of Public Participation in Subsequent Environmental Review: A draft environmental impact statement will be prepared for comment. The comment period on the draft environmental impact statement will be for 45 days from the date the Environmental Protection Agency publishes the Notice of Availability in the **Federal Register**. The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC,* 435 U.S. 519, 553 (1978). Also, environmental objections that could be raised at the draft environmental impact statement stage but that are not raised until after completion of the final environmental impact statement may be waived or dismissed by the courts. *City of Angoon* v. *Hodel,* 803 F.2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc.* v. *Harris,* 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45-day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the final environmental impact statement.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the draft environmental impact statement should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the draft environmental impact statement or the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

Comments received, including the names and addresses of those who comment, will be considered part of the public record on this proposal and will be available for public inspection.

Authority: 40 CFR 1501.7 and 1508.22; Forest Service Handbook 1909.15, Section 21.

Dated: June 8, 2011.

Craig Bobzien,

Forest Supervisor, Black Hills National Forest.

[FR Doc. 2011–15052 Filed 6–16–11; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Scoria Mining Addition, Medicine Bow-Routt National Forests and Thunder Basin National Grassland; Campbell County, WY

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The Forest Service proposes to authorize Thunder Basin Coal Company, LLC to expand the area of its existing scoria gravel pit development to include public domain minerals on parcels of National Forest System (NFS) lands on Thunder Basin National Grassland. NFS lands within the analysis area include portions of Sections 11–14 and 23–25, T43N R70W, 6th Principal Meridian, Campbell County.

DATES: Comments concerning the project or the scope of the planned environmental analysis must be received by July 20, 2011. The draft environmental impact statement (DEIS) is expected to be available by October 2011, and the final environmental impact statement (FEIS) is expected to be completed by April 2012.

ADDRESSES: Send written comments to Richard A. Cooksey, Deputy Forest Supervisor, Medicine Bow-Routt National Forests and Thunder Basin National Grassland, 2250 East Richards Street, Douglas, Wyoming 82633, or e-mail comments to *comments-rm-mbr-douglas-thunder-basin@fs.fed.us*.

All comments, including names and addresses of commenters, when provided, are placed in the record and are available for public inspection and copying. The public may review the comments at the Douglas Ranger District at the address noted above. Visitors are encouraged to call ahead to (307) 358–4690 to facilitate entry into the building.

FOR FURTHER INFORMATION, CONTACT: Peter Rose, Solid Minerals Project Manager, Douglas Ranger District, 2250 East Richards St, Douglas, WY 82633, (307) 358–4690.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: Federal coal lessee, Thunder Basin Coal Company, LLC (TBCC), filed with the USDA, Forest Service a request for authorization to access and mine aggregate material (scoria) on NFS lands. The purpose of this action is to ensure that an adequate supply of aggregate material is available for road construction and maintenance in order to support required maintenance and changes in infrastructure necessary for the uninterrupted mining of their Federal coal lease.

The Forest Service proposes to authorize TBCC to remove scoria from NFS lands from an area totaling approximately 459 acres. The analysis will also include 566 acres of private surface lands. The total lands encumbered by mining activity will not include the total above acreage all at one time but will encumber only those lands reasonably needed for the existing scoria mining and will progress over a 10- to 15-year timeframe. Scoria removal will occur in small incremental sections of approximately 10 acres in size, not to exceed 20 acres in any given year, for the purpose of using that scoria on adjacent roads needed for coal mining operations. As the scoria mining moves forward, TBCC will reclaim lands equivalent to the amount of acreage that is being mined. It should be noted that not all lands within the analysis area will be mined. Only those acres that have the potential for scoria material will be disturbed during the proposed mining project.

Richard Cooksey, Deputy Forest Supervisor, Medicine Bow-Routt National Forests and Thunder Basin National Grassland, 2468 Jackson Street, Laramie, Wyoming 82070 is the Official responsible for making the decision on this action. The responsible Official will consider the results of the analysis and its findings and then document the final decision in a Record of Decision (ROD). The decision will include a determination on whether or not to authorize the Scoria Mining Addition to occur in the above described lands as proposed by the applicant (TBCC), or to

allow an alternative to the proposed action.

In addition to this notice, the scoping process will include the distribution of letters to interested parties requesting comments on the proposed action, and a public notice will be published in area media.

The Forest Service has identified the following preliminary issues: (1) Potential impacts to wildlife in the proposed project area; (2) potential impacts to the watershed; (3) potential impacts to cultural and paleontological resources; (4) potential impacts to adjacent private lands; and (5) potential impacts to livestock grazing permits on the National Grassland.

This notice is to inform the public of the proposed action and invite the public to participate by providing any comments or information they may have concerning the proposal. This information will be used to identify important issues and determine the extent of the analysis necessary to make an informed decision on the proposal. Such issues will assist in the formulation of additional alternatives and the development of mitigation measures necessary to reduce impacts.

A DEIS will be prepared for comment. The comment period on the DEIS will be 45 days from the date the Environmental Protection Agency publishes the notice of availability in the **Federal Register**.

The Forest Service believes it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, as a result of *Vermont Yankee Nuclear Power Corp.* v. *NRDC, 435 U.S. 519, 553 (1978),* reviewers of DEISs must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. Also, in conjunction with *City of Angoon* v. *Hodel, 803 F.2d 1016, 1022 (9th Cir. 1986)* and *Wisconsin Heritages, Inc.* v. *Harris, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980),* environmental objections that could be raised at the DEIS stage but that are not raised until after completion of the FEIS may be waived or dismissed by the courts. Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45-day comment period so that comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the FEIS.

To assist the Forest Service in identifying and considering issues and concerns, comments on the DEIS should be as specific as possible to the proposed action. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the DEIS or the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

Authority: 40 CFR 1501.7 and 1508.22; Forest Service Handbook 1909.15, Section 21)

[FR Doc. 2011–15050 Filed 6–16–11; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Glenn/Colusa Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Glenn/Colusa Resource Advisory Committee will meet in Willows, California. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L. 110–343) (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with the title II of the Act. The meeting is open to the public. The purpose of the meeting is review and discuss existing projects, and review new proposals for additional projects.

DATES: The meeting will be held June 20, 2011 at 1:30 p.m.

ADDRESSES: The meeting will be held at Mendocino National Forest, Grindstone Ranger District Office, Black Butte and Snow Mountain Conference Rooms, located at 825 N. Humboldt, Willows, CA 95988. Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION.**

All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at Grindstone Ranger District, Stonyford Work Center, 5171 Stonyford-Elk Creek Rd., Stonyford, CA 95979. Please call ahead to 530–963–3128 to facilitate entry into the building to view comments.

FOR FURTHER INFORMATION CONTACT: Laurie L. Pearson, Visitor Information Assistant, and Glenn/Colusa R.A.C. Coordinator, Grindstone Ranger District, 530–963–3128, *LLPearson@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday. Requests for reasonable accommodation for access to the facility or proceedings may be made by contacting the person listed **FOR FURTHER INFORMATION.**

SUPPLEMENTARY INFORMATION: The following business will be conducted: 1 Introductions, 2. Approval of Minutes, 3. RAC Admin. Updates, 4. Public Comment, 5. Voting on New Proposals, 6. Project Reviews, 7. Schedule Monitoring Field Trip, 8. General Discussion, 9. Meeting Schedule, 10. Adjourn.

Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by June 10, 2011 to be scheduled on the agenda. Written comments and requests for time for oral comments must be sent to Stonyford Work Center, Attn: Laurie L. Pearson, Glenn/Colusa R.A.C. Coordinator, PO Box 160, Stonyford, CA 95979, or by e-mail to *LLPearson@fs.fed.us,* or via facsimile to 530–963–3173.

Dated: June 1, 2011.

Eduardo Olmedo,

Designated Federal Official.

[FR Doc. 2011–15053 Filed 6–16–11; 8:45 am]

BILLING CODE 3410–11–P

BROADCASTING BOARD OF GOVERNORS

SES Performance Review Board Membership

AGENCY: Broadcasting Board of Governors (BBG).

ACTION: Notice of Membership of SES Performance Review Board.

SUMMARY: Title 5 United States Code, Section 4314, requires that notice of the appointment of an individual to serve as a member of a performance review board (PRB) shall be published in the **Federal Register**. The following

individuals have been appointed to serve as PRB members for BBG: Jon C. Brause, Deputy Assistant Administrator, Bureau for Democracy, Conflict and Humanitarian Services, U.S. Agency for International Development; Nigel Mote, Executive Director, U.S. Nuclear Waste Technical Review Board; and Ariane Whittemore, Special Assistant, Total Force Management, Manpower and Reserve Affairs, Office of the Assistant Secretary, U.S. Department of the Navy.

ADDRESSES: Broadcasting Board of Governors, 330 Independence Ave., SW., Washington, DC 20237.

FOR FURTHER INFORMATION CONTACT: Donna S. Grace, Director, Office of Human Resources, 202–382–7500.

Jeffrey N. Trimble,

Executive Director, Broadcasting Board of Governors.

[FR Doc. 2011–15033 Filed 6–16–11; 8:45 am]

BILLING CODE 8610–01–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–821–809]

Continuation of Suspended Antidumping Duty Investigation on Certain Hot-Rolled Flat-Rolled Carbon-Quality Steel Products From the Russian Federation

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: As a result of the determination by the Department of Commerce (''the Department'') and the International Trade Commission (''ITC'') that termination of the suspended antidumping duty investigation on certain hot-rolled flat-rolled carbon quality steel products (''hot-rolled steel'') from the Russian Federation (''Russia'') would likely lead to continuation or recurrence of dumping, and material injury to an industry in the United States, the Department is publishing notice of the continuation of this suspended antidumping duty investigation.

DATES: *Effective Date:* June 17, 2011.

FOR FURTHER INFORMATION CONTACT: Anne D'Alauro or Sally Gannon, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–4830 or (202) 482–0162, respectively.

SUPPLEMENTARY INFORMATION:

Background

On April 1, 2010, the Department initiated, and the ITC instituted, a sunset review of the suspended antidumping duty investigation on hot-rolled steel from Russia (''the Agreement''), pursuant to section 751(c) of the Tariff Act of 1930, as amended (''the Act''). *See Initiation of Five-year (''Sunset'') Review,* 75 FR 16437 (April 1, 2010). As a result of its review, the Department determined that termination of the suspended antidumping duty investigation on hot-rolled steel from Russia would likely lead to a continuation or recurrence of dumping and notified the ITC of the magnitude of the margins likely to prevail, should the Agreement be terminated. *See Certain Hot-Rolled Flat-Rolled Steel Products from the Russian Federation; Final Results of the Expedited Sunset Review of Antidumping Duty Suspended Investigation,* 75 FR 47263 (August 5, 2010).

On June 2, 2011, pursuant to section 751(c) of the Act, the ITC determined that termination of the Agreement on hot-rolled steel from Russia would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time. See *Hot-Rolled Flat-Rolled Carbon-Quality Steel Products from Brazil, Japan, and Russia,* 76 FR 34101 (June 10, 2011).

Therefore, pursuant to section 351.218(f)(4) of the Department's regulations, the Department is publishing this notice of the continuation of the Agreement on hot-rolled steel from Russia.

Scope

See Appendix 1.

Continuation

As a result of the respective determinations by the Department and the ITC that termination of the Agreement on hot-rolled steel from Russia would likely lead to continuation or recurrence of dumping and material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act, the Department hereby gives notice of the continuation of the Agreement on hot-rolled steel from Russia. The effective date of continuation will be the date of publication in the **Federal Register** of this Continuation Notice. Pursuant to sections 751(c)(2) of the Act, the Department intends to initiate the next five-year sunset review of the Agreement on hot-rolled steel from Russia not later than May 2016.

This five-year (sunset) review and notice are in accordance with section 751(c) of the Act and published pursuant to section 777(i)(1) of the Act.

Dated: June 9, 2011.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

Appendix I

For the purposes of this Suspension Agreement, ''hot-rolled steel'' means certain hot-rolled flat-rolled carbon-quality steel products of a rectangular shape, of a width of 0.5 inch or greater, neither clad, plated, nor coated with metal and whether or not painted, varnished, or coated with plastics or other non-metallic substances, in coils (whether or not in successively superimposed layers) regardless of thickness, and in straight lengths, of a thickness less than 4.75 mm and of a width measuring at least 10 times the thickness.

Universal mill plate (*i.e.,* flat-rolled products rolled on four faces or in a closed box pass, of a width exceeding 150 mm but not exceeding 1250 mm and of a thickness of not less than 4 mm, not in coils and without patterns in relief) of a thickness not less than 4.0 mm is not included within the scope of this agreement.

Specifically included in this scope are vacuum degassed, fully stabilized (commonly referred to as interstitial-free (''IF'')) steels, high strength low alloy (''HSLA'') steels, and the substrate for motor lamination steels. IF steels are recognized as low carbon steels with micro-alloying levels of elements such as titanium and/or niobium added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, titanium, vanadium, and molybdenum. The substrate for motor lamination steels contains micro-alloying levels of elements such as silicon and aluminum.

Steel products to be included in the scope of this agreement, regardless of HTSUS definitions, are products in which: (1) Iron predominates, by weight, over each of the other contained elements; (2) the carbon content is 2 percent or less, by weight; and (3) none of the elements listed below exceeds the quantity, by weight, respectively indicated: 1.80 percent of manganese, or 1.50 percent of silicon, or 1.00 percent of copper, or 0.50 percent of aluminum, or 1.25 percent of chromium, or 0.30 percent of cobalt, or 0.40 percent of lead, or 1.25 percent of nickel, or 0.30 percent of tungsten, or 0.012 percent of boron, or 0.10 percent of molybdenum, or 0.10 percent of niobium, or 0.41 percent of titanium, or 0.15 percent of vanadium, or 0.15 percent of zirconium.

All products that meet the physical and chemical description provided above are within the scope of this agreement unless otherwise excluded. The following products, by way of example, are outside and/or specifically excluded from the scope of this agreement:

—Alloy hot-rolled steel products in which at least one of the chemical elements exceeds those listed above (including *e.g.,* ASTM specifications A543, A387, A514, A517, and A506).

—SAE/AISI grades of series 2300 and higher.

—Ball bearing steels, as defined in the HTSUS.

—Tool steels, as defined in the HTSUS.
—Silico-manganese (as defined in the HTSUS) or silicon electrical steel with a silicon level exceeding 1.50 percent.
—ASTM specifications A710 and A736.
—USS Abrasion-resistant steels (USS AR 400, USS AR 500).
—Hot-rolled steel coil which meets the following chemical, physical and mechanical specifications:

C	Mn	P	S	Si	Cr	Cu	Ni
0.10–0.14%	0.90% Max	0.025% Max	0.005% Max	0.30–0.50%	0.50–0.70%	0.20–0.40%	0.20% Max.

Width = 44.80 inches maximum; Thickness = 0.063–0.198 inches;
Yield Strength = 50,000 ksi minimum; Tensile Strength = 70,000–88,000 psi.
—Hot-rolled steel coil which meets the following chemical, physical and mechanical specifications:

C	Mn	P	S	Si	Cr	Cu	Ni
0.10–0.16% ..... Mo 0.21% Max	0.70–0.90%	0.025% Max	0.006% Max	0.30–0.50%	0.50–0.70%	0.25% Max	0.20% Max.

Width = 44.80 inches maximum; Thickness = 0.350 inches maximum;
Yield Strength = 80,000 ksi minimum; Tensile Strength = 105,000 psi Aim.
—Hot-rolled steel coil which meets the following chemical, physical and mechanical specifications:

C	Mn	P	S	Si	Cr	Cu	Ni
0.10–0.14% ..... V(wt.) ..... 0.10 Max	1.30–1.80% ..... Cb. 0.08% Max.	0.025% Max	0.005% Max	0.30–0.50%	0.50–0.70%	0.20–0.40%	0.20% Max.

Width = 44.80 inches maximum; Thickness = 0.350 inches maximum;
Yield Strength = 80,000 ksi minimum; Tensile Strength = 105,000 psi Aim.
—Hot-rolled steel coil which meets the following chemical, physical and mechanical specifications:

C	Mn	P	S	Si	Cr	Cu	Ni
0.15% Max ..... Nb ..... 0.005% Min	1.40% Max ..... Ca ..... Treated	0.025% Max .... Al. 0.01–0.07%.	0.010% Max	0.50% Max	1.00% Max	0.50% Max	0.20% Max.

Width = 39.37 inches; Thickness = 0.181 inches maximum; Yield Strength = 70,000 psi minimum for thicknesses ≤ 0.148 inches and 65,000 psi minimum for thicknesses >0.148 inches; Tensile Strength = 80,000 psi minimum.
—Hot-rolled dual phase steel, phase-hardened, primarily with a ferritic-martensitic microstructure, contains 0.9 percent up to and including 1.5 percent silicon by weight, further characterized by either (i) tensile strength between 540 N/mm² and 640 N/mm²; and an elongation percentage ≥ 26 percent for thicknesses of 2 mm and above, or (ii) a tensile strength between 590 N/mm² and 690 N/mm² and an elongation percentage ≥ 25 percent for thicknesses of 2 mm and above.
—Hot-rolled bearing quality steel, SAE grade 1050, in coils, with an inclusion rating of 1.0 maximum per ASTM E 45, Method A, with excellent surface quality and chemistry restrictions as follows: 0.012 percent maximum phosphorus, 0.015 percent maximum sulfur, and 0.20 percent maximum residuals including 0.15 percent maximum chromium.

• Grade ASTM A570–50 hot-rolled steel sheet in coils or cut lengths, width of 74 inches (nominal, within ASTM tolerances), thickness of 11 gauge (0.119 inches nominal), mill edge and skin passed, with a minimum copper content of 0.20 percent.

The covered merchandise is classified in the *Harmonized Tariff Schedule of the United States* (''HTSUS'') at subheadings: 7208.10.15.00, 7208.10.30.00, 7208.10.60.00, 7208.25.30.00, 7208.25.60.00, 7208.26.00.30, 7208.26.00.60, 7208.27.00.30, 7208.27.00.60, 7208.36.00.30, 7208.36.00.60, 7208.37.00.30, 7208.37.00.60, 7208.38.00.15, 7208.38.00.30, 7208.38.00.90, 7208.39.00.15, 7208.39.00.30, 7208.39.00.90, 7208.40.60.30, 7208.40.60.60, 7208.53.00.00, 7208.54.00.00, 7208.90.00.00, 7210.70.30.00, 7210.90.90.00, 7211.14.00.30, 7211.14.00.90, 7211.19.15.00, 7211.19.20.00, 7211.19.30.00, 7211.19.45.00, 7211.19.60.00, 7211.19.75.30, 7211.19.75.60, 7211.19.75.90, 7212.40.10.00, 7212.40.50.00, 7212.50.00.00. Certain hot-rolled flat-rolled carbon-quality steel covered include: Vacuum degassed, fully stabilized; high strength low alloy; and the substrate for motor lamination steel may also enter under the following tariff numbers: 7225.11.00.00, 7225.19.00.00, 7225.30.30.50, 7225.30.70.00, 7225.40.70.00, 7225.99.00.90, 7226.11.10.00, 7226.11.90.30, 7226.11.90.60, 7226.19.10.00, 7226.19.90.00, 7226.91.50.00, 7226.91.70.00, 7226.91.80.00, and 7226.99.00.00. Although the HTSUS subheadings are provided for convenience and Customs purposes, the written description of the covered merchandise is dispositive.

[FR Doc. 2011–15129 Filed 6–16–11; 8:45 am]
BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–588–804, A–412–801]

Ball Bearings and Parts Thereof From Japan and the United Kingdom: Notice of Court Decision Not in Harmony With Continuation of Antidumping Duty Orders

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On June 1, 2005, the Department of Commerce (the Department) initiated and the International Trade Commission (ITC) instituted the second sunset reviews of the antidumping duty orders on ball bearings and parts thereof from Japan and the United Kingdom. On April 20,

2011, the Court of International Trade (CIT) entered its final judgment sustaining the ITC's remand redetermination that revocation of the antidumping duty orders on ball bearings and parts thereof from Japan and the United Kingdom would not be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

DATES: *Effective Date:* April 30, 2011.

FOR FURTHER INFORMATION CONTACT: Sandra Stewart or Richard Rimlinger, AD/CVD Operations, Office 5, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; *telephone:* (202) 482–0768 or (202) 482–4477, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 15, 1989, the Department published the antidumping duty orders on ball bearings and parts thereof from Japan and the United Kingdom (collectively, the orders) in the **Federal Register**. *See Antidumping Duty Orders: Ball Bearings, Cylindrical Roller Bearings, and Spherical Plain Bearings, and Parts Thereof From Japan, 54 FR 20904 (May 15, 1989), and Antidumping Duty Orders and Amendments to the Final Determinations of Sales at Less Than Fair Value: Ball Bearings, and Cylindrical Roller Bearings and Parts Thereof From the United Kingdom,* 54 FR 20910 (May 15, 1989). Pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act), the Department initiated and the ITC instituted the second sunset reviews of the orders on June 1, 2005. See *Initiation of Five-Year (''Sunset'') Reviews,* 70 FR 31423 (June 1, 2005), and *Certain Bearings From China, France, Germany, Italy, Japan, Singapore, and the United Kingdom,* 70 FR 31531 (June 1, 2005). See also 19 CFR 351.218. As a result of its reviews, the Department found that revocation of the orders would be likely to lead to the continuation or recurrence of dumping and notified the ITC of the magnitude of the margins likely to prevail were the orders to be revoked. See *Antifriction Bearings and Parts Thereof From France, Germany, Italy, and the United Kingdom; Five-Year Sunset Reviews of Antidumping Duty Orders; Final Results,* 70 FR 58183 (October 5, 2005), *Ball Bearings and Parts Thereof From Japan and Singapore; Five-Year Sunset Reviews of Antidumping Duty Orders; Final Results,* 71 FR 26321 (May 4, 2006), and *Ball Bearings and Parts Thereof From Japan; Five-Year Sunset Review of Antidumping Duty Order: Amended Final Results,* 71 FR 30378 (May 26, 2006).

On August 31, 2006, the ITC published its determination that, pursuant to section 751(c) of the Act, revocation of the orders, among others, would be likely to lead to the continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time. See *Certain Bearings From China, France, Germany, Italy, Japan, Singapore, and the United Kingdom,* 71 FR 51850 (August 31, 2006), and ITC Publication 3876 (August 2006) entitled *Certain Bearings from China, France, Germany, Italy, Japan, Singapore, and the United Kingdom, Investigation Nos. 731–TA–344, 391–A, 392–A and C, 393–A, 394–A, 396, and 399–A (Second Review).* NSK Corporation, NSK Ltd., and NSK Europe Ltd. and JTEKT Corporation and Koyo Corporation of U.S.A. filed appeals of this determination with the CIT.

In its third [1] and fourth [2] remand determinations, the ITC found that revocation of the orders would not be likely to lead to the continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time. On April 20, 2011, the CIT affirmed the ITC's fourth remand and entered judgment in the case. See *NSK* v. *United States,* Court No. 06–334, Slip Op. 11–43 (CIT April 20, 2011) (NSK). Therefore, there is now a final CIT decision in the case sustaining negative injury determinations concerning ball bearings and parts thereof from the United Kingdom and Japan.[3] *Id.*

Timken Notice

In its decision in *Timken Co.* v. *United States,* 893 F.2d 337, 341 (Fed. Cir. 1990), the Court of Appeals for the Federal Circuit held that, pursuant to section 516A(c)(1) of the Act, the Department must publish a notice of a court decision that is not ''in harmony'' with a Department determination and must suspend liquidation of entries pending a ''conclusive'' court decision. The April 20, 2011, decision by the CIT in NSK constitutes a final CIT decision that is not in harmony with the Department's continuation of the orders (*Tapered Roller Bearings and Parts Thereof From the People's Republic of China and Ball Bearings and Parts Thereof From France, Germany, Italy, Japan, and the United Kingdom: Continuation of Antidumping Duty Orders,* 71 FR 54469 (September 15, 2006)). This notice is published in fulfillment of the publication requirement in *Timken.*

Accordingly, the Department intends to issue instructions to U.S. Customs and Border Protection to suspend liquidation of all unliquidated entries of subject merchandise from Japan and the United Kingdom which are entered, or withdrawn from warehouse, for consumption on or after July 11, 2005, the five-year anniversary date of the continuation of the orders. See *Continuation of Antidumping Duty Orders: Certain Bearings From France, Germany, Italy, Japan, Singapore, the United Kingdom and the People's Republic of China,* 65 FR 42665 (July 11, 2000), and 19 CFR 351.222(i)(2). Pursuant to *Timken,* all entries entered, or withdrawn from warehouse, for consumption on or after July 11, 2005, that remain unliquidated and not deemed liquidated as of April 30, 2011, will be suspended during the pendency of the appeals process so that they may be liquidated at the court-approved rate after a ''conclusive'' court decision.

This notice is published pursuant to section 516A(c)(1) of the Act.

Dated: June 10, 2011.

Ronald K. Lorentzen

Deputy Assistant Secretary for Import Administration.

[FR Doc. 2011–15128 Filed 6–16–11; 8:45 am]

BILLING CODE 3510–DS–P

[1] See ITC Publication 4194, *Ball Bearings and Parts Thereof From Japan and the United Kingdom, Investigation Nos. 731–TA–394A and 399A (Second Review) (Third Remand)* (August 2010).

[2] See ITC Publication 4223, *Certain Ball Bearings and Parts Thereof From Japan and the United Kingdom, Investigation Nos. 394–A and 399–A (Second Review) (Fourth Remand)* (March 2011).

[3] Although the CIT issued a temporary stay of the effect of its judgment, it lifted the stay on May 13, 2011. On May 17, 2011, the Federal Circuit issued a temporary stay of the judgment in this case. *NSK Corp.* v. *United States,* Court Nos. 2011–1362, –1382, –1383 (May 17, 2011). The Department will not revoke the applicable orders while the stay remains in place.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–847]

Persulfates From the People's Republic of China: Notice of Correction to the Final Results of the 2009–2010 Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* June 17, 2011.

FOR FURTHER INFORMATION CONTACT: Brandon Petelin, AD/CVD Operations, Office 4, Import Administration, International Trade Administration,

U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; *telephone:* (202) 482–8173.

SUPPLEMENTARY INFORMATION:

Correction

On May 17, 2011, the Department of Commerce (''Department'') published in the **Federal Register** the final results of the 2009–2010 administrative review of the antidumping duty order on persulfates from the People's Republic of China (''PRC'').[1] The period of review covered July 1, 2009, through June 30, 2010. The published **Federal Register** notice contained a ministerial error, in that it identified the incorrect case number associated with persulfates from the PRC (*i.e.,* case number A–570–878).[2] The correct case number associated with persulfates from the PRC is A–570–847. Pursuant to section 751(h) of the Tariff Act of 1930, as amended (''the Act''), the Department shall correct any ministerial errors within a reasonable time after the determination issues. A ministerial error is defined as an error ''in addition, subtraction, or other arithmetic function, clerical errors resulting from inaccurate copying, duplication, or the like, and any other type of unintentional error.'' This notice serves to correct the case number reported in the *Final Results.*

This correction is published in accordance with sections 751(h) and 777(i) of the Act.

Dated: June 1, 2011.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 2011–15131 Filed 6–16–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–801]

Certain Frozen Fish Fillets From the Socialist Republic of Vietnam: Final Results of the Antidumping Duty New Shipper Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On January 25, 2011, the Department of Commerce (''Department'') published the *Preliminary Results* of the seventh new shipper reviews of the antidumping duty order on certain frozen fish fillets (''frozen fish fillets'') from the Socialist Republic of Vietnam (''Vietnam'').[1] We gave interested parties an opportunity to comment on the *Preliminary Results* and, based upon our analysis of the comments and information received, we made changes to the margin calculations for the final results of these reviews. The final weighted-average margins are listed below in the ''Final Results of the Reviews'' section of this notice. The period of review (''POR'') is August 1, 2009, through February 15, 2010.

DATES: *Effective Date:* June 17, 2011.

FOR FURTHER INFORMATION CONTACT: Alan Ray, AD/CVD Operations, Office 9, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; *telephone:* (202) 482–5403.

SUPPLEMENTARY INFORMATION:

Case History

As noted above, on January 25, 2011, the Department published the *Preliminary Results* of these new shipper reviews. We extended the deadlines for submission of surrogate value comments and case briefs.[2] On March 9, 2011, the Department published a notice fully extending the time limit for completion of the final results of these new shipper reviews.[3]

We invited interested parties to comment on the *Preliminary Results.* Between May 2, 2011, and May 12, 2011, we received case and rebuttal briefs from Petitioners[4] and the Respondents. As a result of our analysis, we have made changes to the *Preliminary Results.*

Scope of the Order[5]

The product covered by the order is frozen fish fillets, including regular, shank, and strip fillets and portions thereof, whether or not breaded or marinated, of the species *Pangasius Bocourti, Pangasius Hypophthalmus* (also known as *Pangasius Pangasius*), and *Pangasius Micronemus.* Frozen fish fillets are lengthwise cuts of whole fish. The fillet products covered by the scope include boneless fillets with the belly flap intact (''regular'' fillets), boneless fillets with the belly flap removed (''shank'' fillets), boneless shank fillets cut into strips (''fillet strips/finger''), which include fillets cut into strips, chunks, blocks, skewers, or any other shape. Specifically excluded from the scope are frozen whole fish (whether or not dressed), frozen steaks, and frozen belly-flap nuggets. Frozen whole dressed fish are deheaded, skinned, and eviscerated. Steaks are bone-in, cross-section cuts of dressed fish. Nuggets are the belly-flaps. The subject merchandise will be hereinafter referred to as frozen ''basa'' and ''tra'' fillets, which are the Vietnamese common names for these species of fish. These products are classifiable under tariff article codes 1604.19.4000, 1604.19.5000, 0305.59.4000, 0304.29.6033 (Frozen Fish Fillets of the species *Pangasius* including basa and tra) of the Harmonized Tariff Schedule of the United States (''HTSUS'').[6] The order covers all frozen fish fillets meeting the above specification, regardless of tariff classification. Although the HTSUS subheading is provided for convenience and customs purposes, our written description of the scope of the order is dispositive.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties are addressed in ''Certain Frozen Fish Fillets from the Socialist Republic of Vietnam (''Vietnam''): Issues and Decision Memorandum for the Final Results,'' (June 13, 2011) (''I&D Memo''). A list of the issues which parties raised, and to which we responded in the I&D Memo,

[1] *See Persulfates from the People's Republic of China: Final Results of 2009–2010 Antidumping Duty Administrative Review,* 76 FR 28419 (May 17, 2011) (*''Final Results''*).

[2] *Id.* at 28419.

[1] *See Certain Frozen Fish Fillets From the Socialist Republic of Vietnam: Notice of Preliminary Results of Antidumping Duty New Shipper Reviews,* 76 FR 4292 (January 25, 2011) (*''Preliminary Results''*).

[2] *See* Letter from Alex Villanueva, Program Manager, Office 9, to Interested Parties: Extending Surrogate Value Submission & Briefing Schedule for New Shipper Reviews of Certain Frozen Fish Fillets from the Socialist Republic of Vietnam (February 10, 2011). *See also* Letter from Matthew Renkey, Acting Program Manager, Office 9, to Interested Parties: Extending Surrogate Value Submission & Briefing Schedule for New Shipper Reviews of Certain Frozen Fish Fillets from the Socialist Republic of Vietnam (March 25, 2011).

[3] *See Certain Frozen Fish Fillets From the Socialist Republic of Vietnam: Notice of Extension of Time Limit for the Final Results of the Sixth Antidumping Duty Administrative and New Shipper Reviews,* 75 FR 80795 (December 23, 2010).

[4] The Catfish Farmers of America and individual U.S. Catfish Processors: America's Catch, Consolidated Catfish Companies, LLC dba Country Select Catfish, Delta Pride Catfish, Inc., Harvest Select Catfish, Inc., Heartland Catfish Company, Pride of the Pond, Simmons Farm Raised Catfish, Inc., and Southern Pride Catfish Company LLC (collectively, ''Petitioners'').

[5] *See Notice of Antidumping Duty Order: Certain Frozen Fish Fillets From the Socialist Republic of Vietnam,* 68 FR 47909 (August 12, 2003) (*''Order''*).

[6] Until July 1, 2004, these products were classifiable under tariff article codes 0304.20.60.30 (Frozen Catfish Fillets), 0304.20.60.96 (Fish Fillets, NESOI), 0304.20.60.43 (Frozen Freshwater Fish Fillets) and 0304.20.60.57 (Frozen Sole Fillets) of the HTSUS. Until February 1, 2007, these products were classifiable under tariff article code 0304.20.60.33 (Frozen Fish Fillets of the species *Pangasius* including basa and tra) of the HTSUS.

is attached to this notice as an Appendix. The I&D Memo is a public document and is on file in the Central Records Unit (''CRU''), Main Commerce Building, Room 7046, and is accessible on the Department's Web site at *http://www.trade.gov/ia.* The paper copy and electronic version of the memorandum are identical in content.

Changes Since the Preliminary Results

Based on a review of the record, verification, as well as comments received from interested parties regarding our *Preliminary Results,* we have made certain revisions to the margin calculation for IDI and THIMACO for the final results. For the reasons explained in the I&D Memo at Comment I, we have changed our surrogate country selection from the Philippines to Bangladesh. For all other changes to the calculations of IDI and THIMACO, *see* the I&D Memo and company specific analysis memoranda. For changes to the surrogate values, *see* the I&D Memo and ''Memorandum to the File, through Matthew Renkey, Acting Program Manager, AD/CVD Operations, Office 9, from Alan Ray, Case Analyst, and Emeka Chukwudebe, Case Analyst, AD/CVD Operations, Office 9, Antidumping Duty New Shipper Reviews of Certain Frozen Fish Fillets from the Socialist Republic of Vietnam: Surrogate Values for the Final Results,'' (June 13, 2011).

Final Results of the Reviews

The weighted-average dumping margins for the POR are as follows:

Exporter	Weighted-average margin (dollars per kilogram)
(1) THIMACO	$0.00
(2) IDI	0.00

Assessment

The Department will determine, and U.S. Customs and Border Protection (''CBP'') shall assess, antidumping duties on all appropriate entries, pursuant to 19 CFR 351.212(b). We have calculated importer-specific duty assessment rates on a per-unit basis. Specifically, we divided the total dumping margins (calculated as the difference between normal value and export price or constructed export price) for each importer by the total quantity of subject merchandise sold to that importer during the POR to calculate a per-unit assessment amount. In this and any future review, we will direct CBP to assess importer-specific assessment rates based on the resulting per-unit (*i.e.,* per-kilogram) rates by the weight in kilograms of each entry of the subject merchandise during the POR. The Department intends to issue appropriate assessment instructions directly to CBP 15 days after publication of the final results of this new shipper review.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of this final results of these new shipper reviews for all shipments of subject merchandise by THIMACO and IDI, entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Tariff Act of 1930, as amended (''Act''): (1) For subject merchandise produced and exported by IDI or THIMACO, the cash deposit rate will be zero; (2) for subject merchandise exported by IDI or THIMACO, but not manufactured by IDI or THIMACO, the cash deposit rate will continue to be the Vietnam-wide rate of $2.11/Kilogram; and (3) for subject merchandise manufactured by IDI or THIMACO, but exported by any party other than NTSF, the cash deposit rate will be the rate applicable to the exporter. These cash deposit requirements will remain in effect until further notice.

Reimbursement of Duties

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties has occurred and the subsequent assessment of doubled antidumping duties.

Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective orders (''APO'') of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing this determination in accordance with sections 751(a)(2)(B) and 777(i) of the Act, and 19 CFR 351.214(h) and 351.221(b)(5).

Dated: June 10, 2011.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

Appendix I—Issues & Decision Memorandum

General Issues

Comment I: Selection of Surrogate Country

A. Economic Comparability

B. Significant Producer of the Comparable Merchandise

C. Data Considerations

Comment II: Surrogate Values

A. Financial Ratios

i. Whether To Reject Gemini's Financial Ratios Due to the Subsidies Listed in the Financial Statement

ii. Which Financial Statements Represent the Best Source for Calculating Financial Ratios

B. Byproducts

i. Fish Waste

ii. Fish Skin

Company-Specific Issues

Comment III: Adjustments to THIMACO's Margin Calculation

A. Adjust ''International Freight'' from a Per Pound to a Per Kilogram Basis

B. Adjust Calculation of ''Insurance'' To Be Percentage Applied to Gross Unit Price

C. Should the Department Alter Its Preliminary Decision To Use the Intermediate Input Methodology (''IIM'') and Instead Accept THIMACO's Farming Factors, the Department Should Apply AFA to THIMACO's Farming Labor and Medicine FOPs

Comment IV: Adjustments to IDI's Margin Calculation

A. Adjust ''Other Discounts'' and ''International Freight'' Pound to Kilogram Basis

B. Adjust Calculation of Brokerage and Handling Expense

C. Calculation of IDI's Carton Boxes

[FR Doc. 2011–15125 Filed 6–16–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Civil Nuclear Trade Advisory Committee Public Meeting

AGENCY: International Trade Administration, DOC.

ACTION: Notice of Federal Advisory Committee Meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a meeting of the Civil Nuclear Trade Advisory Committee (CINTAC).

DATES: The meeting is scheduled for Thursday, July 14, 2011, at 10 a.m. Eastern Daylight Time (EDT).

ADDRESSES: The meeting will be held in Room 4830, U.S. Department of Commerce, Herbert Clark Hoover Building, 1401 Constitution Ave., NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Mr. David Kincaid, Office of Energy & Environmental Industries, International Trade Administration, Room 4053, 1401 Constitution Ave., NW., Washington, DC 20230. (Phone: 202–482–1706; Fax: 202–482–5665; e-mail: *David.Kincaid@trade.gov*).

SUPPLEMENTARY INFORMATION:

Background: The CINTAC was established under the discretionary authority of the Secretary of Commerce and in accordance with the Federal Advisory Committee Act (5 U.S.C. App.), in response to an identified need for consensus advice from U.S. industry to the U.S. Government regarding the development and administration of programs to expand United States exports of civil nuclear goods and services in accordance with applicable United States regulations, including advice on how U.S. civil nuclear goods and services export policies, programs, and activities will affect the U.S. civil nuclear industry's competitiveness and ability to participate in the international market.

Topics to be considered: The agenda for the July 14, 2011 CINTAC meeting is as follows:

Public Session

1. Opening remarks.
2. Trade Promotion Activities Update, including U.S. industry program at the International Atomic Energy Agency.
3. Public comment period.

Closed Session

1. Discussion of matters determined to be exempt from the provisions relating to public meetings found in 5 U.S.C. App. (10)(a)1 and 10(a)(3).

The open session will be disabled-accessible. Public seating is limited and available on a first-come, first-served basis. Members of the public wishing to attend the meeting must notify Mr. David Kincaid at the contact information below by 5 p.m. EDT on Friday, July 8, 2011 in order to pre-register for clearance into the building. Please specify any requests for reasonable accommodation at least five business days in advance of the meeting. Last minute requests will be accepted, but may be impossible to fill.

A limited amount of time will be available for pertinent brief oral comments from members of the public attending the meeting. To accommodate as many speakers as possible, the time for public comments will be limited to two (2) minutes per person, with a total public comment period of 30 minutes. Individuals wishing to reserve speaking time during the meeting must contact Mr. Kincaid and submit a brief statement of the general nature of the comments and the name and address of the proposed participant by 5 p.m. EDT on Friday, July 8, 2011. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, the International Trade Administration (ITA) may conduct a lottery to determine the speakers. Speakers are requested to bring at least 20 copies of their oral comments for distribution to the participants and public at the meeting.

Any member of the public may submit pertinent written comments concerning the CINTAC's affairs at any time before and after the meeting. Comments may be submitted to the Civil Nuclear Trade Advisory Committee, Office of Energy & Environmental Industries, Room 4053, 1401 Constitution Ave., NW., Washington, DC 20230. For consideration during the meeting, and to ensure transmission to the Committee prior to the meeting, comments must be received no later than 5 p.m. EDT on Friday, July 8, 2011. Comments received after that date will be distributed to the members but may not be considered at the meeting.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on April 20, 2011, pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App. (10)(d)), that the portion of the meeting dealing with matters the disclosure of which would be likely to frustrate significantly implementation of an agency action as described in 5 U.S.C. 552b(c)(9)(B) shall be exempt from the provisions relating to public meetings found in 5 U.S.C. App. (10)(a)(1) and 10(a)(3). The portion of the meeting dealing with matters requiring disclosure of trade secrets and commercial or financial information as described in 5 U.S.C. 552b(c)(4) shall be exempt from the provisions relating to public meetings found in 5 U.S.C. App. (10)(a)(1) and 10(a)(3). The remaining portions of the meeting will be open to the public.

Copies of CINTAC meeting minutes will be available within 90 days of the meeting.

Edward A. O'Malley,

Director, Office of Energy and Environmental Industries.

[FR Doc. 2011–15022 Filed 6–16–11; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–821–801]

Solid Urea From the Russian Federation: Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on solid urea from the Russian Federation (Russia). The review covers one producer/exporter of the subject merchandise, MCC EuroChem (EuroChem). The period of review (POR) is July 1, 2009, through June 30, 2010. We preliminarily determine that EuroChem sold the subject merchandise at less than normal value during the POR.

We invite interested parties to comment on these preliminary results. Parties who submit argument in this proceeding are requested to submit with the argument (1) a statement of the issue and (2) a brief summary of the argument.

DATES: *Effective Date:* June 17, 2011.

FOR FURTHER INFORMATION CONTACT: Dustin Ross or Minoo Hatten, AD/CVD Operations, Office 5, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–0747 or (202) 482–1690, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 14, 1987, the Department published the antidumping duty order on solid urea from the Union of Soviet Socialist Republics (Soviet Union). See *Antidumping Duty Order; Urea From the Union of Soviet Socialist Republics,* 52 FR 26367 (July 14, 1987). Following the break-up of the Soviet Union, the antidumping duty order on solid urea from the Soviet Union was transferred to the individual members of the Commonwealth of Independent States. See *Solid Urea From the Union of Soviet Socialist Republics; Transfer of the Antidumping Duty Order on Solid Urea From the Union of Soviet Socialist Republics to the Commonwealth of Independent States and the Baltic States and Opportunity to Comment,* 57 FR 28828 (June 29, 1992).

Pursuant to section 751(a)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(b), the Ad Hoc Committee of Domestic Nitrogen Producers and its individual urea-producing members, CF Industries, Inc., and PCS Nitrogen (collectively, the petitioner), requested an administrative review of the antidumping duty order on solid urea from Russia with respect to EuroChem on July 28, 2010. On August 31, 2010, in accordance with 19 CFR 351.221(c)(1)(i), we published a notice of initiation of administrative review of the order. See *Initiation of Antidumping and Countervailing Duty Administrative Reviews and Deferral of Initiation of Administrative Review,* 75 FR 53274 (August 31, 2010). On March 23, 2011, we extended the deadline for the preliminary results by 75 days to June 16, 2011. See *Solid Urea From the Russian Federation: Extension of Time Limit for Preliminary Results of Antidumping Duty Administrative Review,* 76 FR 17380 (March 29, 2011). We are conducting the administrative review of the order in accordance with section 751(a) of the Act.

Scope of the Order

The merchandise subject to the order is solid urea, a high-nitrogen content fertilizer which is produced by reacting ammonia with carbon dioxide. The product is currently classified under the Harmonized Tariff Schedule of the United States (HTSUS) item number 3102.10.00.00. Such merchandise was classified previously under item number 480.3000 of the Tariff Schedules of the United States. Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the merchandise subject to the order is dispositive.

Fair-Value Comparisons

To determine whether EuroChem's sales of solid urea from Russia were made in the United States at less than normal value, we compared the constructed export price (CEP) to the normal value as described in the ''Constructed Export Price'' and ''Normal Value'' sections of this notice.

When making this comparison in accordance with section 771(16) of the Act, we considered all products sold in the home market as described in the ''Scope of the Order'' section of this notice, above, that were in the ordinary course of trade for purposes of determining an appropriate product comparison to the U.S. sale. If an identical home-market model with identical physical characteristics as described below was reported, we made comparisons to weighted-average home-market prices that were based on all sales of the identical product during a contemporaneous month. If there were no contemporaneous sales of an identical model, we identified sales of the most similar merchandise that were most contemporaneous with the U.S. sale in accordance with 19 CFR 351.414(e).

Product Comparisons

In accordance with section 771(16) of the Act, we compared products produced by EuroChem and sold in the U.S. and home markets on the basis of the comparison product which was closest in terms of the physical characteristics to the product sold in the United States. In the order of importance, these characteristics are form, grade, nitrogen content, size, urea-formaldehyde content, other additive/conditioning agent, coating agent, and biuret content.

Date of Sale

Section 351.401(i) of the Department's regulations states that, normally, the Department will use the date of invoice, as recorded in the producer's or exporter's records kept in the ordinary course of business, as the date of sale. The regulation provides further that the Department may use a date other than the date of the invoice if the Secretary is satisfied that a different date better reflects the date on which the material terms of sale are established. The Department has a long-standing practice of finding that, where shipment date precedes invoice date, shipment date better reflects the date on which the material terms of sale are established. See *Notice of Final Determination of Sales at Less Than Fair Value and Negative Final Determination of Critical Circumstances: Certain Frozen and Canned Warmwater Shrimp From Thailand,* 69 FR 76918 (December 23, 2004), and accompanying Issues and Decision Memorandum at Comment 10; see also *Notice of Final Determination of Sales at Less Than Fair Value: Structural Steel Beams From Germany,* 67 FR 35497 (May 20, 2002), and accompanying Issues and Decision Memorandum at Comment 2.

For all U.S. sales, EuroChem reported contract date as the date of sale. EuroChem defines contract date as the date on which the material terms of sale are established and no longer subject to change. In those cases where a price addendum to the contract was issued, EuroChem considers the addendum date to be the final contract date where all the material terms of sale are established and no longer subject to change. Based on record evidence, all material terms of sale are established on the date of contract or the date of the price addendum to the contract. Therefore, we have used contract date as reported by EuroChem as the date of sale for all U.S. sales.

With respect to EuroChem's home-market sales, price and quantity are subject to change until invoicing. Because the material terms of sale are not established until invoicing, we have used invoice date as the date of sale in the home market except, in cases where shipment date precedes invoice date, we have used the shipment date as the date of sale in the home market.

Constructed Export Price

In accordance with section 772(b) of the Act, we used CEP for EuroChem because the subject merchandise was sold in the United States by a U.S. seller affiliated with the producer and export price was not otherwise indicated.

We calculated CEP based on the free-on-board or delivered price to unaffiliated purchasers in, or for exportation to, the United States. We also made deductions for any movement expenses in accordance with section 772(c)(2)(A) of the Act. In accordance with section 772(d)(1) of the Act, we calculated the CEP by deducting selling expenses associated with economic activities occurring in the United States, which includes direct selling expenses and indirect selling expenses. Finally, we made an adjustment for profit allocated to these expenses in accordance with section 772(d)(3) of the Act.

Normal Value

In order to determine whether there is a sufficient volume of sales in the home market to serve as a viable basis for

calculating normal value (*i.e.,* the aggregate volume of home-market sales of the foreign like product is five percent or more of the aggregate volume of U.S. sales), we compared the volume of EuroChem's home-market sales of the foreign like product to the volume of its U.S. sales of subject merchandise in accordance with section 773(a)(1)(C) of the Act. Based on this comparison, we determined that EuroChem had a viable home market during the POR. Consequently, we based normal value on home-market sales to unaffiliated purchasers made in the usual quantities in the ordinary course of trade and sales made to affiliated purchasers where we find prices were made at arm's length, described in detail below.

We based normal value on the starting prices to home-market customers. Pursuant to section 773(a)(6)(B)(ii) of the Act, we deducted movement expenses EuroChem incurred on its home-market sales. Pursuant to section 773(a)(6)(B)(i) of the Act, we deducted home-market packing costs. We made deductions for direct selling expenses, as appropriate.

Affiliation

The Department may calculate normal value based on a sale to an affiliated party only if it is satisfied that the price to the affiliated party is comparable to the price at which sales are made to parties not affiliated with the exporter or producer, *i.e.,* sales were made at arm's-length prices. See 19 CFR 351.403(c). We exclude from our analysis transactions to affiliated customers for consumption in the home market that we determine were not sold at arm's-length prices.

To test whether EuroChem's sales to affiliated parties were made at arm's-length prices, we compared the prices of sales of comparable merchandise to affiliated and unaffiliated customers, net of all rebates, movement charges, direct selling expenses, and packing. Pursuant to 19 CFR 351.403(c) and in accordance with our practice, when the prices charged to an affiliated party were, on average, between 98 and 102 percent of the prices charged to unaffiliated parties for merchandise comparable to that sold to the affiliated party, we determined that the sales to the affiliated party were at arm's-length prices. See *Antidumping Proceedings: Affiliated Party Sales in the Ordinary Course of Trade,* 67 FR 69186 (November 15, 2002). We included in our calculation of normal value those sales to affiliated parties that were made at arm's-length prices. Where we excluded sales because they were not at arm's-length prices, we used, based on the information we requested and EuroChem provided, data related to sales of the foreign like product made by the affiliated parties' home-market customers.

The petitioner alleges in this review that, through the provisions of its concession agreement with its home-market franchisees, EuroChem is in a position, potentially, to exhibit control over the franchisees. Therefore, they assert, the Department should treat EuroChem's franchisees as affiliates and, for sales to those franchisees that do not pass the arm's-length test, request the data for downstream sales.

Based on information on the record, the Department preliminarily does not find that affiliation exists between EuroChem and its franchisees. For a detailed discussion of this issue, see Memorandum to Laurie Parkhill dated concurrently with this notice entitled ''Solid Urea from the Russian Federation—Affiliation Analysis.''

Level of Trade

To the extent practicable, we determined normal value for sales at the same level of trade as the U.S. sales. When there were no sales at the same level of trade, we compared U.S. sales to home-market sales at a different level of trade. The normal-value level of trade is that of the starting-price sales in the home market. To determine whether home-market sales are at a different level of trade than U.S. sales, we examined stages in the marketing process and selling functions along the chain of distribution between the producer and the unaffiliated customer.

In the home market, EuroChem reported a single channel of distribution. Within this single channel of distribution, EuroChem reported a single level of trade for all three customer types (*i.e.,* distributors, traders, and end-users). After analyzing the data on the record with respect to the selling functions performed for each customer type, we find that EuroChem made all home-market sales at a single marketing stage (*i.e.,* one level of trade) in the home market.

In the U.S. market, EuroChem had only CEP sales through its affiliated reseller to unaffiliated customers through a single channel of distribution and, thus, a single level of trade. See section 772(b) of the Act. We found that there were significant differences between the selling activities associated with the CEP level of trade and those associated with the home-market level of trade. For example, the CEP level of trade involved little or no sales-strategic and economic planning, personnel training, advertising, distributor/dealer training, procurement/sourcing service, packing, and sales/marketing support. Therefore, we considered the CEP level of trade to be different from the home-market level of trade and at a less advanced stage of distribution than the home-market level of trade. Consequently, we could not match U.S. sales to sales at the same level of trade in the home market nor could we determine a level-of-trade adjustment based on EuroChem's home-market sales of the foreign like product. Because the data available do not provide an appropriate basis to determine a level-of-trade adjustment and the home-market level of trade is at a more advanced stage of distribution than the CEP, we have made a CEP-offset adjustment to normal value in accordance with section 773(a)(7)(B) of the Act. The CEP offset is the sum of indirect selling expenses incurred on the home-market sales up to the amount of indirect selling expenses incurred on the U.S. sales.

Preliminary Results of the Review

As a result of this review, we preliminarily determine that a dumping margin of 1.17 percent exists for EuroChem for the period July 1, 2009, through June 30, 2010.

Disclosure and Comment

We will disclose the calculations used in our analysis to parties to this review within five days of the date of publication of this notice. See 19 CFR 351.224(b). Any interested party may request a hearing within 30 days of the publication of this notice in the **Federal Register**. See 19 CFR 351.310(c). If a hearing is requested, the Department will notify interested parties of the hearing schedule.

Interested parties are invited to comment on the preliminary results of this review. Interested parties may submit case briefs within 30 days of the date of publication of this notice. See 19 CFR 351.309(c). Rebuttal briefs, which must be limited to issues raised in the case briefs, may be filed not later than 35 days after the date of publication of this notice. See 19 CFR 351.309(d). Parties who submit case briefs or rebuttal briefs in this review are requested to submit with each argument (1) a statement of the issue and (2) a brief summary of the argument with an electronic version included.

We intend to issue the final results of this administrative review, including the results of our analysis of issues raised in the case briefs, within 120 days after the date on which the preliminary results are published. See 19 CFR 351.213(h)(1).

Assessment Rates

The Department shall determine, and the U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries. In accordance with 19 CFR 351.212, we have calculated for EuroChem an importer/customer-specific assessment rate for these preliminary results of review. We will instruct CBP to assess the importer/customer-specific rate on applicable entries of subject merchandise made by the importer during the POR.

The Department clarified its ''automatic assessment'' regulation on May 6, 2003. This clarification applies to entries of subject merchandise during the POR produced by EuroChem where EuroChem did not know that its merchandise was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction. For a full discussion of this clarification, see *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

The Department intends to issue assessment instructions to CBP 15 days after the date of publication of the final results of this administrative review.

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of the notice of final results of administrative review for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided by section 751(a)(1) of the Act: (1) The cash deposit rate for EuroChem will be the rate established in the final results of this review; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review or the less-than-fair-value investigation but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; (4) the cash deposit rate for all other manufacturers or exporters will continue to be 64.93 percent, the all-others rate established in *Urea From the Union of Soviet Socialist Republics; Final Determination of Sales at Less Than Fair Value,* 52 FR 19557 (May 26, 1987). These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: June 10, 2011.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 2011–15123 Filed 6–16–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XR75

Essential Fish Habitat (EFH) Components of Fishery Management Plans (Northeast Multispecies, Atlantic Sea Scallop, Monkfish, Atlantic Herring, Skates, Atlantic Salmon, and Atlantic Deep-Sea Red Crab) 5-Year Review

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Supplemental notice of intent (NOI) to prepare a programmatic environmental impact statement (EIS).

SUMMARY: The New England Fishery Management Council (Council) is in the process of preparing a programmatic EIS for an Omnibus EFH Amendment to the fishery management plans (FMPs) for Northeast (NE) multispecies, Atlantic sea scallop, monkfish, Atlantic herring, NE skate complex, Atlantic salmon, and Atlantic deep-sea red crab. The Council will expand the scope of this action to include review of, and possible changes to, the NE multispecies closed areas. During this comment period, the Council is seeking comments on the possible revision of these management areas.

DATES: Written comments must be received on or before 5 p.m. e.s.t., July 18, 2011.

ADDRESSES: You may submit comments by any of the following methods:

- *E-mail: HabitatNOI@noaa.gov.*
- *Mail:* Paul J. Howard, Executive Director, New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.
- *Fax:* (978) 465–3116.

FOR FURTHER INFORMATION CONTACT: Paul J. Howard, Executive Director, New England Fishery Management Council (978) 465–0492.

SUPPLEMENTARY INFORMATION: The purpose of this notification is to alert the interested public of the Council's intent to consider changes to the NE multispecies closed areas in the Omnibus EFH Amendment. A description of the background and need for the Omnibus EFH Amendment can be found in the original NOI dated February 24, 2004, (69 FR 8367) and is not repeated here. The amendment has been developed in two phases. Phase 1 included a review and update of EFH designations, consideration of habitat areas of particular concern, an updated prey species list, and an update of non-fishing impacts. A notice of availability for the Phase 1 Draft EIS (DEIS) was published on April 6, 2007 (72 FR 17157).

Phase 2 will include an evaluation of the effects of fishing on EFH, and management measures to minimize the adverse effects of fishing on EFH across all FMPs. A subset of the alternatives to minimize the impacts of EFH will focus specifically on minimizing the impacts of fishing on deep-sea corals. During early meetings to develop Phase 2 alternatives in late 2009 and early 2010, the Council's Habitat Oversight Committee concluded that development and implementation of new or modified habitat management areas was complicated substantially by the existence of the NE multispecies closed areas. There is considerable spatial overlap between the NE multispecies closed areas and the current habitat areas which are closed to bottom tending mobile gears. Generally, the NE multispecies closed areas are closed to all gear capable of catching groundfish, including but not limited to mobile gears, although there are specific exemptions for certain fisheries and gear types. Specifically, the Habitat Oversight Committee was concerned about the feasibility of implementing new habitat management areas outside of the boundaries of the NE multispecies closed areas, in particular the year round closures, even if current habitat management areas were eliminated, as this would substantially increase in the amount of seabed closed to fishing for some types of gears/fisheries.

At the January 2011 Council meeting, the Habitat Oversight Committee raised the issue of modifying or eliminating the NE multispecies closed areas via the Omnibus EFH Amendment. At its April 2011 meeting, the Council reviewed available information related to this issue, including how this change in scope would affect the Omnibus EFH Amendment's timeline given other priorities established for 2011, and then voted to expand the scope of the Amendment to consider modifying the NE multispecies closed areas in conjunction with the establishment of any new habitat closed areas.

Following public comment on all alternatives, including any alternatives related to the NE multispecies closed areas as well alternatives to designate EFH and HAPCs, minimize impacts to EFH, and protect deep-sea corals, the Council will select final alternatives and then prepare and submit a final EIS document. It is anticipated that all selected alternatives from both phases of the Omnibus EFH Amendment will be implemented via a single rulemaking. Considering this expansion of scope, the expected implementation date for the Omnibus EFH Amendment will be delayed beyond the previously anticipated date of summer 2012.

Stakeholders are encouraged to submit comments on this change in scope as well as on other issues related to the development of EFH impacts minimization alternatives. Comments are specifically sought on the utility of existing or alternative closures to address the needs of groundfish stocks, as well as on the impacts of changes to the existing closures on groundfish fishing and other activities (such as Special Access Programs, exempted/certified bycatch fisheries, recreational fishing opportunities, endangered or threatened species protection, *etc.*).

Authority: 16 U.S.C. 1801 *et seq.*

Dated: June 13, 2011.

Margo Schulze-Haugen,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2011–15152 Filed 6–16–11; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XA457

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Shrimp Fisheries of the Gulf of Mexico and Southern Atlantic States

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of receipt of an application for an exempted fishing permit; request for comments.

SUMMARY: NMFS announces the receipt of an application for an exempted fishing permit (EFP) from the Gulf and South Atlantic Fisheries Foundation, Inc. (Foundation). If granted, the EFP would authorize the applicant, with certain conditions, to collect and retain limited numbers of specimens that would otherwise be prohibited from possession and retention. This study, to be conducted in the exclusive economic zone (EEZ) of the Gulf of Mexico (Gulf) and South Atlantic, is intended to characterize catch and bycatch within the shrimp fisheries of the Gulf and South Atlantic.

DATES: Comments must be received no later than 5 p.m., eastern time, on July 15, 2011.

ADDRESSES: You may submit comments on the application by any of the following methods:

- *E-mail: Steve.Branstetter@noaa.gov.* Include in the subject line of the e-mail comment the following document identifier: ''FND_EFP''.
- *Mail:* Steve Branstetter, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

The application and related documents are available for review upon written request to any of the above addresses.

FOR FURTHER INFORMATION CONTACT: Steve Branstetter, 727–824–5305; *e-mail: Steve.Branstetter@noaa.gov.*

SUPPLEMENTARY INFORMATION: The EFP is requested under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*), and regulations at 50 CFR 600.745(b) concerning exempted fishing.

The applicant proposes research as part of the Cooperative Research Program, which is intended to involve commercial fishermen in the collection of fundamental fisheries information. The described research is part of three ongoing Cooperative Agreements (No. NA08NMF4330406, No. NA09NMF4540135, and No. NA10NMF4540108), plus two pending Cooperative Research Program projects. Resource collection efforts support the development and evaluation of fisheries management and regulatory options.

The proposed collection for scientific research involves activities otherwise prohibited by regulations at 50 CFR part 622, as they pertain to fish and invertebrates managed by the Gulf of Mexico and South Atlantic Fishery Management Councils (Councils) specific to the shrimp fisheries of the Gulf and South Atlantic. The applicant requires authorization through the EFP to collect these Council-managed species that may be taken in association with the commercial shrimp fisheries of the southeast United States. This proposed collection would include reef fish, red drum, coastal migratory pelagics, stone crab, and lobsters in the Gulf, and snapper-grouper, coastal migratory pelagics, dolphin and wahoo, and lobsters in the South Atlantic.

The EFP exempts personnel from the Foundation from bag limits, size limits, quotas, seasonal restrictions, and gear authorizations, when possessing Council-managed species as part of scientific research activities from August 1, 2011, through December 31, 2013. Specimens would be collected from Federal waters of the Gulf and South Atlantic, and sampling would occur during normal fishing operations of the trawl gear component of the penaeid shrimp commercial sector. Sampling would occur year-round, collecting as many as 500 fish during the course of the study. These species would be retained only in the event of the need for subsequent shore-side identification or as documentation of quality assurance in the data collection process. Data collection for this study would support improved information about the catch, bycatch, discards, and the ability to reduce bycatch for species taken by the shrimp fisheries of the Gulf and South Atlantic. These data would provide insight on a stock's resilience to fishing, and would help improve estimates of long-term biological productivity of the stocks. Currently, these data are unavailable, and it is anticipated that project results will yield valuable data within these fisheries.

NMFS finds this application warrants further consideration. Based on a preliminary review, NMFS intends to issue an EFP. The limited sampling program and associated methodology listed in the EFP is not expected to impact the fishery stocks; the estimated

500 fish to be retained through the duration of the EFP represents a small fraction of average annual landings.

Conditions the agency will impose on this permit, if it is indeed granted, include but are not limited to, a prohibition of conducting research within marine protected areas, marine sanctuaries, or special management zones, without additional authorization. Additionally, NMFS will prohibit the possession of Nassau or goliath grouper, and require any sea turtles taken incidentally during the course of fishing or scientific research activities to be handled with due care to prevent injury to live specimens, observed for activity, and returned to the water. All Foundation-associated personnel who conduct onboard sampling activities have undergone formal sea turtle handling training through NMFS, and are considered NMFS-designated agents while conducting work under the identified Cooperative Agreements.

A final decision on issuance of the EFP will depend on a NMFS review of public comments received on the application, consultations with the affected states, the Councils, and the U.S. Coast Guard, and a determination that the EFP is consistent with all applicable laws.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: June 13, 2011.

Margo Schulze-Haugen,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2011–15162 Filed 6–16–11; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Science Advisory Board; Meeting

AGENCY: Office of Oceanic and Atmospheric Research (OAR), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of open meeting.

SUMMARY: The Science Advisory Board (SAB) was established by a Decision Memorandum dated September 25, 1997, and is the only Federal Advisory Committee with responsibility to advise the Under Secretary of Commerce for Oceans and Atmosphere on strategies for research, education, and application of science to operations and information services. SAB activities and advice provide necessary input to ensure that National Oceanic and Atmospheric Administration (NOAA) science programs are of the highest quality and provide optimal support to resource management.

Time and Date: The meeting will be held Wednesday, July 20, 2011, from 9:30 a.m. to 5:30 p.m. and Thursday, July 21, 2011, from 8:30 a.m. to 2:30 p.m. These times and the agenda topics described below are subject to change. Please refer to the Web page *http://www.sab.noaa.gov/Meetings/meetings.html* for the most up-to-date meeting agenda.

Place: On July 20, 2011 the meeting will be held at the Michigan League at the University of Michigan, 911 N. University Avenue, Ann Arbor, Michigan. On July 21, 2011 the meeting will be held at NOAA's Great Lakes Environmental Research Laboratory, 4840 S. State Street, Ann Arbor, Michigan.

Please check the SAB Web site *http://www.sab.noaa.gov* for confirmation of the venue and for directions.

Status: The meeting will be open to public participation with a 15 minute public comment period on July 20 at 5:15 p.m. (check Web site to confirm time). The SAB expects that public statements presented at its meetings will not be repetitive of previously submitted verbal or written statements. In general, each individual or group making a verbal presentation will be limited to a total time of five (5) minutes. Individuals or groups planning to make a verbal presentation should contact the SAB Executive Director by July 15, 2011 to schedule their presentation. Written comments should be received in the SAB Executive Director's Office by July 15, 2011 to provide sufficient time for SAB review. Written comments received by the SAB Executive Director after July 15, 2011 will be distributed to the SAB, but may not be reviewed prior to the meeting date. Seating at the meeting will be available on a first-come, first-served basis.

Matters To Be Considered: The meeting will include the following topics: (1) Report from the Joint SAB Environmental Information Services and Climate Working Groups' Climate Partnership Task Force (2)Review of the SAB Working Groups' Comments on the Working Group Concept of Operations; (3)NOAA Response to the SAB Proposal for Re-alignment of Working Groups (4) Proposal for a Satellite Working Group of the SAB; (4) Results of the External Review of the NESDIS Center for Satellite Applications and Research (STAR) and the NOAA Response; (5) NOAA Response to the Office of Science and Technology Policy Memorandum on Scientific Integrity; (6) NOAA Science Challenge Workshops; (7) SAB Role in Optimizing NOAA's Research and Development Enterprise; (8) Presentations on NOAA programs and research in the Great Lakes; and (9) Updates from SAB Working Groups.

FOR FURTHER INFORMATION CONTACT: Dr. Cynthia Decker, Executive Director, Science Advisory Board, NOAA, Rm. 11230, 1315 East-West Highway, Silver Spring, Maryland 20910. *Phone:* 301–734–1156, *Fax:* 301–713–1459, *E-mail: Cynthia.Decker@noaa.gov;* or visit the NOAA SAB Website at *http://www.sab.noaa.gov.*

Dated: June 14, 2011.

Mark E. Brown,

Chief Financial Officer/Chief Administrative Officer, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2011–15106 Filed 6–16–11; 8:45 am]

BILLING CODE 3510–KD–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XA369

Marine Mammals; File No. 14326

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of permit amendment.

SUMMARY: Notice is hereby given that a major amendment to Permit No. 14326 has been issued to NMFS National Marine Mammal Laboratory, Seattle, WA.

ADDRESSES: The permit amendment and related documents are available for review upon written request or by appointment in the following offices:

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 713–2289; fax (301) 713–0376; and Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802–1668; phone (907) 586–7221; fax (907) 586–7249.

FOR FURTHER INFORMATION CONTACT: Tammy Adams or Amy Sloan, (301) 713–2289.

SUPPLEMENTARY INFORMATION: On April 18, 2011, notice was published in the **Federal Register** (76 FR 21703) that a request for an amendment to Permit No. 14326 to conduct research on Steller sea lions (*Eumetopias jubatus*) in the North Pacific Ocean, including rookeries and haulouts in CA, OR, WA, and AK, had

been submitted by the above-named applicant. The requested permit amendment has been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

The amendment grants authorization for the following in AK: (1) Double the number of non-pup sea lions surveyed to accommodate one winter aerial survey of the Aleutian Islands per year; (2) shift some resight effort from the non-breeding season (August-May) to the breeding season (June-July) with increased potential disturbance for June-July and for August-May; (3) visit additional sites to supplement aerial surveys if logistics prevent aircraft access to sites with increased potential disturbance; (4) permanently mark (hot-brand) additional pups annually at rookeries in the Aleutian Islands (west of 170° W) in 2011 and 2013; and (5) for a subset of pups handled for permanent marking, add collection of blubber biopsies for fatty acid and toxicology analyses; collection of fecal loops for determination of parasites, disease, and hormone concentrations; collection of milk by stomach lavage; pulling a vibrissae; and external ultrasound. The amendment also includes authorization for the following in CA, OR, and WA: (1) Increase the number of aerial surveys flown per year from 4 to 12; (2) increase the number of vessel surveys that may occur at any one site per year (depending on funding, staffing, vessel availability, weather) from 12 to 24; and (3) increase the number of ground surveys that may occur at any one site per year (depending on funding, staffing, vessel availability, weather) from 5 to 24.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), NMFS has determined that the activities proposed are consistent with the Preferred Alternative in the Final Programmatic Environmental Impact Statement for Steller Sea Lion and Northern Fur Seal Research (NMFS 2007), and that issuance of the permit would not have a significant adverse impact on the human environment.

As required by the ESA, issuance of this permit was based on a finding that such permit: (1) Was applied for in good faith; (2) will not operate to the disadvantage of such endangered species; and (3) is consistent with the purposes and policies set forth in section 2 of the ESA.

Dated: June 13, 2011.

P. Michael Payne,

Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2011–15134 Filed 6–16–11; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XA495

Marine Mammals; File No. 16000

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of permit.

SUMMARY: Notice is hereby given that a permit has been issued to Wild Horizons LTD, 59 Cotham Hill, Cotham, Bristol, BS6 6JR, United Kingdom to conduct commercial/educational photography.

ADDRESSES: The permit and related documents are available for review upon written request or by appointment in the following offices: Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 713–2289; fax (301) 713–0376; and Southeast Region, NMFS, 263 13th Avenue South, Saint Petersburg, Florida 33701; phone (727) 824–5312; fax (727) 824–5309.

FOR FURTHER INFORMATION CONTACT: Joselyd Garcia-Reyes or Kristy Beard, (301) 713–2289.

SUPPLEMENTARY INFORMATION: On January 18, 2011, notice was published in the **Federal Register** (76 FR 2888) that a request for a permit to conduct commercial/educational photography of bottlenose dolphins (*Tursiops truncatus*) had been submitted by the above-named applicant. The requested permit has been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*) and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

Wild Horizons LTD is authorized to film bottlenose dolphin strand feeding events in the estuaries and creeks of Bull Creek and around Hilton Head, South Carolina. Filmmakers may use two filming platforms: an inflatable 21ft boat and a helicopter. Up to 500 dolphins annually may be approached and filmed. Footage will be used to create a 7-part television series, Wild Planet: North America, for the Discovery Channel. The premise of the series is to provide a definitive guide to the natural history of the North American Continent and have a dedicated episode on each biome. The permit will expire August 31, 2012.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Dated: June 13, 2011.

P. Michael Payne,

Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2011–15155 Filed 6–16–11; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Applications for Trademark Registration

ACTION: Proposed collection; comment request.

SUMMARY: The United States Patent and Trademark Office (USPTO), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on the extension of a continuing information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before August 16, 2011.

ADDRESSES: You may submit comments by any of the following methods:

- *E-mail: InformationCollection@uspto.gov.* Include ''0651–0009 comment'' in the subject line of the message.
- *Mail:* Susan K. Fawcett, Records Officer, Office of the Chief Information Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.
- *Federal Rulemaking Portal: http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Catherine Cain,

Attorney Advisor, Office of the Commissioner for Trademarks, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–8946; or by e-mail to *catherine.cain@uspto.gov* with ''Paperwork'' in the subject line. Additional information about this collection is also available at *http://www.reginfo.gov* under ''Information Collection Review.''

SUPPLEMENTARY INFORMATION

I. Abstract

The United States Patent and Trademark Office (USPTO) administers the Trademark Act, 15 U.S.C. 1051 *et seq.,* which provides for the Federal registration of trademarks, service marks, collective trademarks and service marks, collective membership marks, and certification marks. Individuals and businesses who use their marks, or intend to use their marks, in commerce regulable by Congress, may file an application with the USPTO to register their marks. Registered marks remain on the register indefinitely, so long as the owner of the registration files the necessary maintenance documents.

The rules implementing the Trademark Act are set forth in 37 CFR part 2. The Act and rules mandate that each certificate of registration include the mark, the particular goods and/or services for which the mark is registered, the owner's name, dates of use of the mark in commerce, and certain other information. The USPTO also provides similar information to the public concerning pending applications. Individuals or businesses may access the register and pending application information through the USPTO's Web site to determine availability of a mark. Accessing and reviewing the USPTO's publicly available information may reduce the possibility of initiating use of a mark previously registered or adopted by another. Thus, the Federal trademark registration process may lessen the filing of papers in court and between parties. The information in this collection is available to the public.

Trademarks can be registered on either the Principal or Supplemental Register. Registrations on the Principal Register confer all of the benefits of registration provided under the Trademark Act. Certain marks that are not eligible for registration on the Principal Register, but are capable of functioning as a trademark, may be registered on the Supplemental Register. Registrations on the Supplemental Register do not have all of the benefits of marks on the Principal Register. Registrations on the Supplemental Register cannot be transferred to the Principal Register, but owners of registrations on the Supplemental Register may apply for registration of their marks on the Principal Register.

The information in this collection can be submitted in paper format or electronically through the Trademark Electronic Application System (TEAS) using a regular TEAS application form or a TEAS Plus application form. Applicants that file their applications using the TEAS Plus form pay a reduced filing fee if they file a complete application, agree to file certain communications regarding the application through TEAS, and agree to receive communications concerning the application by e-mail. TEAS Plus applications are only available for trademark/service mark applications. There are no TEAS Plus application forms available for the certification marks, collective marks, collective membership marks, and applications for registration on the Supplemental Register at this time. This collection contains three paper forms and six electronic forms.

II. Method of Collection

Electronically if applicants submit the information using the TEAS forms. By mail or hand delivery if applicants choose to submit the information in paper form.

III. Data

OMB Number: 0651–0009.

Form Number(s): PTO Forms 4.8, 4.9, 1478, and 1478(a).

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits; and not-for-profit institutions.

Estimated Number of Respondents: 380,289 responses per year.

Estimated Time per Response: The USPTO estimates that it takes the public approximately 18 minutes (0.30 hours) to 30 minutes (0.50 hours) to complete this information, depending on the application. This includes the time to gather the necessary information, prepare the application, and submit the completed request to the USPTO. The time estimates shown for the electronic forms in this collection are based on the average amount of time needed to complete and electronically file the associated form.

Estimated Total Annual Respondent Burden Hours: 132,106 hours.

Estimated Total Annual Respondent Cost Burden: $42,934,450. The USPTO expects that associate attorneys will complete these applications. The professional hourly rate for attorneys in private firms is $325. Using this hourly rate, the USPTO estimates that the total respondent cost burden for this collection is $42,934,450 per year.

Item	Estimated time for response	Estimated annual responses	Estimated annual burden hours
Use-Based Trademark/Service Mark Application, including: • Trademark/Service Mark Application. • Collective Trademark/Service Mark Application. • Collective Membership Mark. • Certification Mark Application.	30 minutes	2,342	1,171
TEAS Use-Based Trademark/Service Mark Application, including: • Trademark/Service Mark Application. • Collective Trademark/Service Mark Application. • Collective Membership Mark. • Certification Mark Application.	25 minutes	92,902	39,019
TEAS Plus Use-Based Trademark/Service Mark Application	25 minutes	46,842	19,674
Intent to Use Trademark/Service Mark Application, including: • Trademark/Service Mark Application. • Collective Trademark/Service Mark Application. • Collective Membership Mark. • Certification Mark Application.	23 minutes	3,548	1,348
TEAS Intent to Use Trademark/Service Mark Application, including: • Trademark/Service Mark Application.	18 minutes	140,720	42,216

Item	Estimated time for response	Estimated annual responses	Estimated annual burden hours
• Collective Trademark/Service Mark Application. • Collective Membership Mark. • Certification Mark Application.			
TEAS Plus Intent to Use Trademark/Service Mark Application	18 minutes	70,951	21,285
Application for Registration of Trademark/Service Mark under § 44(d) and (e), including: • Trademark/Service Mark Application. • Collective Trademark/Service Mark Application. • Collective Membership Mark. • Certification Mark Application.	25 minutes	379	159
TEAS Application for Registration of Trademark/Service Mark under § 44(d) and (e), including: • Trademark/Service Mark Application. • Collective Trademark/Service Mark Application. • Collective Membership Mark. • Certification Mark Application.	19 minutes	15,028	4,809
TEAS Plus Application for Registration of Trademark/Service Mark under § 44(d) and (e).	19 minutes	7,577	2,425
Totals		380,289	132,106

Estimated Total Annual (Non-hour) Respondent Cost Burden: $117,791,578. There are no capital start-up, maintenance, or operating fees associated with this information collection. However, this collection does have annual (non-hour) cost burden in the form of postage costs, as well as filing and processing fees.

Applicants incur postage costs when submitting the non-electronic information to the USPTO by mail through the United States Postal Service. The USPTO estimates that the majority (98%) of the paper forms are submitted to the USPTO via first class mail. Out of 6,269 paper forms, the USPTO estimates that 6,143 forms will be mailed, with a first class postage cost of 44 cents. Therefore, the USPTO estimates that the postage costs for this collection will be $2,703.

Item	Responses (yr) (a)	Postage costs (b)	Total cost (yr) (a) x (b)
Use-Based Trademark/Service Mark Application, including • Trademark/Service Mark Application. • Collective Trademark/Service Mark Application. • Collective Membership Mark. • Certification Mark Application.	2,295	0.44	$1,010.00
Intent to Use Trademark/Service Mark Application, including • Trademark/Service Mark Application. • Collective Trademark/Service Mark Application. • Collective Membership Mark. • Certification Mark Application.	3,477	0.44	1,530.00
Application for Registration of Trademark/Service Mark under § 44 (d) and (e), including • Trademark/Service Mark Application. • Collective Trademark/Service Mark Application. • Collective Membership Mark. • Certification Mark Application.	371	0.44	163.00
Total	6,143		2,703.00

There is also annual (non-hour) cost burden in the way of filing fees associated with this collection. Applicants who choose to file their applications electronically instead of submitting them in paper pay a reduced filing fee. Those who choose to file TEAS Plus applications pay a further reduced fee. An application must include a filing fee for each class of goods and services. Therefore, the total filing fees associated with this collection can vary depending on the number of classes in each application. The total filing fees of $117,638,875 shown here are based on the minimum fee of one class per application.

Item	Responses (a)	Filing fee * ($) (b)	Total non-hour cost burden (yr) (a) × (b) (c)
Use-Based Trademark/Service Mark Application, including • Trademark/Service Mark Application. • Collective Trademark/Service Mark Application. • Collective Membership Mark.	2,342	$375.00	$878,250.00

Item	Responses (a)	Filing fee * ($) (b)	Total non-hour cost burden (yr) (a) × (b) (c)
• Certification Mark Application.			
TEAS Use-Based Trademark/Service Mark Application, including	92,902	325.00	30,193,150.00
• Trademark/Service Mark Application.			
• Collective Trademark/Service Mark Application.			
• Collective Membership Mark.			
• Certification Mark Application.			
TEAS Plus Use-Based Trademark/Service Mark Application	46,842	275.00	12,881,550.00
Intent to Use Trademark/Service Mark Application, including	3,548	375.00	1,330,500.00
• Trademark/Service Mark Application.			
• Collective Trademark/Service Mark Application.			
• Collective Membership Mark.			
• Certification Mark Application.			
TEAS Intent to Use Trademark/Service Mark Application, including	140,720	325.00	45,734,000.00
• Trademark/Service Mark Application.			
• Collective Trademark/Service Mark Application.			
• Collective Membership Mark.			
• Certification Mark Application.			
TEAS Plus Intent to Use Trademark/Service Mark Application	70,951	275.00	19,511,525.00
Application for Registration of Trademark/Service Mark under § 44(d) and (e), including	379	375.00	142,125.00
• Trademark/Service Mark Application.			
• Collective Trademark/Service Mark Application.			
• Collective Membership Mark.			
• Certification Mark Application.			
TEAS Application for Registration of Trademark/Service Mark under § 44(d) and (e), including	15,028	325.00	4,884,100.00
• Trademark/Service Mark Application.			
• Collective Trademark/Service Mark Application.			
• Collective Membership Mark.			
• Certification Mark Application.			
TEAS Plus Application for Registration of Trademark/Service Mark under § 44(d) and (e)	7,577	275.00	2,083,675.00
Total	380,289	.....	117,638,875.00

* NOTE: All filing fees are based on per class filing.

In addition, the USPTO charges a processing fee of $50 to process applications that were originally filed as TEAS Plus applications, but which failed to meet the requirements stated above. The USPTO estimates that out of the 125,370 TEAS Plus use-based, intent to use, and § 44(d) and (e) applications filed, 3,000 will be subject to the processing fee. A processing fee is charged for each class of goods and services in the application, so the total processing fee can vary depending on the number of classes. The total processing fees shown here are based on the minimum fee of one class per application. Therefore, the USPTO estimates that at a minimum, the processing fees will add $150,000 to the filing fees estimated above.

Item	Responses (yr) (a)	Processing fee * ($) (b)	Total Non-hour cost burden (yr) (a) × (b) (c)
TEAS Plus Use-Based Applications That Do Not Meet TEAS Plus Requirements	1,121	$50.00	$56,050.00
TEAS Plus Intent to Use Applications That Do Not Meet TEAS Plus Requirements	1,698	50.00	84,900.00
TEAS Plus Application for Registration of Trademark/Service Mark under § 44(d) and (e) That Do Not Meet TEAS Plus Requirements	181	50.00	9,050.00
Total	3,000	.....	150,000.00

Note: All processing fees are based on per class filing.

The USPTO estimates that the total non-hour cost burden associated with the filing and processing fees for this collection will be $117,788,875.

Therefore, the USPTO estimates that the total annual (non-hour) cost burden for this collection, in the form of postage costs and filing and processing fees is $117,791,578 per year.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and

clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, e.g., the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: June 13, 2011.

Susan K. Fawcett,

Records Officer, USPTO, Office of the Chief Information Officer.

[FR Doc. 2011–15016 Filed 6–16–11; 8:45 am]

BILLING CODE 3510–16–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Addition

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Addition to the Procurement List.

SUMMARY: This action adds a service to the Procurement List that will be provided by a nonprofit agency employing persons who are blind or have other severe disabilities.

DATES: *Effective Date:* 7/18/2011.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia, 22202–3259.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, *Telephone:* (703) 603–7740, *Fax:* (703) 603–0655, or e-mail *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Additions

On 4/29/2011 (76 FR 23998), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed addition to the Procurement List.

After consideration of the material presented to it concerning capability of a qualified nonprofit agency to provide the service and impact of the addition on the current or most recent contractors, the Committee has determined that the service listed below is suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organization that will provide the service to the Government.

2. The action will result in authorizing small entities to provide the service to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the service proposed for addition to the Procurement List.

End of Certification

Accordingly, the following service is added to the Procurement List:

Service

Service Type/Location: Custodial Service, US Military Academy Preparatory School, West Point, NY.
NPA: New Dynamics Corporation, Middletown, NY.
Contracting Activity: Dept of the Army, W6QM West Point Doc, West Point, NY.

Barry S. Lineback

Director, Business Operations.

[FR Doc. 2011–15065 Filed 6–16–11; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to and deletions from the procurement list.

SUMMARY: The Committee is proposing to add products and a service to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes products and a service previously furnished by such agencies.

Comments Must Be Received On Or Before: 7/18/2011.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia, 22202–3259.

FOR FURTHER INFORMATION OR TO SUBMIT COMMENTS CONTACT: Barry S. Lineback, *Telephone:* (703) 603–7740, *Fax:* (703) 603–0655, or *e-mail: CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C 47(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the products and service listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products and service to the Government.

2. If approved, the action will result in authorizing small entities to furnish the products and service to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products and service proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

End of Certification

The following products and service are proposed for addition to Procurement List for production by the nonprofit agencies listed:

Products:

Cell Phone Privacy and Glare Shields

NSN: 7045–00–NIB–0326—Glare Shield for iPhone.
NSN: 7045–00–NIB–0327—Glare Shield for Blackberry Bold.
NSN: 7045–00–NIB–0328—Glare Shield for Blackberry Storm2.
NSN: 7045–00–NIB–0366—Glare Shield for Blackberry Curve2.
NSN: 7045–00–NIB–0329—Universal PDA Glare Shield.
NSN: 7045–00–NIB–0330—Privacy Shield for iPhone.
NSN: 7045–00–NIB–0331—Privacy Shield for Blackberry Bold.
NSN: 7045–00–NIB–0332—Privacy Shield for Blackberry Storm2.
NSN: 7045–00–NIB–0333—Privacy Shield for PDA, Universal.
NSN: 7045–00–NIB–0365—Privacy Shield for Blackberry Curve2.
NPA: Wiscraft, Inc., Milwaukee, WI.
Contracting Activity: General Services Administration, New York, NY.
Coverage: B-List for the Broad Government Requirement as aggregated by the General Services Administration.

NSN: 7930–01–490–7301—Detergent, Laundry, Biobased with Bleach, Powdered.
NPA: Association for the Blind and Visually Impaired—Goodwill Industries of Greater Rochester, Rochester, NY.
Contracting Activity: General Services Administration, Fort Worth, TX.
Coverage: A-List for the Total Government Requirement as aggregated by the General Services Administration.

Pocket Folder, Classification and Retention Envelope/Jacket

NSN: 7530–00–NIB–0993—Letter Size, Earth Red.
NSN: 7530–00–NIB–0994—Letter Size, Light Green.
NSN: 7530–00–NIB–0995—Letter Size, Dark Green.
NSN: 7530–00–NIB–0996—Letter Size, Light Blue.
NSN: 7530–00–NIB–0997—Letter Size, Dark Blue.
NSN: 7530–00–NIB–0998—Letter Size, Dark Red.
NSN: 7530–00–NIB–0999—Letter Size, Yellow.
NSN: 7530–00–NIB–1000—Legal Size, Earth Red.
NSN: 7530–00–NIB–1001—Legal Size, Light Green.
NSN: 7530–00–NIB–1002—Retention Envelope/Jacket, Letter and Legal Sizes.
NPA: Georgia Industries for the Blind, Bainbridge, GA.
Contracting Activity: General Services Administration, New York, NY.
Coverage: A-List for the Total Government Requirement as aggregated by the General Services Administration.
NSN: 7045–00–NIB–0369—Privacy Shield, 16:9 Aspect Ratio Computer Monitor, 14.0 Widescreen.
NSN: 7045–00–NIB–0370—Privacy Shield, 16:9 Aspect Ratio Computer Monitor, 15.6 Widescreen.
NSN: 7045–00–NIB–0374—Privacy Shield, 16:9 Aspect Ratio Computer Monitor, 17.3 Widescreen.
NSN: 7045–00–NIB–0371—Privacy Shield, 16:9 Aspect Ratio Computer Monitor, 18.5 Widescreen.
NSN: 7045–00–NIB–0372—Privacy Shield, 16:9 Aspect Ratio Computer Monitor, 20.0 Widescreen.
NSN: 7045–00–NIB–0373—Privacy Shield, 16:9 Aspect Ratio Computer Monitor, 21.5 Widescreen.
Coverage: A-List for the Total Government Requirement as aggregated by the General Services Administration.
NSN: 7045–00–NIB–0367—Anti-Glare Display Shield, iPad.
NSN: 7045–00–NIB–0368—Privacy Shield, iPad.
NSN: 7045–00–NIB–0345—Privacy Shield, Netbooks, 10.1 Widescreen.
Coverage: B-List for the Broad Government Requirement as aggregated by the General Services Administration.
NPA: Wiscraft, Inc., Milwaukee, WI.
Contracting Activity: General Services Administration, New York, NY.

MR SKILCRAFT Rags, Cleaning

NSN: M.R. 1031—Red.
NSN: M.R. 1032—White.
NPA: Winston-Salem Industries for the Blind, Inc., Winston-Salem, NC.
Contracting Activity: Military Resale-Defense Commissary Agency, Fort Lee, VA.
Coverage: C-List for the requirements of military commissaries and exchanges as aggregated by the Defense Commissary Agency.

Tool Kit, Peel & Stick NonSkid Application

NSN: 5180–00–NIB–0007—New Installation, Standard Sizes.
NSN: 5180–00–NIB–0008—New Installation, Custom Kits.
NSN: 5180–00–NIB–0009—Repair and Maintenance, All Kits.
NPA: Louisiana Association for the Blind, Shreveport, LA.
Contracting Activity: Dept of Homeland Security, U.S. Coast Guard, HQ Contract Operations (CG–912), Washington, DC.
Coverage: C-List for 100% of the requirement of the U.S. Coast Guard as aggregated by the U.S. Coast Guard, Lockport, LA.

Professional Grade Paint Brushes, Roller Covers and Roller Frames

NSN: 8020–00–NIB–0011—Brush, Paint, Flat Sash, 3″, Silver Filament.
NSN: 8020–00–NIB–0035—Brush, Paint, Angle Sash, 2.5″, White Filament.
NSN: 8020–00–NIB–0039—Frame, Paint roller, Professional Grade.
NSN: 8020–00–NIB–0040—Pole, Extension, Paint 4–8″.
NSN: 8020–00–NIB–0041—Tray, Paint, Plastic, 1 Quart.
NSN: 8020–00–NIB–0042—Liner, Tray, Paint, Plastic, 1 Quart.
NSN: 8020–00–NIB–0013—Brush, Paint, Angle Sash, 2″, Silver Filament.
NSN: 8020–00–NIB–0014—Brush, Paint, Angle Sash, 2.5″ Silver Filament.
NSN: 8020–00–NIB–0019—Cover, Paint roller, 9″, Knit fabric, Extra Strength Core, 1/2″ Nap.
NSN: 8020–00–NIB–0023—Cover, Paint Roller, 9″, Woven fabric, 3/8″ NAP; High Capacity, Professional Grade.
NSN: 8020–00–NIB–0024—Cover, Paint Roller, 9″, Woven fabric, 1/2″ Nap.
NSN: 8020–00–NIB–0033—Brush, Paint, Flat Sash, 3″, White Filament.
NSN: 8020–00–NIB–0020—Cover, Paint Roller, 9″, Knit Fabric, 3/8″ NAP; High Capacity.
NSN: 8020–00–NIB–0034—Brush, Paint, Angle Sash, 2″, White Filament.
NPA: Industries for the Blind, Inc., West Allis, WI.
Contracting Activity: General Services Administration, FSS/Tools Acquisition Division I, Kansas City, MO.
Coverage: B-List for the Broad Government Requirement as aggregated by the General Services Administration.
NSN: M.R. 1150—Set, Mold, Cupcake, Red, Giant Cupcake, 3pc.
NSN: M.R. 1151—Set, Pan, Bake, Perfect Brownie Pan, 3pc.
NSN: M.R. 1152—Set, Pasta Cooker, Blue, Pasta Express, 7pc.
NSN: M.R. 1155—Glove, Oven, Flexi.
NSN: M.R. 1156—Device, Cutting, Multi-Use, Green, Snip It.
NSN: M.R. 1157—Set, Knife and Peeler, Ceramic, Kitchen Samurai.
NPA: Industries for the Blind, Inc., West Allis, WI.
Contracting Activity: Military Resale-Defense Commissary Agency, Fort Lee, VA.
Coverage: C-List for the requirements of military commissaries and exchanges as aggregated by the Defense Commissary Agency.
NSN: 7045–00–NIB–0348—Encrypted Compact Disc, Recordable, 25 CDs on Spindle, Silver.
NSN: 7045–00–NIB–0349—Encrypted Digital Video Disc,—Recordable, 25 DVDs on Spindle, Silver.
NPA: North Central Sight Services, Inc., Williamsport, PA.
Contracting Activity: Defense Logistics Agency Troop Support, Philadelphia, PA.
Coverage: A-List for the Total Government Requirement as aggregated by the Defense Logistics Agency, Philadelphia, PA.
NSN: 8465–01–580–1664—MOLLE Component, Shoulder Straps, Frame, Enhanced, OCP.
NPAs: Winston-Salem Industries for the Blind, Inc., Winston-Salem, NC; Blind Industries & Services of Maryland, Baltimore, MD.
NSN: 8465–01–580–1316—Hydration System, MOLLE Components, OCP.
NPA: The Lighthouse for the Blind, Inc. (Seattle Lighthouse), Seattle, WA.
NSN: 8465–01–580–1319—Carrier, Hydration System, MOLLE Components, OCP.
NPA: Lions Services, Inc., Charlotte, NC.
Contracting Activity: Department of the Army Research, Development, & Engineering Command, Natick, MA.
Coverage: C-List for 100% of the requirement for initial fielding and Rapid Fielding Initiative of the Department of the Army, as aggregated by the Department of the Army Research, Development, & Engineering Command, Natick, MA.

SERVICE:

Service Type/Location: Laundry Services, Department of Veterans Affairs, Indianapolis, IN, (Offsite: 118 E Court Street, Paris, IL).
NPA: Human Resources Center of Edgar and Clark Counties, Paris, IL.
Contracting Activity: Department of Veterans Affairs, Indianapolis, IN.

Deletions

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. If approved, the action may result in authorizing small entities to furnish the products and service to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products and service proposed for deletion from the Procurement List.

End of Certification

The following products and service are proposed for deletion from the Procurement List:

Products:

Line, Tent

NSN: 8340–00–252–2268.
NSN: 8340–00–252–2270.
NSN: 8340–00–252–2271.
NSN: 8340–00–252–2273.
NSN: 8340–00–252–2280.
NSN: 8340–00–252–2282.
NSN: 8340–00–252–2285.
NSN: 8340–00–252–2286.
NSN: 8340–00–252–2293.
NSN: 8340–00–252–2297.
NSN: 8340–00–252–2299.
NSN: 8340–00–556–9689.
NPA: ASPIRO, Inc., Green Bay, WI.
Contracting Activity: Defense Logistics Agency Troop Support, Philadelphia, PA.
NSN: 7520–01–578–9289—Highlighter, Biodegradable.
NPA: West Texas Lighthouse for the Blind, San Angelo, TX.
Contracting Activity: General Services Administration, New York, NY.

Service

Service Type/Location: Grounds Maintenance, Naval & Marine Corps Reserve Center, 410 N. Gettysburg Ave., Dayton, OH.
NPA: Eastway Corporation, Dayton, OH.
Contracting Activity: Dept of the Navy, NSWC Crane, Crane, IN.

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2011–15066 Filed 6–16–11; 8:45 am]

BILLING CODE 6353–01–P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

TIME AND DATE: 10 a.m., Friday July 1, 2011.

PLACE: 1155 21st St., NW., Washington, DC, 9th Floor Commission Conference Room.

STATUS: Closed.

Matters To Be Considered

Surveillance and Enforcement Matters. In the event that the times or dates of these or any future meetings change, an announcement of the change, along with the new time and place of the meeting will be posted on the Commission's Web site at *http://www.cftc.gov.*

CONTACT PERSON FOR MORE INFORMATION: Sauntia S. Warfield, 202–418–5084.

Sauntia S. Warfield,

Assistant Secretary of the Commission.

[FR Doc. 2011–15299 Filed 6–15–11; 4:15 pm]

BILLING CODE 6351–01–P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

TIME AND DATE: 10 a.m., Friday July 22, 2011.

PLACE: 1155 21st St., NW., Washington, DC, 9th Floor Commission Conference Room.

STATUS: Closed.

Matters To Be Considered

Surveillance and Enforcement Matters. In the event that the times or dates of these or any future meetings change, an announcement of the change, along with the new time and place of the meeting will be posted on the Commission's Web site at *http://www.cftc.gov.*

CONTACT PERSON FOR MORE INFORMATION: Sauntia S. Warfield, 202–418–5084.

Sauntia S. Warfield,

Assistant Secretary of the Commission.

[FR Doc. 2011–15302 Filed 6–15–11; 4:15 pm]

BILLING CODE 6351–01–P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

TIME AND DATE: 10 a.m., Friday July 29, 2011.

PLACE: 1155 21st St., NW., Washington, DC, 9th Floor Commission Conference Room.

STATUS: Closed.

Matters To Be Considered

Surveillance and Enforcement Matters. In the event that the times or dates of these or any future meetings change, an announcement of the change, along with the new time and place of the meeting will be posted on the Commission's Web site at *http://www.cftc.gov.*

CONTACT PERSON FOR MORE INFORMATION: Sauntia S. Warfield, 202–418–5084.

Sauntia S. Warfield,

Assistant Secretary of the Commission.

[FR Doc. 2011–15303 Filed 6–15–11; 4:15 pm]

BILLING CODE 6351–01–P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

The following notice of scheduled meetings is published pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, 5 U.S.C. 552b.

AGENCY HOLDING THE MEETINGS: Commodity Futures Trading Commission.

TIMES AND DATES: The Commission has scheduled meetings for the following dates:

July 7, 2011 at 9:30 a.m.
July 19, 2011 at 9:30 a.m.
August 4, 2011 at 9:30 a.m.
September 8, 2011 at 9:30 a.m.
September 22, 2011 at 9:30 a.m.

PLACE: Three Lafayette Center, 1155 21st St., NW., Washington, DC, Lobby Level Hearing Room (Room 1000).

STATUS: Open.

Matters To Be Considered

The Commission has scheduled these meetings to consider various rulemaking matters, including the issuance of proposed rules and the approval of final rules. The Commission may also consider and vote on dates and times for future meetings. Agendas for each of the scheduled meetings will be made available to the public and posted on the Commission's Web site at *http://www.cftc.gov* at least seven (7) days prior to the meeting. In the event that the times or dates of the meetings change, an announcement of the change, along with the new time and place of the meeting will be posted on the Commission's Web site.

CONTACT PERSON FOR MORE INFORMATION: David A. Stawick, Secretary of the Commission, 202–418–5071.

David A. Stawick,

Secretary of the Commission.

[FR Doc. 2011–15304 Filed 6–15–11; 4:15 pm]

BILLING CODE 6351–01–P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

TIME AND DATE: 10 a.m., Friday July 15, 2011.

PLACE: 1155 21st St., NW., Washington, DC, 9th Floor Commission Conference Room.

STATUS: Closed.

Matters To Be Considered

Surveillance and Enforcement Matters. In the event that the times or

dates of these or any future meetings change, an announcement of the change, along with the new time and place of the meeting will be posted on the Commission's Web site at *http://www.cftc.gov.*

CONTACT PERSON FOR MORE INFORMATION: Sauntia S. Warfield, 202–418–5084.

Sauntia S. Warfield,

Assistant Secretary of the Commission.

[FR Doc. 2011–15301 Filed 6–15–11; 4:15 pm]

BILLING CODE 6351–01–P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

TIME AND DATES: 10 a.m., Friday July 8, 2011.

PLACE: 1155 21st St., NW., Washington, DC, 9th Floor Commission Conference Room.

STATUS: Closed.

Matters To Be Considered

Surveillance and Enforcement Matters. In the event that the times or dates of these or any future meetings change, an announcement of the change, along with the new time and place of the meeting will be posted on the Commission's Web site at *http://www.cftc.gov*.

CONTACT PERSON FOR MORE INFORMATION: Sauntia S. Warfield, 202–418–5084.

Sauntia S. Warfield,

Assistant Secretary of the Commission.

[FR Doc. 2011–15300 Filed 6–15–11; 4:15 pm]

BILLING CODE 6351–01–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting Notice

TIME AND DATE: Wednesday, June 22, 2011; 10 a.m.–11 a.m.

PLACE: Hearing Room 420, Bethesda Towers, 4330 East West Highway, Bethesda, Maryland.

STATUS: Closed to the Public.

Matter To Be Considered

Compliance Status Report

The Commission staff will brief the Commission on the status of compliance matters. For a recorded message containing the latest agenda information, call (301) 504–7948.

CONTACT PERSON FOR MORE INFORMATION: Todd A. Stevenson, Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, (301) 504–7923.

Dated: June 15, 2011.

Todd A Stevenson,

Secretary.

[FR Doc. 2011–15263 Filed 6–15–11; 4:15 pm]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting Notice

TIME AND DATE: Thursday, June 16, 2011, 9 a.m.–11.a.m.*

PLACE: Room 420, Bethesda Towers, 4330 East West Highway, Bethesda, Maryland.

STATUS: Commission Meeting—Open to the Public.

Matter To Be Considered

Briefing and Decisional Matter: Crib Rule—Compliance Date.

A live webcast of the Meeting can be viewed at *http://www.cpsc.gov/webcast.* For a recorded message containing the latest agenda information, call (301) 504–7948.

CONTACT PERSON FOR MORE INFORMATION: Todd A. Stevenson, Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, (301) 504–7923.

Dated: June 15, 2011.

Todd A. Stevenson,

Secretary.

[FR Doc. 2011–15306 Filed 6–15–11; 4:15 pm]

BILLING CODE 6355–01–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Proposed Information Collection; Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (hereinafter the ''Corporation''), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. Sec. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirement on respondents can be properly assessed.

Currently, the Corporation is soliciting comments concerning its proposed renewal of the Current Population Survey (CPS) Civic Engagement Supplement. Copies of the information collection request can be obtained by contacting the office listed in the addresses section of this notice.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by August 16, 2011.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) By mail sent to: Corporation for National and Community Service, Office of Strategy and Special Initiatives, Attention Nathan Dietz, Room 10907; 1201 New York Avenue, NW., Washington, DC 20525.

(2) By hand delivery or by courier to the Corporation's mailroom at Room 8100 at the mail address given in paragraph (1) above, between 9 a.m. and 4 p.m. Eastern Time, Monday through Friday, except Federal holidays.

(3) By fax to: (202) 606–3464.

(4) Electronically through *http://www.regulations.gov.* Individuals who use a telecommunications device for the deaf (TTY–TDD) may call 1–800–833–3722 between 8 a.m. and 8 p.m. Eastern Time, Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Nathan Dietz, (202) 606–6633, or by e-mail at *ndietz@cns.gov.*

SUPPLEMENTARY INFORMATION: The Corporation is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Corporation, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are expected to respond, including the

* The Commission unanimously determined by recorded vote that Agency business requires calling the meeting without seven calendar days advance public notice.

use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (*e.g.,* permitting electronic submissions of responses).

Background

The Corporation plans to request clearance for the collection of data concerning the Civic Engagement Supplement, to be conducted by the U.S. Census Bureau in conjunction with the annual November Current Population Survey (CPS). In even-numbered years since 2008, the November CPS has included the Voting Supplement as well as the Civic Engagement Supplement; in odd-numbered years, the November CPS has only one supplement, the Civic Engagement Supplement.

The Corporation uses the Civic Engagement Supplement to collect data for the Civic Health Assessment, an annual report that is mandated by the Serve America Act. The Civic Engagement Supplement provides information on the extent to which American communities are places where individuals are civically active. It also provides information on the number of Americans who are active in their communities, communicating with one another on issues of public concern, and interacting with public institutions and private enterprises.

The supplement also provides data on Americans who engage in activities that promote positive relationships with those of equal and differing socioeconomic or professional levels. This survey is the only source of nationally representative data on such information as: Level of participation in organized groups, extent of political action and knowledge, extent of connections with other community members, and how often individuals get news and information from various media sources.

When combined with demographic characteristics (age, sex, race, education, occupation, income), the data provides information on the relationship between these characteristics and the level of civic engagement in the United States. Government agency analysts and private, state and local leaders have use the data to compare levels specific to their geographic area to the national level of civic engagement, and to formulate policies that foster healthy communities.

Current Action

The Corporation seeks to renew the current information collection that is currently cleared under control number 0607–0466, by the Census Bureau. The information collected under this clearance will be used in the same manner as under the existing clearance.

Type of Review: Renewal.

Agency: Corporation for National and Community Service.

Title: Current Population Survey Civic Engagement Supplement

OMB Number: 0607–0466 [existing Census clearance number].

Agency Number: None.

Affected Public: Individuals or households.

Total Respondents: 54,000.

Frequency: Annual.

Average Time per Response: Ten minutes per household.

Estimated Total Burden Hours: 9,000.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintenance): None.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: June 13, 2011.

Heather Peeler,

Chief Strategy Officer.

[FR Doc. 2011–15037 Filed 6–16–11; 8:45 am]

BILLING CODE 6050–$$–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Sunshine Act Meeting Notice

The National Civilian Community Corps Advisory Board gives notice of the following meeting:

DATE AND TIME: Thursday, June 30, 2011, 2 p.m.–3:30 p.m.

PLACE: Conference Room #8312, 8th floor, Corporation for National and Community Service Headquarters, 1201 New York Avenue, NW., Washington, DC 20525

CALL-IN INFORMATION: This meeting is available to the public through the following toll-free call-in number: 888–790–1862 conference call access code number 5481825. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls they initiate over wireless lines, and the Corporation will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Replays are generally available one hour after a call ends. The toll-free phone number for the replay is 800–489–7535, passcode 5478958. The end replay date: July 7, 2011, 10:59 PM (CT).

STATUS: Open.

Matters To Be Considered

I. Meeting Convenes
II. Approval of Minutes
III. Director's Report
IV. Committee Reports:
- Projects and Partnership Committee.
- Member Services Committee.
- Policy and Operations Committee.

V. Public Comment

ACCOMMODATIONS: Anyone who needs an interpreter or other accommodation should notify the Corporation's contact person by 5 p.m. Friday, June 17, 2011.

CONTACT PERSON FOR MORE INFORMATION: Erma Hodge, NCCC, Corporation for National and Community Service, 9th Floor, Room 9802B, 1201 New York Avenue, NW., Washington, DC 20525. Phone (202) 606–6696. Fax (202) 606–3459. TTY: (800) 833–3722. E-mail: *ehodge@cns.gov*.

Dated: June 14, 2011.

Wilsie Y. Minor,

Deputy General Counsel.

[FR Doc. 2011–15190 Filed 6–15–11; 11:15 am]

BILLING CODE 6050–$$–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2011–OS–0065]

Privacy Act of 1974; System of Records

AGENCY: Office of the Secretary, DoD.

ACTION: Notice to Alter a System of Records.

SUMMARY: The Office of the Secretary of Defense proposes to alter a system of records in its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This proposed action would be effective without further notice on July 18, 2011 unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and/Regulatory Information Number (RIN) and title, by any of the following methods:

* *Federal Rulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.

* *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301–1160.

Instructions: All submissions received must include the agency name and

docket number or Regulatory Information Number (RIN) for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Cindy Allard, Chief, OSD/JS Privacy Office, Freedom of Information Directorate, Washington Headquarters Services, 1155 Defense Pentagon, Washington, DC 20301–1155 or by phone at (703) 588–6830.

SUPPLEMENTARY INFORMATION: The Office of the Secretary of Defense notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT.**

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on June 8, 2011, to the House Committee on Oversight and Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: June 8, 2011.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DHA 10

SYSTEM NAME:

DoD Women, Infants, and Children Overseas Participant Information Management System (November 18, 2004, 69 FR 67547).

CHANGES:

* * * * *

SYSTEM LOCATION:

Delete entry and replace with ''Choctaw Archiving Enterprise, Suite 308, 2161 NW.Military Highway, San Antonio, TX 78213–1844 and at DoD installations outside the United States (and its territories and possessions). For a complete listing of facility addresses that maintain records, please contact the system manager.''

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with ''Members of the Armed Forces and eligible civilians serving with, employed by or accompanying the Armed Forces outside the United States (and its territories and possessions) and their family members who are eligible for the DoD Women, Infants, and Children Overseas Program.''

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with ''Records consist of the individual or sponsor name, Social Security Number (SSN) and/or DoD identification (ID) number, current address, income information, nutritional/medical history data, and data on whether participants received nutritional education and counseling.''

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with ''10 U.S.C. 1060a, Special Supplemental Food Program; 42 U.S.C. Chapter 13A, Child Nutrition; 32 CFR 199.23, Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), Special Supplemental Food; HA Policy 09–004, Policy Memorandum for Women, Infants, and Children Overseas Program, Under Secretary of Defense, Personnel and Readiness; and E.O. 9397 (SSN), as amended.''

PURPOSE(S):

Delete entry and replace with ''DoD implements the Women Infants and Children (WIC) program for members of the Armed Forces or eligible civilians serving with, employed by or accompanying the Armed Forces outside the United States (and its territories and possessions) and their family members who are eligible for the DoD Women, Infants, and Children Overseas Program. The program provides eligible participants with supplemental nutritious food, nutrition counseling and education, and nutrition-health screening.''

* * * * *

STORAGE:

Delete entry and replace with ''Paper file folders and electronic storage media.''

RETRIEVABILITY:

Delete entry and replace with ''Access and retrieval of information is by the sponsor's name, SSN and/or DoD ID number; or the participant's name, SSN, and/or DoD ID number.''

SAFEGUARDS:

Delete entry and replace with ''Records are maintained in access controlled facilities. Physical entry is restricted by use of locks, guards, or administrative procedures to officials that require access to perform their official duties consistent with the purpose of the collection of the information. Proper data protection training is required for all personnel with official duties that require access to, and use of, the information. Computer terminals are located in supervised areas with access control. The system provides two-factor authentication, using either a Common Access Card (CAC) and personal identification number or a unique logon identification and password. Passwords must be frequently changed.''

RETENTION AND DISPOSAL:

Delete entry and replace with ''Disposition pending (treat records as permanent until the National Archives and Records Administration approves the proposed retention and disposition).''

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with ''Program Manager, WIC Overseas Program, TRICARE Management Activity, Policy and Operations Directorate, Skyline 5, Suite 810, 5111 Leesburg Pike, Falls Church, VA 22041–3206.''

NOTIFICATION PROCEDURE:

Delete entry and replace with ''Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the TRICARE Management Activity, Department of Defense, ATTN: TMA Privacy Officer, Skyline 5, Suite 810, 5111 Leesburg Pike, Falls Church, VA 22041–3206.

Requests must contain participant's and/or sponsor's full name, SSN and/or DoD ID number, current address, and telephone number.''

RECORD ACCESS PROCEDURES:

Delete entry and replace with ''Individuals seeking access to information about themselves contained in this system of records should address written inquiries to the TRICARE Management Activity, Attention: Freedom of Information Act Requester Service Center, 16401 East Centretech Parkway, Aurora, CO 80011–9066.

Written requests must contain participant's and/or sponsor's full name, SSN and/or DoD ID number, current address, telephone number, name and number of this system of records notice, and be signed.''

* * * * *

RECORD SOURCE CATEGORIES:

Delete entry and replace with ''Individuals applying for the program benefits.''

* * * * *

DHA 10

SYSTEM NAME:

DoD Women, Infants, and Children Overseas Participant Information Management System.

SYSTEM LOCATION:

Choctaw Archiving Enterprise, Suite 308, 2161 NW Military Highway, San Antonio, TX 78213–1844 and at DoD installations outside the United States (and its territories and possessions). For a complete listing of facility addresses that maintain records, please contact the system manager.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Members of the Armed Forces and eligible civilians serving with, employed by or accompanying the Armed Forces outside the United States (and its territories and possessions) and their family members who are eligible for the DoD Women, Infants, and Children Overseas Program.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records consist of the individual or sponsor name, Social Security Number (SSN) and/or DoD identification (ID) number, current address, income information, nutritional/medical history data, and data on whether participants received nutritional education and counseling.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 1060a, Special Supplemental Food Program; 42 U.S.C. Chapter 13A, Child Nutrition; 32 CFR 199.23, Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), Special Supplemental Food; HA Policy 09–004, Policy Memorandum for Women, Infants, and Children Overseas Program, Under Secretary of Defense, Personnel and Readiness; and E.O. 9397 (SSN), as amended.

PURPOSE(S):

DoD implements the Women Infants and Children (WIC) program for members of the Armed Forces or eligible civilians serving with, employed by or accompanying the Armed Forces outside the United States (and its territories and possessions) and their family members who are eligible for the DoD Women, Infants, and Children Overseas Program. The program provides eligible participants with supplemental nutritious food, nutrition counseling and education, and nutrition-health screening.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, these records may specifically be disclosed outside of the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3).

The DoD 'Blanket Routine Uses' set forth at the beginning of the Office of the Secretary of Defense (OSD) compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper file folders and electronic storage media.

RETRIEVABILITY:

Access and retrieval of information is by the sponsor's name, SSN and/or DoD ID number; or the participant's name, SSN, and/or DoD ID number.

SAFEGUARDS:

Records are maintained in access controlled facilities. Physical entry is restricted by use of locks, guards, or administrative procedures to officials that require access to perform their official duties consistent with the purpose of the collection of the information. Proper data protection training is required for all personnel with official duties that require access to, and use of, the information. Computer terminals are located in supervised areas with access control. The system provides two-factor authentication, using either a Common Access Card (CAC) and personal identification number or a unique logon identification and password. Passwords must be frequently changed.

RETENTION AND DISPOSAL:

Disposition pending (treat records as permanent until the National Archives and Records Administration approves the proposed retention and disposition).

SYSTEM MANAGER(S) AND ADDRESS:

Program Manager, WIC Overseas Program, TRICARE Management Activity, Policy and Operations Directorate, Skyline 5, Suite 810, 5111 Leesburg Pike, Falls Church, VA 22041–3206.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the TRICARE Management Activity, Department of Defense, ATTN: TMA Privacy Officer, Skyline 5, Suite 810, 5111 Leesburg Pike, Falls Church, VA 22041–3206.

Requests must contain participant's and/or sponsor's full name, SSN and/or DoD ID number, current address, and telephone number.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system of records should address written inquiries to the TRICARE Management Activity, Attention: Freedom of Information Act Requester Service Center, 16401 East Centretech Parkway, Aurora, CO 80011–9066.

Written requests must contain participant's and/or sponsor's full name, SSN and/or DoD ID number, current address, telephone number, name and number of this system of records notice, and be signed.

CONTESTING RECORD PROCEDURES:

The OSD rules for accessing records, contesting contents, and appealing initial agency determinations are published in OSD Administrative Instruction 81; 32 CFR Part 311; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individuals applying for the program benefits.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 2011–15017 Filed 6–16–11; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2011–OS–0064]

Privacy Act of 1974; System of Records

AGENCY: Office of the Secretary, DoD.

ACTION: Notice to Alter a System of Records.

SUMMARY: The Office of the Secretary of Defense proposes to alter a system of records in its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This proposed action would be effective without further notice on July 18, 2011 unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and/

Regulatory Information Number (RIN) and title, by any of the following methods:

• *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301–1160.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Cindy Allard, Chief, OSD/JS Privacy Office, Freedom of Information Directorate, Washington Headquarters Services, 1155 Defense Pentagon, Washington, DC 20301–1155 or by phone at (703) 588–6830.

SUPPLEMENTARY INFORMATION: The Office of the Secretary of Defense notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT**.

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on June 8, 2011, to the House Committee on Oversight and Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: June 8, 2011.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DHRA 06

SYSTEM NAME:

National Security Education Program Records (December 30, 2008, 73 FR 79833).

CHANGES:

SYSTEM ID:

Delete entry and replace with ''DHRA 09.''

* * * * *

SYSTEM LOCATION:

Delete entry and replace with ''National Security Education Program, 1101 Wilson Boulevard, Suite 1210, Arlington, VA 22209–2248.

Institute of International Education, 1400 K Street, NW., Suite 650, Washington, DC 20005–2473.

IT–CNP, Inc., 2657G Annapolis Road, Hanover, MD 21076–1262.

Telophase Corporation, 2000 N. 14th Street, Suite 770, Arlington, VA 22201–2539.''

* * * * *

PURPOSE(S):

Delete entry and replace with ''To provide Americans with the resources and encouragement needed to acquire skills and experiences in areas of the world critical to the future security of nations in exchange for a commitment to seek work in the federal government. This will enable the National Security Education Program to select qualified applicants to be awarded National Security Education Program scholarships and fellowships.

A record is maintained in the system for each student who receives an award. The progress that each student makes toward fulfilling their Federal service obligation is tracked within our system.''

* * * * *

RETRIEVABILITY:

Delete entry and replace with ''Individual's name and last four digits of SSN.''

SAFEGUARDS:

Delete entry and replace with ''Paper and electronic media containing information is restricted to those who require the data in the performance of their official duties. Access to information is further restricted by the use of passwords that are changed periodically as well as via Common Access Card (CAC). Physical entry is restricted by the use of locks, guards, and administrative procedures. Contract officers are required to incorporate all appropriate Privacy Act clauses and contractor personnel are required to sign non-disclosure documents holding them to all provisions of the Privacy Act.''

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with ''Director, National Security Education Program, 1101 Wilson Boulevard, Suite 1210, Arlington, VA 22209–2248.''

NOTIFICATION PROCEDURE:

Delete entry and replace with ''Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the Director, National Security Education Office, 1101 Wilson Boulevard, Suite 1210, Arlington, VA 22209–2248.

Requests should contain the name and number of this system of records notice, individuals name, address, award year and type, SSN, and must be signed.''

RECORD ACCESS PROCEDURES:

Delete entry and replace with ''Individuals seeking access to information about themselves contained in this system should address written inquiries to the Office of the Secretary of Defense (OSD)/Joint Staff Freedom of Information Act Requester Service Center, 1155 Defense Pentagon, Washington, DC 20301–1155.

Requests should contain the name and number of this system of records notice, individuals name, address, award year and type, SSN and must be signed.''

* * * * *

DHRA 09

SYSTEM NAME:

National Security Education Program Records.

SYSTEM LOCATION:

National Security Education Program, 1101 Wilson Boulevard, Suite 1210, Arlington, VA 22209–2248.

Institute of International Education, 1400 K Street, NW., Suite 650, Washington, DC 20005–2473.

IT–CNP, Inc., 2657G Annapolis Road, Hanover, MD 21076–1262.

Telophase Corporation, 2000 N. 14th Street, Suite 770, Arlington, VA 22201–2539.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who apply for the following scholarships or fellowships: David L. Boren Scholarships, English for Heritage Language Speakers Scholarships, David L. Boren Fellowships, and Flagship Fellowships.

CATEGORIES OF RECORDS IN THE SYSTEM:

Information collected on the online application and an award recipient includes: Title; full name; current address, city, state, and zip code; permanent address, city, state; Social Security Number (SSN); current telephone number and permanent telephone number; email address; voting district; date of birth; country or state of birth; naturalization information; educational information; region, country, and language to be

studied under award; other languages spoken; proficiency in language studied at time of award; overseas experience; relevant activities; honors and awards; government agencies of interest; proposed study abroad program information and budget; other scholarship funding information; gender; ethnicity; employer name and employer address; supervisor name, title, and telephone number; position title; employment dates and hours; language used in position; security clearance held for position; award type; date of award completion; graduation date; length of service requirement; date of availability for work; information on veterans preference, Federal employment history, and preferences with regard to being contacted by intelligence agencies; degree information; foreign language information; job history; overseas experience; other information e.g., special recognitions or memberships; special skills and qualifications; fieldwork or volunteer experience.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

50 U.S.C. 1901 *et seq.,* as amended, the David L. Boren National Security Education Act of 1991; DoD Instruction 1025.02, National Security Education Program; and E.O. 9397 (SSN), as amended.

PURPOSE(S):

To provide Americans with the resources and encouragement needed to acquire skills and experiences in areas of the world critical to the future security of nations in exchange for a commitment to seek work in the Federal government. This will enable the National Security Education Program to select qualified applicants to be awarded National Security Education Program scholarships and fellowships.

A record is maintained in the system for each student who receives an award. The progress that each student makes toward fulfilling their Federal service obligation is tracked within our system.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, these records may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To authorized Federal hiring officials to facilitate the recruiting of National Security Education Program award recipients into Federal service for the purpose of fulfilling National Security Education Programs mission.

To the Boren Forum, the non-profit National Security Education Program alumni organization to confirm the name, award year and type of award of National Security Education Program award recipients.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Disclosures pursuant to 5 U.S.C. 552a(b)(12) may be made from this system to 'consumer reporting agencies' as defined in the Fair Credit Reporting Act (14 U.S.C. 1681a(f)) or the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)). The purpose of this disclosure is to aid in the collection of outstanding debts owed to the Federal government, typically to provide an incentive for debtors to repay delinquent Federal government debts by making these debts part of their credit records.

The disclosure is limited to information necessary to establish the identity of the individual, including name, address, and taxpayer identification number (Social Security Number); the amount, status, and history of the claim; and the agency or program under which the claim arose for the sole purpose of allowing the consumer reporting agency to prepare a commercial credit report.

The DoD ''Blanket Routine Uses'' set forth at the beginning of the Office of the Secretary of Defense (OSD) compilation of systems of records notices apply to this system of records.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders and electronic storage media.

RETRIEVABILITY:

Individual's name and last four digits of SSN.

SAFEGUARDS:

Paper and electronic media containing information is restricted to those who require the data in the performance of their official duties. Access to information is further restricted by the use of passwords that are changed periodically as well as via Common Access Card (CAC). Physical entry is restricted by the use of locks, guards, and administrative procedures. Contract officers are required to incorporate all appropriate Privacy Act clauses and contractor personnel are required to sign non-disclosure documents holding them to all provisions of the Privacy Act.

RETENTION AND DISPOSAL:

Disposition pending (until the National Archives and Records Administration approves retention and disposal schedule, records will be treated as permanent).

SYSTEM MANAGER(S) AND ADDRESS:

Director, National Security Education Program, 1101 Wilson Boulevard, Suite 1210, Arlington, VA 22209–2248.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the Director, National Security Education Office, 1101 Wilson Boulevard, Suite 1210, Arlington, VA 22209–2248.

Requests should contain the name and number of this system of records notice, individuals name, address, award year and type, SSN, and must be signed.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system should address written inquiries to the Office of the Secretary of Defense (OSD)/Joint Staff Freedom of Information Act Requester Service Center, 1155 Defense Pentagon, Washington, DC 20301–1155.

Requests should contain the name and number of this system of records notice, individuals name, address, award year and type, SSN and must be signed.

CONTESTING RECORD PROCEDURES:

The OSD rules for accessing records, for contesting contents and appealing initial agency determinations are published in OSD Administrative Instruction 81; 32 CFR Part 311; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individual; DD Form 2752, National Security Education Program Service Agreement for Scholarship and Fellowship Awards; and DD Form 2753, National Security Education Program Service Agreement Report (SAR) for Scholarship and Fellowship.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 2011–15020 Filed 6–16–11; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

Information Collection Requirement; Defense Federal Acquisition Regulation Supplement; Acquisition of Information Technology

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Notice and request for comments regarding a proposed extension of an approved information collection requirement.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), DoD announces the proposed extension of a public information collection requirement and seeks public comment on the provisions thereof. *DoD invites comments on:* (a) Whether the proposed collection of information is necessary for the proper performance of the functions of DoD, including whether the information will have practical utility; (b) the accuracy of the estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. The Office of Management and Budget (OMB) has approved this information collection requirement for use through July 31, 2011. DoD proposes that OMB extend its approval for three additional years.

DATES: DoD will consider all comments received by August 16, 2011.

ADDRESSES: You may submit comments, identified by OMB Control Number 0704–0341, using any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail: dfars@osd.mil.* Include OMB Control Number 0704–0341 in the subject line of the message.
- *Fax:* 703–602–0350.
- *Mail:* Defense Acquisition Regulations System, Attn: Mr. Julian Thrash, OUSD(AT&L)DPAP/DARS, Room 3B855, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov*, including any personal information provided. To confirm receipt of your comment(s), please check *http://www.regulations.gov* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Julian Thrash (703) 602–0310. The information collection requirements addressed in this notice are available electronically on the Internet at: *http://www.acq.osd.mil/dpap/dfars/index.htm.* Paper copies are available from Mr. Julian Thrash, OUSD(AT&L)DPAP(DARS), Room 3B855, 3060 Defense Pentagon, Washington, DC 20301–3060.

SUPPLEMENTARY INFORMATION:

Title and OMB Number: Defense Federal Acquisition Regulation Supplement (DFARS) Part 239, Acquisition of Information Technology, and the associated clauses at DFARS 252.239–7000 and 252.239–7006; OMB Control Number 0704–0341.

Needs and Uses: This requirement provides for the collection of information from contractors regarding security of information technology; tariffs pertaining to telecommunications services; and proposals from common carriers to perform special construction under contracts for telecommunications services. Contracting officers and other DoD personnel use the information to ensure that information systems are protected; to participate in the establishment of tariffs for telecommunications services; and to establish reasonable prices for special construction by common carriers.

Affected Public: Businesses or other for-profit and not-for-profit institutions.

Number of Respondents: 571.

Responses per Respondent: 14.

Annual Responses: 7,994.

Average Burden per Response: 0.5 hour.

Annual Burden Hours: 3,997.

Frequency: On occasion.

Summary of Information Collection

The clause at DFARS 252.239–7000, Protection Against Compromising Emanations, requires that the contractor provide, upon request of the contracting officer, documentation that information technology used or provided under the contract meets appropriate information assurance requirements.

The clause at DFARS 252.239–7006, Tariff Information, requires that the contractor provide to the contracting officer: (1) Upon request, a copy of the contractor's existing tariffs (including changes); (2) before filing, a copy of any application to a Federal, State, or other regulatory agency for new rates, charges, services, or regulations relating to any tariff or any of the facilities or services to be furnished solely or primarily to the Government, and, upon request, a copy of all information, material, and data developed or prepared in support of or in connection with such an application; and (3) a notification to the contracting officer of any application submitted by anyone other than the contractor that may affect the rate or conditions of services under the agreement or contract.

DFARS 239.7408 requires the contracting officer to obtain a detailed special construction proposal from a common carrier that submits a proposal or quotation that has special construction requirements related to the performance of basic telecommunications services.

Mary Overstreet,

Editor, Defense Acquisition Regulations Council.

[FR Doc. 2011–15113 Filed 6–16–11; 8:45 am]

BILLING CODE 5001–08–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

Information Collection Requirements; Defense Federal Acquisition Regulation Supplement; Construction and Architect-Engineer Contracts

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Notice and request for comments regarding a proposed extension of an approved information collection requirement.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), DoD announces the proposed extension of a public information collection requirement and seeks public comment on the provisions thereof. *DoD invites comments on:* (a) Whether the proposed collection of information is necessary for the proper performance of the functions of DoD, including whether the information will have practical utility; (b) the accuracy of the estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. The Office of Management and Budget (OMB) has approved this information

collection requirement for use through October 31, 2011. DoD proposes that OMB extend its approval for three additional years.

DATES: DoD will consider all comments received by August 16, 2011.

ADDRESSES: You may submit comments, identified by OMB Control Number 0704–0255, using any of the following methods:

- *Regulations.gov: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *E-mail: dfars@osd.mil.* Include OMB Control Number 0704–0248 in the subject line of the message.
- *Fax:* 703–602–0350.
- *Mail:* Defense Acquisition Regulations System, *Attn:* Mr. Manuel Quinones, OUSD(AT&L)DPAP(DARS), 3060 Defense Pentagon, Room 3B855, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov*, including any personal information provided. To confirm receipt of your comment, please check *http://www.regulations.gov* approximately two to three days after submission to verify posting, except allow 30 days for posting of comments submitted by mail.

FOR FURTHER INFORMATION CONTACT: Mr. Manuel Quinones, 703–602–8383. The information collection requirements addressed in this notice are available on the World Wide Web at: *http://www.acq.osd.mil/dpap/dars/dfars.html*. Paper copies are available from Mr. Manuel Quinones, OUSD(AT&L)DPAP(DARS), 3060 Defense Pentagon, Room 3B855, Washington, DC 20301–3060.

SUPPLEMENTARY INFORMATION: *Title and OMB Number:* Defense Federal Acquisition Regulation Supplement (DFARS) Part 236, Construction and Architect-Engineer Contracts, and Related Clauses at DFARS 252.236; OMB Control Number 0704–0255.

Needs and Uses: DoD contracting officers need this information to evaluate contractor proposals for contract modifications; to determine that a contractor has removed obstructions to navigation; to review contractor requests for payment for mobilization and preparatory work; to determine reasonableness of costs allocated to mobilization and demobilization; and to determine eligibility for the 20 percent evaluation preference for United States firms in the award of some overseas construction contracts.

Affected Public: Businesses or other for-profit and not-for-profit institutions.

Annual Burden Hours: 359,015.

Number of Respondents: 3539.

Responses per Respondent: Approximately 1.

Annual Responses: 3587.

Average Burden per Response: Approximately 100 hours.

Frequency: On occasion.

Summary of Information Collection

DFARS 236.570(a) prescribes use of the clause at DFARS 252.236–7000, Modification Proposals—Price Breakdown, in all fixed-price construction contracts. The clause requires the contractor to submit a price breakdown with any proposal for a contract modification.

DFARS 236.570(b) prescribes use of the following clauses in fixed-price construction contracts as applicable:

(1) The clause at DFARS 252.236–7002, Obstruction of Navigable Waterways, requires the contractor to notify the contracting officer of obstructions in navigable waterways.

(2) The clause at DFARS 252.236–7003, Payment for Mobilization and Preparatory Work, requires the contractor to provide supporting documentation when submitting requests for payment for mobilization and preparatory work.

(3) The clause at DFARS 252.236–7004, Payment for Mobilization and Demobilization, permits the contracting officer to require the contractor to furnish cost data justifying the percentage of the cost split between mobilization and demobilization, if the contracting officer believes that the proposed percentages do not bear a reasonable relation to the cost of the work.

DFARS 236.570(c) prescribes use of the following provisions in solicitations for military construction contracts that are funded with military construction appropriations and are estimated to exceed $1,000,000:

(1) The provision at DFARS 252.236–7010, Overseas Military Construction—Preference for United States Firms, requires an offeror to specify whether or not it is a United States firm.

(2) The provision at DFARS 252.236–7012, Military Construction on Kwajalein Atoll-Evaluation Preference, requires an offeror to specify whether it is a United States firm, a Marshallese firm, or other firm.

Mary Overstreet,

Editor, Defense Acquisition Regulations System.

[FR Doc. 2011–15132 Filed 6–16–11; 8:45 am]

BILLING CODE 5001–08–P

DEPARTMENT OF DEFENSE

Department of the Army; Corps of Engineers

Notice of Intent to Grant Partially Exclusive License of the United States Patent Application No. 12/365,698, ''Reusable Sample Holding Device Permitting Ready Loading of Very Small Wet Samples,'' Filed Feb 4, 2009

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DOD.

ACTION: Notice of intent.

SUMMARY: In accordance with 37 CFR 404.7(a) (1) (i), announcement is made of a prospective partially exclusive license of the following U.S. Patent Application 12/365,698 Filed February 04, 2009 (published on Aug. 5, 2010 with Pub. No. US 2010/0193398 A1) to Hummingbird Scientific, Inc for achieving commercial sales of a reusable sample holding device permitting ready loading of very small wet samples for use with high resolution imaging systems of various types, to include those requiring a vacuum environment.

DATES: Written objections must be filed not later than 15 days following publication of this announcement.

ADDRESSES: United States Army Engineer Research and Development Center, *Attn:* CEERD–OT (Ms. Bea Shahin), 2902 Newmark Drive, Champaign, IL 6182–1076.

FOR FURTHER INFORMATION CONTACT: Ms. Bea Shahin (217) 373–7234, FAX (217) 373–7210, *e-mail: Bea.S.Shahin@usace.army.mil.*

SUPPLEMENTARY INFORMATION: This patent application claims a reusable sample-holding device for readily loading very small wet samples for observation of the samples by microscopic equipment, in particular in a vacuum environment. Embodiments may be used with a scanning electron microscope (SEM), a transmission electron microscope (TEM), an X-ray microscope, optical microscope, and the like. For observation of the sample, embodiments provide a thin-membrane window etched in the center of each of two silicon wafers abutting to contain the sample in a small uniform gap formed between the windows. This gap may be adjusted by employing spacers. Alternatively, the thickness of a film established by the fluid in which the sample is incorporated determines the gap without need of a spacer. To optimize resolution each window may have a thickness on the order of 50 nm and the gap may be on the order of 50 nm.

Dated: June 14, 2011.

David B. Olson,

Federal Register Liaison Officer, U.S. Army Corps of Engineers.

[FR Doc. 2011–15084 Filed 6–16–11; 8:45 am]

BILLING CODE 3720–58–P

DENALI COMMISSION

Denali Commission Fiscal Year 2011 Draft Work Plan

AGENCY: Denali Commission.

ACTION: Notice

SUMMARY: The Denali Commission (Commission) is an independent federal agency based on an innovative federal-state partnership designed to provide critical utilities, infrastructure and support for economic development and in training in Alaska by delivering federal services in the most cost-effective manner possible. The Commission was created in 1998 with passage of the October 21, 1998 Denali Commission Act (Act) (Title III of Pub. L. 105–277, 42 USC 3121). The Denali Commission Act requires that the Commission develop proposed work plans for future spending and that the annual Work Plan be published in the **Federal Register**, providing an opportunity for a 30-day period of public review and written comment.

This **Federal Register** notice serves to announce the 30-day opportunity for public comment on the Denali Commission Draft Work Plan for Federal Fiscal Year 2011.

DATES: Comments and related material to be received by July 13, 2011.

ADDRESSES: Submit comments to the Denali Commission, Attention: Sabrina Hoppas, 510 L Street, Suite 410, Anchorage, AK 99501.

FOR FURTHER INFORMATION CONTACT: Ms. Sabrina Hoppas, Denali Commission, 510 L Street, Suite 410, Anchorage, AK 99501. Telephone: (907) 271–1414. E-mail: *shoppas@denali.gov.*

Background: The Denali Commission (Commission) is an independent federal agency based on an innovative federal-state partnership designed to provide critical utilities, infrastructure and support for economic development and training in Alaska by delivering federal services in the most cost-effective manner possible. The Commission was created in 1998 with passage of the October 21, 1998, Denali Commission Act (Act) (Title III of Pub. L. 105–277, 42 U.S.C. 3121).

The Commission's mission is to partner with tribal, federal, state, and local governments and collaborate with all Alaskans to improve the effectiveness and efficiency of government services, to develop a well-trained labor force employed in a diversified and sustainable economy, and to build and ensure the operation and maintenance of Alaska's basic infrastructure.

By creating the Commission, Congress mandated that all parties involved partner together to find new and innovative solutions to the unique infrastructure and economic development challenges in America's most remote communities.

Pursuant to the Denali Commission Act, as amended, the Commission determines its own basic operating principles and funding criteria on an annual federal fiscal year (October 1 to September 30) basis. The Commission outlines these priorities and funding recommendations in an annual Work Plan. The Work Plan is adopted on an annual basis in the following manner, which occurs sequentially as listed:

- Commissioners first forward an approved draft version of the Work Plan to the Federal Co-Chair.
- The Federal Co-Chair approves the draft Work Plan for publication in the **Federal Register** providing an opportunity for a 30-day period of public review and written comment. During this time, the draft Work Plan is also disseminated widely to Commission program partners including, but not limited to the Bureau of Indian Affairs (BIA), the Economic Development Administration (EDA), and the United States Department of Agriculture—Rural Development (USDA–RD).
- Public comment concludes and Commission staff provides the Federal Co-Chair with a summary of public comment and recommendations, if any, associated with the draft Work Plan.
- If no revisions are made to the draft, the Federal Co-Chair provides notice of approval of the Work Plan to the Commissioners, and forwards the Work Plan to the Secretary of Commerce for approval; or, if there are revisions the Federal Co-Chair provides notice of modifications to the Commissioners for their consideration and approval, and upon receipt of approval from Commissioners, forwards the Work Plan to the Secretary of Commerce for approval.
- The Secretary of Commerce approves the Work Plan.

The Work Plan authorizes the Federal Co-Chair to enter into grant agreements, award grants and contracts and obligate the federal funds identified by appropriation in the chart below.

FY 11 Appropriations Summary

The Denali Commission has historically received several federal funding sources (identified by the varying colors in the table below). These fund sources are governed by the following general principles:

- In FY 2011 no project specific earmarks were directed.
- The Energy and Water Appropriation is eligible for use in all programs, but has historically been used substantively to fund the Energy Program.
- The Energy Policy Act of 2005 established new authorities for the Commission's Energy Program, with an emphasis on renewable and alternative energy projects. No new funding accompanied the Energy Policy Act, and prior fiscal year Congressional direction has indicated that the Commission should fund renewable and alternative Energy Program activities from the available Energy and Water appropriation.
- All other funds outlined below may be used only for the specific program area and may not be used across programs. For instance, Federal Transit Administration funding, which has in the past been appropriated for the Transportation Program, may not be moved to the Energy Program.
- Final transportation funds received may be reduced due to agency modifications, reductions and fees determined by the U.S. Department of Transportation. Final program available figures may not be provided until later this spring.
- All Energy and Water Appropriation funds, including operational funds, designated as ''up to'' may be reassigned to the Legacy Energy Program, Bulk Fuel and Rural Power System Upgrades, if they are not fully expended in a program component area or a specific project.
- Total FY 2011 Budgetary Resources Provided in the Continuing Resolution

These are the figures that appear in the rows entitled ''FY 2011 Appropriation'' and are the original appropriations amounts which do not include Commission overhead deductions. These funds are identified by their source name (*i.e.,* Energy and Water Appropriation, USDA–RUS, etc.). The grand total for all appropriations appears at the end of the FY 2011 Funding Table.

- Total FY 11 Program Available Funding

These are the figures that appear in the rows entitled ''FY 2011 Appropriations—Program Available'' and are the amounts of funding

available for program(s) activities after Commission overhead has been deducted. The grand total for all program available funds appears at the end of the FY 2011 Funding Table.

- Program Funding

These are the figures that appear in the rows entitled with the specific Program and Sub-Program area, and are the amounts of funding the Draft FY 2011 Work Plan recommends, within each program fund source for program components.

- Subtotal of Program Funding

These are the figures that appear in rows entitled ''subtotal'' and are the subtotals of all program funding within a given fund source. The subtotal must always equal the Total FY 2011 Program Available Funding.

Denali Commission FY 2011 Funding Table	Totals
FY 2011 Energy & Water Appropriation	$10,700,000
FY 2011 Across the Board Reduction	$21,400
FY 2011 Energy & Water Appropriation—Administrative Funds	$2,558,250
FY 2011 Energy & Water Appropriation—Program Available	$8,120,350
Energy	
Emerging Energy Technology Program	$2,400,000
Bulk Fuel/RPSU Planning, Design & Construction	$3,770,350
Renewable Energy Technical Assistance	Up to $300,000
Total Energy Projects	$6,470,350
Health	$700,000
Training Program—emphasis on building maintenance for an array of facilities to include health clinics	$500,000
Economic Development	$250,000
Solid Waste Program	$100,000
Sponsorship Program	$100,000
Sub-total $	$8,120,350
FY 2011 USDA, Rural Utilities Service (RUS)—pending estimate	$0–$5,350,000
FY 2011 USDA, Rural Utilities Service (RUS)—Program Available (less 4% overhead)	$0–$5,136,000
Bulk Fuel/RPSU Planning, Design & Construction	$0–$5,136,000
Sub-total $	$0–$5,136,000
FY 2011 Trans Alaska Pipeline Liability (TAPL) Trust	$7,010,000
FY 2011 Trans Alaska Pipeline Liability (TAPL)—Program Available (less 5% overhead)	$6,659,500
Bulk Fuel Planning, Design & Construction	$6,659,500
Sub-total $	$6,659,500
FY 2011 Federal Transit Administration (FTA)—Estimate	$5,000,000
$5,000,000 from section 3011 (FTA) for docks and harbors	
FY 2011 Federal Highway Administration (FHWA)—Estimate	$14,025,000
For necessary, expenses for the Denali Access System Program as authorized under Section 1960 of Public Law 109–59	
FY 2011 Transportation Program Available—(less 5% overhead)—Estimate	$18,073,750
Transportation Program: Docks & Harbors—Estimate	$4,750,000
Transportation Program: Roads—Estimate	$13,323,750
Sub-total $	$18,073,750
Total FY 2011 Federal Program Available—Estimate	$32,853,600–$37,989,600

FY 11 Program Details & General Information

The following section provides narrative discussion, by each of the Commission Programs identified for FY 08 funding in the table above, in the following categories:

- Program History and Approach;
- FY 2011 Project Description;
- FY 2011 Project Selection Process;
- FY 2011 Program and Project Policy Issues (as applicable).

Government Coordination

The Commission is charged with the special role of increasing the effectiveness of government programs by acting as a catalyst to coordinate the many federal and state programs that serve Alaska. In FY 2011 the Commission will continue its role of coordinating State and Federal agencies and other partner organizations to accomplish its overall mission of developing Alaska's communities. Particular focus will be given to the collaborative efforts of the Commission's Federal and State Memorandum of Understanding (MOU) and the Sustainable Rural Communities initiative. Strategies and next steps for this effort will be formulated as the Denali Commission leads this unique collaborative effort. No funding is dedicated to this activity.

Energy Program

The Energy Program is the Commission's original program and is identified as a ''legacy'' program. The program focuses on bulk fuel facilities (BFU) and rural power system upgrades/power generation (RPSU) across rural Alaska. About 94% of electricity in rural communities is produced by diesel generators and about half the fuel storage in most villages is used for these power plants for distribution. Alternative means of generating power can reduce the capacity needed for fuel storage and ultimately reduce the cost of power to the community.

Alternative/Renewable Program

The *Energy Policy Act of 2005* established new authorities for the Commission's Energy Program with an emphasis on alternative and renewable energy projects. Although the 2005 Energy Policy Act did not include appropriations, the Commission is expected to carry out the intent of the Act through a portion of its Energy and Water Appropriation funding. To date, the Commission has co-funded a number of renewable projects and each year new initiatives are considered. In 2007, the State of Alaska passed legislation and funded the Renewable Energy Fund (REF) which modeled the project selection process set forth by the Commission's early investment.

Emerging Technologies

With the advent of the REF, more resources to meet commercial-ready renewable technology needs are now available. The area of emerging technologies, meaning pre-commercial, yet post-research/development, has become an appropriate role for the Commission in keeping with the congressional direction in 2005. A solicitation was conducted in FY 2009 identifying over $50 million in project requests (and only $4 million in available funds). In FY 2010, the Commission provided $3.1 million in funding to the program and a solicitation process is currently underway. Similar to the REF, this initiative is a leveraging opportunity with State of Alaska's recent legislation for an emerging technology fund that could accept funds from multiple sources to meet needs. The goal of the program is to fund demonstration projects for applied research and further technologies focusing on replication in rural Alaska so they are commercially viable.

Other Renewable Initiatives

In addition to the emerging technology program, the Commission has funded energy efficiency efforts with the goal of energy cost reduction and leveraging of funding sources. For example, in FY 2009 the Commission provided match funding to tribes that submitted group applications to the Energy Efficiency and Conservation Block Grant program under the Department of Energy. The Commission received 8 eligible group applications, representing 106 Alaskan tribes, totaling $456,710 in Commission funding and leveraging over $4 million of federal funding. While the FY 2011 Work Plan allocates all renewable funds toward emerging technologies, it also recommends that if funds become available to support efforts to incentivize energy efficiency or other coordination opportunities around energy for rural Alaska, it be considered allowable. *No funds are currently set aside for these needs.*

The FY 2011 Work Plan outlines a strategy to balance the Energy Program in both legacy and renewable components, providing up to $2.4 million of available program funds specifically toward the emerging technology program pending state match. If match for this program is not provided, this funding shall be reallocated to legacy projects.

FY 2011 Program & Project Policy Issues

Cost Share Match

The approved FY 2008 Denali Commission Policy Document requires and prioritizes cost share match for funded projects. In implementing this policy, 10%, match was required in FY 2010. In FY 2011, in anticipation of mandated match language through one version of the appropriations process, Energy Advisory Committee (EAC) concurred with this direction of 50% for non-distressed and 20% for distressed communities. Since that language was not included in the final passed Continuing Resolution, the minimum 10% match will be required and projects with greater match may be prioritized for funding as in prior years. It is expected that future year appropriations will statutorily require match in the amounts of 50% for non-distressed and 20% for distressed communities.

Sustainability Policy

All energy construction grants will proceed after business plans are reviewed and approved by Commission staff. Additionally, Commission staff is expected to be engaged throughout the planning process of projects to assure policy requirements are adhered to earlier in the process.

Construction Contingency Pool

The Commission has historically handled construction cost overruns on an ongoing basis, with the requirement that those in excess of 10% be reported to Commissioners via an ''exceptions report''. *No funding for contingency is recommended for FY 2011.*

FY 2011 Project Selection Process

The Energy Advisory Committee (EAC) provides guidance to Commissioners and staff on the program, and is comprised of members involved in energy development in Alaska. Members include representatives of Associated General Contractors, Alaska AFL–CIO, Department of Energy National Renewable Energy Lab, the University of Alaska Institute of Northern Engineering, USDA, Kotzebue Electric Association and two public members representing rural Alaska. The EAC provided general recommendations supporting the ongoing priority for funding Bulk Fuel/Rural Power System Upgrade planning, design and construction, providing match funding for the emerging energy technology program and for renewable energy regional planning in coordination with the Alaska Energy Authority's initiative to meet statewide energy infrastructure needs for all of the above.

Legacy Program (Bulk Fuel/RPSU)

Due to the nature of the due diligence requirement of energy projects, seasonal logistics in Alaska and funding restrictions (*i.e.* TAPL funds may only be used for bulk fuel projects)—a project may not progress as quickly as another. Given the late timing of funding in FY 2011, summer construction grants are not anticipated. A final project list will be developed based on available funds, project readiness, available match and other due diligence. EAC feedback on a final project list will be solicited prior to final grant execution.

Emerging Technologies Program

Newly passed state legislation creates a project selection process involving a Governor-appointed technical advisory committee to develop selection criteria and review proposals. Final project/grant approval for Commission funds is subject to final approvalby the Federal Co-Chair.

FY 2011 Energy Funding Strategy

The energy funding strategy for the Energy Program allows for an estimated range of funds available for this legacy program with other areas fixed. Commissioners recommended funding strategy including $3,770,350 (Base), $5,136,000 (pending RUS) and $6,659,500 (TAPL) for legacy program. Following summarizes the total energy program funding strategy:

Bulk Fuel and RPSU Legacy Program.	$10.4M–$15.6M
Renewable Energy Planning.	$300K (up to)
Emerging Technology Fund.	$2.4M
Total Estimated Energy Funds.	~$13.1M–$18.3M

Health Facilities Program

The Denali Commission Act was amended in 1999 to provide for the ''planning, constructing and equipping of health facilities.'' Since 1999, the Health Facilities Program has been methodically investing in the planning, design and construction of primary care clinics across Alaska.

Primary care clinics have remained the ''legacy'' priority for the Program. However, in 2003 the ''Other Than'' primary care component of the Program was adopted in response to Congressional direction to fund a mix of other health and social service related facility needs. Over time, the Program has developed Program sub-areas such as Behavioral Health Facilities, Domestic Violence Facilities, Elder Housing, Primary Care in Hospitals, Emergency Medical Services Equipment and Hospital Designs. The Program has utilized a ''universe of need'' model for primary care and a competitive selection process for other sub-program areas. In 1999 the Program created a deficiency list for primary care clinics, which totaled 288 communities statewide in need of clinic replacement, expansion and/or renovation. Over the course of its history, the Commission has invested approximately $300 million in health projects, contributing to the repair, renovation or replacement of more than 115 clinics. This substantial investment represents progress in meeting the universe of needs; however, the facility work accomplished to date leaves a number of projects with the greatest need, limited local capacity, and in many cases low population.

The Program is guided by the Health Steering Committee, an advisory body comprised of the following membership organizations: The State of Alaska, Alaska Primary Care Association, the Alaska Native Tribal Health Consortium, the Alaska Mental Health Trust Authority, the Alaska Native Health Board, the Indian Health Service, the Alaska State Hospital and Nursing Home Association, and the University of Alaska.

Consistent with the decrease in funding, the Health Program proposes one major project in FY 2011:

Small Clinic Program

Partner: Alaska Native Tribal Health Consortium (ANTHC)

Several small communities and villages across Alaska remain identified with prioritized health facility needs. High energy costs and small populations create a dilemma for these communities that need new clinics. The newly developed small clinic prototypes (all under 1,000 SF) are suitable for many of these communities. The Health Program will provide technical assistance, planning and design for a small number of communities.

Funding Summary

For historical context, the following reflects the past allocations of Health Facilities Program appropriations across the program component areas:

Fiscal year	Primary care clinics	Primary care in hospitals	Elder supportive housing	Behavioral health	Other program areas
2007	$37,119,040	$2,500,000	$0	$5,063,000	$637,000
2008	23,319,040	4,000,000	5,840,890	5,000,000	0
2009	14,758,102	1,526,746	1,901,420	1,017,831	0
2010	7,267,400	734,700	805,000	492,900	0
2011	700,000	0	0	0	0

Training Program

Consistent with the Commission's sustainability policy, the Training Program was instituted in 1999 as a core focus area of the Commission to ensure local residents were trained to construct, maintain and operate Commission investments in rural Alaska. The Training Advisory Committee (TrAC) provides guidance to Commissioners and staff on the program, and is comprised of members involved in rural job training. Members include representatives of Associated General Contractors, Department of Labor, Bristol Bay Area Health Corporation, State of Alaska Office of Economic Development, Alaska AFL–CIO, Alaska Native Coalition on Employment and Training, and the University of Alaska.

Primary Training Goals

The Training Program is based on two primary goals. First, the Training Program supports the Denali Commission's Sustainability Policy through workforce development. In rural Alaska, jobs are seasonal and rural residents are versatile in taking on a wide range of job types based on availability. Often rural residents move from construction to administration to allied health and other lines of work to sustain their families and remain in their community. It has been a longstanding goal of the Commission to create and sustain local jobs as a result of infrastructure development.

The second goal is to assure rural training systems can stand-alone and/or are upheld by federal, state, regional and local collaboration. These training systems have augmented a community's ability to remain competent on the management and operations of public facilities. The Commission continues to provide a nexus to federal, state, regional and local entities for improved coordination between project development and job training.

Program Partners

- Department of Labor and Workforce Development is the administrator of the Denali Training Fund (DTF), a public competitive grant opportunity targeted at training for Denali Commission projects, energy conservation and public facility operation, maintenance and management.
- University of Alaska develops and facilitates the delivery of allied health training to rural communities via distant and on-site learning methods.
- Alaska Works Partnership develops and facilitates the delivery of construction trade training and registered apprenticeship programs to rural Alaska.
- Associated General Contractors/ Construction Education Foundation (CEF) is developing access to construction trades through the enhancement of construction career pathways and the development of Rural Construction Academies in Nome, Bethel, Kodiak and Bristol Bay.
- First Alaskans facilitates a successful leadership development project for young Alaskans.

Training Funding Strategy

Commissioner recommendation for FY11 Training Program funding totals $500,000 of Energy & Water Appropriations. These funds are intended to accomplish the specific goal of protecting the Commission's

infrastructure investment by providing both training and financial support toward all phases of facility maintenance in rural Alaska. This activity shall include, but is not limited to, a focus on the ~125 Commission-funded health facilities, multi-use and community facilities, energy facilities or other rural infrastructure. The funds shall be allocated through a clear strategy that is not duplicative of existing programs, yet may identify existing programs that may be supplanted to accomplish this objective. The strategy may identify existing gaps in current systems while emphasizing protecting Commission-funded infrastructure through building maintenance and construction activities.

Transportation

Section 309 of the Denali Commission Act 1998 (amended), created the Commission's Transportation Program, including the Transportation Advisory Committee. The advisory committee is composed of nine members appointed by the Governor of the State of Alaska including the Chairman of the Denali Commission; four members who represent existing regional native corporations, native nonprofit entities, or tribal governments, including one member who is a civil engineer; and four members who represent rural Alaska regions or villages, including one member who is a civil engineer.

The Transportation Program addresses two areas of rural Alaska transportation infrastructure: Roads and waterfront development. There is consensus among agencies and communities that the program is successfully addressing improvements to local and regional transportation systems. This is largely a function of the TAC's success at project selection and monitoring, and the success of the program's project development partners. The program is generally a competitively-bid contractor or materials-based project opportunity grounded in Title 23 CFR. These strict project development and construction guidelines have presented some challenges to the Commission's ability to respond quickly to targets of opportunity, but they have also had the positive effect of ensuring project design and construction is executed at a professional level. The program operates under a reimbursable payment system that requires local and program partner sponsors to pay close attention to accounting procedures prior to their payments to contractors and vendors. This system helps ensure project payments are eligible when submitted to the Commission.

In FY 2011 the program will continue its focus on barge landings and mooring points in rural communities. These projects range from one or two mooring points to secure a barge, to small dock structures, depending on community size and barge operation characteristics. The value of these structures lies in improved fuel/freight transfer operations and improved worker and environmental safety. The Commission and the U.S. Army Corps of Engineers (USACE) will continue to work through the prioritized list of barge landing and mooring point projects which were identified in a formal analysis conducted in FY 2009 and FY 2010. The universe of need for the first generation of projects is in the range of $40,000,000.

The TAC met on January 18–20, 2011 to select waterfront projects and March 3–4, 2011 to select road project priorities for FY 2011. Final project approvals and funding amounts have been approved by the Federal Co-Chair and are available on the Commission's Web site.

Economic Development

One of the purposes of the Commission is to support economic development activities across Alaska. The Commission supports the development of public infrastructure upon which allows for job creation and strategic wealth reinvestment. Additionally, the Commission supports projects which can ensure that good business ideas have a chance to become long-term, self-sustaining enterprises.

Over the history of the program, the Commission has supported and advanced a wide-array of Economic Development Program activities ranging from community profile mapping to supporting innovative models for lending, and equity investment in Alaska.

The program is guided by Commission staff and the Economic Development Advisory Committee (EDAC), which provides general policy guidance and funding recommendations in broad categories. The EDAC met on April 20, 2011 to recommend projects and program funding amounts to the Commission for FY 2011.

Other Program and Policy Issues

Solid Waste Program

In Fiscal Years 2004 through 2009, the Denali Commission received annual funding to address deficiencies in solid waste disposal sites threatening to contaminate rural drinking water supplies. Annual funding reached than $1.5 million in FY 2005. By FY 2008 program funding for the Solid Waste Program was $437,000. Solid waste continues to be a major health and safety issue in rural Alaska.

In keeping with the Commission's goal of intergovernmental coordination and leveraging of funding sources, an opportunity in FY 2011 to leverage funds for the Solid Waste Program has been identified. Through partnerships with the USDA-Rural Development, RuralCap, Rural Community Assistance Corporation (RCAC) and the U.S. Environmental Protection Agency (EPA), funding in the amount of $250–350k can be leveraged with $100k in match from the Commission. The FY 2011 Draft Work Plan document includes $100,000 in Energy and Water funding for this purpose. Grants will be awarded through a competitive Request For Proposal (RFP) process utilizing a multi-agency review panel to score and select projects to fund. Of note, this investment in solid waste may be an example for future Commission program funding. Historically, the solid waste projects were largely funded by the Commission. With this FY 2011 solid waste effort, the Commission funding will be a minority funder to the USDA community facilities program (which is one of few USDA programs that can be ''matched'' with other Federal funding sources).

Sponsorship Program

The Commission plans to continue conference sponsorships in FY 2011. Commissioners reinstated Conference sponsorship funding for events that were consistent with the Commission's mission and values in 2006.

Sponsorship activities provide a positive venue for communicating Commission activities. Sponsorship opportunities also provide Commission outreach to a wide variety of events and audiences. Events sponsored by the Commission promote key programmatic areas that are in alignment with the Commission's values and mission, including efforts in alternative-renewable energy conferences, health, training and leadership and transportation.

In FY 2011 this program will be funded in the amount of $100,000. Events funded will be in line with the major program areas at the Commission and will have a statewide focus.

Corrine Eilo,

Director of Administration.

[FR Doc. 2011–15051 Filed 6–16–11; 8:45 am]

BILLING CODE 3300–01–P

DEPARTMENT OF EDUCATION

Federal Need Analysis Methodology for the 2012–2013 Award Year

Correction

In notice document 2010–12812 appearing on pages 30139 through 30142 in the issue of Tuesday, May 24, 2011, make the following corrections:

1. On page 30139, in the third column, the last paragraph—''The IPAs for single independent students and independent students without dependents other than a spouse for award year 2012–13 are:''—should appear on page 30140 following the table ''Parents of Dependent Students'' and its two footnotes.

2. On page 30140, in the first column, in the table at the bottom of the column, in the table's third line of values, ''$115,00 to $350,000'' should read ''$115,001 to $350,000''.

[FR Doc. C1–2011–12812 Filed 6–16–11; 8:45 am]

BILLING CODE 1505–01–D

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9320–3, EPA–HQ–OW–2010–0782]

Draft National Pollutant Discharge Elimination System (NPDES) General Permit for Stormwater Discharges From Construction Activities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Extension of Comment Period.

SUMMARY: On April 25, 2011, EPA published a draft NPDES general permit entitled ''Draft National Pollutant Discharge Elimination System (NPDES) General Permit for Stormwater Discharges from Construction Activities.'' As initially published in the **Federal Register**, written comments on the draft general permit were to be submitted to EPA on or before June 24, 2011 (a 60-day public comment period). Since publication, EPA has received several requests for additional time to submit comments. Therefore, the public comment period is being extended for 17 days and will now end on July 11, 2011.

DATES: Comments on the draft general permit must be received on or before July 11, 2011.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OW–2010–0782, by one of the following methods:

1. *http://www.regulations.gov:* Follow the online instructions for submitting comments.

2. *E-mail: ow-docket@epa.gov.*

3. *Mail to:* Water Docket, U.S. Environmental Protection Agency, Mail Code: 2822T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, Attention: Docket ID No. EPA–HQ–OW–2010–0782. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OW–2010–0782. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through www.regulations.gov your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at a docket facility. The Office of Water (OW) Docket Center is open from 8:30 until 4:30 p.m., Monday through Friday, excluding legal holidays. The OW Docket Center telephone number is (202) 566–2426, and the Docket address is OW Docket, EPA West, Room 3334, 1301 Constitution Avenue, NW., Washington, DC 20004. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744.

FOR FURTHER INFORMATION CONTACT: For further information on the draft NPDES general permit, contact the appropriate EPA Regional office listed in Section I.D, or Greg Schaner, EPA Headquarters, Office of Water, Office of Wastewater Management at tel.: 202–564–0721 or e-mail: *schaner.greg@epa.gov,* or Erika Farris, EPA Headquarters, Office of Water, Office of Wastewater Management at tel.: 202–564–7548, or e-mail *farris.erika@epa.gov.*

SUPPLEMENTARY INFORMATION: This supplementary information is organized as follows:

I. General Information

A. Does this action apply to me?

The draft construction general permit (''draft CGP'') applies to the following construction activities:

TABLE 1—ENTITIES POTENTIALLY REGULATED BY THIS PERMIT

Category	Examples of affected entities	North American Industry Classification System (NAICS) code
Industry	Construction site operators disturbing 1 or more acres of land, or less than 1 acre but part of a larger common plan of development or sale if the larger common plan will ultimately disturb 1 acre or more, and performing the following activities:	
	Building, Developing and General Contracting	233

TABLE 1—ENTITIES POTENTIALLY REGULATED BY THIS PERMIT—Continued

Category	Examples of affected entities	North American Industry Classification System (NAICS) code
	Heavy Construction	234

EPA does not intend the preceding table to be exhaustive, but provides it as a guide for readers regarding entities likely to be regulated by this action. This table lists the types of activities that EPA is now aware of that could potentially be affected by this action. Other types of entities not listed in the table could also be affected. To determine whether your facility is regulated by this action, you should carefully examine the definition of ''construction activity'' and ''small construction activity'' in existing EPA regulations at 40 CFR 122.26(b)(14)(x) and 122.26(b)(15), respectively. If you have questions regarding the applicability of this action to a particular entity, consult one of the persons listed for technical information in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. How can I get copies of these documents and other related information?

1. *Docket.* EPA has established an official public docket for this action under Docket ID No. EPA–HQ–OW–2010–0782. The official public docket is the collection of materials that is available for public viewing at the Water Docket in the EPA Docket Center, (EPA/DC) EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC 20460. Although all documents in the docket are listed in an index, some information is not publicly available, *i.e.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Publicly available docket materials are available in hard copy at the EPA Docket Center Public Reading Room, open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744 and the telephone number for the Water Docket is (202) 566–2426.

2. *Electronic Access.* You may access this **Federal Register** document electronically through the United States government online source for Federal regulations at *http://www.regulations.gov.*

Electronic versions of this draft permit and fact sheet are available on EPA's NPDES Web site at *http://www.epa.gov/npdes/stormwater/cgp.*

An electronic version of the public docket is available through the EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.regulations.gov* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. For additional information about EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/dockets.* Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the Docket Facility identified in Section I.B.1.

C. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *http://www.regulations.gov* or e-mail. Clearly mark all of the information that you claim to be CBI. For CBI information on computer disks mailed to EPA, mark the surface of the disk as CBI. Also identify electronically the specific information contained in the disk or that you claim is CBI. In addition to one complete version of the specific information claimed as CBI, you must submit a copy that does not contain the information claimed as CBI for inclusion in the public document. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

- Identify this permit by docket number and other identifying information (subject heading, **Federal Register** date, and page number).
- Where possible, respond to specific questions or organize comments by referencing a section or part of this permit.
- Explain why you agree or disagree, suggest alternatives, and suggest substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible.
- To ensure that EPA can read, understand, and therefore properly respond to comments, the Agency would prefer that commenters cite, where possible, the paragraph(s) or section in the fact sheet or permit to which each comment refers.
- Make sure to submit your comments by the comment period deadline identified.

D. Who are the EPA regional contacts for this draft permit?

For EPA Region 1, contact Jessica Hing at tel.: (617) 918–1560 or e-mail at *hing.jessica@epa.gov.*

For EPA Region 2, contact Stephen Venezia at tel.: (212) 637–3856 or e-mail at *venezia.stephen@epa.gov,* or for Puerto Rico, contact Sergio Bosques at

tel.: (787) 977–5838 or e-mail at *bosques.sergio@epa.gov.*

For EPA Region 3, contact Chuck Schadel at tel.: (215) 814–5761 or e-mail at *schadel.chuck@epa.gov.*

For EPA Region 4, contact Michael Mitchell at tel.: (404) 562–9303 or e-mail at *mitchell.michael@epa.gov.*

For EPA Region 5, contact Brian Bell at tel.: (312) 886–0981 or e-mail at *bell.brianc@epa.gov.*

For EPA Region 6, contact Suzanna Perea at tel.: (214) 665–7217 or e-mail at: *perea.suzanna@epa.gov.*

For EPA Region 7, contact Mark Matthews at tel.: (913) 551–7635 or e-mail at: *matthews.mark@epa.gov.*

For EPA Region 8, contact Amy Clark at tel.: (303) 312–7014 or e-mail at: *clark.amy@epa.gov.*

For EPA Region 9, contact Eugene Bromley at tel.: (415) 972–3510 or e-mail at *bromley.eugene@epa.gov.*

For EPA Region 10, contact Misha Vakoc at tel.: (206) 553–6650 or e-mail at *vakoc.misha@epa.gov.*

II. Extension of Comment Period for Draft CGP

A. Draft CGP

On April 25, 2011, EPA announced in the **Federal Register** the publication of proposed modifications to the next iteration of its CGP. See 79 FR 22882. The **Federal Register** notice provided summary details of the changes in the proposed permit, as compared to the existing CGP, and the supporting legislative and regulatory background behind these modifications. A key difference between the draft CGP and past versions of the permit is the fact that for the first time EPA's permit is required to include new requirements promulgated by the Agency in its Construction and Development Effluent Limitations Guidelines and New Source Performance Standards, also referred to as the ''C&D rule''. Copies of the draft permit are available on EPA's Web site at *http://cfpub.epa.gov/npdes/stormwater/cgp.cfm.* More information regarding EPA's C&D rule can be found at *http://water.epa.gov/scitech/wastetech/guide/construction/index.cfm.*

B. Extension of Comment Period

EPA is extending the deadline for submitting comments on the draft CGP to July 11, 2011. The original deadline for comments, based on a 60-day comment period, was June 24, 2011. EPA's decision responds to a request from several organizations to extend the comment deadline in order to provide a longer period of time in which to provide comments. EPA is hopeful that this 17-day extension, although not as long as the 60-day extension that at least one organization requested, will assist in providing an adequate amount of additional time for these organizations as well as other members of the public to review the draft permit and to provide written comments.

Authority: Clean Water Act, 33 U.S.C. 1251 *et seq.*

Dated: June 7, 2011.

H. Curtis Spalding,

Regional Administrator, EPA Region 1.

Dated: June 6, 2011.

Kevin Bricke,

Acting Division Director, Division of Environmental Planning & Protection, EPA Region 2.

Dated: June 8, 2011.

José C. Font,

Acting Division Director, Caribbean Environmental Protection Division, EPA Region 2.

Dated: June 7, 2011.

Jon M. Capacasa,

Director, Water Protection Division, EPA Region 3.

Dated: June 7, 2011.

Douglas Mundrick,

Acting Director, Water Protection Division, EPA Region 4.

Dated: June 7, 2011.

Tinka G. Hyde,

Director, Water Division, EPA Region 5.

Dated: June 7, 2011.

Jane B. Watson,

Acting Director, Water Quality Protection Division, EPA Region 6.

Dated: June 7, 2011.

Karen Flournoy,

Acting Director, Water, Wetlands and Pesticides Division, EPA Region 7.

Dated: June 6, 2011.

Stephen S. Tuber,

Assistant Regional Administrator, Offices of Partnerships and Regulatory Assistance, EPA Region 8.

Dated: June 6, 2011.

Alexis Strauss,

Director, Water Division, EPA Region 9.

Dated: June 6, 2011.

Michael A. Bussell,

Director, Office of Water and Watersheds, EPA Region 10.

[FR Doc. 2011–15101 Filed 6–16–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–8997–5]

Environmental Impacts Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–1399 or *http://www.epa.gov/compliance/nepa/.*

Weekly receipt of Environmental Impact Statements.

Filed 06/06/2011 Through 06/10/2011. Pursuant to 40 CFR 1506.9.

Notice

In accordance with Section 309(a) of the Clean Air Act, EPA is required to make its comments on EISs issued by other Federal agencies public. Historically, EPA met this mandate by publishing weekly notices of availability of EPA comments, which includes a brief summary of EPA's comment letters, in the **Federal Register**. Since February 2008, EPA has included its comment letters on EISs on its Web site at: *http://www.epa.gov/compliance/nepa/eisdata.html.* Including the entire EIS comment letters on the Web site satisfies the Section 309(a) requirement to make EPA's comments on EISs available to the public. Accordingly, on March 31, 2010, EPA discontinued the publication of the notice of availability of EPA comments in the **Federal Register**.

EIS No. 20110183, Final EIS, BR, CA, Madera Irrigation District Water Supply Enhancement Project, Constructing and Operating a Water Bank on the Madera Property, Madera County, CA, *Review Period Ends:* 07/18/2011, *Contact:* Chuck Siek 559–487–5138.

EIS No. 20110184, Final EIS, FHWA, WA, WA–520, I–5 to Medina Bridge Replacement and HOV Project, To Improve Mobility for People and Goods across Lake Washington, in Seattle, King County, WA, *Review Period Ends:* 07/18/2011, *Contact:* Allison Hanson 206–805–2880.

EIS No. 20110186, Draft EIS, NPS, 00, Big South Fork National River and Recreation Area and Obed Wild and Scenic River, Non-Federal Oil and Gas Management Plan, Implementation, KY and TN, *Comment Period Ends:* 08/15/2011, *Contact:* Dan Niosi 303–369–2068.

EIS No. 20110187, Draft EIS, NOAA, 00, Comprehensive Annual Catch Limit (ACL) Amendment for the South Atlantic Regions: Amendment 2 to the Fishery Management Plan for the Dolphin Wahoo Fishery; Amendment

2 to the Fishery Management Plan for Pelagic Sargassum Habitat; Amendment 5 to the Fishery Management Plan for the Golden Crab Fishery and Amendment 25 to the Fishery Management Plan for the Snapper Grouper Fishery, South Atlantic Region, *Comment Period Ends:* 08/01/2011, *Contact:* Roy E. Crabtree 727–824–5301.

Amended Notices

EIS No. 20110122, Draft EIS, FHWA, UT, Bangerter 600 West Project, Proposes Improvements to Address Projected Transportation Demand and Safety, Salt Lake County, UT, *Comment Period Ends:* 07/15/2011, *Contact:* Bryan Dillon 801–955–3517.

This document is available on the Internet at: *http://www.udot.utah.gov/bangerter600west/documents.html.*

Revision to FR Notice Published 04/22/2011: Extending Comment Period from 06/13/2011 to 07/15/2011

Dated: June 14, 2011.

Cliff Rader,

Acting Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2011–15103 Filed 6–16–11; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL HOUSING FINANCE AGENCY

[No. 2011–N–07]

Federal Home Loan Bank Members Selected for Community Support Review

AGENCY: Federal Housing Finance Agency.

ACTION: Notice.

SUMMARY: The Federal Housing Finance Agency (FHFA) is announcing the Federal Home Loan Bank (Bank) members it has selected for the 2010 third round review cycle under the FHFA's community support requirements regulation. This notice also prescribes the deadline by which Bank members selected for review must submit Community Support Statements to FHFA.

DATES: Bank members selected for the review cycle under the FHFA's community support requirements regulation must submit completed Community Support Statements to FHFA on or before August 1, 2011.

ADDRESSES: Bank members selected for the 2010 third round review cycle under the FHFA's community support requirements regulation must submit completed Community Support Statements to FHFA either by hard-copy mail at the Federal Housing Finance Agency, Housing Mission and Goals, 1625 Eye Street, NW., Washington, DC 20006, or by electronic mail at *hmgcommunitysupportprogram@fhfa.gov.*

FOR FURTHER INFORMATION CONTACT: Rona Richardson, Office Assistant, Housing Mission and Goals, Federal Housing Finance Agency, by telephone at 202–408–2945, by electronic mail at *Rona.Richardson@FHFA.gov,* or by hard-copy mail at the Federal Housing Finance Agency, 1625 Eye Street, NW., Washington, DC 20006.

SUPPLEMENTARY INFORMATION:

I. Selection for Community Support Review

Section 10(g)(1) of the Federal Home Loan Bank Act (Bank Act) requires FHFA to promulgate regulations establishing standards of community investment or service Bank members must meet in order to maintain access to long-term advances. *See* 12 U.S.C. 1430(g)(1). The regulations promulgated by FHFA must take into account factors such as the Bank member's performance under the Community Reinvestment Act of 1977 (CRA), 12 U.S.C. 2901 *et seq.,* and record of lending to first-time homebuyers. *See* 12 U.S.C. 1430(g)(2). Pursuant to section 10(g) of the Bank Act, FHFA has promulgated a community support requirements regulation that establishes standards a Bank member must meet in order to maintain access to long-term advances, and review criteria FHFA must apply in evaluating a member's community support performance. *See* 12 CFR Part 1290. The regulation includes standards and criteria for the two statutory factors—CRA performance and record of lending to first-time homebuyers. 12 CFR 1290.3. Only members subject to the CRA must meet the CRA standard. 12 CFR 1290.3(b). All members, including those not subject to CRA, must meet the first-time homebuyer standard. 12 CFR 1290.3(c).

Under the rule, FHFA selects approximately one-eighth of the members in each Bank district for community support review each calendar quarter. 12 CFR 1290.2(a). FHFA will not review an institution's community support performance until it has been a Bank member for at least one year. Selection for review is not, nor should it be construed as, any indication of either the financial condition or the community support performance of the member.

Each Bank member selected for review must complete a Community Support Statement and submit it to FHFA by the August 1, 2011 deadline prescribed in this notice. 12 CFR 1290.2(b)(1)(ii) and (c). On or before July 1, 2011, each Bank will notify the members in its district that have been selected for the 2010 third round community support review cycle that they must complete and submit to FHFA by the deadline a Community Support Statement. 12 CFR 1290.2(b)(2)(i). The member's Bank will provide a blank Community Support Statement Form (OMB No. 2590–0005), which also is available on the FHFA's Web site: *http://www.fhfa.gov/webfiles/2924/FHFAForm060.pdf.* Upon request, the member's Bank also will provide assistance in completing the Community Support Statement.

FHFA has selected the following members for the 2010 third round community support review cycle:

Federal Home Loan Bank of Boston—District 1

Northwest Community Bank	Winsted	Connecticut.
Aroostook County Federal Savings & Loan Association	Caribou	Maine.
Kennebec Federal Savings and Loan Association	Waterville	Maine.
First Federal Savings & Loan Association of Bath	Bath	Maine.
Camden National Bank	Camden	Maine.
Bar Harbor Bank and Trust	Bar Harbor	Maine.
Kennebunk Savings Bank	Kennebunk	Maine.
Colonial Federal Savings Bank	Quincy	Massachusetts.
Boston Private Bank & Trust Company	Boston	Massachusetts.
Danversbank	Danvers	Massachusetts.
Mechanics' Co-operative Bank	Taunton	Massachusetts.
The Savings Bank	Wakefield	Massachusetts.
Colonial Co-operative Bank	Gardner	Massachusetts.

Eagle Bank	Everett	Massachusetts.
Hingham Institution for Savings	Hingham	Massachusetts.
Northampton Cooperative Bank	Northampton	Massachusetts.
Cambridge Savings Bank	Cambridge	Massachusetts.
PeoplesBank	Holyoke	Massachusetts.
Clinton Savings Bank	Clinton	Massachusetts.
First Trade Union Bank	Boston	Massachusetts.
Reading Co-operative Bank	Reading	Massachusetts.
Spencer Savings Bank	Spencer	Massachusetts.
Foxboro Federal Savings	Foxboro	Massachusetts.
Middlesex Federal Savings, F.A.	Somerville	Massachusetts.
Georgetown Savings Bank	Georgetown	Massachusetts.
Saugusbank, A Cooperative Bank	Saugus	Massachusetts.
Federal Savings Bank	Dover	New Hampshire.
Salem Co-operative Bank	Salem	New Hampshire.
Franklin Savings Bank	Franklin	New Hampshire.
Newport Federal Savings Bank	Newport	Rhode Island.
Northfield Savings Bank	Northfield	Vermont.

Federal Home Loan Bank of New York—District 2

Amboy Bank	Old Bridge	New Jersey.
OceanFirst Bank	Tom Rivers	New Jersey.
Roma Bank	Robbinsville	New Jersey.
Glen Rock Savings Bank	Hawthorne	New Jersey.
GSL Savings Bank	Guttenberg	New Jersey.
Audubon Savings Bank	Audubon	New Jersey.
Century Savings Bank	Vineland	New Jersey.
Kearny Federal Savings Bank	Fairfield	New Jersey.
Gloucester County Federal Savings Bank	Sewell	New Jersey.
Oritani Savings Bank	Township of Washington	New Jersey.
Wallkill Valley Federal Savings & Loan Association	Wallkill	New York.
Provident Bank	Montebello	New York.
Glens Falls National Bank and Trust Company	Glens Falls	New York.
Massena Savings & Loan Association	Massena	New York.
Evans Bank	Hamburg	New York.
Cross County Federal Savings Bank	Middle Village	New York.
Maple City Savings Bank, FSB	Hornell	New York.
The Lyons National Bank	Lyons	New York.
Cattaraugus County Bank	Little Valley	New York.
Five Star Bank	Warsaw	New York.
Canandaigua National Bank and Trust Company	Canandaigua	New York.
The Berkshire Bank	New York	New York.
Oriental Bank & Trust	San Juan	Puerto Rico.

Federal Home Loan Bank of Pittsburgh—District 3

First Federal Savings & Loan Association of Greene County	Waynesburg	Pennsylvania.
Slovenian Savings & Loan Association of Franklin-Conemaugh	Conemaugh	Pennsylvania.
Reliance Bank	Altoona	Pennsylvania.
United-American Savings Bank	Pittsburgh	Pennsylvania.
Prudential Savings Bank	Philadelphia	Pennsylvania.
Slovak Savings Bank	Pittsburgh	Pennsylvania.
Eureka Bank	Pittsburgh	Pennsylvania.
Polonia Bank	Huntingdon Valley	Pennsylvania.
The First National Bank of Mifflintown	Mifflintown	Pennsylvania.
VIST Bank	Wyomissing	Pennsylvania.
Hamlin Bank and Trust Company	Smethport	Pennsylvania.
Liberty Savings Bank, FSB	Pottsville	Pennsylvania.
Washington Financial Bank	Washington	Pennsylvania.
First Citizens National Bank	Mansfield	Pennsylvania.
Peoples State Bank of Wyalusing	Wyalusing	Pennsylvania.
West View Savings Bank	Pittsburgh	Pennsylvania.
Eagle National Bank	Upper Darby	Pennsylvania.
The Bryn Mawr Trust Company	Bryn Mawr	Pennsylvania.
Mauch Chunk Trust Company	Jim Thorpe	Pennsylvania.
Republic First Bank	Philadelphia	Pennsylvania.
Clarion County Community Bank	Clearfield	Pennsylvania.
First Federal Savings Bank	Monessen	Pennsylvania.
Northwest Savings Bank	Warren	Pennsylvania.
Community State Bank of Orbisonia	Orbisonia	Pennsylvania.
Beneficial Mutual Savings Bank	Philadelphia	Pennsylvania.
Nextier Bank, NA	Evans City	Pennsylvania.
City National Bank of WV	Cross Lanes	West Virginia.
United Bank, Inc.	Parkersburg	West Virginia.

Federal Home Loan Bank of Atlanta—District 4		
Brantley Bank and Trust Company	Brantley	Alabama.
The Slocomb National Bank	Slocomb	Alabama.
Bank of Wedowee	Wedowee	Alabama.
First National Bank	Hamilton	Alabama.
FirstState Bank	Lineville	Alabama.
The Exchange Bank of Alabama	Altoona	Alabama.
First Citizens Bank	Luverne	Alabama.
Frontier Bank	Chelsea	Alabama.
Central State Bank	Calera	Alabama.
Security Federal Savings Bank	Jasper	Alabama.
The Camden National Bank	Camden	Alabama.
First State Bank of Florida Keys	Key West	Florida.
Mercantile Commercebank, National Association	Miami	Florida.
Natbank, National Association	Hollywood	Florida.
Wauchula State Bank	Wauchula	Florida.
Bank of St. Augustine	St. Augustine	Florida.
Urban Trust Bank	Orlando	Florida.
The Claxton Bank	Claxton	Georgia.
Peoples Bank	Lyons	Georgia.
Gateway Bank and Trust	Ringgold	Georgia.
Newton Federal Bank	Covington	Georgia.
Bank of Alapaha	Alapaha	Georgia.
The Citizens Bank	Nashville	Georgia.
Farmers & Merchants Bank	Statesboro	Georgia.
BankSouth	Greensboro	Georgia.
Capital Bank	Fort Oglethorpe	Georgia.
Farmers State Bank	Lincolnton	Georgia.
Spivey State Bank	Swainsboro	Georgia.
Mount Vernon Bank	Mt. Vernon	Georgia.
Central Bank of Georgia	Ellaville	Georgia.
Bank of Eastman	Eastman	Georgia.
Farmers and Merchants Bank	Eatonton	Georgia.
Bank of Camilla	Camilla	Georgia.
Presidential Bank, FSB	Bethesda	Maryland.
Community First Bank	Baltimore	Maryland.
Severn Savings Bank, F.S.B.	Annapolis	Maryland.
Easton Bank and Trust	Easton	Maryland.
First Shore Federal Savings & Loan Association	Salisbury	Maryland.
The Peoples Bank	Chestertown	Maryland.
Saint Casimirs Savings Bank	Baltimore	Maryland.
Eastern Savings Bank, FSB	Hunt Valley	Maryland.
Piedmont Federal Savings Bank	Winston Salem	North Carolina.
Branch Banking and Trust Company	Lumberton	North Carolina.
High Point Bank and Trust Company	High Point	North Carolina.
The East Carolina Bank	Engelhard	North Carolina.
RBC Bank (USA)	Raleigh	North Carolina.
The Bank of Charlotte County	Phenix	Virginia.
Virginia Commonwealth Bank	Petersburg	Virginia.
Valley Bank	Roanoke	Virginia.
Community Bank	Staunton	Virginia.
First State Bank	Danville	Virginia.

Federal Home Loan Bank of Cincinnati—District 5		
Central Kentucky Federal Savings Bank	Danville	Kentucky.
The Citizens National Bank	Lebanon	Kentucky.
Carrollton Federal Bank	Carrollton	Kentucky.
Bank of Edmonson County	Brownsville	Kentucky.
Citizens Bank & Trust Company	Campbellsville	Kentucky.
The First National Bank of Muhlenburg County	Central City	Kentucky.
Farmers National Bank	Walton	Kentucky.
Bank of Clarkson	Clarkson	Kentucky.
Traditional Bank, Inc.	Mt. Sterling	Kentucky.
Kentucky Home Bank, Inc.	Bardstown	Kentucky.
Citizens Bank	Mt. Vernon	Kentucky.
Home Federal Bank Corporation	Middlesboro	Kentucky.
The Farmers National Bank of Cynthiana	Cynthiana	Kentucky.
First Federal Bank	Lexington	Kentucky.
First Federal Savings & Loan Association of Morehead	Morehead	Kentucky.
Commonwealth Bank, FSB	Mt. Sterling	Kentucky.
The Home Savings and Loan Company of Kenton, Ohio	Kenton	Ohio.
Ohio River Bank	Ironton	Ohio.
Greenville Federal Savings and Loan Association	Greenville	Ohio.
First Federal Bank of the Midwest	Defiance	Ohio.

Ohio Heritage Bank	Coshocton	Ohio.
Valley Savings Bank	Cuyahoga Falls	Ohio.
Monroe Federal Savings and Loan Association	Tipp City	Ohio.
Adams County Building and Loan Company	West Union	Ohio.
The National Bank of Oak Harbor	Oak Harbor	Ohio.
Home Savings Bank	Wapakoneta	Ohio.
Peoples Savings and Loan Company	Bucyrus	Ohio.
Columbia Savings Bank	Cincinnati	Ohio.
Home City Federal Savings Bank	Springfield	Ohio.
The Brookville Building and Savings Association	Brookville	Ohio.
The Citizens National Bank of Bluffton	Bluffton	Ohio.
Liberty Federal Savings Bank	Ironton	Ohio.
The Franklin Savings and Loan Company	Cincinnati	Ohio.
New Foundation Loan and Building Company	Cincinnati	Ohio.
Fairfield Federal Savings & Loan Association of Lancaster	Lancaster	Ohio.
Home Savings Bank	Kent	Ohio.
Belmont Savings Bank	Bellaire	Ohio.
North Valley Bank	Zanesville	Ohio.
Leesburg Federal Savings Bank	Leesburg	Ohio.
First Federal Savings & Loan Association of Lakewood	Lakewood	Ohio.
The Park National Bank	Newark	Ohio.
American Savings Bank, FSB	Portsmouth	Ohio.
The Citizens Banking Company	Sandusky	Ohio.
Warsaw Federal Savings & Loan Association of Cincinnati	Cincinnati	Ohio.
The Citizens Bank of Logan	Logan	Ohio.
NCB, FSB	Hillsboro	Ohio.
1st National Bank	Lebanon	Ohio.
Sherwood State Bank	Sherwood	Ohio.
Farmers and Merchants Bank	Dyer	Tennessee.
First Citizens National Bank of Dyersburg	Dyersburg	Tennessee.
Home Federal Bank of Tennessee	Knoxville	Tennessee.
First South Credit Union	Bartlett	Tennessee.
F&M Bank	Clarksville	Tennessee.
The Bank of Jackson	Jackson	Tennessee.
Bank of Bartlett	Bartlett	Tennessee.
Elizabethton Federal Savings Bank	Elizabethton	Tennessee.
TNBANK	Oak Ridge	Tennessee.
Citizens Bank	New Tazewell	Tennessee.

Federal Home Loan Bank of Indianapolis—District 6

First Merchants Bank, NA	Muncie	Indiana.
American Savings, FSB	Munster	Indiana.
Farmers and Mechanics Federal Savings & Loan Association	Bloomfield	Indiana.
Independent Federal Credit Union	Anderson	Indiana.
The First State Bank	Bourbon	Indiana.
Peoples FSB of Dekalb County	Auburn	Indiana.
First Federal Savings Bank	Evansville	Indiana.
First Financial Bank	Terre Haute	Indiana.
Home Bank, SB	Martinsville	Indiana.
La Porte Savings Bank	La Porte	Indiana.
Mid-Southern Savings Bank, FSB	Salem	Indiana.
Mutual, FSB	Muncie	Indiana.
Owen County State Bank	Spencer	Indiana.
Peoples Bank, SB	Munster	Indiana.
Security Federal Savings Bank	Logansport	Indiana.
The First National Bank of Monterey	Monterey	Indiana.
Bank of Wolcott	Wolcott	Indiana.
Indiana Bank and Trust Co.	Columbus	Indiana.
Hastings City Bank	Hastings	Michigan.
Commercial Bank	Alma	Michigan.
Eaton Federal Savings Bank	Charlotte	Michigan.
First Federal of Northern Michigan	Alpena	Michigan.
Tri-County Bank	Brown City	Michigan.
First National Bank of St. Ignace	St. Ignace	Michigan.
Kalamazoo County State Bank	Schoolcraft	Michigan.
Northwestern Bank	Traverse City	Michigan.
Thumb National Bank & Trust	Pigeon	Michigan.

Federal Home Loan Bank of Chicago—District 7

1st State Bank of Mason City	Mason City	Illinois.
BankFinancial, FSB	Burr Ridge	Illinois.
Citizens First National Bank	Princeton	Illinois.
Community Bank—Wheaton/Glen Ellyn	Glen Ellyn	Illinois.
Diamond Bank FSB	Chicago	Illinois.

First National Bank of Illinois	Lansing	Illinois.
First State Bank of Illinois	LaHarpe	Illinois.
Herrin Security Bank	Herrin	Illinois.
Illini State Bank	Oglesby	Illinois.
Mutual Federal Bank	Chicago	Illinois.
National Bank of Petersburg	Petersburg	Illinois.
Oak Bank	Chicago	Illinois.
South End Savings, s.b.	Homewood	Illinois.
The Bradford National Bank	Greenville	Illinois.
West Suburban Bank	Lombard	Illinois.
Central Federal Savings & Loan Association of Chicago	Chicago	Illinois.
Eureka Savings Bank	La Salle	Illinois.
Farmers State Bank of Camp Point	Camp Point	Illinois.
First Federal Savings Bank of Champaign-Urbana	Champaign	Illinois.
First Security Bank	Mackinaw	Illinois.
Glenview State Bank	Glenview	Illinois.
Herget Bank, National Association	Pekin	Illinois.
Hickory Point Bank & Trust, FSB	Decatur	Illinois.
Marine Bank	Springfield	Illinois.
The Granville National Bank	Granville	Illinois.
The Poplar Grove State Bank	Poplar Grove	Illinois.
Washington Federal Bank for Savings	Chicago	Illinois.
Wheaton Bank & Trust Company	Northfield	Illinois.
Citizens State Bank of Shipman	Shipman	Illinois.
First National Bank of Litchfield	Litchfield	Illinois.
The Havana National Bank	Havana	Illinois.
First National Bank	Moline	Illinois.
First Community Bank and Trust	Beecher	Illinois.
AnchorBank, FSB	Madison	Wisconsin.
Baylake Bank	Sturgeon Bay	Wisconsin.
Bremer Bank, National Association	Menomonie	Wisconsin.
Community First Bank	Boscobel	Wisconsin.
Fidelity National Bank	Medford	Wisconsin.
First Citizens State Bank	Whitewater	Wisconsin.
Fox Valley Savings Bank	Fond du Lac	Wisconsin.
Guaranty Bank	Milwaukee	Wisconsin.
Home Savings Bank	Madison	Wisconsin.
International Bank of Amherst	Amherst	Wisconsin.
Ladysmith Federal Savings & Loan Association	Ladysmith	Wisconsin.
Markesan State Bank	Markesan	Wisconsin.
Merrill Federal Savings and Loan Association	Merrill	Wisconsin.
Middleton Community Bank	Middleton	Wisconsin.
PremierBank	Fort Atkinson	Wisconsin.
PyraMax Bank, FSB	Greenfield	Wisconsin.
The Farmers State Bank of Waupaca	Waupaca	Wisconsin.
The Peoples Community Bank	Mazomanie	Wisconsin.
Westbury Bank	West Bend	Wisconsin.

Federal Home Loan Bank of Des Moines—District 8

Atkins Savings Bank & Trust	Atkins	Iowa.
First State Bank	Sumner	Iowa.
Northwestern Bank	Orange City	Iowa.
Farmers & Traders Savings Bank	Bancroft	Iowa.
First State Bank	Hawarden	Iowa.
Community State Bank	Tipton	Iowa.
First Security Bank and Trust Company	Charles City	Iowa.
Page County Federal Savings Association	Clarinda	Iowa.
Security State Bank	Guttenburg	Iowa.
Community Savings Bank	Edgewood	Iowa.
Fidelity Bank & Trust	Dubuque	Iowa.
First National Bank of Ames	Ames	Iowa.
Guaranty Bank & Trust Company	Cedar Rapids	Iowa.
Cherokee State Bank	Cherokee	Iowa.
Solon State Bank	Solon	Iowa.
Citizens Bank	Sac City	Iowa.
Community Bank	Alton	Iowa.
Farmers & Merchants Savings Bank	Iowa City	Iowa.
First Federal Savings Bank of Iowa	Fort Dodge	Iowa.
Keystone Savings Bank	Keystone	Iowa.
Ashton State Bank	Ashton	Iowa.
Independence Federal Bank for Savings	Independence	Iowa.
Randall-Story State Bank	Story City	Iowa.
State Central Bank	Keokuk	Iowa.
Chelsea Savings Bank	Belle Plaine	Iowa.
Citizens State Bank	Wyoming	Iowa.

Community State Bank, NA	Ankeny	Iowa.
First American Bank	Fort Dodge	Iowa.
First Trust and Savings Bank	Coralville	Iowa.
Northwest Bank	Spencer	Iowa.
Webster City Federal Savings Bank	Webster City	Iowa.
First State Bank of Bigfork	Bigfork	Minnesota.
State Bank of Bellingham	Bellingham	Minnesota.
Farmers State Bank of Adams	Adams	Minnesota.
Security State Bank of Wanamingo	Wanamingo	Minnesota.
Viking Savings Bank	Alexandria	Minnesota.
First Independent Bank	Russell	Minnesota.
Minnwest Bank, MV	Redwood Falls	Minnesota.
Queen City Federal Savings Bank	Virginia	Minnesota.
The First National Bank of Deerwood	Deerwood	Minnesota.
Brainerd Savings & Loan Association, A Federal Association	Brainerd	Minnesota.
First National Bank Minnesota	St. Peter	Minnesota.
The First National Bank of Plainview	Plainview	Minnesota.
Highland Bank	Saint Michael	Minnesota.
Lake Elmo Bank	Lake Elmo	Minnesota.
Kanabec State Bank	Mora	Minnesota.
Prairie Sun Bank	Milan	Minnesota.
RiverWood Bank	Baxter	Minnesota.
State Bank of Faribault	Faribault	Minnesota.
Central Federal Savings and Loan Association of Rolla	Rolla	Missouri.
Home Savings & Loan Association of Norborne, FA	Norborne	Missouri.
Ozark Mountain Bank	Branson	Missouri.
Security Bank & Trust Company	Scott City	Missouri.
Guaranty Bank	Springfield	Missouri.
North American Savings Bank, FSB	Grandview	Missouri.
Security Bank of Pulaski County	Waynesville	Missouri.
Southern Bank	Poplar Bluff	Missouri.
Bank of New Madrid	New Madrid	Missouri.
Blue Ridge Bank & Trust Company	Independence	Missouri.
First Federal Bank, FSB	Kansas City	Missouri.
FMB Bank	Wright City	Missouri.
Horizon State Bank	Cameron	Missouri.
Jonesburg State Bank	Jonesburg	Missouri.
Lindell Bank & Trust Company	St. Louis	Missouri.
Ozark Bank	Ozark	Missouri.
F&M Bank and Trust Company	Hannibal	Missouri.
Montgomery Bank, NA	Sikeston	Missouri.
Midwest Federal Savings & Loan Association of St. Joseph	St. Joseph	Missouri.
Bank Forward	Hannaford	North Dakota.
The Ramsey National Bank & Trust Company of Devils Lake	Devils Lake	North Dakota.
Security State Bank	Dunseith	North Dakota.
The Goose River Bank	Mayville	North Dakota.
Alerus Financial, NA	Grand Forks	North Dakota.
The First State Bank of Munich	Munich	North Dakota.
The National Bank of Harvey	Harvey	North Dakota.
Starion Financial	Bismarck	North Dakota.
TCF National Bank	Sioux Falls	South Dakota.
Quoin Financial Bank	Miller	South Dakota.
Bryant State Bank	Bryant	South Dakota.
American State Bank	Oldham	South Dakota.
American State Bank of Pierre	Pierre	South Dakota.

Federal Home Loan Bank of Dallas—District 9

Corning Savings and Loan Association	Corning	Arkansas.
Southern Bancorp Bank of Arkansas	Arkadelphia	Arkansas.
First Bank	Camden	Arkansas.
First National Bank	Paragould	Arkansas.
First National Banking Company	Ash Flat	Arkansas.
One Bank & Trust, NA	Little Rock	Arkansas.
Priority Bank	Ozark	Arkansas.
The Bank of Star City	Star City	Arkansas.
United Bank	Springdale	Arkansas.
Farmers Bank & Trust Company	Magnolia	Arkansas.
Merchants and Farmers Bank	Dumas	Arkansas.
Diamond State Bank	Murfreesboro	Arkansas.
Beauregard Federal Savings Bank	DeRidder	Louisiana.
Citizens Progressive Bank	Columbia	Louisiana.
Fidelity Homestead Association	New Orleans	Louisiana.
Union Savings and Loan Association	New Orleans	Louisiana.
Citizens Bank and Trust Company	Springhill	Louisiana.
Home Bank	Lafayette	Louisiana.

BNA Bank	New Albany	Mississippi.
Bank of Yazoo City	Yazoo City	Mississippi.
First Federal Savings & Loan	Pascagoula	Mississippi.
BankFirst Financial Services	Columbus	Mississippi.
1st National Bank	Artesia	New Mexico.
Century Bank	Santa Fe	New Mexico.
Community First Bank Las Vegas	Las Vegas	New Mexico.
Western Bank of Clovis	Clovis	New Mexico.
American National Bank	Wichita Falls	Texas.
Commerce Bank	Laredo	Texas.
First Federal Bank Texas	Tyler	Texas.
First Security State Bank	Cranfills Gap	Texas.
Houston Community Bank, NA	Houston	Texas.
National Bank	Gatesville	Texas.
Texas Bank and Trust	Longview	Texas.
TrustTexas Bank, SSB	Cuero	Texas.
Alliance Bank	Sulphur Springs	Texas.
Angelina Savings Bank, FSB	Lufkin	Texas.
Colonial Savings, FA	Fort Worth	Texas.
Dalhart Federal Savings and Loan Association	Dalhart	Texas.
Fayette Savings Bank, SSB	La Grange	Texas.
First Bank & Trust Company	Lubbock	Texas.
First Command Bank	Fort Worth	Texas.
First National Bank of Mount Vernon	Mount Vernon	Texas.
Firstbank Southwest	Amarillo	Texas.
Guaranty Bond Bank	Mt. Pleasant	Texas.
Henderson Federal Savings Bank	Henderson	Texas.
Inwood National Bank	Dallas	Texas.
Lubbock National Bank	Lubbock	Texas.
National Bank & Trust	La Grange	Texas.
Pilgrim Bank	Pittsburg	Texas.
PointBank	Pilot Point	Texas.
Southwest Securities Bank	Arlington	Texas.
Texas Bank	Brownwood	Texas.
The First National Bank of Beeville	Beeville	Texas.
The First State Bank	Columbus	Texas.
The Morris County National Bank	Naples	Texas.
Affiliated Bank, FSB	Arlington	Texas.
East Texas Professional Credit Union	Longview	Texas.
Happy State Bank	Happy	Texas.
Prosperity Bank	El Campo	Texas.
The First National Bank of Weatherford	Weatherford	Texas.
First National Bank in Munday	Munday	Texas.
Gulf Coast Educators Federal Credit Union	Pasadena	Texas.

Federal Home Loan Bank of Topeka—District 10

Frontier Bank	Lamar	Colorado.
Pikes Peak National Bank	Colorado Springs	Colorado.
Vectra Bank Colorado	Denver	Colorado.
Colorado East Bank & Trust	Lamar	Colorado.
Gunnison Savings and Loan Association	Gunnison	Colorado.
Peoples National Bank	Colorado Springs	Colorado.
The First National Bank of Ordway	Ordway	Colorado.
Capitol Federal Savings Bank	Topeka	Kansas.
Caldwell State Bank	Caldwell	Kansas.
First Option Bank	Osawatomie	Kansas.
Kendall State Bank	Valley Falls	Kansas.
The Plains State Bank	Plains	Kansas.
First State Bank	Norton	Kansas.
The Bank of Tescott	Salina	Kansas.
First National Bank in Cimarron	Cimarron	Kansas.
Central Bank and Trust Company	Hutchinson	Kansas.
Citizens Savings and Loan Association, FSB	Leavenworth	Kansas.
Guaranty State Bank & Trust Company	Beloit	Kansas.
The Bank of Commerce & Trust Company	Wellington	Kansas.
Farmers Bank & Trust, NA	Great Bend	Kansas.
First National Bank of Syracuse	Syracuse	Kansas.
Mutual Savings Association, FSA	Leavenworth	Kansas.
Silver Lake Bank	Topeka	Kansas.
The University National Bank of Lawrence	Lawrence	Kansas.
Auburn State Bank	Auburn	Nebraska.
American Interstate Bank	Elkhorn	Nebraska.
Arbor Bank	Nebraska City	Nebraska.
Community Bank	Alma	Nebraska.
Nebraska Energy Federal Credit Union	Columbus	Nebraska.

Bruning State Bank	Bruning	Nebraska.
South Central State Bank	Campbell	Nebraska.
Butte State Bank	Butte	Nebraska.
Cedar Security Bank	Fordyce	Nebraska.
Clarkson Bank	Clarkson	Nebraska.
Enterprise Bank, NA	Omaha	Nebraska.
Points West Community Bank	Sidney	Nebraska.
First National Bank & Trust Company	Columbus	Nebraska.
Genoa National Bank	Genoa	Nebraska.
Western Heritage Credit Union	Alliance	Nebraska.
Community National Bank of Okarche	Okarche	Oklahoma.
Legacy Bank	Hinton	Oklahoma.
The Bankers Bank	Oklahoma City	Oklahoma.
First Bank & Trust Company	Clinton	Oklahoma.
First National Bank in Okeene	Okeene	Oklahoma.
American Bank of Oklahoma	Collinsville	Oklahoma.
Chickasha Bank and Trust Company	Chickasha	Oklahoma.
City National Bank & Trust Company	Lawton	Oklahoma.
Community Bank	Bristow	Oklahoma.
Anadarko Bank and Trust Company	Anadarko	Oklahoma.
Citizens Bank of Edmond	Edmond	Oklahoma.
Community Bank of the Arbuckles	Sulphur	Oklahoma.
Lakeside State Bank	Oologah	Oklahoma.
Republic Bank & Trust	Norman	Oklahoma.
High Plains Bank	Keyes	Oklahoma.
Triad Bank, NA	Tulsa	Oklahoma.
First National Bank of Oklahoma	Oklahoma City	Oklahoma.

Federal Home Loan Bank of San Francisco—District 11

Central Arizona Bank	Scottsdale	Arizona.
Gateway Commercial Bank	Mesa	Arizona.
Horizon Community Bank	Lake Havasu City	Arizona.
Metro Phoenix Bank	Phoenix	Arizona.
Mississippi Valley Life Insurance Company	Phoenix	Arizona.
Pacific Life & Annuity Company	Phoenix	Arizona.
Sunrise Bank of Arizona	Phoenix	Arizona.
The Foothills Bank	Yuma	Arizona.
Borrego Springs Bank, N.A.	Borrego Springs	California.
National Bank of California	Los Angeles	California.
Summit State Bank	Rohnert Park	California.
First Federal Savings & Loan Association of San Rafael	San Rafael	California.
North Valley Bank	Redding	California.
Pacific Premier Bank	San Bernardino	California.
Community Bank	Pasadena	California.
Metropolitan Bank	Oakland	California.
East West Bank	San Marino	California.
International City Bank	Long Beach	California.
CapitalSource Bank	Brea	California.
Chinatrust Bank (USA)	Torrance	California.
CoastHills Federal Credit Union	Lompoc	California.
Commerce Bank of Temecula Valley	Murrieta	California.
Evertrust Bank	City of Industry	California.
First Financial Credit Union	West Covina	California.
First Security Business Bank	Orange	California.
Fullerton Community Bank, FSB	Fullerton	California.
Golden State Bank	Upland	California.
Mendo Lake Credit Union	Ukiah	California.
Metro United Bank	San Diego	California.
Mission Oaks National Bank	Temecula	California.
Pacific Mercantile Bank	Costa Mesa	California.
River Valley Community Bank	Yuba City	California.
San Francisco Federal Credit Union	San Francisco	California.
Santa Clara County Federal Credit Union	San Jose	California.
Santa Clara Valley Bank, N.A.	Santa Paula	California.
SchoolsFirst Federal Credit Union	Santa Ana	California.
Sierra Vista Bank	Folsom	California.
SkyOne Federal Credit Union	Hawthorne	California.
Summit Bank	Oakland	California.
The Golden 1 Credit Union	Sacramento	California.
TomatoBank, National Association	Los Angeles	California.
Union Bank, N.A.	San Francisco	California.
First Security Bank of Nevada	Las Vegas	Nevada.
Meadows Bank	Las Vegas	Nevada.

Federal Home Loan Bank of Seattle—District 12		
Mountain West Bank	Coeur D'Alene	Idaho.
Stockman Bank of Montana	Miles City	Montana.
First Security Bank	Bozeman	Montana.
Big Sky Western Bank	Bozeman	Montana.
First Federal Savings & Loan of McMinnville	McMinnville	Oregon.
Albina Community Bank	Portland	Oregon.
Pacific Continental Bank	Eugene	Oregon.
Home Savings Bank	Salt Lake City	Utah.
Valley Bank	Puyallup	Washington.
Raymond Federal Bank	Raymond	Washington.
First Savings Bank Northwest	Renton	Washington.
Timberland Bank	Hoquiam	Washington.

II. Public Comments

To encourage the submission of public comments on the community support performance of Bank members, on or before July 1, 2011, each Bank will notify its Advisory Council and nonprofit housing developers, community groups, and other interested parties in its district of the members selected for community support review in the 2010 third round review cycle. 12 CFR 1290.2(b)(2)(ii). In reviewing a member for community support compliance, FHFA will consider any public comments it has received concerning the member. 12 CFR 1290.2(d). To ensure consideration by FHFA, comments concerning the community support performance of members selected for the 2010 third round review cycle must be delivered to FHFA, either by hard-copy mail at the Federal Housing Finance Agency, Housing Mission and Goals, 1625 Eye Street, NW., Washington, DC 20006, or by electronic mail to *hmgcommunitysupportprogram@fhfa.gov* on or before the August 1, 2011 deadline for submission of Community Support Statements.

Dated: June 13, 2011.

Edward J. DeMarco,

Acting Director, Federal Housing Finance Agency.

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BILLING CODE 8070–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS–0990–0330]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary. HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed information collection request for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov,* or call the Reports Clearance Office on (202) 690–6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above email address within 60 days.

Proposed Project—Annual Appellant Climate Survey—0990–0330—Revision—Office of Medicare Hearings and Appeals (OMHA).

Abstract: The OMHA Appellant Climate Survey is a survey of Medicare beneficiaries, providers, and suppliers who had a hearing before an Administrative Law Judge (ALJ) at the Office of Medicare Hearings and Appeals (OMHA). Appellants dissatisfied with the outcome of their Level 2 appeal may request a hearing before an OMHA ALJ. The Appellant Climate Survey will be used to measure appellant satisfaction with their OMHA appeals experience, as opposed to their satisfaction with a specific ruling.

OMHA was established by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 (Pub. L. 108–173) and became operational on July 1, 2005. The MMA legislation and implementing regulations issued on March 8, 2007 instituted a number of changes in the appeals process. The MMA legislation also directed the U.S. Department of Health and Human Services to consider the feasibility of conducting hearings using telephone or video-teleconference technologies. In carrying out this mandate, OMHA makes extensive use of video-teleconferencing to provide appellants with a vast nationwide network of access points for hearings close to their homes. The survey will gauge appellants' satisfaction with this new service along with the overall appeals experience. The first three-year administration cycle of the OMHA survey began in FY08. The survey will continue to be conducted annually over a three-year period, beginning in FY12. Results from the surveys will be used to gauge progress made in increasing satisfaction among appellants.

ESTIMATED ANNUALIZED BURDEN TABLE

Forms	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response (in hours)	Total burden hours
OMHA Appellant Climate Survey	Appellants	400	1	11/60	73

Mary Forbes,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2011–15078 Filed 6–16–11; 8:45 am]

BILLING CODE 4150–46–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS–0990–New]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed information collection request for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov*, or call the Reports Clearance Office on (202) 690–6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above e-mail address within 60-days.

Proposed Project

Multisite Evaluation of the In Community Spirit Program—Prevention of HIV/AIDS for Native/American Indian and Alaska Native Women Living in Rural and Frontier Indian Country—OMB No. 0990–New—Office on Women's Health (OWH)

Abstract: The Office on Women's Health (OWH), within the Office of the Assistant Secretary for Health, will conduct the Multisite Evaluation of the *In Community Spirit* Program—Prevention of HIV/AIDS for Native/American Indian and Alaska Native (AI/AN) Women Living in Rural and Frontier Indian Country (*In Community Spirit* Program). The *In Community Spirit* Program is an initiative comprising three types of program components being implemented with women in AI/AN communities for HIV prevention: (1) Community awareness, (2) capacity building, and (3) prevention education. The multisite evaluation will provide data on the content and context of programs and the outcomes of program activities on participant knowledge and behavior related to sexual health.

The multisite evaluation is comprised of two main activities across three program components: (1) Surveys and (2) key informant interviews. There are two versions of key informant interviews: Baseline and follow-up. There are also two versions of the survey: (1) Community Awareness Version for administration with women targeted through the community awareness activities and (2) Prevention Education Version to be administered to women who receive prevention education through the program.

The average annual respondent burden is estimated below. The estimate reflects the average annual number of respondents, the average annual number of responses, the time it will take for each response, and the average annual burden across 3 years of OMB clearance, which includes 2 years of data collection.

ESTIMATED ANNUALIZED BURDEN TABLE

Form	Type of respondent	Number of respondents	Number of responses per respondent per year	Average burden per response (hrs)	Total burden hours**
Key Informant Interviews BL and Follow-up.	Agency Provider (Administrator)	6	1	45/60	5
Key Informant Interviews BL and Follow-up.	Agency Staff (Health Educators and Support Workers).	24	1	45/60	18
HEAL Survey—Community Awareness.	Community Member	900	0.5	15/60	113
HEAL Survey—Prevention Education	Community Member	1200	1.5	15/60	450
Total		2130			586

Mary Forbes,

Paperwork Reduction Act Clearance Officer, Office of the Secretary.

[FR Doc. 2011–15079 Filed 6–16–11; 8:45 am]

BILLING CODE 4150–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS–0990–New; 60-Day Notice]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed information collection request for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov,* or call the Reports Clearance Office on (202) 690–6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above e-mail address within 60-days.

Proposed Project: HIV/AIDS Prevention and Support Service for Women Partners of Incarcerated/Recently Released Men—OMB No. 0990–New-Office of Women's Health

Abstract: The mission of the Office on Women's Health (OWH) is to provide leadership to promote health equity for women and girls through sex/gender-specific approaches. To that end, OWH has established public/private partnerships to address critical women's health issues nationwide including cooperative agreements awarded to eight community-based organizations in 2009 to design and implement innovative and gender responsive HIV prevention programs to meet the unique risks and needs of women within their communities who have currently incarcerated or recently released male partners (''women partners''). The information presented in this evaluation study is needed to determine the overarching outcomes of the set of the eight programs. The three-year study will include quantitative data collected at three time points, intervention baseline, post-intervention, and 30 day follow-up. The study will also include qualitative data collected through focus groups facilitated with program participants at each of the eight program sites, as well as interviews with one to two key intervention staff at each of the program sites.

ESTIMATED ANNUALIZED BURDEN TABLE

Forms	Type of respondent	Number of respondents	Number of responses per respondent	Average burden (in hours) per response	Total burden hours
Baseline Survey	Program Participant	320	1	15/60	80
Post Intervention Survey	Program Participant	288	1	15/60	72
30 day Follow-up Survey	Program Participant	256	1	15/60	64
Focus Group	Program Participant	64	1	1.0	64
Staff Interview	Intervention Staff	8	1	1.0	8
Total					288

Mary Forbes,

Paperwork Reduction Act Clearance Officer Office of the Secretary.

[FR Doc. 2011–15077 Filed 6–16–11; 8:45 am]

BILLING CODE 4150–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–1856 and CMS–1893]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* (CMS–1856) Request for Certification in the Medicare and/or Medicaid Program to Provide Outpatient Physical Therapy and/or Speech Pathology Services, and (CMS–1893) Outpatient Physical Therapy—Speech Pathology Survey Report; *Use:* CMS–1856 is used as an application to be completed by providers of outpatient physical therapy and/or speech-language pathology services requesting participation in the Medicare and Medicaid programs. This form initiates the process for obtaining a decision as to whether the conditions of participation are met as a provider of outpatient physical therapy and/or

speech-language pathology services. It is used by the State agencies to enter new provider into the Automated Survey Process Environment (ASPEN). CMS–1893 is used by the State survey agency to record data collected during an on-site survey of a provider of outpatient physical therapy and/or speech-language pathology services, to determine compliance with the applicable conditions of participation, and to report this information to the Federal government. The form is primarily a coding worksheet designed to facilitate data reduction and retrieval into the ASPEN system. The information needed to make certification decisions is available to CMS only through the use of information abstracted from the form; *Form Numbers:* CMS–1856 and CMS–1893 (OMB#: 0938–0065); *Frequency:* Annually, occasionally; *Affected Public:* Private Sector; Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 2,968; *Total Annual Responses*: 495; *Total Annual Hours:* 866. (For policy questions regarding this collection contact Georgia Johnson at 410–786–6859. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *July 18, 2011:* OMB, Office of Information and Regulatory Affairs, *Attention:* CMS Desk Officer, *Fax Number:* (202) 395–6974, *E-mail: OIRA_submission@omb.eop.gov.*

Dated: June 14, 2011.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2011–15057 Filed 6–16–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–10334 and CMS–10373]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Application for Coverage in the Pre-Existing Condition Insurance Plan; *Use:* The Department of Health and Human Services (HHS) Centers for Medicare & Medicaid Services, Center for Consumer Information and Insurance Oversight is requesting clearance by the Office of Management and Budget for modifications to this previously approved collection package. These changes are being requested to (1) provide a mechanism for a PCIP enrollee who has moved from a state-administered PCIP to quickly and efficiently enroll into the federally-administered PCIP (2) provide a mechanism for a PCIP applicant to identify a third party entity will pay their premium to ensure appropriate premium billing (3) provide a mechanism whereby a licensed insurance agent or broker may identify their referral of an applicant (4) request employer information to expand ways to identify and prevent instances of insurer dumping and (5) make clarifications to existing application language. *Form Number:* CMS–10334 (OCN: 0938–1095) *Frequency:* Once; *Affected Public:* Individuals or households; *Number of Respondents:* 83,333; *Number of Responses:* 83,333; *Total Annual Hours:* 179,499. (For policy questions regarding this collection, contact Laura Dash at 410–786–8623. For all other issues call (410) 786–1326.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medical Loss Ratio Quarterly Reporting; *Use:* Under Section 2718 of the Affordable Care Act and implementing regulations at 45 CFR Part 158 (75 FR 74865, December 1, 2010) as modified by technical corrections on December 30, 2010 (75 FR 82277), a health insurance issuer (issuer) offering group or individual health insurance coverage must submit a report to the Secretary concerning the amount the issuer spends each year on claims, quality improvement expenses, non-claims costs, Federal and State taxes and licensing or regulatory fees, and the amount of earned premium. An issuer must provide an annual rebate to enrollees if the amount it spends on certain costs compared to its premium revenue (excluding Federal and States taxes and licensing or regulatory fees) does not meet a certain ratio, referred to as the medical loss ratio (MLR). An interim final rule (IFR) implementing the MLR was published on December 1, 2010 (75 FR 74865) and modified by technical corrections on December 30, 2010 (75 FR 82277), which added Part 158 to Title 45 of the Code of Federal Regulations. The IFR is effective January 1, 2011. Issuers are required to submit annual MLR reporting data for each large group market, small group market, and individual market within each State in which the issuer conducts business. For policies that have a total annual limit of $250,000 or less (sometimes referred to as ''mini-med plans'') and for group policies that primarily cover employees working outside the United States (referred to as ''expatriate plans''), the IFR applies a special circumstance adjustment to the MLR data for the 2011 MLR reporting year. In order to evaluate the appropriateness of this special circumstance adjustment for years 2012 and beyond, issuers that provide such policies are required to submit quarterly MLR data to the Secretary for the 2011 MLR reporting year. We received several comments in response to the emergency 30-day comment period that was associated with CMS–10373. We have taken into consideration all of the revisions that were proposed and have amended the quarterly reporting form to include issuer contact information and

technical amendments to better align the proposed quarterly reporting form to the reporting forms that issuers submit to the National Association of Insurance Commissioners (NAIC). We have also amended the form to create two separate, but practically identical, forms with corresponding instructions, so as to allow issuers to nationally aggregate the experience of expatriate plans and to allow issuers to separately report the experience of mini-med plans and expatriate plans. We have also supplied the instructions in a separate document rather than at the bottom of each reporting form. *Form Number:* CMS–10373 (OCN: 0938–1132); *Frequency:* Quarterly; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 75; *Number of Responses:* 825; *Total Annual Hours:* 51,480. (For policy questions regarding this collection, contact Carol Jimenez at (301) 492–4109. For all other issues, call (410) 786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site at *http://www.cms.gov/PaperworkReductionActof1995/PRAL/list.asp#TopOfPage* or email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office at 410–786–1326.

In commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *August 16, 2011:*

1. Electronically. You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. By regular mail. You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, *Attention:* Document Identifier/OMB Control Number, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: June 14, 2011.

Martique Jones,

Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2011–15072 Filed 6–16–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–1856 and CMS–1893, CMS–10381 and CMS–10342]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* (CMS–1856) Request for Certification in the Medicare and/or Medicaid Program to Provide Outpatient Physical Therapy and/or Speech Pathology Services, and (CMS–1893) Outpatient Physical Therapy—Speech Pathology Survey Report; *Use:* CMS–1856 is used as an application to be completed by providers of outpatient physical therapy and/or speech-language pathology services requesting participation in the Medicare and Medicaid programs. This form initiates the process for obtaining a decision as to whether the conditions of participation are met as a provider of outpatient physical therapy and/or speech-language pathology services. It is used by the State agencies to enter new provider into the Automated Survey Process Environment (ASPEN). CMS–1893 is used by the State survey agency to record data collected during an on-site survey of a provider of outpatient physical therapy and/or speech-language pathology services, to determine compliance with the applicable conditions of participation, and to report this information to the Federal government. The form is primarily a coding worksheet designed to facilitate data reduction and retrieval into the ASPEN system. The information needed to make certification decisions is available to CMS only through the use of information abstracted from the form; *Form Numbers:* CMS–1856 and CMS–1893 (OMB#: 0938–0065); *Frequency:* Annually, occasionally; *Affected Public:* Private Sector; Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 2,968; *Total Annual Responses*: 495; *Total Annual Hours:* 866. (For policy questions regarding this collection contact Georgia Johnson at 410–786–6859. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Version 5010/ICD–10 Industry Readiness Assessment, *Use:* The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires the Secretary of HHS to adopt transaction standards that covered entities are required to use when electronically conducting certain health care administrative transactions, such as claims, remittance, eligibility and claims status requests and responses. Accordingly, on January 16, 2009, HHS published final rules adopting by regulation two sets of standards for HIPAA transactions: Version 5010 standards for eight types of electronic health care transactions (claims, eligibility inquiries, remittance advices, etc.) and ICD–10 code set standards. The final rules set compliance dates of January 1, 2012 for Version 5010 standards and October 1, 2013 for ICD–10 standards. HIPAA transactions not meeting the standards by those dates will be rejected. The final rules also outlined interim milestones that organizations should meet in order to achieve compliance by the required dates. For Version 5010, these interim milestones include completing internal testing and being able to send and receive compliant transactions by December 2010, commencing external testing with trading partners by January 2011, and completing that testing and moving into production by the compliance date of January 1, 2012.

Entities cannot implement ICD–10 standards until they are in compliance with Version 5010; the interim milestone for ICD–10 is to begin compliance activities (gap analysis, design, development, internal testing) by January 2011.

CMS has developed an education and communication campaign to support the adoption of and transition to Version 5010 and ICD–10. The education and communication activities will be targeted towards the millions of professionals across the health care industry who must take steps to prepare for the implementation of the new codes and transaction standards. CMS is requesting Office of Management and Budget (OMB) approval to conduct survey research to monitor the health care industry's awareness of, and preparation for, the transition to Version 5010 and ICD–10. The aggregated data obtained through the survey will help inform CMS outreach and education efforts to help affected entities (health care providers, health plans, clearinghouses, and then vendors who service them) meet interim milestones and achieve timely compliance so that they can continue to process HIPAA transactions without interruption.

CMS has contracted to conduct a tracking survey of populations charged with implementing Version 5010 and ICD–10 electronic transaction processing, specifically payers (health insurance plans and managed care organizations), providers (hospitals and primary care providers), and vendors (software providers, third-party billers and clearinghouses). A self-administered web-based survey will be the data collection. The data collection field period is expected to be four weeks in Summer 2011. *Form Number:* CMS–10381 (OMB#: 0938–NEW); *Frequency:* Once; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 600; *Total Annual Responses:* 600; *Total Annual Hours:* 150. (For policy questions regarding this collection contact Rosali Topper at 410–786–7260. For all other issues call 410–786–1326.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Annual Limits Waiver Online Application Form; *Use:* Under section 2711(a)(2) of the Public Health Service Act, as amended by the Affordable Care Act section 1302(b), The Secretary of Health and Human Services is required to impose restrictions on the dollar value of essential benefits provided by new or existing group health plans or individual policies in the market between September 23, 2010 and January 1, 2014. The interim final regulations published June 28, 2010 (45 CFR 147.126) give the Secretary the authority to waive these restricted annual limits if compliance would result in a significant increase in premium or significant decrease in access to benefits for those already covered. CMS is in the process of evaluating applications for waivers of annual limits and seeks to publish an updated Microsoft Excel spreadsheet to standardize and simplify the data collection process. Applicants must fill out (1) spreadsheet per application. The spreadsheet is a mandatory component of each waiver application necessary to fulfill the statutory requirements under section 2711(a)(2) of the Public Health Service Act. The information collected includes applicant contact information; information about the annual limit(s) on the overall plan or policy and on essential health benefits (as defined by the Affordable Care Act section 1302(b)); information about plan design such as copayment, coinsurance, and deductibles; financial projections by enrollee tier; and a description of how a significant decrease in access to benefits would result from compliance with section 2711(a)(2) of the Affordable Care Act. This information is required to accurately and objectively assess whether compliance with the restricted annual limits would result in the aforementioned significant increase in premium or significant decrease in access to benefits, on which the grant of a waiver is conditioned in the interim final regulations. The updated spreadsheet contains a more detailed description of what values should be entered into each cell. This description should save applicants time when completing the spreadsheet initially, and it should lessen the need for applicants to go back and correct mistakes after submission. *Form Number:* CMS–10342 (OCN: 0938–1105); *Frequency:* Annually; *Affected Public:* Private Sector; *Number of Respondents:* 4,872; *Number of Responses:* 4,608,372; *Total Annual Hours:* 178,183. (For policy questions regarding this collection, contact Erika Kottenmeier at (301) 492–4170. For all other issues call (410) 786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on July 18, 2011.

OMB, Office of Information and Regulatory Affairs, *Attention:* CMS Desk Officer, *Fax Number:* (202) 395–6974, *E-mail: OIRA_submission@omb.eop.gov.*

Dated: June 14, 2011.

Martique Jones,

Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2011–15071 Filed 6–16–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Child and Family Services Plan (CFSP), Annual Progress and Servicers Review (ASPR), and Annual Budget Expenses Request and Estimated Expenditures (CFS–101).

OMB No.: 0980–0047.

Description

Under title IV–B, subparts 1 and 2, of the Social Security Act (the Act), States, Territories, and Tribes are required to submit a Child and Family Services Plan (CFSP). The CFSP lays the groundwork for a system of coordinated, integrated, and culturally relevant family services for the subsequent five years (45 CFR 1357.15(a)(1)). The CFSP outlines initiatives and activities the State, Tribe or territory will carry out in administering programs and services to promote the safety, permanency, and well-being of children and families. By June 30 of each year, States, Territories, and Tribes are also required to submit an Annual Progress and Services Report (APSR) and a financial report called the CFS–101. The APSR is a Yearly report that discusses progress made by a State, Territory or Tribe in accomplishing the goals and objectives cited in its CFSP (45 CFR 1357.16(a)). The APSR contains new and updated information about service needs and organizational capacities throughout the five-year plan period. The CFS–101 has three parts. Part I is an annual budget request for the upcoming fiscal year. Part II includes a summary of planned expenditures by

program area for the upcoming fiscal year, the estimated number of individuals or families to be served, and the geographical service area. Part III includes actual expenditures by program area, numbers of families and individuals served by program area, and the geographic areas served for the last complete fiscal year.

The Child and Family Services Improvement Act of 2006 amended Title IV–B, subparts 1 and 2, adding a number of requirements that affect reporting through the APSR and the CFS–101. Of particular note, the law added a provision requiring States (including Puerto Rico and the District of Columbia) to report data on caseworker visits (section 424(e) of the Act). States must provide annual data on (1) the percentage of children in foster care under the responsibility of the State who were visited on a monthly basis by the caseworker handling the case of the child; and (2) the percentage of the visits that occurred in the residence of the child. In addition, by June 30, 2008, States must set target percentages and establish strategies to meet the goal that; by October 1, 2011; at least 90 percent of the children in foster care are visited by their caseworkers on a monthly basis and that the majority of these visits occur in the residence of the child (section 424(e)(2)(A) of the Act).

Respondents

States, Territories, and Tribes must complete the CFSP, APSR, and CFS–101. Tribes and territories are exempted from the monthly caseworker visits reporting requirement of the APSR. There are approximately 180 Tribal entities that are eligible for IV–B funding. There are 52 States (including Puerto Rico and the District of Columbia) that must complete the CFSP, APSR, and CFS–101. There are a total of 232 possible respondents.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ASPR	232	1	76.58	17,766.56
CFSP	232	1	120.25	27,898
CFS–101, Parts I, II, and III	232	1	4.38	1,016.16
Caseworker Visits	52	1	99.33	5,165.16

Estimated Total Annual Burden Hours: 51,845.88.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. *E-mail address: infocollection@acf.hhs.gov.*

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202–395–7285, *E-mail: oira_submission@omb.eop.gov, Attn:* Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–15076 Filed 6–16–11; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0583]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Radioactive Drug Research Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Radioactive Drug Research Committees'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 3, 2011 (76 FR 11786), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0053. The approval expires on May 31, 2014. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: June 13, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–15045 Filed 6–16–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0084]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget

(OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 18, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, *Fax:* 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0562. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Consideration—(OMB Control Number 0910–0562)—Extension

The Food Quality Protection Act of 1996, which amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (the FD&C Act), established a new safety standard for pesticide residues in food, with an emphasis on protecting the health of infants and children. The Environmental Protection Agency (EPA) is responsible for regulating the use of pesticides (under FIFRA) and for establishing tolerances or exemptions from the requirement for tolerances for residues of pesticide chemicals in food commodities (under the FD&C Act). EPA may, for various reasons, *e.g.,* as part of a systematic review or in response to new information concerning the safety of a specific pesticide, reassess whether a tolerance for a pesticide residue continues to meet the safety standard in section 408 of the FD&C Act (21 U.S.C. 346a). When EPA determines that a pesticide's tolerance level does not meet that safety standard, the registration for the pesticide may be canceled under FIFRA for all or certain uses. In addition, the tolerances for that pesticide may be lowered or revoked for the corresponding food commodities. Under section 408(l)(2) of the FD&C Act, when the registration for a pesticide is canceled or modified due to, in whole or in part, dietary risks to humans posed by residues of that pesticide chemical on food, the effective date for the revocation of such tolerance (or exemption in some cases) must be no later than 180 days after the date such cancellation becomes effective or 180 days after the date on which the use of the canceled pesticide becomes unlawful under the terms of the cancellation, whichever is later.

When EPA takes such actions, food derived from a commodity that was lawfully treated with the pesticide may not have cleared the channels of trade by the time the revocation or new tolerance level takes effect. The food could be found by FDA, the Agency that is responsible for monitoring pesticide residue levels and enforcing the pesticide tolerances in most foods (the U.S. Department of Agriculture has responsibility for monitoring residue levels and enforcing pesticide tolerances in egg products and most meat and poultry products), to contain a residue of that pesticide that does not comply with the revoked or lowered tolerance. FDA would normally deem such food to be in violation of the law by virtue of it bearing an illegal pesticide residue. The food would be subject to FDA enforcement action as an ''adulterated'' food. However, the channels of trade provision of the FD&C Act addresses the circumstances under which a food is not unsafe solely due to the presence of a residue from a pesticide chemical for which the tolerance has been revoked, suspended, or modified by EPA. The channels of trade provision (section 408(l)(5) of the FD&C Act) states that food containing a residue of such a pesticide shall not be deemed ''adulterated'' by virtue of the residue, if the residue is within the former tolerance, and the responsible party can demonstrate to FDA's satisfaction that the residue is present as the result of an application of the pesticide at a time and in a manner that were lawful under FIFRA.

In the **Federal Register** of May 18, 2005 (70 FR 28544), FDA announced the availability of a guidance document entitled ''Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Considerations.'' The guidance represents the Agency's current thinking on its planned enforcement approach to the channels of trade provision of the FD&C Act and how that provision relates to FDA-regulated products with residues of pesticide chemicals for which tolerances have been revoked, suspended, or modified by EPA under dietary risk considerations. The guidance can be found at *http://www.cfsan.fda.gov/guidance.html.* FDA anticipates that food bearing lawfully applied residues of pesticide chemicals that are the subject of future EPA action to revoke, suspend, or modify their tolerances, will remain in the channels of trade after the applicable tolerance is revoked, suspended, or modified. If FDA encounters food bearing a residue of a pesticide chemical for which the tolerance has been revoked, suspended, or modified, it intends to address the situation in accordance with provisions of the guidance. In general, FDA anticipates that the party responsible for food found to contain pesticide chemical residues (within the former tolerance) after the tolerance for the pesticide chemical has been revoked, suspended, or modified will be able to demonstrate that such food was handled, *e.g.,* packed or processed, during the acceptable timeframes cited in the guidance by providing appropriate documentation to the Agency as discussed in the guidance document. FDA is not suggesting that firms maintain an inflexible set of documents where anything less or different would likely be considered unacceptable. Rather, the Agency is leaving it to each firm's discretion to maintain appropriate documentation to demonstrate that the food was so handled during the acceptable timeframes.

Examples of documentation that FDA anticipates will serve this purpose consist of documentation associated with packing codes, batch records, and inventory records. These are types of documents that many food processors routinely generate as part of their basic food-production operations.

FDA is requesting the extension of OMB approval for the information collection provisions in the guidance.

Description of Respondents: The likely respondents to this collection of information are firms in the produce and food-processing industries that handle food products that may contain residues of pesticide chemicals after the tolerances for the pesticide chemicals have been revoked, suspended, or modified.

In the **Federal Register** of March 9, 2011 (76 FR 12967), FDA published a 60-day notice requesting public comment on the proposed collection of

information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Documentation Submission	1	1	1	3	3

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA expects the total number of pesticide tolerances that are revoked, suspended, or modified by EPA under dietary risk considerations in the next 3 years to remain at a low level, as there have been no changes to the safety standard for pesticide residues in food since 1996. Thus, FDA expects the number of submissions it will receive under the guidance document will also remain at a low level. However, to avoid counting this burden as zero, FDA has estimated the burden at one respondent making one submission a year for a total of one annual submission.

FDA based its estimate of the hours per response on the assumption that the information requested in the guidance is readily available to the submitter. We expect that the submitter will need to gather information from appropriate persons in the submitter's company and to prepare this information for submission to FDA. The submitter will almost always merely need to copy existing documentation. We believe that this effort should take no longer than 3 hours per submission.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
Maintenance of Documentation	1	1	1	16	16

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In determining the estimated annual recordkeeping burden, FDA estimated that at least 90 percent of firms maintain documentation, such as packing codes, batch records, and inventory records, as part of their basic food production or import operations. Therefore, the recordkeeping burden was calculated as the time required for the 10 percent of firms that may not be currently maintaining this documentation to develop and maintain documentation, such as batch records and inventory records. In previous information collection requests, this recordkeeping burden was estimated to be 16 hours per record. FDA has retained its prior estimate of 16 hours per record for the recordkeeping burden. As shown in table 1, FDA estimates that one respondent will make one submission per year. Although FDA estimates that only 1 out of 10 firms will not be currently maintaining the necessary documentation, to avoid counting the recordkeeping burden for the 1 submission per year as 1/10 of a recordkeeper, FDA estimates that 1 recordkeeper will take 16 hours to develop and maintain documentation recommended by the guidance.

Dated: June 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–15044 Filed 6–16–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0432]

Draft Guidance for Industry on Clinical Trial Endpoints for the Approval of Non-Small Cell Lung Cancer Drugs and Biologics; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Clinical Trial Endpoints for the Approval of Non-Small Cell Lung Cancer Drugs and Biologics.'' This draft guidance provides recommendations to applicants on endpoints for lung cancer clinical trials submitted to FDA to support effectiveness claims in new drug applications, biologics license applications, or supplemental applications. This draft guidance should speed the development and improve the quality of protocols submitted to the Agency to support anticancer effectiveness claims.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 16, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written

comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:
Rajeshwari Sridhara, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 3512, Silver Spring, MD 20903–0002, 301–796–2070;
or
Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Clinical Trial Endpoints for the Approval of Non-Small Cell Lung Cancer Drugs and Biologics.'' FDA is developing guidance on oncology endpoints through a process that includes public workshops of oncology experts and discussions before FDA's Oncologic Drugs Advisory Committee (ODAC). This draft guidance considers the discussions regarding lung cancer endpoints from the April 15, 2003, workshop and the December 16, 2003, ODAC meeting. Applicants are encouraged to use this guidance to design clinical trials for the treatment of lung cancer and to discuss protocols with the Agency. This draft guidance is a companion to the guidance for industry entitled ''Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics;'' [1] it is the first in a series of oncology indication-specific guidances, and focuses on endpoints for lung cancer to support drug approval or labeling claims. The endpoints discussed in this draft guidance are for drugs to treat patients with lung cancer. This guidance does not address endpoints for drugs to prevent or decrease the incidence of lung cancer.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on clinical trial endpoints for the approval of non-small cell lung cancer drugs and biologics. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

[1] ''See the FDA Drugs guidance Web page at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.''*

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312, 314, and 601 have been approved under OMB control numbers 0910–0014, 0910–0001, and 0910–0338, respectively.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov.*

Dated: June 8, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–15089 Filed 6–16–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 14, 2011, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Caleb Briggs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, e-mail: *ODAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On July 14, 2011, during the morning session, the committee will discuss biologics license application (BLA) 125388, with the proposed trade name ADCETRIS (brentuximab vedotin) for injection, submitted by Seattle Genetics, Inc. The proposed indication (use) for this product is for the treatment of relapsed or refractory (resistant to previous standard treatments) Hodgkin's lymphoma.

During the afternoon session, the committee will discuss BLA 125399, with the proposed trade name ADCETRIS (brentuximab vedotin) for injection, submitted by Seattle Genetics, Inc. The proposed indication (use) for this product is for the treatment of relapsed or refractory systemic anaplastic large cell lymphoma.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background

material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before July 6, 2011. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m. and 3:30 p.m. to 4 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 29, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 30, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Caleb Briggs at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 9, 2011.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011–15019 Filed 6–16–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Healthy Communities Study: How Communities Shape Children's Health (HCS)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Healthy Communities Study: How Communities Shape Children's Health (HCS). *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The HCS will address the need for a cross-cutting national study of community programs and policies and their relationship to childhood obesity. The HCS is an observational study of communities conducted over five years that aims to (1) Determine the associations between community programs/policies and Body Mass Index (BMI), diet, and physical activity in children; and (2) identify the community, family, and child factors that modify or mediate the associations between community programs/policies and BMI, diet, and physical activity in children. A total of 279 communities and over 23,000 children and their parents will be part of the HCS over the five-year study. A HCS community is defined as a high school catchment area and the age range of children is 3–15 years upon entry into the study. The study examines quantitative and qualitative information obtained from community-based initiatives; community characteristics (*e.g.,* school environment); measurements of children's physical activity levels and dietary practices; and children's and parents' BMIs. Results from the Healthy Communities Study may influence the future development and funding of policies and programs to reduce childhood obesity. Furthermore, HCS results will be published in scientific journals and will be used for the development of future research initiatives targeting childhood obesity. *Frequency of Response:* Varies by participant type from once to 2.74 times. *Affected Public:* Families or households; businesses, other for-profit, and non-profit. *Type of Respondents:* Parents, children, community key informants (who have knowledge about community programs/policies related to healthy nutrition, physical activity, and healthy weight of children), food service personnel, physical education instructors, state health department employees, and physicians or medical secretaries. The annual reporting burden is as follows: *Estimated number of respondents:* 247,619; *Estimated Number of Responses per Respondent:* 1.1; *Average (Annual) Burden Hours per Response:* 0.12; and *Estimated Total Burden Hours Requested:* 32,958. The annualized cost to respondents is estimated at $213,764.58. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Type of respondents	Estimated number of respondents *	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested *
Parents (screening)	169,650	1	0.17	9,614
Parents/Caregivers	20,358	1.46	1.14	11,295
Second Parents	10,179	1	0.12	407
Parents who refuse to participate	2,410	1	0.17	137
Children	20,358	1.46	0.78	7,728
Key Informants (screening)	4,820	1	0.08	129
Key Informants	3,615	2.74	0.85	2,806
Food Service Personnel	964	1	0.42	135
Physical Education Instructors	964	1	0.25	80

Type of respondents	Estimated number of respondents *	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested *
State Health Department employees	50	1	0.30	5
Physicians/medical secretaries	14,251	1	0.17	808
Total	247,619			33,144

* Estimated for first three years of the five-year study.

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments contact: Dr. Sonia Arteaga, NIH, NHLBI, 6701 Rockledge Drive, MSC 7936, Bethesda, MD 20892–7936, or call non-toll free number (301) 435–0377 or E-mail your request, including your address to: *hcs@nhlbi.nih.gov.*

DATES: *Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: June 7, 2011.

Suzanne Freeman,

NHLBI Project Clearance Liaison, National Institutes of Health.

Michael S. Lauer,

Director, DCVS, National Institutes of Health.

[FR Doc. 2011–15021 Filed 6–16–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Ancillary Study.

Date: July 11, 2011.

Time: 2:30 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications,

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Maria E. Davila-bloom, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 758, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7637, *davila-bloomm@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: June 13, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–15097 Filed 6–16–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Bioanalytical and Imaging Technologies.

Date: July 11, 2011.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Ross D Shonat, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6172, MSC 7892, Bethesda, MD 20892, 301–435–2786. *ross.shonat@nih.hhs.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR10–225: Program Project: Biophysics Collaborative Access Team.

Date: July 12–14, 2011.

Time: 6 p.m. to 11 a.m.

Agenda: To review and evaluate grant applications.

Place: Argonne National Laboratory, 9700 S. Cass Avenue, Argonne, IL 60439.

Contact Person: James W. Mack, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4154, MSC 7806, Bethesda, MD 20892, (301) 435–2037, *mackj2@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Language and Communication.

Date: July 14, 2011.
Time: 9 a.m. to 7 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Biao Tian, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3089B, MSC 7848, Bethesda, MD 20892, (301) 402–4411, *tianbi@csr.nih.gov.*
Name of Committee: Center for Scientific Review Special Emphasis Panel, Small Business: Devices and Detection Systems.
Date: July 18–19, 2011.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.
Contact Person: Ross D Shonat, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6172, MSC 7892, Bethesda, MD 20892, 301–435–2786, *ross.shonat@nih.hhs.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 13, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–15095 Filed 6–16–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR10–074: Program Project: Structural Studies of the Nucleotide, Excision Repair Machinery.
Date: July 19–20, 2011.
Time: 7 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Kathryn M Koeller, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4166, MSC 7806, Bethesda, MD 20892, 301–435–2681,*koellerk@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR11–081: NMR Shared Instrumentation.
Date: July 19–20, 2011.
Time: 11 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: William A. Greenberg, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4168, MSC 7806, Bethesda, MD 20892, (301) 435–1726, *greenbergwa@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR09–129: MLPCN High Throughput Screening Assays for Drug Discovery.
Date: July 20–21, 2011.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.
Contact Person: Ping Fan, MD, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5154, MSC 7840, Bethesda, MD 20892, 301–408–9971, *fanp@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Fellowships: Immunology.
Date: July 21–22, 2011.
Time: 8 a.m. to 2 p.m.
Agenda: To review and evaluate grant applications.
Place: Avenue Hotel Chicago, 160 E. Huron Street, Chicago, IL 60611.
Contact Person: Calbert A Laing, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4210, MSC 7812, Bethesda, MD 20892, 301–435–1221, *laingc@csr.nih.gov.*

Name of Committee: AIDS and Related Research Integrated Review Group, AIDS-associated Opportunistic Infections and Cancer Study Section.
Date: July 21, 2011.
Time: 8 a.m. to 6 p.m.
Agenda: To review and evaluate grant applications.
Place: Washington Marriot Wardman Park, 2660 Woodley Road NW.,Washington, DC 20008.
Contact Person: Eduardo A Montalvo, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7852, Bethesda, MD 20892, (301) 435–1168,*montalve@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Epigenomics of Human Health and Diseases.
Date: July 21, 2011.
Time: 8 a.m. to 7 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive,Bethesda, MD 20892, (Virtual Meeting).
Contact Person: Michael K. Schmidt, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2214, MSC 7890, Bethesda, MD 20892, (301) 435–1147, *mschmidt@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR–11–099: US–India Bilateral Brain Research Collaborative Partnership.
Date: July 21, 2011.
Time: 8:30 a.m. to 4:30 p.m.
Agenda: To review and evaluate grant applications.
Place: Ritz Carlton Hotel, 1150 22nd Street, NW., Washington, DC 20037.
Contact Person: Seetha Bhagavan, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892, (301) 237–9838, *bhagavas@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 13, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–15093 Filed 6–16–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To obtain a copy of these documents, see the following link: *http://www.samhsa.gov/grants/blockgrant/.*

Project: Uniform Application for the Community Mental Health Services Block Grant and Substance Abuse and Prevention Treatment Block Grant FY 2012–2013 Application Guidance and Instructions (OMB No. 0930–0168)—Revision

The Substance Abuse and Mental Health Services Administration (SAMHSA), is requesting approval from the Office of Management and Budget (OMB) for a revision of the 2012 and 2013 Community Mental Health Services Block Grant (MHSBG) and Substance Abuse Prevention and Treatment Block Grant (SAPTBG) Guidance and Instructions into a uniform block grant application. To minimize the burden, the two separate clearances for the block grant applications will be merged into one.

Currently, the SAPTBG and the MHSBG differ on a number of their practices (*e.g.,* data collection at individual or aggregate levels) and statutory authorities (*e.g.,* method of calculating MOE, stakeholder input requirements for planning, set asides for specific populations or programs, etc.). Historically, the Centers within SAMHSA that administer these Block Grants have had different approaches to application requirements and reporting. To compound this variation, States have different structures for accepting, planning, and accounting for the Block Grants and the Prevention Set Aside within the SAPTBG. As a result, how these dollars are spent and what is known about the services and clients that receive these funds varies by Block Grant and by State.

In addition, between 2012 and 2015, 32 million individuals who are uninsured will have the opportunity to enroll in Medicaid or private health insurance. This expansion of health insurance coverage will have a significant impact on how State Mental Health Authorities (SMHAs) and State Substance Abuse Authorities (SSAs) use their limited resources. Many individuals served by these authorities are funded through Federal Block Grant funds. SAMHSA proposes that Block Grant funds be directed toward four purposes: (1) To fund priority treatment and support services for individuals without insurance or who cycle in and out of health insurance coverage; (2) to fund those priority treatment and support services not covered by Medicaid, Medicare or private insurance offered through the exchanges and that demonstrate success in improving outcomes and/or supporting recovery; (3) to fund universal, selective and targeted prevention activities and services; and (4) to collect performance and outcome data to determine the ongoing effectiveness of behavioral health prevention, treatment and recovery support services and to plan the implementation of new services on a nationwide basis.

States should begin planning now for FY 2014 when more individuals are insured. To ensure sufficient and comprehensive preparation, SAMHSA will use FY 2012 and 2013 to work with States to plan for and transition the Block Grants to these four purposes. This transition includes fully exercising SAMHSA's existing authority regarding States' and Jurisdictions' (subsequently referred to as ''States'') use of Block Grant funds, and a shift in SAMHSA staff functions to support and provide technical assistance for States receiving Block Grant funds as they move through these changes.

The proposed Mental Health Block Grant and the Substance Abuse Prevention and Treatment Block Grant build on ongoing efforts to reform health care, ensure parity and provide States and Territories with new tools, new flexibility, and state/territory-specific plans for available resources to provide their residents the health care benefits they need. The revised planning section of the Block Grant application provides a process for States and Territories to identify priorities for individuals who need behavioral health services in their jurisdictions, develop strategies to address these needs, and decide how to expend Block Grant Funds. In addition, the Planning Section of the Block Grant requests additional information from States that could be used to assist them in their reform efforts. The plan submitted by each State and Territory will provide information for SAMHSA and other Federal partners to use in working with States and Territories to improve their behavioral health systems over the next two years as health care and economic conditions evolve.

Currently, States and Territories are asked to provide strategies for seventeen areas that were developed almost twenty years ago. This new Block Grant application guides and prompts States and Territories to consider multiple populations and program areas that are likely to be priorities for States and Territories today, and to consider how changes in other funding streams that were not as relevant in prior years might fit with Block Grant funds today and in the future.

In addition, the new Block Grant application provides States and Territories the flexibility to submit one rather than two separate Block Grant applications if they choose. It also allows States and Territories to develop and submit a bi-annual rather than an annual plan, recognizing that the demographics and epidemiology do not often change on an annual basis. These options may decrease the number of applications submitted from four in two years to one.

Over the next several months, SAMHSA will assist States and Territories (individually and in smaller groups) as they develop their Block Grant applications. While there are some specific statutory requirements that SAMHSA will look for in each submitted application, SAMHSA intends to approach this process with the goal of assisting States and Territories in setting a clear direction for system improvements over time, rather than as a simple effort to seek compliance with minimal requirements.

Consistent with previous applications, the FY 2012–2013 application has sections that are required and other sections where additional information is requested, but not required. The FY 2012–2013 application requires States to submit a face sheet, a table of contents, a behavioral health assessment and plan, reports of expenditures and persons served, executive summary, and funding agreements and certifications. In addition, SAMHSA is requesting information on key areas that are critical to their success to address health reform and parity. States will continue to receive their annual grant funding if they only chose to submit the required section of their State Plans or choose to submit separate plans for the MHBG or SAPTBG. Therefore, as part of this Block Grant planning process, SAMHSA is asking States and Territories to identify their technical assistance needs to implement the strategies they identify in their plans for FY 2012 and 2013.

To facilitate an efficient application process for States in FY 2012–2013, SAMHSA convened an internal workgroup to develop the application for the Block Grant planning section. In addition, SAMHSA consulted with representatives from the state mental health and state substance abuse authorities to receive input regarding proposed changes to the Block Grant. Based on these discussions with States, SAMHSA is proposing several changes to the Block Grant programs, discussed in greater detail below.

Changes to Assessment and Planning Activities

Under the previous SAPTBG, States were requested to address seventeen national goals. Some of these seventeen goals were population specific (pregnant

women), while others were service specific (substance abuse prevention strategies). The MHSBG required States to address a set of criterion for children with serious emotional disturbances and adults with serious mental illness. While both Block Grants required States to do an assessment and plan, they did not always allow the State or SAMHSA to obtain an overall picture of the State's behavioral health needs and to incorporate consistent priorities and planning activities, especially for individuals with a co-occurring mental and substance use disorder. States will be asked to follow a four-step planning process which consists of: (1) Assessing the strengths and needs of the service system; (2) identifying the unmet service needs and critical gaps within the current system; (3) prioritize the State planning activities, and; (4) develop goals, strategies and performance indicators.

The revised Block Grant application requires States to identify and analyze the strengths, needs, and priorities of their behavioral health systems. One important change is that States will be requested to take into account the priorities for the specific populations that are the current focus of the Block Grants in the context of the changing health care environment and SAMHSA's strategic initiatives. The focus of SAMHSA's Block Grant programs has not changed significantly over the past 20 years. While many of these populations originally targeted for the Block Grants are still a priority, additional populations have evolving needs that should be addressed. These include military families, youth who need substance use disorder services, individuals who experience trauma, increased numbers of individuals released from correctional facilities, and lesbian, gay, bi-sexual, transgender and questioning (LGBTQ) individuals. The uniform plan required in the Block Grant application must address the statutory populations (as appropriate for each Block Grant) and should address these other populations.

One population of particular note in 2014 will be the newly-insured. States should begin planning now for individuals with low-incomes who are currently uninsured but will gain health coverage in 2014 when additional coverage options are available. Many of these individuals will be covered by Medicaid or private insurance in FY 2014, and this will present new opportunities for behavioral health systems to expand access and capacity. In addition, States should identify who will not be covered after FY 2014, as well as whose coverage is insufficient and how Federal funds will be used to support these individuals who may need treatment and supports.

SAMHSA is also encouraging SMHAs and SSAs to develop and submit a combined plan to address a number of other common areas, including bi-directional integration of behavioral health and primary care services, provision of recovery support services and a combined plan for the provision of services for individuals with co-occurring mental and substance use disorders. These combined plans should be included in a State's application (for those states submitting one Block Grant application). For States that submit separate Block Grant applications, these combined plans for these activities should be included in both the State MHSBG and SAPTBG applications.

The new Block Grant application requires States to follow the following planning steps:

- *Step One:* Assess the strengths and needs of the service system to address the specific populations. This will include a description of the organization of the current public system, the roles of the state, county, and localities in the provision of service and the ability of the system to address diverse needs.
- *Step Two:* Identify the unmet service needs and critical gaps within the current system. Included in this step is the identification of data sources used to determine the needs and gaps for the populations identified as a priority.
- *Step Three:* Prioritize State planning activities. Given the information in Step 2, the States will prioritize the target populations as appropriate for each Block Grant as well as other priority populations as determined by the State.
- *Step Four:* Develop goals, strategies and performance indicators. For each of the priorities identified in Step 3, the state will identify at least one goal, strategies to reach that goal, and the performance indicators to be examined over the next two years.

In addition to the planning steps, States are requested to provide the following information:

- *Information on the Use of Block Grant Dollars for Block Grant Activities*—States should project how Block Grant funds will be used to provide services for the target populations or areas identified in their plans for States that have a combined MHSBG and SAPTBG application. SAMHSA encourages States to use MHSBG and SAPTBG funds to support their or other agencies' efforts to develop reimbursement strategies that support innovation. For example, States could use Block Grant funds to support various demonstration projects through other Federal programs (Medicaid, HUD, Veterans Affairs). The new Block Grant application asks States to describe their overall reimbursement approach for services purchased with MHSBG and SAPTBG funds. States must identify the reimbursement methodology proposed for each service, prevention and emotional health development strategy, and system improvement. States are requested to project their expenditures under the MHSBG and the SAPTBG for treatment and support services.
- *Information on Activities that Support Individuals in Directing the Services*—In the new Block Grant application, States are asked to provide information regarding policies and programs that allow individuals with mental illness and/or substance use disorder to direct their own care.
- *Information on Data and Information Technology*—SAMHSA is requesting States to provide unique client-level encounter data for specific services that are purchased with Block Grant funds. States will be requested to complete the service utilization table in the Reporting Section of the Application. States should provide information on the number of unduplicated individuals by each service purchased with Block Grant Funds. If the State is currently unable to provide unique client level data for any part of its behavioral health system, the State is requested to describe in the Block Grant application their plan, process, resources needed and timeline for developing such capacity.
- *Description of State's Quality Improvement Reporting*—States have been reporting the program performance monitoring activities to include the use of independent peer review to improve the quality and appropriateness of treatment services delivered by providers receiving funds from the block grant (*See* 42 U.S.C. 300x–53(a) and 45 CFR 96.136), States are asked to attach their current quality improvement plan to their Block Grant application.
- *Description of State's Consultation with Tribes*—SAMHSA is required by the 2009 Memorandum on Tribal Consultation to submit plans on how it is to engage in regular and meaningful consultation and collaboration with tribal officials in the development of Federal policies that have Tribal implications. SAMHSA is requesting that States provide a description of how they consulted with Tribes in their State. This description should indicate how concerns of the Tribes were addressed in the State Block Grant plan(s). States shall not require any

Tribe to waive its sovereign immunity in order to receive funds or in order for services to be provided for Tribal members on Tribal lands.

• *Description of State's Service Management Strategies*—SAMHSA, similar to other public and private payers of behavioral health services, seeks to ensure that services purchased under the Block Grant are provided to individuals in the right scope, amount and duration. The Block Grant application asks States to describe the processes that they will employ over the next planning period to identify trends in over/underutilization of SAPTBG or MHSBG funded services. They must also describe the strategies that they will deploy to address these utilization issues. SAMHSA is also requesting the States to describe the resources needed to implement utilization management strategies and the timeframes for implementing these strategies.

• *Development of State Dashboards*—An important change to the administration of the MHSBG and SAPTBG is the creation of State dashboards on key performance indicators. National dashboard indicators will be based on outcome and performance measures that will be developed by SAMHSA in FY 2011. For FY 2012, States will be requested to identify a set of state-specific performance measures for this incentive program. In addition, SAMHSA will identify several national indicators to supplement the state-specific measures for the incentive program. The State, in consultation with SAMHSA, will establish a baseline in the first year of the planning cycle and identify the thresholds for performance in the subsequent year. The State will also propose the instrument used to measure the change in performance for the subsequent year. The State dashboards will be used to determine if States receive an incentive based on performance. SAMHSA is considering a variety of incentive options for this dashboard program and will solicit input from the States on the options.

• *Information of State's Suicide Prevention Plan*—As an attachment to the Block Grant application(s), States are requested to provide the most recent copy of their suicide prevention plan. While this is not a required plan, SAMHSA is interested in knowing the strategies that State's are proposing to address suicide prevention. If a State does not have a suicide prevention plan or if it has not been updated in the past three years States are requested to describe when they will create or update their plan.

• *Identification of Technical Assistance Needs*—States are requested to describe the data and technical assistance needs identified by the State during the process of developing this plan that will be needed or helpful to implement the proposed plan.

• *Process for Comment on State Plan*—Current statute requires that, as a condition of the funding agreement for the grant, States will provide opportunity for the public to comment on the State plan. In the application, States are asked to describe their efforts and procedures to obtain public comment on the State plan.

• *Description of Processes to Involve Individuals and Families*—In the Block Grant application States are requested to describe their efforts to actively engage individuals and families in developing, implementing and monitoring the State mental health and substance abuse systems.

• *Description of the Use of Technology*—Interactive Communication Technologies (ICTs) are more frequently being used to deliver various health care services. In the Block Grant application, States are requested to provide information on their use or planned use of ICTs.

• *Process for Obtaining Support of State Partners*—The success of a State's MHSBG and SAPTBG will rely heavily on the strategic partnership that SMHAs and SSAs have or will develop with other health, social services, education and other State and local governmental entities. States are requested to identify these partners in their Block Grant application and describe the roles they will play in assisting the State to implement the priorities identified in the plan. SAMHSA is requesting States to provide a letter of support indicating agreement with the description of their role and collaboration with the SSA and/or SMHA and other State agencies (e.g. State education authorities, the State Medicaid agency, etc.)

• *Description of State Behavioral Health Advisory Council*—Each State is required to establish and maintain a State advisory council for services for individuals with a mental disorder. SAMHSA strongly encourages States to expand and use the same council to advise and consult regarding issues and services for persons with or at risk of substance abuse and substance use disorders as well.

Other Changes

States will be allowed to submit a joint application for the Mental Health Services Block Grant and the Substance Abuse and Prevention and Treatment Block Grant.

States will no longer be required to submit an annual plan. The new application allows States to submit a two-year plan for FY 2012 and 2014.

Although the statutory dates for submitting the Block Grant application, plan and annual report remain unchanged, SAMHSA requests that the MHSBG and SAPTBG applications be submitted on the same date. In addition, the dates for submitting the plans have been changed to better comport with most States fiscal and planning years (July 1st through June 30th of the following year). More information can be found in the application overview.

Also, the dates States are requested to submit the annual reports have been changed for the SAPTBG. These annual reports will be due on the same date as the reports for the MHSBG, December 1st. Opting not to submit the Block grant application, plan and annual report on the same date for the SAPTBG as the MHSBG will not affect State funding in any way (amount or timeliness of payment).

Various reporting requirements for narrative descriptions have been deleted and included as an assurance to confirm compliance.

Summary of Changes as a Result of the Federal Register Notice

On April 11, 2011 a **Federal Register** Notice was posted to obtain comments on the proposed collection of information sought through the revised application for the SAPTBG and the MHSBG. In total, 772 comments from 522 individuals or organizations were received. The comments were (1) Supportive of the changes proposed to the FY 2012–2013 Block Grant Application, (2) requested clarification regarding certain areas or (3) requested specific changes to the Block Grant Application.

The most frequent comments in support of the revised Block Grant application focused on the following areas:

• Allowing States to submit a bi-annual plan instead of an annual plan.

• Having a standard format for both the MHSBG and SAPTBG.

• SAMHSA's efforts to encourage States to use the revised Block Grant application process to be better prepared to respond to several major Federal initiatives.

• Focus on planning for populations that are uninsured and below 133% of the Federal poverty level that may become insured in FY 2014.

• Inclusion of family involvement, tribal consultation and a focus on the provision of recovery support services.

• Commending SAMHSA on including adolescents as a target group that States can include in their needs assessment and State Plan.

The most frequent comments seeking clarification in the revised Block Grant application focused on the following areas:

• Requesting clarification on the sections of the Block Grant application that were required versus requested.

• Requesting that SAMHSA provide States flexibility regarding the submission of Block Grant applications post the statutory submission given the compressed timeframes.

• Requesting assurances that SAMHSA will not disapprove a State Plan or payment that did not include the requested information in the block grant application.

• Clarification that SAMHSA is not consolidating the MHBG and SAPTBG funds.

• Requesting definitions and procedure codes for the services that are included in Table 5 of the State Plan document and the reporting sections.

• Additional clarification regarding the process to develop dashboard measures for States and the proposed incentive program.

• Additional clarification and technical assistance regarding strategies to perform formal Tribal consultation.

• Comments regarding SAMHSA's proposed FY 2012 budget and the creation of State Prevention Grants. The comments were not in support of the FY 2012 proposal. While these were important comments that were not relevant to the FRN regarding the changes in the Block grant application.

During the 60 day review period SAMHSA conducted fourteen teleconferences to review the changes to the MHSBG and SAPTBG with State Substance Abuse authorities, State Mental Health Authorities and other stakeholders. SAMHSA also did a significant public outreach effort to solicit comments on the revised block grant application through announcements in various periodicals, trade association materials and prominently displayed the FRN and the application on the SAMHSA Web site.

Based on the comments received through the **Federal Register** Notice, SAMHSA has made changes to the revised block grant application. These changes include:

• Clarifying which sections of the block grant application are required to be submitted as part of the State Plan and which sections SAMHSA is requesting, but not requiring States to submit. SAMHSA continues to strongly encourage States to submit this information. This will allow SAMHSA to understand the Applicant State's efforts and identify how it can assist the applicant State meet its goals in a changing environment. In addition, this information will identify States that are models and assist other States with areas of common concern.

• Clarify to States that not submitting this information will not change SAMHSA's approval of their Plan or payment, States are strongly encouraged to submit as much as they can so the nation as a whole will have a complete picture of needs of individuals with behavioral health conditions as well as the innovative approaches States are undertaking in these areas as well as the barriers they encounter to design and implement important policies and programs.

• Provided some additional clarity regarding specific sections of the plan in the following areas: Data and Information Technology, consultation with Tribes, Support of State Partners, and State behavioral Health Advisory Council.

• Provided additional clarification on specific sections of the reporting section for the MHBG and SABG.

Estimates of Annualized Hour Burden

The estimated annualized burden for a uniform application is 37, 429 hours. Burden estimates are broken out in the following tables showing burden separately for Year 1 and Year 2. Year 1 includes the estimates of burden for the uniform application and annual reporting. Year 2 includes the estimates of burden for the application update and annual reporting. The reporting burden remains constant for both years.

TABLE 1—ESTIMATES OF APPLICATION AND REPORTING BURDEN FOR YEAR 1

Application element	Number respondents	Responses/ respondents	Burden/ response (hours)	Total burden
Application Burden:				
Yr One Plan (separate submissions)	30 (CMHS) .. 30 (SAPT) ...	1	282	16,920
Yr One Plan (combined submission)	30	1	282	8,460
Application Sub-total	60			25,380
Reporting Burden:				
MHBG Report	59	1	186	10,974
URS Tables	59	1	35	2,065
SAPTBG Report	60[1]	1	186	11,160
Table 5	15[2]	1	4	60
Reporting Subtotal	60			24,259
Total	119			49,639

[1] Redlake Band of the Chippewa Indians from MN receives a grant.
[2] Only 15 States have a management information system to complete Table 5.

TABLE 2—ESTIMATES OF APPLICATION AND REPORTING BURDEN FOR YEAR 2

Application element	Number respondents	Responses/ respondents	Burden/ response (hours)	Total burden
Application Burden:				
Yr Two Plan	24	1	40	960
Application Sub-total	24			960

TABLE 2—ESTIMATES OF APPLICATION AND REPORTING BURDEN FOR YEAR 2—Continued

Application element	Number respondents	Responses/ respondents	Burden/ response (hours)	Total burden
Reporting Burden:				
MHBG Report	59	1	186	10,974
URS Tables	59	1	35	2,065
SAPTBG Report	60	1	186	11,160
Table 5	15	1	4	60
Reporting Subtotal	60	.....	.....	24,259
Total	119	.....	.....	25,219

The total annualized burden for the application and reporting is 37,429 hours (49,639 + 25,219 = 74,858/2 years = 37,429).

Link for the application: http://www.samhsa.gov/grants/blockgrant/.

Written comments and recommendations concerning the proposed information collection should be sent by July 18, 2011 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202–395–7285.

Dated: June 13, 2011.

Elaine Parry,

Director, Office of Management, Technology and Operations.

[FR Doc. 2011–15070 Filed 6–16–11; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2011–0046]

DHS Data Privacy and Integrity Advisory Committee

AGENCY: Privacy Office, DHS.

ACTION: Committee Management; Notice of Federal Advisory Committee Meeting.

SUMMARY: The DHS Data Privacy and Integrity Advisory Committee will meet on July 11, 2011, in Washington, DC. The meeting will be open to the public.

DATES: The DHS Data Privacy and Integrity Advisory Committee will meet on Thursday, July 11, 2011, from 10 a.m. to 1 p.m. Please note that the meeting may end early if the Committee has completed its business.

ADDRESSES: The meeting will be held in the U.S. Citizenship and Immigration Services Tomich Center, 111 Massachusetts Avenue, NW., (corner of New Jersey Avenue), Washington, DC 20529.

For information on facilities or services for individuals with disabilities, or to request special assistance at the meeting, contact Martha K. Landesberg, Executive Director, DHS Data Privacy and Integrity Advisory Committee, as soon as possible.

To facilitate public participation, we invite public comment on the issues to be considered by the Committee as listed in the **SUPPLEMENTARY INFORMATION** section below. A public comment period will be held during the meeting from 12 p.m. to 12:30 p.m., and speakers are requested to limit their comments to 3 minutes. If you would like to address the Committee at the meeting, we request that you register in advance by contacting Martha K. Landesberg at the address provided below or sign up at the registration desk on the day of the meeting. The names and affiliations, if any, of individuals who address the Committee are included in the public record of the meeting. Please note that the public comment period may end before the time indicated, following the last call for comments. Written comments and requests to have a copy of your materials distributed to each member of the Committee prior to the meeting should be sent to Martha K. Landesberg, Executive Director, DHS Data Privacy and Integrity Advisory Committee, by July 5, 2011. Persons who wish to submit comments and who are not able to attend or speak at the meeting may submit comments at any time. All submissions must include the Docket Number (DHS–2011–0046) and may be submitted by any *one* of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *E-mail: PrivacyCommittee@dhs.gov*. Include the Docket Number (DHS–2011–0046) in the subject line of the message.
- *Fax:* (703) 483–2999.
- *Mail:* Martha K. Landesberg, Executive Director, Data Privacy and Integrity Advisory Committee, Department of Homeland Security, Washington, DC 20528.

Instructions: All submissions must include the words ''Department of Homeland Security Data Privacy and Integrity Advisory Committee'' and the Docket Number (DHS–2011–0046). Comments received will be posted without alteration at *http://www.regulations.gov*, including any personal information provided.

If you wish to attend the meeting, please plan to arrive at the Tomich Center by 9:30 a.m., to allow extra time to be processed through security, and bring a photo I.D. The DHS Privacy Office encourages you to register for the meeting in advance by contacting Martha K. Landesberg, Executive Director, DHS Data Privacy and Integrity Advisory Committee, at *PrivacyCommittee@dhs.gov.* Advance registration is voluntary. The Privacy Act Statement below explains how DHS uses the registration information you may provide and how you may access or correct information retained by DHS, if any.

Docket: For access to the docket to read background documents or comments received by the DHS Data Privacy and Integrity Advisory Committee, go to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Martha K. Landesberg, Executive Director, DHS Data Privacy and Integrity Advisory Committee, Department of Homeland Security, Washington, DC 20528, by telephone (703) 235–0780, by fax (703) 235–0442, or by e-mail to *PrivacyCommittee@dhs.gov*.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2 The DHS Data Privacy and Integrity Advisory Committee provides advice at the request of the Secretary of Homeland Security and the

DHS Chief Privacy Officer on programmatic, policy, operational, administrative, and technological issues within the DHS that relate to personally identifiable information, as well as data integrity and other privacy-related matters. The committee was established by the Secretary of Homeland Security under the authority of 6 U.S.C. 451.

Agenda

During the meeting, the Chief Privacy Officer will provide the Committee an update on the activities of the DHS Privacy Office. In support of the Committee's ongoing advice to the Department on implementing privacy protections in DHS operations, the Committee will also hear and discuss a presentation on the Department's international information sharing programs and a presentation on the DHS Programs and Protection Directorate's implementation of Department privacy policy. The agenda will be posted in advance of the meeting on the Committee's Web site at *http://www.dhs.gov/privacy.* Please note that the meeting may end early if all business is completed.

Privacy Act Statement: DHS's Use of Your Information

Authority: DHS requests that you voluntarily submit this information under its following authorities: The Federal Records Act, 44 U.S.C. 3101; the FACA, 5 U.S.C. App. 2; and the Privacy Act of 1974, 5 U.S.C. 552a.

Principal Purposes: When you register to attend a DHS Data Privacy and Integrity Advisory Committee meeting, DHS collects your name, contact information, and the organization you represent, if any. We use this information to contact you for purposes related to the meeting, such as to confirm your registration, to advise you of any changes in the meeting, or to assure that we have sufficient materials to distribute to all attendees. We may also use the information you provide for public record purposes such as posting publicly available transcripts and meeting minutes.

Routine Uses and Sharing: In general, DHS will not use the information you provide for any purpose other than the Principal Purposes, and will not share this information within or outside the agency. In certain circumstances, DHS may share this information on a case-by-case basis as required by law or as necessary for a specific purpose, as described in the DHS/ALL–002 Mailing and Other Lists System of Records Notice (November 25, 2008, 73 FR 71659).

Effects of Not Providing Information: You may choose not to provide the requested information or to provide only some of the information DHS requests. If you choose not to provide some or all of the requested information, DHS may not be able to contact you for purposes related to the meeting.

Accessing and Correcting Information: If you are unable to access or correct this information by using the method that you originally used to submit it, you may direct your request in writing to the DHS Deputy Chief FOIA Officer at *foia@dhs.gov.* Additional instructions are available at *http://www.dhs.gov/foia* and in the DHS/ALL–002 Mailing and Other Lists System of Records referenced above.

Dated: June 8, 2011.

Mary Ellen Callahan

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2011–15028 Filed 6–16–11; 8:45 am]

BILLING CODE 4410–9L–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5477–N–24]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7262, Washington, DC 20410; telephone (202) 708–1234; TTY number for the hearing- and speech-impaired (202) 708–2565, (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in *National Coalition for the Homeless* v. *Veterans Administration*, No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: June 9, 2011.

Mark R. Johnston,

Deputy Assistant Secretary for Special Needs.

[FR Doc. 2011–14723 Filed 6–16–11; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5500–N–05]

Notice of Web Availability: Notice of Funding Availability (NOFA) for HUD's Fiscal Year (FY) 2011 Capital Fund Education and Training Community Facilities (CFCF) Program

AGENCY: Office of the Chief of the Human Capital Officer, HUD.

ACTION: Notice.

SUMMARY: HUD announces the availability on its Web site and Grants.gov, applicant information, submission deadlines, funding criteria, and other requirements for HUD's FY2011 Capital Fund Education and Training Community Facilities (CFCF) Program NOFA. Specifically, this NOFA announces the availability of approximately $15 million made available under the Department of Defense and Full-Year Continuing Appropriations Act, 2011, Public Law 112–10, enacted April 15, 2011.

The purpose of the Capital Fund Education and Training Community Facilities (CFCF) Program is to provide capital funding to PHAs for the construction, rehabilitation, or purchase of facilities to provide early childhood education, adult education, and/or job training programs for public housing residents based on an identified need. Additionally, PHAs may use CFCF program funding to rehabilitate existing community facilities that will offer comprehensive, integrated services to help public housing residents achieve better educational and economic outcomes resulting in long-term economic self-sufficiency.

The notice providing information regarding the application process, funding criteria and eligibility requirements, application and instructions can be found using the Department of Housing and Urban Development agency link on the Grants.gov/Find Web site at *http://www.grants.gov/search/agency.do.* A link to the funding opportunity is also available on the HUD Web site at *http://portal.hud.gov/hudportal/HUD?src=/program_offices/administration/grants/fundsavail.*

The link from the funds available page will take you to the agency link on *Grants.gov.* The Catalogue of Federal

Domestic Assistance (CFDA) number for this program is 14.890. Applications must be submitted electronically through *Grants.gov*.

FOR FURTHER INFORMATION CONTACT: Questions regarding specific program requirements should be directed to the agency contact identified in the program NOFA. Program staff will not be available to provide guidance on how to prepare the application. Questions regarding the 2011 General Section should be directed to the Office of Grants Management and Oversight at (202) 708–0667 or the NOFA Information Center at 800–HUD–8929 (toll free). Persons with hearing or speech impairments may access these numbers via TTY by calling the Federal Information Relay Service at 800–877–8339.

Dated: June 10, 2011.

Barbara S. Dorf,

Director, Office of Departmental Grants Management and Oversight, Office of the Chief of the Human Capital Officer.

[FR Doc. 2011–15031 Filed 6–16–11; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5509–N–01]

Notice of Web Availability: Notice of Funding Availability (NOFA) for HUD's Fiscal Year (FY) 2011 Capacity Building for Sustainable Communities Program

AGENCY: Office of the Chief of the Human Capital Officer, HUD.

ACTION: Notice.

SUMMARY: HUD announces the availability on its website and Grants.gov, applicant information, submission deadlines, funding criteria, and other requirements for HUD's FY2011 Capacity Building for Sustainable Communities Program NOFA. Specifically, this NOFA announces the availability of approximately $5.65 million made available under the Department of Defense and Full-Year Continuing Appropriations Act, 2011, Public Law 112–10, enacted April 15, 2011.

Program Purpose: The purpose of the Capacity Building for Sustainable Communities program is twofold. The first purpose is to assemble a collection of capacity building service providers to work directly with the FY2010 and FY2011 HUD Sustainable Communities Regional Planning and Community Challenge grant recipients, HUD Preferred Sustainability Status Communities, and EPA Sustainable Community Technical Assistance recipients and Brownfield Area Wide Planning grant recipients (collectively —Sustainable Communities Grantees), to enable them to fulfill their anticipated outcomes. HUD and other Partnership agencies will work regularly with all selected intermediary service providers to maintain a coordinated and leveraged delivery approach that ensures the maximum benefit to local governments, regions, and planning entities and partners engaged in the prescribed activities.

The second purpose of the Program is to build a national coalition and leadership network of the Sustainable Communities grantees. The purpose of the network is to facilitate the exchange of successful strategies, lessons learned, emerging tools and public engagement strategies, and approaches for avoiding or minimizing pitfalls. HUD will work with the selected intermediaries to develop a robust evaluation component for the network.

The notice providing information regarding the application process, funding criteria and eligibility requirements, application and instructions can be found using the Department of Housing and Urban Development agency link on the Grants.gov/Find Web site at *http://www.grants.gov/search/agency.do.* A link to the funding opportunity is also available on the HUD Web site at *http://portal.hud.gov/hudportal/HUD?src=/program_offices/administration/grants/fundsavail.*

The link from the funds available page will take you to the agency link on *Grants.gov.* The Catalogue of Federal Domestic Assistance (CFDA) number for this program is 14.705. Applications must be submitted electronically through *Grants.gov.*

FOR FURTHER INFORMATION CONTACT: Questions regarding specific program requirements should be directed to the agency contact identified in the program NOFA. Program staff will not be available to provide guidance on how to prepare the application. Questions regarding the 2011 General Section should be directed to the Office of Grants Management and Oversight at (202) 708–0667 or the NOFA Information Center at 800–HUD–8929 (toll free). Persons with hearing or speech impairments may access these numbers via TTY by calling the Federal Information Relay Service at 800–877–8339.

Dated: June 10, 2011.

Barbara S. Dorf,

Director, Office of Departmental Grants, Management, and Oversight, Office of the Chief of the Human Capital Officer.

[FR Doc. 2011–15032 Filed 6–16–11; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5502–N–02]

Notice of Single Family Loan Sales (SFLS 2011–2)

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: This notice announces HUD's intention to competitively sell certain unsubsidized single family mortgage loans in a sealed bid sale offering called SFLS 2011–2, without Federal Housing Administration (FHA) mortgage insurance. This notice also generally describes the bidding process for the sale and certain persons who are ineligible to bid. This second sale of Fiscal Year (FY) 2011 is scheduled for June 22, 2011. HUD's third sale in FY 2011, SFLS 2011–3, is scheduled for September 14, 2011.

DATES: For this sale, the Bidder's Information Package (BIP) was made available to qualified bidders on May 18, 2011. Bids for the 2011–2 sale must be submitted on the bid date, which is currently scheduled for June 22, 2011 (the Bid Date). HUD anticipates that award(s) will be made on or about June 23, 2011 (the Award Date).

ADDRESSES: To become a qualified bidder and receive the BIP, prospective bidders must complete, execute, and submit a Confidentiality Agreement and a Qualification Statement acceptable to HUD. Both documents will be available on the HUD Web site at: *http://www.hud.gov/sfloansales.*

Please mail and fax executed documents to HUD's Asset Sales Office: Asset Sales Office, United States Department of Housing and Urban Development, 451 7th Street, SW., Room 3136, Washington, DC 20410, Attention: Single Family Sale Coordinator, Fax: 202–708–2771.

FOR FURTHER INFORMATION CONTACT: John Lucey, Deputy Director, Asset Sales Office, Office of Housing, Department of Housing and Urban Development, Room 3136, 451 7th Street, SW., Washington, DC 20410–8000; telephone number 202–708–2625, extension 3927. Persons with hearing- or speech-impairments may

access this number through TTY by calling the toll-free Federal Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: HUD announces its intention to sell in SFLS 2011–2 certain unsubsidized non-performing mortgage loans (Mortgage Loans) secured by single family properties located throughout the United States. A listing of the Mortgage Loans will be included in the due diligence materials made available to qualified bidders. The Mortgage Loans will be sold without FHA insurance and with servicing released. HUD will offer qualified bidders an opportunity to bid competitively on the Mortgage Loans.

The Bidding Process

The BIP will describe in detail the procedure for bidding in SFLS 2011–2. The BIP will also include a standardized non-negotiable Conveyance, Assignment and Assumption Agreement (CAA Agreement). Qualified bidders will be required to submit a deposit with their bid. Deposits are calculated based upon each qualified bidder's aggregate bid price.

HUD will evaluate the bids submitted and determine the successful bid, in terms of the best value to HUD, in its sole and absolute discretion. If a qualified bidder is successful, the qualified bidder's deposit will be non-refundable and will be applied toward the purchase price. Deposits will be returned to unsuccessful bidders. For the 2011–2 sale action, settlements are expected to take place on July 13, 2011 and August 18, 2011.

This notice provides some of the basic terms of sale. The CAA Agreement, which will be included in the BIP, will provide comprehensive contractual terms and conditions. To ensure a competitive bidding process, the terms of the bidding process and the CAA Agreement are not subject to negotiation.

Due Diligence Review

The BIP will describe how qualified bidders may access the due diligence materials remotely via a high-speed Internet connection.

Mortgage Loan Sale Policy

HUD reserves the right to remove Mortgage Loans from SFLS 2011–2 at any time prior to the Award Date. HUD also reserves the right to reject any and all bids, in whole or in part, and include any Mortgage Loans in a later sale. Mortgage Loans will not be withdrawn after the Award Date except as specifically provided in the CAA Agreement.

The 2011–2 sale of Mortgage Loans are assigned to HUD pursuant to section 204(a)(1)(A) of the National Housing Act as amended under Title VI of the Departments of Veterans Affairs and Housing and Urban Development and Independent Agencies Appropriations Act, 1999. The sale of the Mortgage Loans is pursuant to section 204(g) of the National Housing Act.

Mortgage Loan Sale Procedure

HUD selected an open competitive whole-loan sale as the method to sell the Mortgage Loans. This method of sale optimizes HUD's return on the sale of these Mortgage Loans, affords the greatest opportunity for all qualified bidders to bid on the Mortgage Loans, and provides the quickest and most efficient vehicle for HUD to dispose of the Mortgage Loans.

Bidder Ineligibility

In order to bid in the 2011–2 sale, a prospective qualified bidder must complete, execute and submit both a Confidentiality Agreement and a Qualification Statement acceptable to HUD. The following individuals and entities are ineligible to bid on any of the Mortgage Loans included in SFLS 2011–2:

1. An employee of HUD, a member of such employee's household, or an entity owned or controlled by any such employee or member of such an employee's household;

2. An individual or entity that is debarred, suspended, or excluded from doing business with HUD pursuant to 24 CFR Part 24, and 2 CFR Part 2424;

3. An individual or entity that has been suspended, debarred or otherwise restricted by any Department or Agency of the Federal Government or of a State Government from doing business with such Department or Agency;

4. An individual or entity that has been debarred, suspended, or excluded from doing mortgage related business, including having a business license suspended, surrendered or revoked, by any federal, state or local government agency, division or department;

5. A contractor, subcontractor and/or consultant or advisor (including any agent, employee, partner, director, principal or affiliate of any of the foregoing) who performed services for or on behalf of HUD in connection with the Sales;

6. An individual or entity that uses the services, directly or indirectly, of any person or entity ineligible under subparagraphs 1 through 3 above to assist in preparing any of its bids on the Mortgage Loans;

7. An individual or entity which employs or uses the services of an employee of HUD (other than in such employee's official capacity) who is involved in single family asset sales;

8. An entity or individual that serviced or held any Mortgage Loan at any time during the 2-year period prior to the Award Date is ineligible to bid on such Mortgage Loan or on the pool containing such Mortgage Loan, and

9. An entity or individual that is: (a) Any affiliate or principal of any entity or individual described in the preceding sentence (sub-paragraph 8); (b) any employee or subcontractor of such entity or individual during that 2-year period prior to Award Date; or (c) any entity or individual that employs or uses the services of any other entity or individual described in this paragraph in preparing its bid on such Mortgage Loan.

Freedom of Information Act Requests

HUD reserves the right, in its sole and absolute discretion, to disclose information regarding SFLS 2011–2, including, but not limited to, the identity of any successful qualified bidder and its bid price or bid percentage for any pool of loans or individual loan, upon the closing of the sale of all the Mortgage Loans. Even if HUD elects not to publicly disclose any information relating to SFLS 2011–2, HUD will have the right to disclose any information that HUD is obligated to disclose pursuant to the Freedom of Information Act and all regulations promulgated thereunder.

Scope of Notice

This notice applies to SFLS 2011–2 and does not establish HUD's policy for the sale of other mortgage loans.

Dated: June 10, 2011.

Robert C. Ryan,

Acting Assistant Secretary for Housing, Federal Housing Commissioner.

[FR Doc. 2011–15029 Filed 6–16–11; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Proposed Renewal of Information Collection; Source Directory of American Indian and Alaska Native Owned and Operated Arts and Crafts Businesses

AGENCY: Indian Arts and Crafts Board, Interior.

ACTION: Notice; request for comments.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Indian Arts and Crafts Board announces the proposed extension of a public information collection and seeks public comments on the provisions thereof.

DATES: Submit written comments on or before August 16, 2011.

ADDRESSES: Send your written comments to Attention: Indian Arts and Crafts Board, U.S. Department of the Interior, 1849 C Street, NW., MS–2528 MIB, Washington, DC 20240. If you wish to submit comments by facsimile, the number is (202) 208–5196, or you may send them by e-mail to *iacb@ios.doi.gov.* Please mention that your comments concern the Source Directory, OMB Control 1085–0001.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the Source Directory application or renewal forms, *i.e.,* the information collection instruments, should be directed to Meridith Z. Stanton, Director, Indian Arts and Crafts Board, 1849 C Street, NW., MS–2528 MIB, Washington, DC 20240. You may also call (202) 208–3773 (not a toll free call), or send your request by e-mail to *iacb@ios.doi.gov* or by facsimile to (202) 208–5196.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Source Directory of American Indian and Alaska Native Owned and Operated Arts and Crafts Businesses (Source Directory) is a program of the Indian Arts and Crafts Board that promotes American Indian and Alaska Native arts and crafts. The Source Directory is a listing of American Indian and Alaska Native-owned and -operated arts and crafts businesses that may be accessed by the public on the Indian Arts and Crafts Board's Web site *http://www.iacb.doi.gov.*

The service of being listed in this directory is provided free-of-charge to members of Federally recognized tribes. Businesses listed in the Source Directory include American Indian and Alaska Native artists and craftspeople, cooperatives, tribal arts and crafts enterprises, businesses privately-owned and -operated by American Indian and Alaska Native artists, designers, and craftspeople, and businesses privately-owned and -operated by American Indian and Alaska Native merchants who retail and/or wholesale authentic Indian and Alaska Native arts and crafts. Business listings in the Source Directory are arranged alphabetically by State.

The Director of the Indian Arts and Crafts Board uses this information collected in information collection 1085–0001 to determine whether an individual or business applying to be listed in the Source Directory meets the requirements for listing. If approved, the application will be included in the Source Directory. The Source Directory is updated annually to include new businesses and to update existing information.

II. Method of Collection

To be listed in the Source Directory, interested individuals and businesses must submit: (1) A draft of their business information in a format like the other Source Directory listings, (2) a copy of the individual's or business owner's tribal enrollment card; and for businesses, proof that the business is organized under tribal, state, or Federal law; and (3) a certification that the business is an American Indian or Alaska Native-owned and -operated cooperative, tribal enterprise, or nonprofit organization, or that the owner of the enterprise is an enrolled member of a Federally recognized American Indian Tribe or Alaska Native group.

The following information is collected in a single-page form that is distributed by the Indian Arts and Crafts Board. Although listing in the Source Directory is voluntary, submission of this information is required for inclusion in the Directory.

Information collected	Reason for collection
Name of business, mailing address, city, zip code (highway location, Indian reservation, etc.), telephone number and e-mail address.	To identify the business to be listed in the *Source Directory,* and method of contact.
Type of organization	To identify the nature of the business entity.
Hours/season of operation	To identify those days and times when customers may contact the business.
Internet Web site address	To identify whether the business advertises and/or sells inventory online.
Main categories of products	To identify the products that the business produces.
Retail or wholesale products	To identify whether the business is a retail or wholesale business.
Mail order and/or catalog	To identify whether the business has a mail order and/or catalog.
Price list information, if applicable	To identify the cost of the listed products.
For a cooperative or tribal enterprise, a copy of documents showing that the organization is formally organized under tribal, state or Federal law.	To determine whether the business meets the eligibility requirement for listing in the Source Directory.
Signed certification that the business is an American Indian or Alaska Native owned and operated cooperative, tribal enterprise, or nonprofit organization.	To obtain verification that the business is an American Indian or Alaska Native owned and operated business.
Copy of the business owner's tribal enrollment card	To determine whether the business owner is an enrolled member of a Federally recognized tribe.
Signed certification that the owner of the business is a member of a Federally recognized tribe.	To obtain verification that the business owner is an enrolled member of a Federally recognized tribe.

The proposed use of the information: The information collected will be used by the Indian Arts and Crafts Board:

(a) To determine whether an individual or business meets the eligibility requirements for inclusion in the Source Directory, *i.e.,* whether they are either an American Indian or Alaska Native-owned and -operated cooperative, tribal enterprise, or nonprofit organization, or an enrolled member of a Federally recognized American Indian Tribe or Alaska Native group;

(b) To identify the applicant's business information to be printed in the Source Directory.

III. Data

(1) *Title:* Department of the Interior, Indian Arts and Crafts Board, Source Directory of American Indian and Alaska Native-owned and -operated arts and crafts businesses.

OMB Control Number: 1085–0001.

Type of Review: Renewal of an existing collection.

Affected Entities: Business or other for-profit; tribes.

Estimated annual number of respondents: 100.

Frequency of response: Annual.

(2) Annual reporting and record keeping burden.

Total annual reporting per respondent: 15 minutes.

Total annual reporting: 25 hours.

(3) Description of the need and use of the information: Submission of this information is required to receive the benefit of being listed in the Indian Arts and Crafts Board Source Directory. The information is collected to determine the applicant's eligibility for the service and to obtain the applicant's name and business address to be added to the online directory.

IV. Request for Comments

The Department of the Interior invites comments on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) The accuracy of the agency's estimate of the burden of the collection and the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(d) Ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other collection techniques or other forms of information technology.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose, or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

All written comments will be available for public inspection in Room 2528 of the Main Interior Building, 1849 C Street, NW., Washington, DC from 9 a.m. until 3 p.m., Monday through Friday, excluding legal holidays. A valid picture identification is required for entry into the Department of the Interior. The comments, with names and addresses, will be available for public view during regular business hours. If you wish us to withhold your personal information, you must prominently state at the beginning of your comment what personal information you want us to withhold. We will honor your request to the extent allowable by law.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget control number.

Dated: June 13, 2011.

Meridith Z. Stanton,

Director, Indian Arts and Crafts Board.

[FR Doc. 2011–15069 Filed 6–16–11; 8:45 am]

BILLING CODE 4310–4H–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R9–IA–2011–N123; 96300–1671–0000–P5]

Endangered Species; Marine Mammals; Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications for permit.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered species, marine mammals, or both. With some exceptions, the Endangered Species Act (ESA) and Marine Mammal Protection Act (MMPA) prohibit activities with listed species unless a Federal permit is issued that allows such activities. Both laws require that we invite public comment before issuing these permits.

DATES: We must receive comments or requests for documents on or before July 18, 2011. We must receive requests for marine mammal permit public hearings, in writing, at the address shown in the **ADDRESSES** section by July 18, 2011.

ADDRESSES: Brenda Tapia, Division of Management Authority, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 212, Arlington, VA 22203; fax (703) 358–2280; or e-mail *DMAFR@fws.gov.*

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, (703) 358–2104 (telephone); (703) 358–2280 (fax); *DMAFR@fws.gov* (e-mail).

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

A. How do I request copies of applications or comment on submitted applications?

Send your request for copies of applications or comments and materials concerning any of the applications to the contact listed under **ADDRESSES**. Please include the **Federal Register** notice publication date, the PRT-number, and the name of the applicant in your request or submission. We will not consider requests or comments sent to an e-mail or address not listed under **ADDRESSES**. If you provide an e-mail address in your request for copies of applications, we will attempt to respond to your request electronically.

Please make your requests or comments as specific as possible. Please confine your comments to issues for which we seek comments in this notice, and explain the basis for your comments. Include sufficient information with your comments to allow us to authenticate any scientific or commercial data you include.

The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) Those that include citations to, and analyses of, the applicable laws and regulations. We will not consider or include in our administrative record comments we receive after the close of the comment period (*see* **DATES**) or comments delivered to an address other than those listed above (*see* **ADDRESSES**).

B. May I review comments submitted by others?

Comments, including names and street addresses of respondents, will be available for public review at the address listed under **ADDRESSES**. The public may review documents and other information applicants have sent in support of the application unless our allowing viewing would violate the Privacy Act or Freedom of Information Act. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

II. Background

To help us carry out our conservation responsibilities for affected species, the Endangered Species Act of 1973, section 10(a)(1)(A), as amended (16 U.S.C. 1531 *et seq.*), and our regulations in the Code of Federal Regulations (CFR) at 50 CFR part 17, the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), and our regulations in the Code of Federal Regulations (CFR) at 50 CFR part 18 require that we invite public comment before final action on these permit applications. Under the MMPA, you may request a hearing on any MMPA application received. If you request a hearing, give specific reasons why a hearing would be appropriate. The holding of such a hearing is at the discretion of the Service Director.

III. Permit Applications

A. Endangered Species

Applicant: Illinois State Museum, Springfield, IL; PRT–42506A

The applicant requests a permit to biological samples from wild Hine's emerald dragonfly (*Somatochlora hineana*), for the purpose of enhancement of the survival of the species.

Applicant: Endangered Species Propagation, Survival & Research Center, Mertzon, TX; PRT–39083A

The applicant requests a permit to authorize interstate and foreign commerce, export and cull of excess Arabian oryx (*Oryx leucoryx*) from the captive herd maintained at their facility for the purpose of enhancement of the survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Forrest Simpson, Conroe, TX; PRT–115344

The applicant requests reissuance of his permit authorizing interstate and foreign commerce, export and cull of excess barashingh (*Rucervus duvauceli*) from the captive herd maintained at their facility for the purpose of enhancement of the survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Harvard University, Museum of Comparative Zoology, Cambridge, MA; PRT–090287

The applicant requests renewal of their permit to export and reimport nonliving museum specimens of endangered and threatened species previously accessioned into the applicant's collection for scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Bishop Museum, Honolulu, HI; PRT–700877

The applicant requests renewal of their permit to export and reimport nonliving museum specimens of endangered and threatened species previously accessioned into the applicant's collection for scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

B. Endangered Marine Mammals and Marine Mammals

Applicant: Matson's Laboratory, Milltown, MT, PRT–166346.

The applicant requests an amendment to the permit to increase the number of teeth to import annually from polar bears (*Ursus maritimus*) which were taken by national and provincial researchers during subsistence harvests in Canada, for age analysis for the purpose of scientific research and enhancement of survival of the species. This notification covers activities to be conducted by the applicant over the remainder of the 5-year period of the permit.

Concurrent with publishing this notice in the **Federal Register**, we are forwarding copies of the above applications to the Marine Mammal Commission and the Committee of Scientific Advisors for their review.

Brenda Tapia,

Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2011–15034 Filed 6–16–11; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[[LLWY922000–L51100000–GA0000–LVEMK09CK36; WYW172657]

Notice of Competitive Coal Lease Sale, Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of competitive coal lease sale.

SUMMARY: Notice is hereby given that certain coal resources in the Caballo West Coal Tract described below in Campbell County, Wyoming, will be offered for competitive lease by sealed bid in accordance with the provisions of the Mineral Leasing Act of 1920, as amended.

DATES: The lease sale will be held at 10 a.m. on Wednesday, August 17, 2011. Sealed bids must be submitted on or before 4 p.m. on Tuesday, August 16, 2011.

ADDRESSES: The lease sale will be held in the First Floor Conference Room (Room 107), of the Bureau of Land Management (BLM) Wyoming State Office, 5353 Yellowstone Road, P.O. Box 1828, Cheyenne, Wyoming 82003. Sealed bids must be submitted to the Cashier, BLM Wyoming State Office, at the address given above.

FOR FURTHER INFORMATION CONTACT: Mavis Love, Land Law Examiner, or Kathy Muller Ogle, Coal Coordinator, at 307–775–6258, and 307–775–6206, respectively.

SUPPLEMENTARY INFORMATION: This coal lease sale is being held in response to a lease by application (LBA) filed by BTU Western Resources, Inc. (successor to Caballo Coal Company), Gillette, Wyoming. The coal resource to be offered consists of all reserves recoverable by surface mining methods in the following-described lands located approximately 8 miles south-southeast of Gillette, Wyoming and east of State Highway 59.

T. 48 N., R. 71 W., 6th Principal Meridian

Sec. 7, lots 12 and 19;
Sec. 8, lot 10;
Sec. 17, lots 1 through 12 inclusive and lots 15 and 16;
Sec. 18, lots 5, 12, and 13;
Sec. 20, lots 1, 2, and 8; and
Sec. 21, lots 11 and 12.

Containing 1,023.99 acres, more or less, in Campbell County, Wyoming.

The LBA tract is adjacent to Federal, private, and State of Wyoming leases along the western lease boundary of the Caballo mine and to the Belle Ayr North LBA along the south. It is adjacent to additional unleased Federal coal to the west. The tract is crossed by Bishop Road along its southern boundary.

All of the acreage offered has been determined to be suitable for mining. Features such as Bishop Road, utilities, and pipelines can be moved to permit coal recovery. In addition, several producing coal bed natural gas wells have been drilled on the tract. The estimate of the bonus value of the coal lease will include consideration of the future production from these wells. An economic analysis of the future income stream from coal mining will consider reasonable compensation to the gas lessee for lost production of the natural gas when the wells are bought out by the coal lessee. The surface estate of the tract is owned by Alpha Coal West, Inc., as well as private individuals and entities.

The tract contains surface mineable coal reserves in the Wyodak-Anderson

coal zone currently being recovered in the adjacent, existing mine. On the LBA tract, there is one recoverable seam, the Wyodak, which averages approximately 75 feet thick and is continuous over the entire tract with no outcrops or subcrops. Overburden depths to this seam average approximately 285 feet on the LBA.

The tract contains an estimated 130,196,000 tons of mineable coal. This estimate of mineable reserves includes the main seam mentioned above but does not include any tonnage from localized seams or splits that are less than 5 feet of coal. Also, it does not include the adjacent private and State of Wyoming leases although these leases are expected to be mined in conjunction with the LBA tract. The total mineable stripping ratio of the coal in bank cubic yards per ton is approximately 4.2:1. Potential bidders for the LBA tract should consider the recovery rate expected from thick seam coal mining. The Caballo West LBA coal is ranked as subbituminous C. The overall average quality on an as-received basis is 8,501 British Thermal Units per pound containing about 0.33 percent sulfur. This quality places these coal reserves in the lower part of the range of coal quality currently being mined in the Wyoming portion of the Powder River Basin.

The tract in this lease offering contains split estate lands. There are qualified surface owners as defined in the regulations at 43 CFR 3400.0–5. Consent granted by the qualified surface owners has been filed with and verified by the BLM. The LBA tract lands included in the consent are:

T. 48 N., R. 71 W., 6th Principal Meridian

Sec. 7, lots 12 and 19; and
Sec. 18, lot 5.

Containing 123.77 acres, more or less, in Campbell County, Wyoming.

The purchase price of the consent as stated in the consent document is ''* * * a royalty of ten cents ($.10) per ton (2,000 pounds) of merchantable coal or one percent (1%) of the gross sale price of such coal F.O.B. the mine, whichever is greater.''

The tract will be leased to the qualified bidder of the highest cash amount provided that the high bid meets or exceeds the BLM's estimate of the fair market value (FMV) of the tract. The minimum bid for the tract is $100 per acre or fraction thereof. No bid that is less than $100 per acre, or fraction thereof, will be considered. The bids should be sent by certified mail, return receipt requested, or be hand delivered. The BLM Wyoming State Office Cashier will issue a receipt for each hand-delivered bid. Bids received after 4 p.m. local time on Tuesday, August 16, 2011, will not be considered. The minimum bid is not intended to represent FMV. The FMV of the tract will be determined by the Authorized Officer after the sale. The lease that may be issued as a result of this offering will provide for payment of an annual rental of $3 per acre, or fraction thereof, and a royalty payment to the United States of 12.5 percent of the value of coal produced by surface mining methods and 8 percent of the value of the coal produced by underground mining methods. The value of the coal will be determined in accordance with 30 CFR 206.250.

Pursuant to the regulation at 43 CFR 3473.2(f), the applicant for the Caballo West Tract, BTU Western Resources, Inc., has paid a total case-by-case cost recovery processing fee in the amount of $78,660. The successful bidder for the Caballo West Tract, if someone other than the applicant, must pay to the BLM the $78,660 previously paid by BTU Western Resources, Inc. Additionally, the successful bidder must pay all processing costs the BLM will incur after the date this sale notice is published in the **Federal Register**, which are estimated to be $17,400.

Bidding instructions for the LBA tract offered and the terms and conditions of the proposed coal lease are available from the BLM Wyoming State Office at the address above. Case file documents, WYW172657, are available for inspection at the BLM Wyoming State Office.

Donald A. Simpson,

State Director.

[FR Doc. 2011–14987 Filed 6–16–11; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLIDB00100 LF10000PP.HT0000 LXSS024D0000 4500021867]

Notice of Public Meeting, Boise District Resource Advisory Council, Idaho

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Public Meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act (FLPMA) and the Federal Advisory Committee Act of 1972 (FACA), the U.S. Department of the Interior, Bureau of Land Management (BLM) Boise District Resource Advisory Council (RAC), will hold a meeting as indicated below.

DATES: The meeting will be held July 13, 2011 at the Boise District Office, located at 3948 S. Development Avenue, Boise, Idaho, beginning at 9 a.m. and adjourning at 4:30 p.m. Members of the public are invited to attend. A public comment period will be held.

FOR FURTHER INFORMATION CONTACT: MJ Byrne, Public Affairs Officer and RAC Coordinator, BLM Boise District, 3948 Development Ave., Boise, ID 83705, Telephone (208) 384–3393.

SUPPLEMENTARY INFORMATION: The 15-member Council advises the Secretary of the Interior, through the BLM, on a variety of planning and management issues associated with public land management in southwestern Idaho. Items on the agenda include reports by the RAC's Resource Management Plan Subgroup on its collaborative actions following the RAC Symposium. Discussion on draft sections of the Four Fivers Field Office Resource Management Plan (RMP) and Bruneau RMP, provided before the meeting will be held. Also included are updates on actions related to implementation of the Owyhee Public Lands Management Act and actions in each field office. Agenda items and location may change due to changing circumstances. The public may present written or oral comments to members of the Council. At each full RAC meeting, time is provided in the agenda for hearing public comments. Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited. Individuals who plan to attend and need special assistance should contact the BLM Coordinator as provided above. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

Dated: June 9, 2011.

Arnold L. Pike,

Acting District Manager.

[FR Doc. 2011–15048 Filed 6–16–11; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLIDI02000.L71220000.EO0000. LVTFD0980300]

Notice of Availability of Record of Decision for the Proposed Blackfoot Bridge Mine, Caribou County, ID

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Availability.

SUMMARY: The Bureau of Land Management (BLM) is announcing the availability of the Record of Decision (ROD) for the proposed Blackfoot Bridge Mine.

DATES: The ROD is now available. Implementation of this decision may begin at the close of an appeal-filing period which begins June 17, 2011 and ends 30 days after June 17, 2011.

ADDRESSES: Copies of the Blackfoot Bridge Mine ROD are available in the BLM Pocatello Field Office at the following address: 4350 Cliffs Drive, Pocatello, Idaho 83204. In addition, an electronic copy of the ROD is available at the following Web site: *http://www.blm.gov/id/st/en/prog/0.html.*

FOR FURTHER INFORMATION CONTACT: Kyle Free, Bureau of Land Management, Pocatello Field Office, 4350 Cliffs Drive, Pocatello, Idaho 83204, phone (208) 478–6368, fax (208) 478–6376. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, seven days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The BLM has made the decision to approve the Blackfoot Bridge Mine and Reclamation Plan as defined by Alternative 1A, subject to the environmental protection measures of the Proposed Action and Alternative 1A, mitigation, monitoring, and conditions developed in the Final Environmental Impact Statement (EIS), and subject to additional conditions described in the ROD. The BLM has also decided to recommend the proposed lease modification to lease I–05613. This decision is consistent with the Prefered Alternative as described and analyzed in the Final EIS.

The BLM approves of Alternative 1A because this alternative employs reasonable measures to satisfy regulatory requirements and adequately reduces potential environmental impacts on local and regional water quality. A Geosynthetic Clay Liner Laminate cover system is the most notable of these mitigation measures, but other measures such as an Overburden Seepage Management System, will also reduce potential impacts. The effectiveness of these measures is enhanced by the development of specific management plans for the implementation of additional environmental control measures. As detailed in the Final EIS, these measures include, but are not limited to the Water Management Plan, the Environmental Monitoring Plan, and the Adaptive Management Plan.

As conditions of approval for the Blackfoot Bridge Mine, P4 or the Federal lease holder, its employees, contractors, agents, assignees, and operators must comply with the mitigation and monitoring measures as well as other requirements defined in the Final EIS, the ROD, and conditions defined by cooperating agencies in their decisions. Conditions of Approval defined in the ROD cover performance bonding, monitoring, construction quality assurance, oversight funding, water rights, and other requirements.

Implementation of the decision may begin at the close of an appeal-filing period which begins with this notice and ends in 30 days. Information and procedures for taking appeals to the Interior Board of Land Appeals are provided in Appendix IV of the ROD.

Authority: Mineral Leasing Act of 1920, as amended (30 U.S.C. 181 *et seq.*); the Federal Land Policy and Management Act of 1976, as amended (43 U.S.C. 1701 *et seq.*); and 40 CFR part 1500.

Joe Kraayenbrink,

BLM Idaho Falls District Manager.

[FR Doc. 2011–15241 Filed 6–16–11; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF THE INTERIOR

National Park Service

[2031–A154–422]

Deer and Vegetation Management Plan/Environmental Impact Statement, Fire Island National Seashore, New York

AGENCY: National Park Service, Department of the Interior.

ACTION: Notice of Intent to prepare an Environmental Impact Statement for a Deer and Vegetation Management Plan, Fire Island National Seashore, New York.

SUMMARY: Pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4332(2)(C), the National Park Service is preparing an Environmental Impact Statement (EIS) for a Deer and Vegetation Management Plan at Fire Island National Seashore, New York. The purpose of taking action at this time is to address issues associated with the abundance and distribution of white-tailed deer at Fire Island National Seashore (Seashore). The issues include impacts from deer on the natural and cultural resources of the Seashore as well as impacts resulting from deer-human interaction. Actions addressing these issues will be designed and undertaken in support of the long-term protection, preservation, and restoration of Seashore resources.

Information collected as part of research conducted at the Seashore has indicated the need for a management plan to address changes in deer abundance and deer behavior due to the presence of human food sources and habituation to the unthreatening presence of humans; adverse impacts on native vegetation resulting from current levels of deer browsing; and adverse impacts on natural and cultural resources at the William Floyd Estate resulting from current deer population levels.

DATES: The National Park Service will accept comments from the public through July 18, 2011.

ADDRESSES: Information will be available for public review and comment online at *http://parkplanning.nps.gov/fiis,* at Park Headquarters (120 Laurel St, Patchogue, NY 11772), the Fire Island Lighthouse, and the Wilderness Visitor Center.

FOR FURTHER INFORMATION CONTACT: Paula Valentine (631–687–4759) or Lindsay Ries (631–687–4768).

SUPPLEMENTARY INFORMATION: For 30 years, Seashore staff have been involved with issues linked to the deer population on Fire Island. Initially, concerns were focused around a noticeable increase in the number of deer within the communities of western Fire Island and the appearance of Lyme disease among island residents and park employees. Later, a re-evaluation of permanent sample plots established in 1967 in the Sunken Forest area of the Seashore documented the impacts of deer browsing on understory vegetation within a decade of the Seashore's establishment. As a result of these concerns, Seashore staff, along with academic and agency scientists, embarked on a series of investigations documenting and describing deer abundance and distribution across the island; ecology of Lyme disease and its host vectors including ticks, birds, and

mammals; browsing impacts on vegetation; fertility control as a potential deer population management tool; community relations relative to garbage disposal, and inadvertent and intentional feeding and/or poisoning of deer; the role of disturbance on the regeneration capacity of the Sunken Forest and the likelihood of its future conservation; and the human dimensions of deer abundance. More recently, Seashore staff has turned their attention to the potential impacts of deer on native vegetation in other natural zones of the Seashore and the cultural landscape of the William Floyd Estate.

Information collected as part of this research has indicated the need for a management plan to address changes in deer abundance and deer behavior due to the presence of human food sources and habituation to the unthreatening presence of humans; adverse impacts on native vegetation resulting from current levels of deer browsing; and adverse impacts on natural and cultural resources at the William Floyd Estate resulting from current deer population levels.

A scoping newsletter will be prepared which identifies the issues and statements of purpose, need, and objectives identified to date during internal scoping meetings. Copies of that information and other updates may be obtained online at *http://parkplanning.nps.gov/fiis* or at the address and phone numbers listed above. If you wish to comment on the purpose, need, objectives, or on any other issues associated with the plan, you may submit your comments via the Internet at *http://parkplanning.nps.gov/fiis* and by mailing or hand-delivering comments to Fire Island National Seashore, *Attn:* Deer and Vegetation Management Plan, 120 Laurel St, Patchogue, NY 11772. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dennis R. Reidenbach,

Regional Director, Northeast Region, National Park Service.

[FR Doc. 2011–15064 Filed 6–16–11; 8:45 am]

BILLING CODE 4310–YV–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–SER–BICY–0601–7609; 5120–SZM]

Cancellation of June 23, 2011, Meeting of the Big Cypress National Preserve Off-Road Vehicle (ORV) Advisory Committee

AGENCY: Department of the Interior, National Park Service, ORV Advisory Committee.

ACTION: Cancellation of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770, 5 U.S.C. App 1, 10), notice is hereby given that the June 23, 2011, meeting of the Big Cypress National Preserve ORV Advisory Committee previously announced in the **Federal Register**, Vol. 76, January 20, 2011, p. 3653, is cancelled.

FOR FURTHER INFORMATION CONTACT: Pedro Ramos, Superintendent, Big Cypress National Preserve, 33100 Tamiami Trail East, Ochopee, Florida 34141–1000; 239–695–1103.

SUPPLEMENTARY INFORMATION: The Committee was established (**Federal Register**, August 1, 2007, pp. 42108–42109) pursuant to the Preserve's 2000 *Recreational Off-road Vehicle Management Plan* and the Federal Advisory Committee Act of 1972 (5 U.S.C. Appendix) to examine issues and make recommendations regarding the management of off-road vehicles (ORVs) in the Preserve. The agendas for these meetings are published by press release and on the *http://parkplanning.nps.gov/projectHome.cfm?parkId=352&projectId=20437* Web site. The meetings are open to the public, and time is reserved for public comment. Oral comments are summarized for the record. If you wish to have your comments recorded verbatim, you must submit them in writing. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: June 1, 2011.

Pedro Ramos,

Superintendent, Big Cypress National Preserve.

[FR Doc. 2011–15068 Filed 6–16–11; 8:45 am]

BILLING CODE 4310–V6–P

DEPARTMENT OF THE INTERIOR

National Park Service

Star-Spangled Banner National Historic Trail Advisory Council

AGENCY: National Park Service, Interior.

ACTION: Notice of meeting.

SUMMARY: As required by the Federal Advisory Committee Act, the National Park Service (NPS) is hereby giving notice that the Advisory Committee on the Star-Spangled Banner National Historic Trail will hold a meeting. Designated through an amendment to the National Trails System Act (16 U.S.C. 1241), the trail consists of ''water and overland routes totaling approximately 290 miles, extending from Tangier Island, Virginia, through southern Maryland, the District of Columbia, and northern Virginia, in the Chesapeake Bay, Patuxent River, Potomac River, and north to the Patapsco River, and Baltimore, Maryland, commemorating the Chesapeake Campaign of the War of 1812 (including the British invasion of Washington, District of Columbia, and its associated feints, and the Battle of Baltimore in summer 1814).'' This meeting is open to the public. Preregistration is required for both public attendance and comment. Any individual who wishes to attend the meeting and/or participate in the public comment session should register via e-mail at *Christine_Lucero@nps.gov* or *telephone:* (757) 258–8914. For those wishing to make comments, please provide a written summary of your comments prior to the meeting. The Designated Federal Official for the Advisory Council is John Maounis, Superintendent, Chesapeake Bay Office, *telephone:* (410) 260–2471.

DATES: The Star-Spangled Banner National Historic Trail Advisory Council will meet from 10 a.m. to 4:30 p.m. on Wednesday, June 29, 2011.

ADDRESSES: The meeting will be held at the Fort McHenry National Monument and Historic Shrine Visitor Center, 2400 East Fort Avenue, Baltimore, MD 21230. For more information, please contact the NPS Chesapeake Bay Office, 410 Severn Avenue, Suite 314, Annapolis, MD 21403.

FOR FURTHER INFORMATION CONTACT: Christine Lucero, Partnership Coordinator for the Star-Spangled Banner National Historic Trail, *telephone:* (757) 258–8914 or *e-mail: Christine_Lucero@nps.gov.*

SUPPLEMENTARY INFORMATION: Under section 10(a)(2) of the Federal Advisory

Committee Act (5 U.S.C. App.), this notice announces a meeting of the Star-Spangled Banner National Historic Trail Advisory Council. Topics to be discussed include a review of the purpose of the Advisory Council, a review of the Comprehensive Management Plan planning process and an assessment of public meeting results. The Committee meeting is open to the public. Members of the public who would like to make comments to the Committee should preregister via e-mail at *Christine_Lucero@nps.gov* or *telephone:* (757) 258–8914; a written summary of comments should be provided prior to the meeting. Comments will be taken for 30 minutes at the end of the meeting (from 4 p.m. to 4:30 p.m.). Before including your address, telephone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. All comments will be made part of the public record and will be electronically distributed to all Committee members.

Dated: June 1, 2011.

John Maounis,

Superintendent, Chesapeake Bay Office, National Park Service, Department of the Interior.

[FR Doc. 2011–15063 Filed 6–16–11; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–0611–7599; 2280–665]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

Nominations for the following properties being considered for listing or related actions in the National Register were received by the National Park Service before May 28, 2011. Pursuant to section 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation. Comments may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St., NW., MS 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye St., NW., 8th floor, Washington, DC 20005; or by fax, 202–371–6447. Written or faxed comments should be submitted by July 5, 2011. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

J. Paul Loether,

Chief, National Register of Historic Places/National Historic Landmarks Program.

TENNESSEE

Blount County

Henry Farm (Boundary Increase), 305 Henry Ln., Brick Mill, 11000417

Davidson County

Alumni Memorial Hall, 2205 West End Ave., Nashville, 11000418

U.S. Naval Reserve Training Center, 1515 Davidson St., Nashville, 11000419

Hamilton County

Oak Grove Elementary School, 1912 S. Willow St., Chattanooga, 11000420

White County

Nashville, Chattanooga and St. Louis Railway Section House, 9479 Crossville Hwy., DeRossett, 11000421

Williamson County

Coats—Hines Archeological Site, Address Restricted, Franklin, 11000422

TEXAS

Bexar County

Heidemann Ranch, (Farms and Ranches of Bexar County, Texas) 26090 Toutant Beauregard Rd., San Antonio, 11000423

Guadalupe County

Hardscramble, 1806 Tschoepe Rd., Seguin, 11000424

Harris County

Idylwood Historic District, (Historic Residential Suburbs in the United States, 1830–1960 MPS) Roughly bounded by Lawndale Ave., N. MacGregor Wy., Sylvan Rd. & Wayside Dr., Houston, 11000425

WASHINGTON

King County

New Richmond Hotel, 308 4th Ave., S., Seattle, 11000426

Queen Anne Post Office and Regional Headquarters, 415 1st Ave., S., Seattle, 11000427

[FR Doc. 2011–15036 Filed 6–16–11; 8:45 am]

BILLING CODE 4312–51–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–777]

In the Matter of Certain Muzzle-Loading Firearms and Components Thereof; Notice of Institution of Investigation; Institution of Investigation Pursuant to 19 U.S.C. 1337

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint and a motion for temporary relief were filed with the U.S. International Trade Commission on May 11, 2011, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Thompson/Center Arms Company, Inc. of Springfield, Massachusetts and Smith & Wesson Corp. of Springfield, Massachusetts. A supplement to the complaint was filed on June 2, 2011. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain muzzle-loading firearms and components thereof by reason of infringement of certain claims of U.S. Patent No. 7,908,781 (''the '781 patent''); U.S. Patent No. 7,814,694 (''the '694 patent''); U.S. Patent No. 7,140,138 (''the '138 patent''); U.S. Patent No. 6,604,311 (''the '311 patent''); U.S. Patent No. 5,782,030 (''the '030 patent''); and U.S. Patent No. 5,639,981 (''the '981 patent''). The complaint further alleges that an industry in the United States exists or is in the process of being established as required by subsection (a)(2) of section 337.

The complainants request that the Commission institute an investigation and, after the investigation, issue an exclusion order and cease and desist orders.

The motion for temporary relief requests that the Commission issue a temporary limited exclusion order and temporary cease and desist order prohibiting the importation into and the sale within the United States after importation of certain muzzle-loading firearms and components thereof that infringe claim 11 of the '781 patent; claims 1–3 and 10–12 of the '694 patent; claims 19 and 20 of the '138 patent; claims 1 and 6 of the '311 patent; claims 1–5 of the '030 patent; and claims 1 and 2 of the '981 patent during the course of the Commission's investigation.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection

during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR ' 210.10 (2011).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on June 13, 2011, *Ordered That*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain muzzle-loading firearms and components thereof that infringe one or more of claim 11 of the '781 patent; claims 1–3 and 10–12 of the '694 patent; claims 19 and 20 of the '138 patent; claims 1 and 6 of the '311 patent; claims 1–5 of the '030 patent; and claims 1 and 2 of the '981 patent, and whether an industry in the United States exists or is in the process of being established as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.58 of the Commission's Rules of Practice and Procedure, 19 C.F.R. § 210.58, the motion for temporary relief under subsection (e) of section 337 of the Tariff Act of 1930, which was filed with the complaint, is provisionally accepted and referred to the presiding administrative law judge for investigation;

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:

Thompson/Center Arms Company, Inc., 2100 Roosevelt Avenue, Springfield, MA 01104.

Smith & Wesson Corp., 2100 Roosevelt Avenue, Springfield, MA 01104.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Dikar Sociedad Cooperativa Limitada, Calle Urarte Kalea—Pol. Ind. San, Lorenzo 26 APTDO 193 20570 Bergara, Spain,

Bergara Barrels Europe, Urarte, 26 Bergara 20570, Spain.

Blackpower Products Inc., 1685 Boggs Road, Suite 300, Duluth, GA 30096.

Connecticut Valley Arms, 1685 Boggs Road, Suite 300, Duluth, GA 30096.

Bergara Barrels North America, 1685 Boggs Road, Suite 300, Duluth, GA 30096.

Ardesa Firearms, Camino de Talleri, s/n, 48170 Zamudio-Vizcoya, Spain.

Traditional Sporting Goods, Inc., d/b/a Traditions Sporting Firearms, 1375 Boston Post Road, P.O. Box 776, Old Saybrook, CT 06475.

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, SW., Suite 401, Washington, DC 20436; and

(4) For the investigation so instituted, the Honorable Paul J. Luckern, Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR § 210.13. Pursuant to 19 CFR § 201.16(d)–(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: June 14, 2011.

James R. Holbein,

Secretary to the Commission.

[FR Doc. 2011–15075 Filed 6–16–11; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–11–015]

Government in the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: June 21, 2011 at 11 a.m.

PLACE: Room 110, 500 E Street, SW., Washington, DC 20436, *Telephone:* (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: none.
2. Minutes.
3. Ratification List.
4. Vote in Inv. No. 731–TA–385 (Third Review) (Granular Polytetrafluoroethylene from Italy). The Commission is currently scheduled to transmit its determination and Commissioners' opinions to the Secretary of Commerce on or before June 29, 2011.
5. Outstanding action jackets: None.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: June 14, 2011.

William R. Bishop,

Hearings and Meetings Coordinator.

[FR Doc. 2011–15188 Filed 6–15–11; 11:15 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under the Comprehensive Environmental Response, Compensation and Liability Act, the Resource Conservation and Recovery Act, and the Clean Water Act

In accordance with Departmental Policy, 28 CFR 50.7, notice is hereby given that on June 13, 2011, a proposed consent decree was lodged with the

United States District Court for the District of Idaho in *United States of America et al.* v. *Hecla Limited,* Civil Action No. 96–0122–N–EJL (D. Idaho), and two consolidated cases (Civil Action Nos. 91–0342–N–EJL and 94–0206–N–HLR). The proposed Consent Decree settles claims of the United States, the Coeur d'Alene Tribe, and the State of Idaho against Hecla Limited, Hecla Mining Company, Hecla Silver Valley, Inc., HLT, Inc., and Silver Hunter Mining Company for response costs and natural resource damages stemming from certain releases of hazardous substances from historic mining and mining-related operations at the Bunker Hill Mining and Metallurgical Complex Superfund Site. The Site is generally located in the Coeur d'Alene Basin watershed in Idaho.

The lawsuit seeks damages for injuries to natural resources such as fish and birds caused by millions of tons of mining wastes that had been released into the South Fork of the Coeur d'Alene River and its tributaries. The United States Environmental Protection Agency has been performing cleanup work in the Coeur d'Alene Basin since the early 1980s, and the suit also seeks reimbursement of EPA's cleanup costs.

Most of the defendants settled before trial. After a 78-day trial, the district court in Idaho ruled in 2003 that the remaining defendants, Hecla and ASARCO, had liability for natural resource damages and response costs and that the amount of their liability would be determined in a second phase of litigation. The litigation in the district court in Idaho was stayed in 2005 when ASARCO filed a petition for reorganization under Chapter 11 of the Bankruptcy Code in the United States Bankruptcy Court for the Southern District of Texas. ASARCO reached settlement with the United States in 2008, and paid the settlement amounts in full after the bankruptcy court in Texas approved ASARCO's plan of reorganization. Accordingly, the federal district court in Idaho dismissed the claims against ASARCO on September 8, 2010. The court also postponed the second phase of the trial against Hecla to allow time to negotiate a settlement. Hecla is the only remaining defendant.

Among other things, the proposed consent decree will require Hecla to pay $263.4 million plus interest to the United States, the Coeur d'Alene Tribe, and the State. Of that total, about $180 million would go toward the United States' past response costs and future response actions to address the mining waste being remediated by EPA; $60 million would go toward natural resources damages for joint federal/state/tribal resources, including the United States Department of the Interior and the United States Department of Agriculture; $17 million would go toward satisfying Hecla's remaining obligations under an earlier consent decree to fund response actions for part of the Site; $4 million would go toward the Tribe's past costs; and $2 million would go toward a State/Tribe management plan for Lake Couer d'Alene.

Those payments are within Hecla's financial means. A settlement based purely on litigation concerns would have been beyond Hecla's ability to fund and remain financially viable. The settlement process involved an in-depth review by the United States' mining and financial experts of Hecla's finances, including proprietary and confidential internal financial information. That review determined that Hecla could not fully pay its alleged liability. The payments to be made by Hecla under the proposed Consent Decree therefore reflect Hecla's ability to pay, given Hecla's financial condition, the highly volatile nature of metal prices, and the fact that Hecla's profitability is extremely sensitive to those metals' prices.

The settlement also includes a process for coordinating Hecla's future mining operations with EPA's cleanup activities in the Couer d'Alene Basin. These provisions are designed to avoid and minimize potential conflicts between cleanup activities and mining operations wherever possible. The proposed consent decree includes a covenant not to sue by the United States under Sections 106 and 107(a) of the Comprehensive Environmental Response, Compensation and Liability Act, 42 U.S.C. 9606 & 9607(a); Section 7003 of the Resource Conservation and Recovery Act, 42 U.S.C. 6973; and Sections 309, 311 and 504 of the Clean Water Act, 33 U.S.C. 1319, 1321 & 1364.

For 30 days after the date of this publication, the Department of Justice will receive comments relating to the proposed consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either e-mailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *United States* v. *Hecla Limited,* DJ Reference Nos. 90–11–3–128L. Commenters may request an opportunity for a public meeting in the affected area, in accordance with Section 7003(d) of RCRA, 42 U.S.C. 6973(d).

The proposed consent decree may be examined at the Office of the United States Attorney for the District of Idaho, Washington Group Plaza IV, 800 Park Blvd., Suite 600, Boise, ID 83712. During the public comment period, the Consent Decree may also be examined on the following Department of Justice Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the proposed consent decree may be obtained by mailing a request to the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611. When requesting a copy by mail, please enclose a check payable to the U.S. Treasury in the amount of $65.50 for the complete consent decree or $16.50 for the consent decree without the appendices (25 cents per page reproduction cost). A copy may also be obtained by faxing or e-mailing a request to Tonia Fleetwood, *tonia.fleetwood@usdoj.gov,* fax number (202) 514–0097, phone confirmation number (202) 514–1547, and sending a check to the Consent Decree Library at the stated address.

Robert E. Maher, Jr.,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2011–15014 Filed 6–16–11; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Material Modification to Consent Decree Under the Clean Air Act

Pursuant to Department of Justice policy, notice is hereby given that, on June 14, 2011, a proposed Second Material Modification to Consent Decree (''Second Decree Modification'') in *United States, et al.* v. *Bunge North America, Inc., et al.,* Civil Action No. 2:06–cv–02209–MPM–DGB (C.D. Ill.) was lodged with the United States District Court for the Central District of Illinois. The original Consent Decree in this matter, entered on January 16, 2007, addressed alleged violations of the Clean Air Act, 42 U.S.C. 7401–7671q, and its implementing regulations at 12 soybean and corn processing facilities owned and operated by Bunge North America, Inc. and several affiliated entities (collectively referred to herein as ''Bunge''). A First Decree Modification, entered on June 30, 2010, required Bunge to reduce air pollutant emissions at its Decatur, Indiana facility by installing new equipment to recover and re-use certain condensed waste water streams at the facility. The proposed Second Decree Modification

would require Bunge to perform two substitute projects at the Decatur facility—in lieu of the waste water recovery project—that are expected to yield greater air pollutant emission reductions: (1) A project to recover waste heat from boilers' continuous blowdown; and (2) an improved turbine flash steam heat recovery system.

The Department of Justice will receive comments relating to the Second Decree Modification for a period of thirty (30) days from the date of this publication. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and mailed either electronically to *pubcomment-ees.enrd@usdoj.gov* or in hard copy to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611. Comments should refer to *United States, et al.* v. *Bunge North America, Inc., et al.,* Civil Action No. 2:06–cv–02209–MPM–DGB (C.D. Ill.) and D.J. Ref. No. 90–5–2–1–07950.

The Second Decree Modification may be examined at: (1) The offices of the United States Attorney, 201 South Vine, Suite 226, Urbana, Illinois; and (2) the offices of the U.S. Environmental Protection Agency, 77 West Jackson Boulevard, 14th Floor, Chicago, Illinois. During the public comment period, the Second Decree Modification may also be examined on the following Department of Justice Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the Second Decree Modification may also be obtained by mail from the Department of Justice Consent Decree Library, P.O. Box 7611, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of $3.25 (13 pages at 25 cents per page reproduction cost) payable to the U.S. Treasury.

Maureen M. Katz,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2011–15099 Filed 6–16–11; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Parole Commission

Sunshine Act Meeting

TIME AND DATE: 10 a.m., Tuesday, June 21, 2011.

PLACE: U.S. Parole Commission, 90 K Street, NE., 3rd Floor, Washington, DC.

STATUS: Open.

MATTERS TO BE CONSIDERED: Approval of February 10, 2011 meeting minutes; reports from the Chairman, the Commissioners, and senior staff; discussion of the draft plan for compliance with Executive Order 13563 and analysis of agency rules; discussion of proposed pilot program for sanctioning persons returned to custody for administrative violations; discussion and vote on a final rule on revising guidelines for rating crack cocaine offenses.

CONTACT PERSON FOR MORE INFORMATION: Patricia W. Moore, Staff Assistant to the Chairman, U.S. Parole Commission, 90 K Street, NE., 3rd Floor, Washington, DC 20530, (202) 346–7009.

Dated: June 10, 2011.

Rockne Chickinell,

General Counsel, U.S. Parole Commission.

[FR Doc. 2011–14928 Filed 6–16–11; 8:45 am]

BILLING CODE 4410–31–M

DEPARTMENT OF JUSTICE

Parole Commission

Sunshine Act Meeting

TIME AND DATE: 11 a.m., Tuesday, June 21, 2011.

PLACE: U.S. Parole Commission, 90 K Street, NE., 3rd Floor, Washington, DC.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Determinations on three petitions for reconsideration in original jurisdiction cases (28 CFR 2.27).

CONTACT PERSON FOR MORE INFORMATION: Patricia W. Moore, Staff Assistant to the Chairman, U.S. Parole Commission, 90 K Street, NE., 3rd Floor, Washington, DC 20530, (202) 346–7009.

Dated: June 9, 2011.

Rockne Chickinell

General Counsel, U.S. Parole Commission.

[FR Doc. 2011–14929 Filed 6–16–11; 8:45 am]

BILLING CODE 4410–31–M

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Application for Permanent Employment Certification

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Employment and Training Administration (ETA) sponsored information collection request (ICR) titled, ''Application for Permanent Employment Certification,'' to the Office of Management and Budget (OMB) for review and approval for continued use in accordance with the Paperwork Reduction Act (PRA) of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35).

DATES: Submit comments on or before July 18, 2011.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site, *http://www.reginfo.gov/public/do/PRAMain,* on the day following publication of this notice or by sending an e-mail to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Department of Labor, Employment and Training Administration (ETA), Office of Management and Budget, Room 10235, Washington, DC 20503, Telephone: 202–395–6929/Fax: 202–395–6881 (these are not toll-free numbers), e-mail: *OIRA_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Contact the DOL Information Management Team by e-mail at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The application form and other information requirements are necessary to the collection of information from U.S. employers wishing to sponsor foreign labor for permanent residency through the Labor Certification process. The information collected is used by the Secretary of Labor to make the necessary certification in compliance with the Immigration and Nationality Act as amended.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information if the collection of information does not display a valid OMB control number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this

information collection under OMB Control Number 1205–0451. The current OMB approval is scheduled to expire on June 30, 2011; however, it should be noted that information collections submitted to the OMB receive a month-to-month extension while they undergo review. For additional information, see the related notice published in the **Federal Register** on January 12, 2011 (76 FR 2143).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within 30 days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should reference OMB Control Number 1205–0451. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: Employment and Training Administration (ETA).

Title of Collection: Application for Permanent Employment Certification.

OMB Control Number: 1205–0451.

Affected Public: Businesses or other for-profits, Farms, and Not-for-profit institutions.

Total Estimated Number of Respondents: 94,600.

Total Estimated Number of Responses: 94,600.

Total Estimated Annual Burden Hours: 223,256.

Total Estimated Annual Other Costs Burden: $750,000.

Linda Watts-Thomas,

Acting Departmental Clearance Officer.

[FR Doc. 2011–15067 Filed 6–16–11; 8:45 am]

BILLING CODE 4510–FP–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Sealing of Abandoned Areas

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Mine Safety and Health Administration (MSHA) sponsored information collection request (ICR) titled, ''Sealing of Abandoned Areas,'' to the Office of Management and Budget (OMB) for review and approval for continued use in accordance with the Paperwork Reduction Act (PRA) of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35).

DATES: Submit comments on or before July 18, 2011.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the *RegInfo.gov* Web site, *http://www.reginfo.gov/public/do/PRAMain,* on the day following publication of this notice or by sending an e-mail to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request to the Office of Information and Regulatory Affairs, *Attn:* OMB Desk Officer for the Department of Labor, Mine Safety and Health Administration (MSHA), Office of Management and Budget, Room 10235, Washington, DC 20503, *Telephone:* 202–395–6929/Fax: 202–395–6881 (these are not toll-free numbers), e-mail: *OIRA_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Contact the DOL Information Management Team by e-mail at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: These standards strengthen the design, construction, maintenance, and repair of seals and monitoring and control of atmospheres behind seals in order to reduce the risk of seal failure and the risk of explosions in abandoned areas of underground coal mines.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information if the collection of information does not display a valid OMB control number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under OMB Control Number 1219–0142. The current OMB approval is scheduled to expire on June 30, 2011; however, it should be noted that information collections submitted to the OMB receive a month-to-month extension while they undergo review. For additional information, see the related notice published in the **Federal Register** on February 17, 2011 (76 FR 9375).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within 30 days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should reference OMB Control Number 1219–0142. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: Mine Safety and Health Administration (MSHA).

Title of Collection: Sealing of Abandoned Areas.

OMB Control Number: 1219–0142.

Affected Public: Businesses or other for-profits.

Total Estimated Number of Respondents: 361.

Total Estimated Number of Responses: 90,234.

Total Estimated Annual Burden Hours: 9,210.

Total Estimated Annual Other Costs Burden: $762,163.

Linda Watts-Thomas,

Acting Departmental Clearance Officer.

[FR Doc. 2011–15090 Filed 6–16–11; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–73,562]

Colville Indian Plywood and Veneer, Colville Tribal Enterprise Corporation Wood Products Division, Including On-Site Workers from Colville Tribal Construction and On-Site Contract Workers from C & K General Contractor, Doran Richter Logging, ERB Corporation, Francis L. Seymour, Gene Matt Trucking, George Marchand, Havillah Logging, Joe Peone, Joe Somday Logging, Jus'n Logging, Laramie Logging, Lone Rock Contracting, Mawdsley Logging, Mccuen Jones, San Poil Logging, Scott Thorndike, Silver Nichol Trucking and Stensgar Logging, Omak, WA; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to apply for Worker Adjustment Assistance on May 20, 2010, applicable to workers of Colville Indian Plywood and Veneer, Colville Tribal Enterprise Corporation Wood Products Division, Omak, Washington. The Department's Notice was published in the **Federal Register** on June 7, 2010 (75 FR 32223). The certification was amended on June 30, 2010 to include on-site contract worker firms. The Department's Notice of amended certification was published in the **Federal Register** on July 19, 2010 (75 FR 41896–41897).

At the request of the Washington State Labor Council, AFL–CIO, and the State agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in activities related to the production of boards and dimensional lumber of ponderosa pine.

The company reports that workers of Colville Tribal Construction were employed on-site at the Omak, Washington location of Colville Indian Plywood and Veneer, Colville Tribal Enterprise Corporation Wood Products Division, to perform construction, electrical and operational maintenance support functions. The Department has determined that these workers were sufficiently under the control of the subject firm to be included in this certification.

Based on these findings, the Department is amending this certification to include employees of Colville Tribal Construction working on-site at the Omak, Washington location of Colville Indian Plywood and Veneer, Colville Tribal Enterprise Corporation Wood Products Division.

The amended notice applicable to TA–W–73,596 is hereby issued as follows:

''All workers of Colville Indian Plywood and Veneer, Colville Tribal Enterprise Corporation Wood Products Division, including on-site workers from Colville Tribal Construction and on-site contract workers from C & K General Contractor, Doran Richter Logging, Erb Corporation, Francis L. Seymour, Gene Matt Trucking, George Marchand, Havillah Logging, Joe Peone, Joe Somday Logging, Jes'N Logging, Laramie Logging, Lone Rock Contracting, Mawdsley Logging, McCuen Jones, San Poil Logging, Scott Thorndike, Silver Nichol Trucking and Stensgar Logging, Omak, Washington, who became totally or partially separated from employment on or after February 24, 2009, through May 20, 2012, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.''

Signed in Washington, DC, this 9th day of June 2011.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–15081 Filed 6–16–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–71,047; TA–W–71,047A]

UAW–Chrysler Technical Training Center, Technology Training Joint Programs Staff, Including On-Site Leased Workers From Cranks, O/E Learning, DBSI, IDEA, and Tonic/MVP, Detroit, MI; UAW–Chrysler Technical Training Center, Technology Training Joint Programs Staff, Including On-Site Leased Workers From Cranks, O/E Learning, DBSI, IDEA, and Tonic/MVP, Warren, MI; Amended Revised Determination on Reconsideration

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor (Department) issued a Revised Determination on Reconsideration on December 22, 2010, applicable to workers and former workers of UAW–Chrysler Technical Training Center, Technology Training Joint Programs Staff, Detroit, Michigan (TA–W–71,047) and Warren, Michigan (TA–W–71,047A). The workers supply technical training services such as applied industrial technology, industrial automation, industrial maintenance and welding. The Department's Notice was published in the **Federal Register** on January 12, 2011 (76 FR 2147–2148).

The certification was amended on May 18, 2011 include on-site leased workers from Manpower. The amended Notice was published in the Federal Regis on May 27, 2011 (76 FR 30974).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm.

New findings show that workers leased from Manpower were erroneously including in the certification document. Company officials and the State workforce agency have confirmed that only workers leased from Cranks, O/E Learning, DBSI, Idea, and Tonic/MVP were employed on-site at the Detroit, Michigan and Warren, Michigan locations of UAW–Chrysler National Training Center, Technology Training Joint Programs Staff. The Department has determined that these workers were sufficiently under the control of UAW–Chrysler National Training Center, Technology Training Joint Programs Staff to be considered leased workers.

Accordingly, the Department is amending this certification to properly reflect this matter.

The intent of the Department's certification is to include all workers of the subject firm who were adversely affected by increased imports.

The amended notice applicable to TA–W–71,047 and TA–W–71,047A are hereby issued as follows:

''All workers of UAW–Chrysler National Training Center, Technology Training Joint Programs Staff, including on-site leased workers from Cranks, O/E Learning, DBSI, Idea, and Tonic/MVP, Detroit, Michigan (TA–W–71,047) and UAW–Chrysler National Training Center, Technology Training Joint Programs Staff, including on-site leased workers from Cranks, O/E Learning, DBSI, Idea, and Tonic/MVP, Warren, Michigan (TA–W–71,047A), who became totally or partially separated from employment on or after May 27, 2008, through December 22, 2012, and all workers in the group threatened with total or partial separation from employment on date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.''

Signed in Washington, DC, this 9th day of June 2011.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–15082 Filed 6–16–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA–W) number and alternative trade adjustment assistance (ATAA) by (TA–W) number issued during the period of May 30, 2011 through June 3, 2011.

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Section (a)(2)(A) all of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. The sales or production, or both, of such firm or subdivision have decreased absolutely; and

C. Increased imports of articles like or directly competitive with articles produced by such firm or subdivision have contributed importantly to such workers' separation or threat of separation and to the decline in sales or production of such firm or subdivision; or

II. Section (a)(2)(B) both of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. There has been a shift in production by such workers' firm or subdivision to a foreign country of articles like or directly competitive with articles which are produced by such firm or subdivision; and

C. One of the following must be satisfied:

1. The country to which the workers' firm has shifted production of the articles is a party to a free trade agreement with the United States;

2. The country to which the workers' firm has shifted production of the articles to a beneficiary country under the Andean Trade Preference Act, African Growth and Opportunity Act, or the Caribbean Basin Economic Recovery Act; or

3. There has been or is likely to be an increase in imports of articles that are like or directly competitive with articles which are or were produced by such firm or subdivision.

Also, in order for an affirmative determination to be made for secondarily affected workers of a firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) Significant number or proportion of the workers in the workers' firm or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The workers' firm (or subdivision) is a supplier or downstream producer to a firm (or subdivision) that employed a group of workers who received a certification of eligibility to apply for trade adjustment assistance benefits and such supply or production is related to the article that was the basis for such certification; and

(3) Either—

(A) The workers' firm is a supplier and the component parts it supplied for the firm (or subdivision) described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) A loss or business by the workers' firm with the firm (or subdivision) described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for the Division of Trade Adjustment Assistance to issue a certification of eligibility to apply for Alternative Trade Adjustment Assistance (ATAA) for older workers, the group eligibility requirements of Section 246(a)(3)(A)(ii) of the Trade Act must be met.

1. Whether a significant number of workers in the workers' firm are 50 years of age or older.

2. Whether the workers in the workers' firm possess skills that are not easily transferable.

3. The competitive conditions within the workers' industry (*i.e.,* conditions within the industry are adverse).

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) of the Trade Act have been met.

None.

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production) of the Trade Act have been met.

None.

The following certifications have been issued. The requirements of Section 222(b) (supplier to a firm whose workers are certified eligible to apply for TAA) of the Trade Act have been met.

None.

The following certifications have been issued. The requirements of Section 222(b) (downstream producer for a firm whose workers are certified eligible to apply for TAA based on increased imports from or a shift in production to Mexico or Canada) of the Trade Act have been met.

None.

Affirmative Determinations for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA–W–80,004; Sensata Technologies, Freeport, IL: February 15, 2010.

TA–W–80,023; The Fenton Art Glass Company, Willamstown, WV: March 1, 2010.

TA–W–80,072; Alcoa, Inc., Rockdale, Texas: December 4, 2010.

TA–W–80,072A; Leased Workers from Bramtex, Concentra Medical, Hagameyer, T&K, Zachary, Rockdale, Texas: March 24, 2010.

TA–W–80,134; Premier Pet Products, Inc. & Premier Pit Products, LLC, Midlothian, VA: April 27, 2010.

TA–W–80,188; Berkline/BenchCraft, LLC, Morristown, TN: August 1, 2011.

TA–W–80,189; Bristol Products Corp., Bristol, TN: May 20, 2010.

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production) and Section 246(a)(3)(A)(ii) of the Trade Act have been met. None.

The following certifications have been issued. The requirements of Section 222(b) (supplier to a firm whose workers are certified eligible to apply for TAA) and Section 246(a)(3)(A)(ii) of the Trade Act have been met. None.

The following certifications have been issued. The requirements of Section 222(b) (downstream producer for a firm whose workers are certified eligible to apply for TAA based on increased imports from or a shift in production to Mexico or Canada) and Section 246(a)(3)(A)(ii) of the Trade Act have been met. None.

Negative Determinations for Alternative Trade Adjustment Assistance

In the following cases, it has been determined that the requirements of 246(a)(3)(A)(ii) have not been met for the reasons specified.

The Department has determined that criterion (1) of Section 246 has not been met. The firm does not have a significant number of workers 50 years of age or older. None.

The Department has determined that criterion (2) of Section 246 has not been met. Workers at the firm possess skills that are easily transferable. None.

The Department has determined that criterion (3) of Section 246 has not been met. Competition conditions within the workers' industry are not adverse. None.

Negative Determinations for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In the following cases, the investigation revealed that the eligibility criteria for worker adjustment assistance have not been met for the reasons specified.

Because the workers of the firm are not eligible to apply for TAA, the workers cannot be certified eligible for ATAA.

The investigation revealed that criteria (a)(2)(A)(I.A.) and (a)(2)(B)(II.A.) (employment decline) have not been met.

TA–W–80,082; United Furniture Industries, Amory, MS.

The investigation revealed that criteria (a)(2)(A)(I.B.) (Sales or production, or both, did not decline) and (a)(2)(B)(II.B.) (shift in production to a foreign country) have not been met. None.

The investigation revealed that criteria (a)(2)(A)(I.C.) (increased imports) and (a)(2)(B)(II.B.) (shift in production to a foreign country) have not been met.

TA–W–80,050; Marelco Power Systems, Inc., Howell, MI.

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA–W–80,001; Mercer (US), Inc., Chicago, IL.

TA–W–80,143; GlobalTex, LLC, Hudson, MA.

The investigation revealed that criteria of Section 222(b)(2) has not been met. The workers' firm (or subdivision) is not a supplier to or a downstream producer for a firm whose workers were certified eligible to apply for TAA. None.

Determinations Terminating Investigations of Petitions for Worker Adjustment Assistance

After notice of the petitions was published in the **Federal Register** and on the Department's Web site, as required by Section 221 of the Act (19 USC 2271), the Department initiated investigations of these petitions. None.

I hereby certify that the aforementioned determinations were issued during the period of *May 30, 2011 through June 3, 2011.* Copies of these determinations may be requested under the Freedom of Information Act. Request may be submitted by fax, courier services, or mail to FOIA Disclosure Officer, Office of Trade Adjustment Assistance (ETA), U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 or *tofoiarequest@dol.gov.* These determinations also are available on the Department's Web site at *http://www.doleta.gov/tradeact* under the searchable listing of determinations.

Dated: June 10, 2011.

Michael W. Jaffe

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–15085 Filed 6–16–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA–W) number and alternative trade adjustment assistance (ATAA) by (TA–W) number issued during the period of May 23, 2011 through May 27, 2011.

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Section (a)(2)(A) all of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. The sales or production, or both, of such firm or subdivision have decreased absolutely; and

C. Increased imports of articles like or directly competitive with articles produced by such firm or subdivision have contributed importantly to such workers' separation or threat of separation and to the decline in sales or production of such firm or subdivision; or

II. Section (a)(2)(B) both of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. There has been a shift in production by such workers' firm or subdivision to a foreign country of articles like or directly competitive with articles which are produced by such firm or subdivision; and

C. One of the following must be satisfied:

1. The country to which the workers' firm has shifted production of the articles is a party to a free trade agreement with the United States;

2. The country to which the workers' firm has shifted production of the articles to a beneficiary country under the Andean Trade Preference Act, African Growth and Opportunity Act, or the Caribbean Basin Economic Recovery Act; or

3. There has been or is likely to be an increase in imports of articles that are like or directly competitive with articles which are or were produced by such firm or subdivision.

Also, in order for an affirmative determination to be made for secondarily affected workers of a firm and a certification issued regarding

eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) Significant number or proportion of the workers in the workers' firm or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The workers' firm (or subdivision) is a supplier or downstream producer to a firm (or subdivision) that employed a group of workers who received a certification of eligibility to apply for trade adjustment assistance benefits and such supply or production is related to the article that was the basis for such certification; and

(3) Either—

(A) The workers' firm is a supplier and the component parts it supplied for the firm (or subdivision) described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) A loss or business by the workers' firm with the firm (or subdivision) described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for the Division of Trade Adjustment Assistance to issue a certification of eligibility to apply for Alternative Trade Adjustment Assistance (ATAA) for older workers, the group eligibility requirements of Section 246(a)(3)(A)(ii) of the Trade Act must be met.

1. Whether a significant number of workers in the workers' firm are 50 years of age or older.

2. Whether the workers in the workers' firm possess skills that are not easily transferable.

3. The competitive conditions within the workers' industry (*i.e.,* conditions within the industry are adverse).

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) of the Trade Act have been met.

None.

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production) of the Trade Act have been met.

None.

The following certifications have been issued. The requirements of Section 222(b) (supplier to a firm whose workers are certified eligible to apply for TAA) of the Trade Act have been met.

None.

The following certifications have been issued. The requirements of Section 222(b) (downstream producer for a firm whose workers are certified eligible to apply for TAA based on increased imports from or a shift in production to Mexico or Canada) of the Trade Act have been met.

None.

Affirmative Determinations for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA–W–80,122; Honeywell International, Skaneateles, NY: September 23, 2010.

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

None.

The following certifications have been issued. The requirements of Section 222(b) (supplier to a firm whose workers are certified eligible to apply for TAA) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

None.

The following certifications have been issued. The requirements of Section 222(b) (downstream producer for a firm whose workers are certified eligible to apply for TAA based on increased imports from or a shift in production to Mexico or Canada) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

None.

Negative Determinations for Alternative Trade Adjustment Assistance

In the following cases, it has been determined that the requirements of 246(a)(3)(A)(ii) have not been met for the reasons specified.

The Department has determined that criterion (1) of Section 246 has not been met. The firm does not have a significant number of workers 50 years of age or older.

None.

The Department has determined that criterion (2) of Section 246 has not been met. Workers at the firm possess skills that are easily transferable.

None.

The Department has determined that criterion (3) of Section 246 has not been met. Competition conditions within the workers' industry are not adverse.

None.

Negative Determinations for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In the following cases, the investigation revealed that the eligibility criteria for worker adjustment assistance have not been met for the reasons specified.

Because the workers of the firm are not eligible to apply for TAA, the workers cannot be certified eligible for ATAA.

The investigation revealed that criteria (a)(2)(A)(I.A.) and (a)(2)(B)(II.A.) (employment decline) have not been met.

None.

The investigation revealed that criteria (a)(2)(A)(I.B.) (Sales or production, or both, did not decline) and (a)(2)(B)(II.B.) (shift in production to a foreign country) have not been met.

None.

The investigation revealed that criteria (a)(2)(A)(I.C.) (increased imports) and (a)(2)(B)(II.B.) (shift in production to a foreign country) have not been met.

None.

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA–W–80,027; William Kelly & Sons Plumbing Contractors, El Cajon, CA.

TA–W–80,070; CBIZ Medical Management Professionals, Reno, NV.

TA–W–80,095; 6ixSigma Apparel Network, LLC, New York, NY.

The investigation revealed that criteria of Section 222(b)(2) has not been met. The workers' firm (or subdivision) is not a supplier to or a downstream producer for a firm whose workers were certified eligible to apply for TAA.

None.

Determinations Terminating Investigations of Petitions for Worker Adjustment Assistance

After notice of the petitions was published in the **Federal Register** and on the Department's Web site, as required by Section 221 of the Act (19

USC 2271), the Department initiated investigations of these petitions.

The following determinations terminating investigations were issued because the petitioning group of workers are covered by active certifications. Consequently, further investigation in these cases would service no purpose since the petition group of workers cannot be covered by more than one certification at a time.

TA–W–80,056; Wellpoint, Inc., Mason, OH.

TA–W–80,117; Precision Dynamics Corp., Valencia, CA.

I hereby certify that the aforementioned determinations were issued during the period of *May 23, 2011 through May 27, 2011.* Copies of these determinations may be requested under the Freedom of Information Act. Request may be submitted by fax, courier services, or mail to FOIA Disclosure Officer, Office of Trade Adjustment Assistance (ETA), U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 or *tofoiarequest@dol.gov.* These determinations also are available on the Department's Web site at *http://www.doleta.gov/tradeact* under the searchable listing of determinations.

Dated: June 10, 2011.

Michael W. Jaffe

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–15088 Filed 6–16–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers by (TA–W) number issued during the period of May 23, 2011 through May 27, 2011.

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Under Section 222(a)(2)(A), the following must be satisfied:

(1) A significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The sales or production, or both, of such firm have decreased absolutely; and

(3) One of the following must be satisfied:

(A) Imports of articles or services like or directly competitive with articles produced or services supplied by such firm have increased;

(B) Imports of articles like or directly competitive with articles into which one or more component parts produced by such firm are directly incorporated, have increased;

(C) Imports of articles directly incorporating one or more component parts produced outside the United States that are like or directly competitive with imports of articles incorporating one or more component parts produced by such firm have increased;

(D) Imports of articles like or directly competitive with articles which are produced directly using services supplied by such firm, have increased; and

(4) The increase in imports contributed importantly to such workers' separation or threat of separation and to the decline in the sales or production of such firm; or

II. Section 222(a)(2)(B) all of the following must be satisfied:

(1) A significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) One of the following must be satisfied:

(A) There has been a shift by the workers' firm to a foreign country in the production of articles or supply of services like or directly competitive with those produced/supplied by the workers' firm;

(B) There has been an acquisition from a foreign country by the workers' firm of articles/services that are like or directly competitive with those produced/supplied by the workers' firm; and

(3) The shift/acquisition contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected workers in public agencies and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) A significant number or proportion of the workers in the public agency have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The public agency has acquired from a foreign country services like or directly competitive with services which are supplied by such agency; and

(3) The acquisition of services contributed importantly to such workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected secondary workers of a firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(c) of the Act must be met.

(1) A significant number or proportion of the workers in the workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The workers' firm is a Supplier or Downstream Producer to a firm that employed a group of workers who received a certification of eligibility under Section 222(a) of the Act, and such supply or production is related to the article or service that was the basis for such certification; and

(3) Either—

(A) The workers' firm is a supplier and the component parts it supplied to the firm described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) A loss of business by the workers' firm with the firm described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected workers in firms identified by the International Trade Commission and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(f) of the Act must be met.

(1) The workers' firm is publicly identified by name by the International Trade Commission as a member of a domestic industry in an investigation resulting in—

(A) An affirmative determination of serious injury or threat thereof under section 202(b)(1);

(B) An affirmative determination of market disruption or threat thereof under section 421(b)(1); or

(C) An affirmative final determination of material injury or threat thereof under section 705(b)(1)(A) or 735(b)(1)(A) of the Tariff Act of 1930 (19 U.S.C. 1671d(b)(1)(A) and 1673d(b)(1)(A));

(2) The petition is filed during the 1-year period beginning on the date on which—

(A) A summary of the report submitted to the President by the International Trade Commission under section 202(f)(1) with respect to the affirmative determination described in paragraph (1)(A) is published in the **Federal Register** under section 202(f)(3); or

(B) Notice of an affirmative determination described in subparagraph (1) is published in the **Federal Register**; and

(3) The workers have become totally or partially separated from the workers' firm within—

(A) The 1-year period described in paragraph (2); or

(B) Notwithstanding section 223(b)(1), the 1-year period preceding the 1-year period described in paragraph (2).

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) of the Trade Act have been met.

TA–W No.	Subject firm	Location	Impact date
75,306	Elmet Technologies, Inc.	Lewiston, ME	March 22, 2010.

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production or services) of the Trade Act have been met.

TA–W No.	Subject firm	Location	Impact date
75,262D	Highmark, Human Resources Division, Leased Workers of Staffmark & PA Teleworkers.	Pittsburgh, PA	February 11, 2010.
75,262E	Highmark, Human Resources Division	Camp Hill, PA	February 11, 2010.
75,262F	Highmark, Human Resources Division	Johnstown, PA	February 11, 2010.

Negative Determinations for Worker Adjustment Assistance

In the following cases, the investigation revealed that the eligibility criteria for worker adjustment assistance have not been met for the reasons specified.

The investigation revealed that the criteria under paragraphs (a)(2)(A) (increased imports) and (a)(2)(B) (shift in production or services to a foreign country) of section 222 have not been met.

TA–W No.	Subject firm	Location	Impact date
75,045	CVS Caremark Northbrook/Bannockburn, Information Technology Division; CVS Caremark; Leased Workers, etc.	Northbrook, IL	
75,278	Wellman Dynamics Twin Cities, Inc, Fansteel Inc.; Leased Workers from American Engineering Testing, etc.	Plymouth, MN	

I hereby certify that the aforementioned determinations were issued during the period of *May 23, 2011 through May 27, 2011.* Copies of these determinations may be requested under the Freedom of Information Act. Requests may be submitted by fax, courier services, or mail to FOIA Disclosure Officer, Office of Trade Adjustment Assistance (ETA), U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 or *tofoiarequest@dol.gov.* These determinations also are available on the Department's Web site at *http://www.doleta.gov/tradeact* under the searchable listing of determinations.

Dated: June 10, 2011.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–15087 Filed 6–16–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than June 27, 2011.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than June 27, 2011.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training

Administration, U.S. Department of Labor, Room N–5428, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC, this 10th day of June 2011.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

Appendix

TAA PETITIONS INSTITUTED BETWEEN 5/30/11 AND 6/3/11

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
80203	Zeledyne Glass Plant (Company)	Tulsa, OK	05/31/11	05/27/11
80204	Starks Manufacturing (State/One-Stop)	Russellville, AR	05/31/11	05/27/11
80205	Nidec Motor Corporation (Company)	Frankfort, IN	05/31/11	05/26/11
80206	West Clermont School (State/One-Stop)	Cincinnati, OH	05/31/11	05/27/11
80207	Tecumseh Products Corporation (Workers)	Ann Arbor, MI	05/31/11	05/19/11
80208	General Motors Component Holdings (GMCH) (Union)	Rochester, NY	06/01/11	05/27/11
80209	MedTec Ambulance Corporation (Workers)	Bradenton, FL	06/01/11	05/23/11
80210	United Solar Ovonics (State/One-Stop)	Greenville, MI	06/02/11	06/01/11
80211	Ringo B.D. Inc (Company)	Passaic, NJ	06/03/11	06/01/11
80212	Unlimited Services (Company)	Oconto, WI	06/03/11	06/01/11
80213	Healthlink (Workers)	St. Louis, MO	06/03/11	05/30/11
80214	California Newspaper Limited Partnership (Company)	Vallejo, CA	06/03/11	06/01/11
80215	Dex One (Workers)	Cary, NC	06/03/11	06/02/11
80216	Solar Power Industries (Company)	Mount Pleasant, PA ..	06/03/11	06/02/11

[FR Doc. 2011–15086 Filed 6–16–11; 8:45 am]

BILLING CODE 4510–FN–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (11–052)]

Notice of Intent To Grant Partially Exclusive License

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of intent to grant partially exclusive license.

SUMMARY: This notice is issued in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i). NASA hereby gives notice of its intent to grant a partially exclusive license in the United States to practice the inventions described and claimed in USPN 6,047,216, Endothelium Preserving Microwave Treatment For Atherosclerosis, NASA Case No. MSC–22724–1, USPN 6,226,553, Endothelium Preserving Microwave Treatment For Atherosclerosis, NASA Case No. MSC–22724–2, USPN 6,223,086, Endothelium Preserving Microwave Treatment For Atherosclerosis, NASA Case No. MSC–22724–3, and USPN 6,496,736, Endothelium Preserving Microwave Treatment For Atherosclerosis, NASA Case No. MSC–22724–5 to Meridian Health Systems, P.C., having its principal place of business in Los Angeles, California. The patent rights in these inventions have been assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. The prospective partially exclusive license will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7.

DATES: The prospective partially exclusive license may be granted unless within fifteen (15) days from the date of this published notice, NASA receives written objections including evidence and argument that establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7. Competing applications completed and received by NASA within fifteen (15) days of the date of this published notice will also be treated as objections to the grant of the contemplated partially exclusive license.

Objections submitted in response to this notice will not be made available to the public for inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

ADDRESSES: Objections relating to the prospective license may be submitted to Patent Counsel, Office of Chief Counsel, 2101 NASA Parkway, Houston, Texas 77058, Mail Code AL; Phone (281) 483–3021; Fax (281) 483–6936.

FOR FURTHER INFORMATION CONTACT: Theodore U. Ro, Intellectual Property Attorney, Office of Chief Counsel, 2101 NASA Parkway, Houston, Texas 77058, Mail Code AL; Phone (281) 244–7148; Fax (281) 483–6936. Information about other NASA inventions available for licensing can be found online at *http://technology.nasa.gov/.*

Dated: June 13, 2011.

Richard W. Sherman,

Deputy General Counsel.

[FR Doc. 2011–15025 Filed 6–16–11; 8:45 am]

BILLING CODE

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (11–053)]

Notice of Intent To Grant Exclusive License

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of intent to grant exclusive license.

SUMMARY: This notice is issued in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i). NASA hereby gives notice of its intent to grant an exclusive patent and copyright license in the United States to practice the invention(s) and computer software described in NASA Case No. LAR–17980–1, entitled ''Space Utilization Optimization Tools,'' to T3W Business Solutions, Inc., having its principal place of business in San Diego, California. The patent rights and copyright in the invention(s) and computer software will be assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. The prospective exclusive license will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7.

DATES: The prospective exclusive license may be granted unless, within fifteen (15) days from the date of this published notice, NASA receives written objections including evidence and argument that establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7. Competing applications completed and received by NASA within fifteen (15) days of the date of this published notice will also be treated as objections to the grant of the contemplated exclusive license.

Objections submitted in response to this notice will not be made available to the public for inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

ADDRESSES: Objections relating to the prospective license may be submitted to Patent Counsel, Office of Chief Counsel, NASA Langley Research Center, MS 30, Hampton, VA 23681; (757) 864–3230 (phone); (757) 864–9190 (fax).

FOR FURTHER INFORMATION CONTACT: Robin W. Edwards, Patent Counsel, Office of Chief Counsel, NASA Langley Research Center, MS 30, Hampton, VA 23681; (757) 864–3230 (phone); (757) 864–9190 (fax). Information about other NASA inventions available for licensing can be found online at *http://technology.nasa.gov.*

Dated: June 13, 2011.

Richard W. Sherman,

Deputy General Counsel.

[FR Doc. 2011–15026 Filed 6–16–11; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 11–054]

NASA Advisory Council; Science Committee; Astrophysics Subcommittee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Astrophysics Subcommittee of the NASA Advisory Council (NAC). This subcommittee reports to the Science Committee of the NAC. The meeting will be held for the purpose of soliciting from the scientific community and other persons, scientific and technical information relevant to program planning.

DATES: Wednesday, July 13, 2011, 8:30 a.m. to 5:30 p.m., and Thursday, July 14, 2011, 8:30 a.m. to 4:30 p.m., Local Time.

ADDRESSES: NASA Headquarters, 300 E Street, SW., Room 5H45, Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Ms. Marian Norris, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–4452, fax (202) 358–4118, or *mnorris@nasa.gov.*

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the capacity of the room. This meeting will also be available telephonically and by WebEx. Any interested person may call the USA toll free conference call number 888–603–9230, pass code APS, to participate in this meeting by telephone. The WebEx link is *https://nasa.webex.com,* the meeting number on July 13 is 991 876 106, and password APS@July132011; the meeting number on July 14 is 994 671 789, and password APS@July142011. The agenda for the meeting includes the following topics:

—Astrophysics Division Update.

—Research and Analysis Update.

—Wide-Field Infrared Survey Telescope Science Definition Team Briefing.

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants. Attendees will be requested to sign a register and to comply with NASA security requirements, including the presentation of a valid picture ID, before receiving an access badge. Foreign nationals attending this meeting will be required to provide a copy of their passport, visa, or green card in addition to providing the following information no less than 10 working days prior to the meeting: Full name; gender; date/place of birth; citizenship; visa/green card information (number, type, expiration date); passport information (number, country, expiration date); employer/affiliation information (name of institution, address, country, telephone); title/position of attendee. To expedite admittance, attendees with U.S. citizenship can provide identifying information 3 working days in advance by contacting Marian Norris via e-mail at *mnorris@nasa.gov* or by telephone at (202) 358–4452.

June 13, 2011.

P. Diane Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2011–15121 Filed 6–16–11; 8:45 am]

BILLING CODE P

NATIONAL COUNCIL ON DISABILITY

Sunshine Act Meetings

TIME AND DATES: The Members of the National Council on Disability (NCD) will meet by phone on Tuesday, June 28, 2011, 2 p.m.–4 p.m. ET.

PLACE: The meeting will occur by phone. NCD staff will participate in the call from the NCD office at 1331 F Street, NW., Suite 850, Washington, DC 20004. Interested parties may join the meeting in person at the NCD office or may join the phone line in a listening-only capacity using the following call-in information: Call-in number: 1–877–723–9522; Passcode: 1331. If asked, the conference call's leader's name is A. Bishop.

MATTERS TO BE CONSIDERED: The Council will meet by phone to discuss and vote on fiscal year 2011 allocations.

CONTACT PERSON FOR MORE INFORMATION: Anne Sommers, NCD, 1331 F Street, NW., Suite 850, Washington, DC 20004; 202–272–2004 (V), 202–272–2074 (TTY).

ACCOMMODATIONS: Those who plan to attend and require accommodations should notify NCD as soon as possible to allow time to make arrangements.

Dated: June 15, 2011.

Aaron Bishop,

Executive Director.

[FR Doc. 2011–15182 Filed 6–15–11; 11:15 am]

BILLING CODE 6820–MA–P

NATIONAL SCIENCE FOUNDATION

National Science Board; Sunshine Act Meetings; Notice

The National Science Board's *ad hoc* Committee on Nominations for the Class of 2012–2018, pursuant to NSF regulations (45 CFR Part 614), the National Science Foundation Act, as amended (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of meetings for the transaction of National Science Board business and other matters specified, as follows:

Date and Time: Tuesday, June 28th at 3 p.m.–4 p.m., EDT.

Subject Matter: Discussion of NSB member nomination review process.

Status: Open.

This meeting will be held by teleconference originating at the National Science Board Office, National Science Foundation, 4201Wilson Blvd., Arlington, VA 22230. A room will be available for the public and NSF staff to listen-in on this teleconference meeting. All visitors must contact the Board Office at least *one day* prior to the meeting to arrange for a visitor's badge and obtain the room number. Call 703–292–7000 to request your badge, which will be ready for pick-up at the visitor's desk on the day of the meeting. All visitors must report to the NSF visitor desk at the 9th and N. Stuart Streets entrance to receive their visitor's badge on the day of the teleconference.

Please refer to the National Science Board Web site (*http://www.nsf.gov/nsb/notices/*) for information or schedule updates, or contact: Kim Silverman, National Science Foundation, 4201Wilson Blvd., Arlington, VA 22230. Telephone: (703) 292–7000.

Ann Ferrante,

Writer-Editor.

[FR Doc. 2011–15176 Filed 6–15–11; 11:15 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

National Science Board

Sunshine Act Meetings; Notice

The National Science Board's Committee on Strategy and Budget's Task Force on Data Policies, pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of meetings for the transaction of National Science Board business and other matters specified, as follows:

DATE AND TIME: Thursday, June 23rd at 3 p.m.–4 p.m., EDT.

SUBJECT MATTER: Discussion of the Recommendations from the March 2011 Workshop.

STATUS: Open.

This meeting will be held by teleconference originating at the National Science Board Office, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. A room will be available for the public and NSF staff to listen-in on this teleconference meeting. All visitors must contact the Board Office at least *one day* prior to the meeting to arrange for a visitor's badge and obtain the room number. Call 703–292–7000 to request your badge, which will be ready for pick-up at the visitor's desk on the day of the meeting. All visitors must report to the NSF visitor desk at the 9th and N. Stuart Streets entrance to receive their visitor's badge on the day of the teleconference.

Please refer to the National Science Board Web site (*http://www.nsf.gov/nsb/notices/*) for information or schedule updates, or contact: Blane Dahl, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. Telephone: (703) 292–7000.

Ann Ferrante,

Writer-Editor.

[FR Doc. 2011–15237 Filed 6–15–11; 4:15 pm]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. NRC–2011–0126]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Notice of pending NRC action to submit an information collection request to the Office of Management and Budget (OMB) and solicitation of public comment.

SUMMARY: The NRC invites public comment about its intention to request the OMB's approval for renewal of an existing information collection that is summarized below. The NRC is required to publish this notice in the **Federal Register** under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* Voluntary Reporting of Performance Indicators.

2. *Current OMB approval number:* 3150–0195.

3. *How often the collection is required:* Quarterly.

4. *Who is required or asked to report:* Power reactor licensees.

5. *The number of annual respondents:* 105.

6. *The number of hours needed annually to complete the requirement or request:* Approximately 85,300 hours (84,000 reporting hours plus 1,300 recordkeeping hours).

7. *Abstract:* As part of a joint industry-NRC initiative, the NRC receives information submitted voluntarily by power reactor licensees regarding selected performance attributes known as performance indicators (PIs). PIs are objective measures of the performance of licensee systems or programs. The NRC uses PI information and inspection results in its Reactor Oversight Process to make decisions about plant performance and regulatory response. Licensees transmit PIs electronically to reduce burden on themselves and the NRC.

Submit, by August 16, 2011, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

The public may examine and have copied for a fee publicly available documents, including the draft supporting statement, at the NRC's Public Document Room, Room O–1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. OMB clearance requests are available at the NRC Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/index.html.* The document will be available on the NRC home page site for 60 days after the signature date of this notice. Comments submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed. Comments submitted should reference Docket No. NRC–2011–0126. You may submit your comments by any of the following methods. Electronic comments: Go to *http://www.regulations.gov* and search for Docket No. NRC–2011–0126. Mail comments to NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Questions about the information collection requirements may be directed to the NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, by telephone at 301–415–6258, or by e-mail to *INFOCOLLECTS.Resource@NRC.GOV.*

Dated at Rockville, Maryland, this 13th day of June 2011

For the Nuclear Regulatory Commission.

Tremaine Donnell,

NRC Clearance Officer, Office of Information Services.

[FR Doc. 2011–15042 Filed 6–16–11; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. NRC–2011–0125]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Notice of pending NRC action to submit an information collection request to the Office of Management and Budget (OMB) and solicitation of public comment.

SUMMARY: The NRC invites public comment about our intention to request the OMB's approval for renewal of an existing information collection that is summarized below. We are required to publish this notice in the **Federal Register** under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* NRC Form 241, ''Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters.''

2. *Current OMB approval number:* 3150–0013.

3. *How often the collection is required:* NRC Form 241 must be submitted each time an Agreement State licensee wants to engage in or revise its activities involving the use of radioactive byproduct material in a non-Agreement State, areas of exclusive Federal jurisdiction, or offshore waters. The NRC may waive the requirements for filing additional copies of NRC Form 241 during the remainder of the calendar year following receipt of the initial form.

4. *Who will be required or asked to report:* Any licensee who holds a specific license from an Agreement State and wants to conduct the same activity in non-Agreement States, areas of exclusive Federal jurisdiction, or offshore waters under the general license in 10 CFR 150.20.

5. *The number of annual respondents:* 172 respondents.

6. *The total number of hours needed annually to complete the requirement or request:* 482 hours (86 hours for initial submission + 119 hours for changes + 277 hours for clarification).

7. *Abstract:* Any Agreement State licensee who engages in the use of radioactive material in non-Agreement States, areas of exclusive Federal jurisdiction, or offshore waters, under the general license in Section 150.20, is required to file, with the NRC regional administrator for the region in which the Agreement State that issues the license is located, a copy of NRC Form 241 (''Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters''), a copy of its Agreement State specific license, and the appropriate fee as prescribed in Section 170.31 at least 3 days before engaging in such activity. This mandatory notification permits NRC to schedule inspections of the activities to determine whether the activities are being conducted in accordance with requirements for protection of the public health and safety.

Submit, by August 16, 2011, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

The public may examine and have copied for a fee publicly available documents, including the draft supporting statement, at the NRC's Public Document Room, Room O–1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. OMB clearance requests are available at the NRC Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/index.html.* The document will be available on the NRC home page site for 60 days after the signature date of this notice. Comments submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed. Comments submitted should reference Docket No. NRC–2011–0125. You may submit your comments by any of the following methods: Electronic comments: Go to *http://www.regulations.gov* and search for Docket No. NRC–2011–0125. Mail comments to NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Questions about the information collection requirements may be directed to the NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, by telephone at 301–415–6258, or by e-mail to *INFOCOLLECTS.Resource@nrc.gov.*

Dated at Rockville, Maryland, this 13th day of June 2011.

For The Nuclear Regulatory Commission.

Tremaine Donnell,

NRC Clearance Officer, Office of Information Services.

[FR Doc. 2011–15043 Filed 6–16–11; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Hispanic Council on Federal Employment; Cancellation of Upcoming Meeting

AGENCY: U. S. Office of Personnel Management.

ACTION: Notice.

SUMMARY: The Hispanic Council on Federal Employment is issuing this notice to cancel the June 17, 2011, public meeting scheduled to be held in Room 230, U.S. Department of Veteran Affairs, 810 Vermont Ave. NW., Washington, DC. The original **Federal Register** notice announcing this meeting was published Wednesday, June 1, 2011, at 76 FR 31645.

FOR FURTHER INFORMATION CONTACT: Veronica E. Villalobos, Director for the Office of Diversity and Inclusion, Office of Personnel Management, 1900 E. St., NW., Suite 5305, Washington, DC 20415. Phone (202) 606–2984 Fax (202) 606–2183 or e-mail at *Edgar.Gonzalez@opm.gov.*

U.S. Office of Personnel Management.

John Berry,

Director.

[FR Doc. 2011–15096 Filed 6–16–11; 8:45 am]

BILLING CODE 6325–49–P

POSTAL SERVICE

Privacy Act of 1974; System of Records

AGENCY: Postal Service.

ACTION: Notice of modification to existing systems of records and the addition of one new system of records.

SUMMARY: The United States Postal Service is proposing to modify nine of its General Privacy Act Systems of Records: USPS 100.000, General Personnel Records; USPS 100.100, Recruiting, Examining, and Placement Records; USPS 100.200, Employee Performance Records; USPS 100.300, Employee Development and Training Records; USPS 100.400, Personnel Compensation and Payroll Records; USPS 100.500, Personnel Resource Management Records; USPS 100.600, Personnel Research Records; USPS 100.700, Medical Records and Related Documents; and USPS 100.950, Employee Assistance Program (EAP) Records. These modifications reflect the changes that have been made in changing from a primarily paper-based record keeping system to an electronic record keeping system.

The United States Postal Service is also amending one Customer Privacy Act System of Records, USPS 810.200, www.usps.com Ordering, Payment, and Fulfillment, which was last updated on May 12, 2009 (74 FR 22186), where the standard routine uses were mistakenly deleted. The change to USPS 810.200 will add the standard routine uses that applied to the system prior to the May 12, 2009, revisions, and will update the retention period from 6 months to 12 months for online user information, and update one of the titles in the System Manger(s) and Address section.

Lastly, the United States Postal Service is adding a new system of records to its General Privacy Act Systems of Records: 500.050 HSPD–12: Identity Management System is being established to support implementation of HSPD–12 identification cards.

DATES: The revision will become effective without further notice on July 18, 2011 unless comments received on or before that date result in a contrary determination.

ADDRESSES: Comments may be mailed or delivered to the Records Office, United States Postal Service, 475 L'Enfant Plaza, SW., Room 4541, Washington, DC 20260–2201. Copies of all written comments will be available at this address for public inspection and photocopying between 8 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Jane Eyre, Manager, Records Office, 202–268–2608.

SUPPLEMENTARY INFORMATION: This notice is in accordance with the Privacy Act requirement that agencies publish their amended systems of records in the **Federal Register** when there is a revision, change, or addition. The Postal Service has reviewed its systems of records and has determined that the Human Resource records system should be revised to modify existing routine uses of records maintained in the system, including system location; categories of individuals; categories of records in the system; purposes; routine uses of records maintained in the system, including categories of users and the purposes of such uses; storage; retrievability; safeguards; retention and disposal; system manager(s) and address; notification procedure; and record source categories of such uses.

I. Background

In 2005, Human Resources and the Privacy Office partnered under the Human Capital Steering Committee to improve all general (non-customer) systems of records. General systems cover all employee systems. Since that last revision, the Postal Service has undertaken a total modernization of how it collects and stores information about employees. The Postal Service has automated personnel actions, implemented an electronic Official Personnel Folder (eOPF), and changed how it tests and hires employees. Redesign of all the processes requires changes to the current systems of records. The Privacy Office worked closely with systems managers to develop the revised general systems. These changes are proposed for the reasons discussed below.

II. Rationale for Changes to USPS Privacy Act Systems of Records

Many businesses and other Federal agencies have automated their Human Resource (HR) processes in order to maintain competitiveness and ensure the most efficient use of resources. The Postal Service, like any other large organization, must cope with the constant demand for information from employees, management, and third parties. These applications assist the Postal Service in ensuring accuracy of data and quick retrieval of data in order to meet that demand. In addition, the introduction of automated systems provides improved service, quick development of reports required for benefits administration, government requirements, and strategic planning. Customized reports enhance analysis, forecasting, and planning.

The other changes outlined update retention periods, administrative changes, and system locations due to the abolishment of local HR offices and movement to a central location for all HR processing in Greensboro, North Carolina. The revisions to 810.200, the only customer system of records in this notice, are required due an inadvertent error that occurred when the system of records was last revised on May 12, 2009, and the routine uses were deleted. This change reinstates those routine uses. Also, 810.200 has an updated retention period from 6 months to 12 months for online user information and an update to one of the titles in the System Manager(s) and Address section.

III. Description of Changes to Systems of Records

The Postal Service is modifying ten systems of records: USPS 100.000, General Personnel Records; USPS 100.100, Recruiting, Examining, and Placement Records; USPS 100.200, Employee Performance Records; USPS 100.300, Employee Development and Training Records; USPS 100.400, Personnel Compensation and Payroll Records; USPS 100.500, Personnel Resource Management Records; USPS 100.600, Personnel Research Records; USPS 100.700, Medical Records and Related Documents; USPS 100.950, Employee Assistance Program (EAP) Records; and USPS 810.200 www.usps.com Ordering, Payment, and Fulfillment. Pursuant to 5 U.S.C. 552a(e)(11), interested persons are invited to submit written data, views, or arguments on this proposal. A report of the proposed modification has been sent to Congress and to the Office of Management and Budget for their evaluation. The Postal Service does not expect this amended notice to have any adverse effect on individual privacy rights. The Postal Service proposes amending the systems as shown below:

USPS 100.000

System Name: General Personnel Records.

USPS 100.100

System Name: Recruiting, Examining, and Placement Records.

USPS 100.200

System Name: Employee Performance Records.

USPS 100.300

System Name: Employee Development and Training Records.

USPS 100.400

System Name: Personnel Compensation and Payroll Records.

USPS 100.500

System Name: Personnel Resource Management Records.

USPS 100.600

System Name: Personnel Research Records.

USPS 100.700

System Name: Medical Records and Related Documents.

USPS 100.950

System Name: Employee Assistance Program (EAP) Records.

USPS 810.200

System Name: www.usps.com Ordering, Payment, and Fulfillment.

IV. Description of New System of Records

The United States Postal Service is adding a new system of records to its General Privacy Act Systems of Records Management System. This new system of records is being established to support implementation of HSPD–12 identification cards. The Postal Service proposes adding the system as shown below:

USPS 500.050

SYSTEM NAME:

HSPD–12: Identity Management System (IDMS).

Accordingly, the Postal Service proposes changes in existing systems of records and addition of a new system of records as follows:

USPS 100.000

SYSTEM NAME:

General Personnel Records.

SYSTEM LOCATION:

[CHANGE TO READ]

All USPS facilities and personnel offices; Integrated Business Solutions Services Centers; National Personnel Records Center; Human Resources Information Systems; Human Resources Shared Services Center; Headquarters; Computer Operations Service Centers; and contractor sites.

CATEGORIES OF RECORDS IN THE SYSTEM:

* * * * *

[CHANGE TO READ]

2. *Official Personnel Folder (OPF) or eOPF (electronic version):* Records related to appointment support, prior federal civilian employment, postal employment, personnel actions, anniversary dates, retirement, benefits, and compensation.

3. *Automated employee information:* Records generated, approved, and stored by electronic means such as *Notification of Personnel Actions,* health benefit elections, tax withholding changes, and address changes.

4. *Reference copies of all discipline or adverse actions:* Letters of warning; notices of removal, suspension and/or reduction in grade or pay; letters of decisions; and documents relating to these actions. These are used only to refute inaccurate statements by witnesses before a judicial or administrative body. They may not be maintained in the employee's OPF or eOPF but must be maintained in a separate file by Labor Relations.

* * * * *

[INSERT NEW TEXT]

8. *Level 2 supervisors' notes:* Records of discussions, letters of warning, and any other relevant official records being maintained at the supervisor's discretion for the purpose of enabling effective management of personnel. (A level 2 supervisor directly supervises bargaining unit employees.)

PURPOSE(S):

* * * * *

[CHANGE TO READ]

2. To maintain a source of readily available information on employees for administrative purposes.

* * * * *

STORAGE:

[CHANGE TO READ]

Automated database, computer storage media, digital files, and paper files. Duplicates of records in the OPF or eOPF and automated employee data may be maintained for localized employee administration or supervision. Records may be filed at offices other than where OPF or eOPF is located, or may be duplicated at a site closer to where the employee works.

SAFEGUARDS:

[INSERT NEW TEXT]

Paper records, computers, and computer storage media are located in controlled-access areas under supervision of program personnel. Access to these areas is limited to authorized personnel, who must be identified with a badge. Nonbargaining unit employee discipline, grievance, and appeals records maintained outside the OPF (hard or soft copy) are kept in locked filing cabinets or secured record storage rooms; and related automated records are protected with password security. Computers are protected by mechanical locks, card key systems, or other physical access control methods. The use of computer systems is regulated with installed security software, computer logon identifications, and operating system controls including access controls, terminal and transaction logging, and file management software.

RETENTION AND DISPOSAL:

[CHANGE TO READ]

1. Permanent OPF or eOPF records are permanently retained. Temporary OPF or eOPF records are generally retained 2 years and are purged upon the employee's separation from USPS.

2. Except as otherwise provided by a collective bargaining agreement, original or copies of discipline or adverse actions are maintained up to 2 years; or, if an additional or more recent disciplinary action has been taken, for a longer period. After 2 years, or lesser time specified in the decision, the employee may request the disciplinary record be purged from the OPF or eOPF provided no subsequent discipline was issued. Records that support a PS Form 50, *Notification of Personnel Action, e.g.,* the separation of an employee for cause or the resignation of an employee pending charges, are considered permanent records and may not be purged at the request of an employee.

3. Reference copies of discipline or adverse actions. These records are kept for historical purposes and are not to be used for decisions about the employee. The retention of these records may not exceed 10 years beyond the employee's separation date. The records are maintained longer if the employee is rehired during the 10-year period. They may not be maintained in the employee's OPF or eOPF, but must be maintained in a separate file by Labor Relations.

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

* * * * *

[INSERT NEW TEXT]

Director of Human Resources, USPS OIG, 1735 N. Lynn Street, 10th floor, Arlington, VA 22209.

NOTIFICATION PROCEDURE:

[CHANGE TO READ]

Individuals wanting to know if information about them is maintained in this system must address inquiries to the facility head where currently or last employed. Headquarters employees must submit inquiries to Corporate Personnel Management, 475 L'Enfant Plaza, SW., Washington, DC 20260. Inquiries must include full name, Social Security Number or Employee Identification Number, name and address of facility where last employed, and the dates of USPS employment.

* * * * *

RECORD SOURCE CATEGORIES:

[INSERT NEW TEXT]

Employees; employees' supervisors; USPS customers; law enforcement agencies; individuals who are personal references; former employers, including other federal agencies; and other systems of records.

* * * * *

USPS 100.100

SYSTEM NAME:

Recruiting, Examining, and Placement Records.

SYSTEM LOCATION:

[CHANGE TO READ]

Pre-employment investigation records are located at USPS Human Resources (HR) offices and contractor locations, except for drug screening and medical examination records, which are maintained in USPS medical facilities and designee offices.

Recruiting, examining, and placement records are located at USPS HR offices, Headquarters, Human Resources Shared Services Center, Integrated Business Solutions Services Centers, the Bolger Center for Leadership Development, the National Center for Employee Development, and contractor locations.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

[INSERT NEW TEXT]

Current and former USPS employees, applicants for employment, and potential applicants with candidate profiles.

CATEGORIES OF RECORDS IN THE SYSTEM:

[CHANGE TO READ]

1. *Applicant, potential applicants with candidate profiles, and employee information:* Name(s), Social Security Number(s), Candidate Identification Number, Employee Identification Number, date(s) of birth, postal assignment or vacancy/job posting history information, work contact information, home address(es) and phone number(s), finance number(s), duty location, and pay location.

2. *Pre-employment investigation information:* Records compiled by USPS, including criminal, employment, military, and driving records; drug screening and medical assessment results. Also includes Special Agency Check with Inquiries (SACI) and National Agency Check with Inquiry (NACI): Investigative records requested by USPS and compiled by the Office of Personnel Management (OPM) for newly hired employees, including postal inspectors' investigative reports.

3. *Recruiting, examining, and placement information:* Records related to candidate profiles, applications, test results, interview documentation, and suitability screening.

PURPOSE(S):

* * * * *

[CHANGE TO READ]

2. To provide managers, HR personnel, and medical officers with information for recruiting and recommending appointment of qualified individuals.

STORAGE:

[INSERT NEW TEXT]

Automated database, computer storage media, digital files, and paper files.

RETRIEVABILITY:

[CHANGE TO READ]

By applicant or employee name, Social Security Number, Candidate Identification Number, Employee Identification Number, duty or pay location, or posting/vacancy to which application was made.

RETENTION AND DISPOSAL:

* * * * *

[CHANGE TO READ]

2. Candidate information and Candidate Identification Number are retained for a minimum of 2 years. Vacancy files, including applicant/employee name, identification number, posting/vacancy number, and information supplied by applicant/employee in response to the vacancy posting, are retained 5 years. Employment registers are retained 10 years. Certain forms related to a successful applicant are filed in the electronic Official Personnel Folder as permanent records.

3. Paper examining answer sheets are retained 6 months; and computer media copies are retained 10 years. Scanned Maintenance Selection System forms are retained 10 years, and related hiring lists are retained 5 years.

* * * * *

NOTIFICATION PROCEDURE:

[CHANGE TO READ]

Individuals wanting to know if information about them is maintained in this system must address inquiries to Human Resources Shared Services Center, P.O. Box 970400, Greensboro, NC 27497–0400. Inquiries must include full name, Candidate Identification Number (as provided during the application process) or Employee Identification Number, name and address of facility where last employed, and dates of USPS employment or date of application.

* * * * *

RECORD SOURCE CATEGORIES:

[INSERT NEW TEXT]

Applicants; potential applicants with candidate profiles; OPM; police, driving, and military records; former employers and named references; medical service providers; school officials; other federal agencies; and state divisions of vocational rehabilitation counselors.

* * * * *

USPS 100.200

SYSTEM NAME:

Employee Performance Records.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

[CHANGE TO READ]

Current and former USPS employees, including supervisors and managers who are responsible for a work location.

CATEGORIES OF RECORDS IN THE SYSTEM:

* * * * *

[CHANGE TO READ]

2. *Employee performance information:* Records related to individual performance evaluation; reports about supervisors and managers who are responsible for a work location; employee recognition; and safe driver awards.

STORAGE:

[CHANGE TO READ]

Automated database, computer storage media, digital files, and paper files.

RETENTION AND DISPOSAL:

[CHANGE TO READ]

1. Pay for performance evaluation records are retained 5 years. Individual performance evaluations are retained 5 years or until separation of the employee, whichever comes first.

2. Incentive award records are retained 7 years. Length of service award records are retained 1 year. Non-USPS awards are retained 2 years. Letters of commendation and appreciation (excluding permanent copies filed in the OPF or eOPF) are retained 2 years.

3. Employee survey records are retained 5 years.

4. Safe Driver Award records are retained 2 years from date of separation, expiration of license, rescission of authorization, transfer of driver into a nondriving status, or other transfer, whichever comes first.

* * * * *

NOTIFICATION PROCEDURE:

[CHANGE TO READ]

Individuals wanting to know if information about them is maintained in this system must address inquiries to the facility head where currently or last employed. Headquarters employees must submit inquiries to Corporate Personnel Management, 475 L'Enfant Plaza, SW., Washington, DC 20260. Inquiries must include full name, Social Security Number or Employee

Identification Number, name and address of facility where last employed, and dates of USPS employment.
* * * * *

USPS 100.300

SYSTEM NAME:

Employee Development and Training Records.

SYSTEM LOCATION:

[CHANGE TO READ]

Management training centers, Integrated Business Solutions Services Centers, and other USPS facilities where career development and training records are stored.

CATEGORIES OF RECORDS IN THE SYSTEM:

[CHANGE TO READ]

1. *Employee information:* Name, Social Security Number, Employee Identification Number, demographic information, photograph, years of service, retirement eligibility, postal assignment information, work contact information, finance number(s), duty location, and pay location.

2. *Employee development and training information:* Records related to career development, work history, skills bank participation, USPS and non-USPS—sponsored training, examinations, evaluations of training, and USPS lodging when a discrepancy report is filed against the student about unauthorized activities while occupying the room.

PURPOSE(S):

[CHANGE TO READ]

1. To provide managers, supervisors, and training and development professionals with decision-making information for employee career development, succession planning, training, and assignment.
* * * * *

STORAGE:

[CHANGE TO READ]

Automated database, computer storage media, digital files, and paper files.

RETENTION AND DISPOSAL:

* * * * *

[CHANGE TO READ]

2. Records related to succession planning and individual development planning are retained 10 years.
* * * * *

NOTIFICATION PROCEDURE:

[CHANGE TO READ]

Individuals wanting to know if information about them is maintained in this system must address inquiries to the facility head where currently or last employed. Headquarters employees must submit inquiries to Corporate Personnel Management, 475 L'Enfant Plaza, SW., Washington, DC 20260. Inquiries must include full name, Social Security Number or Employee Identification Number, name and address of facility where last employed, and dates of USPS employment.
* * * * *

USPS 100.400

SYSTEM NAME:

Personnel Compensation and Payroll Records.

SYSTEM LOCATION:

[CHANGE TO READ]

USPS Area and District Human Resources offices, the Human Resources Shared Services Center, Integrated Business Solutions Services Centers, Computer Operations Services Centers, Accounting Services Centers, other area and district facilities, Headquarters, contractor sites, and all organizational units.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

[CHANGE TO READ]

1. Current and former USPS employees and Postmaster Relief/Leave Replacement employees.
* * * * *

CATEGORIES OF RECORDS IN THE SYSTEM:

[CHANGE TO READ]

* * * * *

2. *Compensation and payroll information:* Records related to payroll, payments, deductions, compensation, and benefits; uniform items purchased; proposals and decisions under monetary awards; suggestion programs and contests; injury compensation; monetary claims for personal property loss or damage; and garnishment of wages.

PURPOSE(S):

* * * * *

[CHANGE TO READ]

5. To administer monetary awards programs and employee contests.
* * * * *

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

* * * * *

[DELETE THE FOLLOWING]

g. Disclosure of records about current and former employees may be made to the Selective Service System under an approved computer matching program to identify individuals eligible for registration under the Military Selective Service Act, to determine whether those individuals have complied with registration requirements and to enforce compliance when necessary.

h. Disclosure of records about current or recently terminated Postal Service employees who live or work in Colorado may be made to the Colorado Bureau of Investigation under an approved computer matching program to identify currently or recently terminated employees who have been arrested for violations of law that relate to postal offenses and/or suitability for continued employment, or who are fugitives, and to assist state or local agents to apprehend fugitives.

[RELETTER THE REMAINING PARAGRAPHS FROM I THROUGH L AS G THROUGH J]

STORAGE:

[CHANGE TO READ]

Automated database, computer storage media, digital files, and paper files.

RETENTION AND DISPOSAL:

* * * * *

[CHANGE TO READ]

3. Records of approved monetary awards are retained 7 years. Records of award submissions not approved are retained 90 days.

[RENUMBER PARAGRAPHS 4 THROUGH 6 AS 5 THROUGH 7]

[ADD TEXT]

4. Automated records of employee ideas are maintained for 7 years.

SYSTEM MANAGER(S) AND ADDRESS:

[ADD TEXT]

Chief Human Resource Officer and Executive Vice President, United States Postal Service, 475 L'Enfant Plaza, SW., Washington, DC 20260.

* * * * *

[CHANGE TO READ]

Vice President, Controller, United States Postal Service, 475 L'Enfant Plaza, SW., Washington, DC 20260.

NOTIFICATION PROCEDURE:

[CHANGE TO READ]

Individuals wanting to know if information about them is maintained in this system must address inquiries to the facility head where currently or last employed. Headquarters employees must submit inquiries to Corporate Personnel Management, 475 L'Enfant Plaza, SW., Washington, DC 20260. Inquiries must include full name, Social Security Number or Employee Identification Number, name and address of facility where last employed, and dates of USPS employment.
* * * * *

USPS 100.500

SYSTEM NAME:

Personnel Resource Management Records.

STORAGE:

[CHANGE TO READ]

Automated database, computer storage media, digital files, and paper files.

RETENTION AND DISPOSAL:

[CHANGE TO READ]

Resource management records related to leave application, time and attendance, and light duty status are retained 3 years. Family and Medical Leave Records are retained 5 years. Other categories of resource management records are retained 1 year. Records existing on paper are destroyed by burning, pulping, or shredding. Records existing on computer storage media are destroyed according to the applicable USPS media sanitization practice.

NOTIFICATION PROCEDURE:

[CHANGE TO READ]

Individuals wanting to know if information about them is maintained in this system must address inquiries to the facility head where currently or last employed. Headquarters employees must submit inquiries to Corporate Personnel Management, 475 L'Enfant Plaza, SW., Washington, DC 20260. Inquiries must include full name, Social Security Number or Employee Identification Number, name and address of facility where last employed, and dates of USPS employment.

* * * * *

USPS 100.600

SYSTEM NAME:

Personnel Research Records.

SYSTEM LOCATION:

[CHANGE TO READ]

USPS Headquarters, Integrated Business Solutions Services Centers, and contractor sites.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

[CHANGE TO READ]

Potential applicants for USPS employment, applicants for USPS employment, USPS employee applicants for reassignment and/or promotion, and employees whose work records or solicited responses are used in research projects.

CATEGORIES OF RECORDS IN THE SYSTEM:

[CHANGE TO READ]

1. *Applicant, potential applicant with candidate profile, and employee information:* Name, Social Security Number, Candidate Identification Number, or respondent identification code, place of birth, postal assignment or vacancy/posting information, work contact information, home address and phone number(s), finance number(s), duty location, and pay location.

2. *Personnel research information:* Records related to race, ethnicity, sex, tenure, age, and disability status (only if volunteered by the individual); research project identifiers; and other information pertinent to personnel research.

PURPOSE(S):

[CHANGE TO READ]

1. To support research and development efforts on personnel assessment instruments, recruitment efforts, workforce analysis, and evaluation of human resource management practices.

2. To assess the impact of selection decisions on applicants in race, ethnicity, sex, tenure, age, and disability categories.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS:

[CHANGE TO READ]

Standard routine uses 1. through 9. apply.

[DELETE TEXT]

a. Disclosure of records about applicants for employment with USPS may be made to the Selective Service System under an approved computer matching program to identify individuals eligible for registration under the Military Selective Service Act, to determine whether those individuals have complied with registration requirements, and to enforce compliance when necessary.

STORAGE:

[CHANGE TO READ]

Automated database, computer storage media, digital files, and paper files.

RETRIEVABILITY:

[CHANGE TO READ]

By individual name, Social Security Number, Candidate Identification Number, Employee Identification Number, or respondent identification code, research project identifiers, postal assignment or vacancy/posting information, duty or pay location, or location where data were collected.

RETENTION AND DISPOSAL:

[CHANGE TO READ]

Retention depends on the type of research project, but does not exceed 10 years. Records existing on paper are destroyed by burning, pulping, or shredding. Records existing on computer storage media are destroyed according to the applicable USPS media sanitization practice.

NOTIFICATION PROCEDURE:

[CHANGE TO READ]

Individuals wanting to know if information about them is maintained in this system of records must address inquiries to the Vice President, Employee Resource Management, 475 L'Enfant Plaza, SW., Washington, DC 20260. In cases of studies involving information not collected through an examination, individuals must address inquiries to the system manager. Inquiries must contain full name; Candidate Identification Number, Employee Identification Number, or respondent identification code; and date and location of their participation.

RECORD SOURCE CATEGORIES:

[CHANGE TO READ]

USPS employees, applicants, and potential applicants with candidate profiles who provide information to personnel research programs and other systems of records.

* * * * *

USPS 100.700

SYSTEM NAME:

[CHANGE TO READ]

Medical Records and Related Documents.

SYSTEM LOCATION:

[CHANGE TO READ]

USPS medical facilities, designee offices, and National Personnel Records Center.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

* * * * *

[CHANGE TO READ]

2. Individuals who have been offered employment but were determined medically unsuitable or who declined the offer.

[DELETE TEXT]

3. Headquarters employees who participate in the Corporate Health and Fitness Program.

4. Employees who volunteer to join the USPS Blood Donor Program.

[RENUMBER REMAINING TEXT TO READ]

3. Current and former USPS employees who are or were required to have a commercial driver's license (CDL) or are otherwise subject to controlled substance and alcohol testing.

[ADD TEXT]

4. Applicants and current or former USPS employees, or persons who

request reasonable accommodation on behalf of an applicant or employee.

CATEGORIES OF RECORDS IN THE SYSTEM:

[CHANGE TO READ]

1. *Employee or applicant information:* Name, Social Security Number, Employee Identification Number, Candidate Identification Number, date of birth, postal assignment information, work contact information, finance number(s), duty location, and pay location.

* * * * *

[DELETE TEXT]

3. *Headquarters Corporate Health and Fitness Program:* Records volunteered about lifestyle and health.

4. *Voluntary blood donation information:* Blood type and date of each donation.

[RENUMBER REMAINING TEXT STARTING WITH 3]

* * * * *

[ADD TEXT]

4. *Reasonable Accommodation folders:* These folders document the decision-making process and contain records related to requests for Reasonable Accommodation.

PURPOSE(S):

[CHANGE TO READ]

1. Medical information maintained in the Employee Medical Folder is used to, but is not limited to, support hiring decisions and determine job-related medical suitability, fitness for duty, and Family Medical Leave Act documentation.

[DELETE TEXT]

2. To provide for a Headquarters health promotion program.

3. To provide the USPS Blood Donation Program with a record of donations.

* * * * *

[RENUMBER REMAINING TEXT STARTING WITH 2]

* * * * *

[ADD TEXT]

4. To assess disability retirement requests.

5. To assist in making determinations about Reasonable Accommodation.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

[DELETE TEXT]

b. Blood donor records may be disclosed to the American Red Cross in response to an inquiry for available donors having a particular blood type.

STORAGE:

[CHANGE TO READ]

Automated database, computer storage media, digital files, and paper files.

RETRIEVABILITY:

[CHANGE TO READ]

By employee or applicant name, Social Security Number, Employee Identification Number, Candidate Identification Number, or duty or pay location.

RETENTION AND DISPOSAL:

* * * * *

[CHANGE TO READ]

2. Candidate medical information for applicants determined to be medically unsuitable for the position offered is retained 2 years in hard copy. Computer data is retained 3 years in a history database.

3. Documentation supporting applicant requests for reasonable accommodation for participation in the hiring or assessment process are maintained for 2 years in hard copy. Computer records of such requests are retained 3 years.

4. Reasonable Accommodation Committee and District Reasonable Accommodation Committee records are maintained for the duration of the employee's tenure with the USPS or until any appeals are adjudicated, whichever is longer. After the official use for these records has been satisfied, the records are to be placed in a sealed envelope, labeled as ''Reasonable Accommodation Committee Records,'' and placed in the Employee Medical Folder (EMF) and retained in accordance with the official retention period for the EMFs.

5. Alcohol test results indicating a breath alcohol concentration of 0.02 or greater, verified positive controlled substance test results, refusals, medical review officer's evaluations, employee statements, and substance abuse professionals' evaluations and referrals are retained 5 years. Alcohol test results indicating a breath alcohol concentration of less than 0.02, and negative and canceled controlled substance test results, are retained 1 year.

NOTIFICATION PROCEDURE:

[CHANGE TO READ]

Individuals wanting to know if information about them is maintained in this system must address inquiries to the facility head where currently or last employed. Headquarters employees must submit inquiries to the National Medical Director, Health and Resource Management, 475 L'Enfant Plaza, SW., Washington, DC 20260. Individuals who requested accommodation for an entrance examination or assessment must submit inquiries to the Manager of Selection, Evaluation, and Recognition, 475 L'Enfant Plaza, SW., Washington, DC 20260. Inquiries must include full name, Social Security Number or Employee Identification Number, name and address of facility where last employed, and dates of USPS employment or date of application.

RECORD SOURCE CATEGORIES:

[CHANGE TO READ]

Employees, applicants for employment; applicant or employee health care provider(s), USPS and Department of Veterans Affairs medical staff, USPS designee testing facilities, substance abuse professionals, and designated contractors.

* * * * *

USPS 100.950

SYSTEM NAME:

Employee Assistance Program (EAP) Records.

SYSTEM LOCATION:

[CHANGE TO READ]

EAP Offices at Philadelphia and Los Angeles USPS facilities. This system does not include records maintained by the supplier of EAP services as outlined in the USPS EAP contract.

STORAGE:

[CHANGE TO READ]

Automated database, computer storage media, digital files, and paper files.

RETENTION AND DISPOSAL:

[CHANGE TO READ]

Records are retained 3 years from the date of the participant's last activity. EAP contractor records are retained 7 years from the date of the participant's last activity or until litigation is resolved. Records existing on paper are destroyed by burning, pulping, or shredding. Records existing on computer storage media are destroyed according to the applicable USPS media sanitization practice.

SYSTEM MANAGER(S) AND ADDRESS:

[CHANGE TO READ]

Vice President, Labor Relations, United States Postal Service, 475 L'Enfant Plaza, SW., Washington, DC 20260.

* * * * *

NOTIFICATION PROCEDURE:

* * * * *

[CHANGE TO READ]

For records maintained by the provider of USPS EAP services through contract, individuals must inquire as instructed by the provider.

* * * * *

USPS 810.200

SYSTEM NAME:

http://www.usps.com Ordering, Payment, and Fulfillment.

ROUTINE USES OF RECORDS IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

[INSERT]

Standard routine uses 1. through 7., 10., and 11. apply. In addition:

* * * * *

RETENTION AND DISPOSAL:

* * * * *

[CHANGE TO READ]

3. Online user information may be retained for 12 months.

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

[CHANGE TO READ]

President and Chief Marketing/Sales Officer, United States Postal Service, 475 L'Enfant Plaza, SW., Washington, DC 20260.

* * * * *

[ADD NEW TEXT/SYSTEM OF RECORD]

USPS 500.050

SYSTEM NAME:

HSPD–12: Identity Management System (IDMS).

SYSTEM LOCATION:

Records relating to the Identity Management System are maintained by a contractor at the contractor's site. This does not include building or computer access records.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

1. Individuals with authorized USPS law enforcement or emergency response duties, including postal inspectors, Office of Inspector General criminal investigators, and USPS executives and their designees.

CATEGORIES OF RECORDS IN THE SYSTEM:

1. *Cardholder information:* Records related to issuance of identity management credentials, including name, date of birth, Social Security Number (SSN), organizational and employee affiliations, fingerprints, digital color photograph, work e-mail address, and phone number(s) as well as additional verification and demographic information. Other types of data contained in the system include federal emergency response official status; law enforcement official status; and Personal Identity Verification (PIV) Card issuance location. Records in the IDMS needed for credential management for enrolled individuals in the PIV Program include: PIV Card serial number (all past and current Card ID numbers are retained); digital certificate(s) serial number; PIV Card issuance and expiration dates; PIV Card personal identification number (PIN); Cardholder Unique Identification Number (CHUID); card management keys.

2. *Card-swipe records:* Records related to employees and visitors who enter and leave participating federal facilities and disaster recovery areas. This does not include direct tracking of access to USPS facilities.

3. *Computer access authorization information:* Records related to computer users, including logon ID; Social Security Number, Employee Identification Number, or other assigned identifier; employment status information; and extent of access granted.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

39 U.S.C. 401, and Homeland Security Presidential Directive 12, Policy for a Common Identification Standard for Federal Employees and Contractors, August 27, 2004.

PURPOSE(S):

1. To assist in making determinations for access to other federal facilities.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Standard routine uses 1. through 9. apply.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Automated database, computer storage media, digital files, and paper files.

RETRIEVABILITY:

1. Records about building access are retrieved by name or Cardholder Unique Identifier Number.

2. Cardholder information may be retrieved by name, logon ID, or other unique identifier of the individual. *Note:* While many Federal agencies utilize the IDMS, USPS will only have access to data on its employees enrolled in the system (not to any other agency's data).

SAFEGUARDS:

All biographic and biometric data collected prior to and during the enrollment process is transmitted to the PIV IDMS over a private network in an encrypted format. Facilities and equipment are secured by limiting physical access to the workspace and system, and by requiring an appropriate verification of identity. Where appropriate, this method uses the PIV card providing up to three factors of authentication. Where necessary, this method also consists of two components (*e.g.,* user id + password). Physical security measures are employed to protect enrollment equipment, facilities, material, and information systems, including locks, ID badges, fire protection, redundant power and climate control to protect IT equipment. The PIV IDMS sends confirmed enrollment information to the card production facility via a secure FTP connection. Cards that are not active cannot be used for access to federal facilities. Certifications are revoked when they are reported lost, stolen, damaged beyond use, or when a cardholder has failed to meet the terms and conditions of enrollment. Cards will be deactivated upon collection of damaged cards or if the employee no longer requires a PIV card.

RETENTION AND DISPOSAL:

1. Building access records are retained according to the policies of the agencies visited.

2. Records of computer access privileges and authorization information are retained 5 years after the cardholder is separated from the Postal Service.

Data will be disposed of according to the requirements of National Institute of Standards and Technology (NIST) Special Publication (SP) 800–88 Guidelines for Media Sanitization. Magnetic media will be degaussed and then destroyed; paper records will be stored in locked bins, transported securely via bonded courier, and shredded.

SYSTEM MANAGER(S) AND ADDRESS:

For collection of cardholder information: Chief Postal Inspector, United States Postal Inspection Service, 475 L'Enfant Plaza, SW., Fl 3, Washington, DC 20260.

For records relating to the Identity Management System and identification cards: Program Manager, HSPD–12 Managed Service Office, Federal Acquisition Service (FAS), General Services Administration, 10304 Eaton Place Fl 3, Fairfax, VA 22030.

For records of building access to other federal buildings, contact that agency.

NOTIFICATION PROCEDURE:

Inquiries for records about building access must be addressed to the facility head. Inquiries about access to the IDMS are to be directed to the Program Manager, Program Manager, HSPD–12 Managed Service Office, Federal

Acquisition Service (FAS), General Services Administration, 10304 Eaton Place Fl 3, Fairfax, VA 22030. Inquiries regarding collection of cardholder information are to be directed to the Chief Postal Inspector, United States Postal Inspection Service, 475 L'Enfant Plaza, SW., Fl 3, Washington, DC 20260. Inquiries must include full name, Social Security Number or Employee Identification Number, and period of employment or residency at the location.

RECORD ACCESS PROCEDURES:

Requests for access must be made in accordance with the Notification Procedure above and USPS Privacy Act regulations regarding access to records and verification of identity under 39 CFR 266.6.

CONTESTING RECORD PROCEDURES:

See Notification Procedure and Record Access Procedures above.

RECORD SOURCE CATEGORIES:

Employees, subject individuals, former employers, and other systems of records.

* * * * *

[END DOCUMENT]

Stanley F. Mires,

Chief Counsel, Legislative.

[FR Doc. 2011–15038 Filed 6–16–11; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission will hold a Closed Meeting on Thursday, June 23, 2011 at 2 p.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the Closed Meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (7), 9(B) and (10) and 17 CFR 200.402(a)(3), (5), (7), 9(ii) and (10), permit consideration of the scheduled matters at the Closed Meeting.

Commissioner Paredes, as duty officer, voted to consider the items listed for the Closed Meeting in a closed session.

The subject matter of the Closed Meeting scheduled for Thursday, June 23, 2011 will be:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings; and

Other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: The Office of the Secretary at (202) 551–5400.

Dated: June 15, 2011.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–15271 Filed 6–15–11; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Release No. 34–64653; File No. SR–CBOE–2011–041

Self-Regulatory Organizations; Chicago Board Options Exchange, Inc.; Order Granting Approval of Proposed Rule Change Establishing Qualified Contingent Cross Orders

June 13, 2011.

I. Introduction

On April 18, 2011, the Chicago Board Options Exchange, Inc. (''CBOE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to establish qualified contingent cross orders (''QCC Order''). The proposed rule change was published in the **Federal Register** on May 4, 2011.[3] The Commission received four comments on the proposal.[4] CBOE submitted a comment response letter on June 6, 2011.[5] This order grants approval of the proposed rule change.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 64354 (April 27, 2011), 76 FR 25392 (''Notice'').

[4] *See* Letters to Elizabeth M. Murphy, Secretary, Commission, from Martin Galivan, dated May 4, 2011(''Galivan Letter''); Ron March, dated May 4, 2011 (''March Letter''); Jesse L. Stamer, dated May 8, 2011 (''Stamer Letter''); and Michael J. Simon, Secretary, International Securities Exchange (''ISE''), dated May 27, 2011 (''ISE Letter'').

[5] *See* Letter to Elizabeth M. Murphy, Secretary, Commission, from Jennifer M. Lamie, Assistant General Counsel, CBOE, dated June 6, 2011 (''CBOE Response Letter'').

II. Description of the Proposal

CBOE proposes to amend CBOE Rule 6.53 to adopt rules related to a new QCC Order type that will be available to CBOE Trading Permit Holders (''TPHs'').[6] CBOE Rule 6.53 would permit QCC Orders to be submitted electronically from either on or off the floor through the CBOE Hybrid Trading System. The QCC Order would permit a TPH to cross the options leg(s) of a qualified contingent trade (''QCT'')[7] in a Regulation NMS stock, on CBOE immediately without exposure if the order is: (i) For at least 1,000 contracts; (ii) is part of a QCT;[8] (iii) is executed at a price at least equal to the national best bid or offer (''NBBO''); and (iv) there are no public customer orders resting in the Exchange's electronic book at the same price. Specifically, the QCC Order type would permit TPHs to provide their customers a net price for the stock-option trade, and then allow the TPH to execute the options leg(s) of the trade on CBOE at a price at least equal to the NBBO while using the QCT exemption to effect the trade in the

[6] In the Notice, the Exchange states that the proposal will permit CBOE to remain competitive with ISE, which has a QCC Order type that is submitted from off the floor, and other options exchanges that may adopt a similar order type. *See* Notice, *supra* note 3, at 25393.

[7] The Commission has granted an exemption for QCTs that meet certain requirements from Rule 611(a) of Regulation NMS, 17 CFR 242.611(a). *See* Securities Exchange Act Release No. 57620 (April 4, 2008), 73 FR 19271 (April 9, 2008) (''QCT Release,'' which supersedes a release initially granting the QCT exemption, Securities Exchange Act Release No. 54389 (August 31, 2006), 71 FR 52829 (September 7, 2006) (''Original QCT Release'')).

[8] CBOE is proposing to define a qualified contingent cross trade substantively identical to the Commission's definition in the QCT Release. A qualified contingent cross trade must meet the following conditions: (i) At least one component must be an NMS stock, as defined in Rule 600 of Regulation NMS, 17 CFR 242.600; (ii) all components must be effected with a product or price contingency that either has been agreed to by all the respective counterparties or arranged for by a broker-dealer as principal or agent; (iii) the execution of one component must be contingent upon the execution of all other components at or near the same time; (iv) the specific relationship between the component orders (*e.g.,* the spread between the prices of the component orders) is determined by the time the contingent order is placed; (v) the component orders must bear a derivative relationship to one another, represent different classes of shares of the same issuer, or involve the securities of participants in mergers or with intentions to merge that have been announced or cancelled; and (vi) the transaction must be fully hedged (without regard to any prior existing position) as a result of other components of the contingent trade. Consistent with the QCT Release, TPHs would be required to demonstrate that the transaction is fully hedged using reasonable risk-valuation methodologies. *See* QCT Release, *supra* note 7, at footnote 9.

equities leg at a price necessary to achieve the net price.[9] The Exchange would not permit the options component(s) of a QCC Order to trade through the NBBO.

III. Comment Letters

Four commenters raised objections to the proposal.[10] One commenter expressed the concern that the QCC Order would prohibit potential price improvement because such order may trade on the Exchange immediately without exposure.[11] The commenter was also concerned that the proposal may promote internalization of order flow to the benefit of a few select firms.[12] Another commenter stated that the proposal may decrease liquidity in the market and was concerned that public customer orders may get traded through.[13] Further, a commenter suggested that the proposal would create an uneven playing field in the market to the benefit of large institutional customers and detriment of small individual investors.

Another commenter questioned the ability of a floor-based exchange to verify that there is not a customer order on the book at the price as a QCC order at the time of execution.[14] The commenter argued that in an electronic trading environment, an exchange's systems can automatically determine if there is a customer order on the book before a QCC order is executed.[15] The commenter stated that how this function would be performed on a floor-based exchange should be clarified, as well as what the time of execution would be for a floor-based trade.[16] The commenter argued that ''[a]llowing a QCC to be implemented in a non-automated environment without a systemic check of whether there is a customer order on the book at the time of execution would effectively eliminate the protections guaranteed in an all electronic trading environment, thus returning [the exchanges] to the unequal competitive environment from which the ISE's QCC proposal originated.'' [17]

In its letter, CBOE responded to the issues raised in the ISE Letter and explained that, even when QCC Orders are submitted for execution from the floor, they are submitted electronically and that these orders would not be represented in ''open outcry.'' [18] CBOE also clarified that the time of execution of a QCC Order would not vary depending on whether the order is submitted from on the floor or off the floor and that the execution would occur when the QCC Order is submitted to the CBOE Hybrid Trading System.[19]

IV. *Discussion and Commission's Findings*

The Commission has carefully reviewed the proposed rule change, the comments received, and finds that it is consistent with the requirements of Section 6(b) of the Act.[20] Specifically, the Commission finds that the proposal is consistent with Sections 6(b)(5) [21] and 6(b)(8),[22] which require, among other things, that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and that the rules of an exchange do no impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. In addition, the Commission finds that the proposed rule change is consistent with Section 11A(a)(1)(C) of the Act,[23] in which Congress found that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure, among other things, the economically efficient execution of securities transactions.

The Commission believes that the proposed rule change, which would permit a clean cross of the options leg of a subset of qualified contingent trades, is appropriate and consistent with the Act.[24] The Commission believes that this order type may facilitate the execution of qualified contingent trades, which the Commission found to be beneficial to the market as a whole by contributing to the efficient functioning of the securities markets and the price discovery process.[25] The QCC Order would provide assurance to parties to stock-option qualified contingent trades that their hedge would be maintained by allowing the options component to be executed as a clean cross.

While the Commission believes that order exposure is generally beneficial to options markets in that it provides an incentive to options market maker to provide liquidity and therefore plays an important role in ensuring competition and price discovery in the options markets, it also has recognized that contingent trades can be ''useful trading tools for investors and other market participants, particularly those who trade the securities of issuers involved in mergers, different classes of shares of the same issuers, convertible securities, and *equity derivatives such as options* [italics added],'' [26] and that ''[t]hose who engage in contingent trades can benefit the market as a whole by studying the relationships between prices of such securities and executing contingent trades when they believe such relationships are out of line with what they believe to be fair value.'' [27] As such, the Commission stated that the transactions that meet the specified requirements of the NMS QCT Exemption could be of benefit to the market as a whole, contributing to the efficient functioning of the securities markets and the price discovery process.[28]

Thus, in light of the benefits provided by both the requirement for exposure as well as by qualified contingent trades such as QCC Orders, the Commission must weigh the relative merits of both for the options markets.[29] The Commission believes that the proposal, in requiring a QCC Order be: (1) Part of a qualified contingent trade under Regulation NMS; (2) for at least 1,000 contracts; (3) executed at a price at or between the NBBO; and (4) cancelled if there is a public customer on the electronic book, strikes an appropriate balance for the options market in that it is narrowly drawn and establishes a limited exception to the general principle of exposure and retains the general principle of customer priority in the options markets. Furthermore, not

[9] CBOE represented that it will adopt policies and procedures to ensure that TPHs use the QCC Order properly and require TPHs to properly mark all QCC Orders as such. Additionally, CBOE will implement an examination and surveillance program to assess TPH compliance with the requirements applicable to QCC Orders, including the requirement that the stock leg of the transaction be executed at or near the same time as the options leg.

[10] *See* note 4, *supra.*

[11] *See* Galivan Letter.

[12] *See* Galivan Letter.

[13] *See* Stamer Letter.

[14] *See* ISE Letter.

[15] *Id.*

[16] *Id.*

[17] *Id.*

[18] *See* CBOE Response Letter, *supra* note 5.

[19] *Id.*

[20] 15 U.S.C. 78f(b). In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[21] 15 U.S.C. 78f(b)(5).

[22] 15 U.S.C. 78f(b)(8).

[23] 15 U.S.C. 78k-1(a)(1)(C).

[24] *See also* Securities Exchange Act Release No. 63955 (February 24, 2011), 76 FR 11533 (March 2, 2011) (SR–ISE–2010–73) (''ISE QCC Approval'').

[25] *See* Original QCT Release, *supra* note 7.

[26] *See id.* at 52830–52831.

[27] *Id.*

[28] *See* QCT Release, *supra* note 7 at 19273.

[29] The Commission notes that it has previously permitted the crossing of two public customer orders, for which no exposure is required on ISE and CBOE. *See* CBOE Rule 6.74A.09 and ISE Rule 715(i) and 721.

only must a QCC Order be part of a qualified contingent trade by satisfying each of the six underlying requirements of the NMS QCT Exemption, the requirement that a QCC Order be for a minimum size of 1,000 contracts provides another limit to its use by ensuring only transactions of significant size may avail themselves of this order type.[30]

The Commission notes that, under CBOE's proposal, QCC Orders may be submitted electronically from either on or off the floor through the CBOE Hybrid Trading System. CBOE has represented that to effect proprietary orders, including QCC Orders, electronically from on the floor of the Exchange, members must qualify for an exemption from Section 11(a)(1) of the Act,[31] which concerns proprietary trading on an exchange by an exchange member. Among other exemptions, common exemptions include: An exemption for transactions by broker dealers acting in the capacity of a market maker under Section 11(a)(1)(A);[32] the ''G'' exemption for yielding priority to non-members under Section 11(a)(1)(G) of the Act and Rule 11a1–1(T) thereunder;[33] and the ''effect vs. execute'' exemption under Rule 11a2–2(T) under the Act.[34] The Exchange recognized in its filing that, consistent with existing Exchange rules for effecting proprietary orders from on the floor of the Exchange, TPHs effecting QCC Orders and relying on the ''G'' exemption would be required to yield priority to any interest, not just public customer orders, in the electronic book at the same price to ensure that non-member interest is protected.[35]

In approving a similar order type for ISE, the Commission considered the issues raised in the Galivan Letter, March Letter, and Stamer Letter, and found that ISE's QCC order type was consistent with the requirements of the Act and the rules and regulations thereunder.[36] In addition, the Commission believes that CBOE's response letter clarified the questions raised by ISE in the ISE Letter.

For the foregoing reasons, the Commission finds that the proposed rule change is consistent with Section 6(b)(5)[37] and 6(b)(8)[38] of the Act. Further, the Commission finds that the proposed rule change is consistent with Section 11A(a)(1)(C) of the Act.[39]

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[40] that the proposed rule change (SR–CBOE–2011–041) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[41]

Cathy H. Ahn,

Deputy Secretary.

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[30] The Commission notes that the requirement that clean crosses be of a certain minimum size is not unique to the QCC Order. *See, e.g.,* NSX 11.12(d), which requires, among other things, that a Clean Cross be for at least 5,000 shares and have an aggregate value of at least $100,000.

[31] 15 U.S.C. 78k(a)(1). Generally, Section 11(a)(1) of the Act restricts any member of a national securities exchange from effecting any transaction on such exchange for: (i) The member's own account, (ii) the account of a person associated with the member, or (iii) an account over which the member or a person associated with the member exercises discretion, unless a specific exemption is available.

[32] 15 U.S.C. 78k(a)(1)(A).

[33] 15 U.S.C. 78k(a)(1)(G) and 17 CFR 240.11a1–1(T).

[34] 17 CFR 240.11a2–2(T).

[35] *See, e.g.,* Securities Exchange Act Release No. 59546 (March 10, 2009), 74 FR 11144 (March 16, 2009) (SR–CBOE–2009–016) and CBOE Regulatory Circular RG09–35 (providing guidance on the application of Section 11(a)(1) and certain of the exemptions, as well as the application of the ''G'' exemption and the Effect vs. Execute exemption to trading on the Hybrid Trading System).

[36] *See* ISE QCC Approval, *supra* note 24.

[37] 15 U.S.C. 78f(b)(5).

[38] 15 U.S.C. 78f(b)(8).

[39] 15 U.S.C. 78k–1(a)(1)(C).

[40] 15 U.S.C. 78s(b)(2).

[41] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–64656; File No. SR–NYSEAmex–2011–36]

Self-Regulatory Organizations; NYSE Amex LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending the NYSE Amex Options Fee Schedule To Adopt a Monthly Fee Cap and Related Service Fee for All Member Firm Proprietary Transactions Executed in Open Outcry and To Increase Both the Existing Monthly Fee Cap and a Related Trading Volume Threshold Applicable to Market Makers

June 13, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that, on June 1, 2011, NYSE Amex LLC (the ''Exchange'' or ''NYSE Amex'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Options Fee Schedule (the ''Schedule'') by adopting (i) A monthly fee cap of $100,000 per month for member firms on all proprietary trading in open outcry, with certain exclusions, and (ii) a related service fee of $.01 per contract for volumes in excess of the cap. The Exchange also proposes to amend the monthly fee cap that is currently applicable to market makers by increasing it from $250,000 to $350,000 for all trades with certain exclusions, while raising the threshold at which capped market makers begin to pay $.01 per contract from 2,500,000 contracts to 3,500,000 contracts. The proposed changes will be operative on June 1, 2011. The text of the proposed rule change is available at the Exchange, the Commission's Public Reference Room, and *http://www.nyse.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposal is to cap all member firm proprietary transactions executed in open outcry at $100,000 per month, with certain exclusions. Once the monthly fee cap has been reached, member firm proprietary transactions in open outcry will be subject to a $.01 per contract service fee for all volumes in excess of the cap.[3] For example, the

[3] The Exchange trades several products subject to Royalty Fees, which are fees charged by the owner of the intellectual property rights associated with an index for the right to trade options on the index. Royalty Fees are not subject to the proposed monthly firm fee cap, and a capped firm will

Continued

member firm rate per contract for open outcry executions is $.25 per contract. Therefore, a member firm will cap once they have executed 400,000 contracts in proprietary transactions in open outcry, and at that point in time all subsequent proprietary transactions executed in open outcry by that member firm will be subject to a $.01 per contract service fee. The proposed service fee is being instituted to defray the Exchange's costs of providing services to members, which include trade matching and processing, post trade allocation, submission for clearing and customer service activities related to trading activity on the Exchange.

The proposed fee cap is functionally similar to the ''Multiply-Listed Option Fee Cap'' in place at the Chicago Board Options Exchange (''CBOE''),[4] the ''Firm Related Equity Option Cap'' in place at NASDAQ OMX PHLX, Inc. (''PHLX''),[5] and a monthly firm proprietary fee cap on the International Securities Exchange (''ISE'') that features a service fee.[6] The Exchange believes the proposed new fee cap would create an incentive for members to continue to send order flow to the Exchange. The Exchange is limiting the proposed new fee cap to manual firm proprietary orders in order to attract large block order flow to the floor of the Exchange, where such orders can be better handled in comparison with electronic orders that are not negotiable. The Exchange notes that NYSE Arca, Inc. also recently established a fee cap of $75,000 per month that is applicable only to manual firm proprietary trades in options.[7]

The Exchange also proposes to amend the current fee cap applicable to market makers [8] by increasing it from $250,000 per month to $350,000 per month and at the same time increasing the threshold from 2,500,000 contracts per month to 3,500,000 contracts per month, at which point the capped market makers will pay $.01 per contract for all subsequent volumes executed that month, subject to certain exclusions.[9] The Exchange is making this change as overall industry volumes and resultant volume on the Exchange have grown. In keeping up with this growth the Exchange is continually enhancing our systems to provide our market makers with the bandwidth necessary to quote competitively, and The Exchange believes that adjusting the fee cap upwards is appropriate given the ongoing costs of providing the throughput needed by high volume market makers.

The proposed changes will be operative on June 1, 2011.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Securities Exchange Act of 1934 (the ''Act''),[10] in general, and Section 6(b)(4) of the Act,[11] in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among its members and other persons using its facilities.

The Exchange believes that adopting the proposed new fee cap for manual firm proprietary trades is reasonable because it will potentially lower transaction fees for members providing liquidity on the Exchange. Members who reach the fee cap during a month will not have to pay regular transaction fees and thus will be able to lower their monthly fees.

The Exchange believes that this proposed new fee cap is not unfairly discriminatory because all member firms are eligible to reach the cap. In addition, the Exchange believes that the proposed monthly fee cap, which applies only to manual firm proprietary trades, is not unfairly discriminatory to other market participants because its purpose is to attract large block order flow to the floor of the Exchange, where such orders can be better handled in comparison with electronic orders that are not negotiable. To the extent that this purpose is achieved, all of the Exchange's market participants should benefit from the improved market liquidity. The Exchange has previously adopted other incentive programs targeting other business areas: no fees for customer orders [12] and fee caps for market makers.[13]

The Exchange further believes the proposal to adopt the fee cap is equitable because it would uniformly apply to all member firms engaged in manual proprietary trading in option classes traded on the Exchange. As noted, market makers currently receive the benefit of a fee reduction once they reach a volume threshold.

The Exchange believes that adopting the service fee is reasonable because it will also potentially lower transaction fees for member firms. Member firms who reach the fee cap during a month will pay the service fee instead of the regular transaction fees and thus will be able to lower their monthly fees. The Exchange believes that charging a service fee is also reasonable because it will allow the Exchange to recoup the costs incurred in providing certain services, which include trade matching and processing, post trade allocation, submission for clearing and customer service activities related to trading activity on the Exchange. The Exchange believes the proposed fee change will attract additional order flow to the Exchange and thereby will benefit all market participants.

The Exchange believes the proposal to adopt the service fee is equitable and not unfairly discriminatory because it would uniformly apply to all member firms engaged in manual proprietary trading. The proposed fee is designed to give member firms that trade a lot on the Exchange a benefit by way of a lower transaction fee.

The Exchange believes the proposed service fee change will benefit market participants by potentially lowering their fees while allowing the Exchange to remain competitive with other exchanges that offer similar fee cap programs. The Exchange notes that the proposed service fee is similar to fees other exchanges charge for providing certain services to their members. For example, ISE's monthly firm proprietary fee cap described above features a service fee that is applicable in

continue to pay Royalty Fees at the rate(s) stated in the Schedule. In addition, Firm Facilitation trades will continue to be executed at a rate of $0.00 per contract regardless of whether a firm is capped or not.

[4] The CBOE fees are capped at $75,000. *See* CBOE Fees Schedule, May 2, 2011, Section 1 (Equity Options Fees) on page 2 of 15 at *http://www.cboe.com/publish/feeschedule/CBOEFeeSchedule.pdf*.

[5] PHLX Firms are subject to a maximum fee of $75,000. *See* PHLX Fee Schedule, May 19, 2011, Section II (Equity Options Fees) on page 8 of 42 at *http://www.nasdaqtrader.com/content/marketregulation/membership/phlx/feesched.pdf*.

[6] ISE firms are capped at $100,000 with certain exclusions and subject to a service fee on all volumes once the cap has been reached. *See* ISE Schedule of Fees, April 11, 2011, footnote 1 on page 15 of 17 at *http://www.ise.com/assets/documents/OptionsExchange/legal/fee/fee_schedule.pdf*.

[7] *See* Securities Exchange Act Release No. 63471 (December 8, 2010), 75 FR 77928 (December 14, 2010) (File No. SR–NYSEArca–2010–108).

[8] This category includes Specialists, eSpecialists, and NYSE Amex Options Market Makers (both Directed and Non-Directed).

[9] The Exchange notes that the current market maker fee cap is exclusive of Royalty Fees charged for transactions in products subject to Royalty Fees. No change is occurring with respect to this, and capped market makers will continue to be subject to the Royalty Fees stated in the Schedule. Similarly, any fees or volume associated with a Strategy Trade will not be counted towards either the $350,000 cap or the volume threshold of 3,500,000 contracts. Additionally, the charge for all non-Public Customers who transact in the electronic Complex Order Book is $.05 per contract, and capped market makers trading in the Complex Order Book will continue to pay $.05 per contract.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(4).

[12] *See* NYSE Amex Options Fee Schedule as of May 11, 2011, Customer Electronic and Customer Manual charges on pages 2–3 of 10 at *http://www.nyse.com/pdfs/NYSEAmex_Options_Fee_Schedule_CLEAN_05_11_11_Effective_Date.pdf*.

[13] *See id*. at footnote 5 on page 9 of 10.

conjunction with the cap.[14] The proposed service fee is also similar to the incremental charge of $.01 per contract that the Exchange currently charges on market maker volume executed in excess of 2,500,000 contracts per month.[15]

The Exchange believes the proposal to amend the monthly market maker fee cap is equitable and not unfairly discriminatory because it would uniformly apply to all market makers. Market maker fee caps generally are designed to give market makers who provide substantial liquidity on the Exchange a benefit by way of a lower transaction fee. The Exchange notes that other exchanges, notably the CBOE,[16] PHLX,[17] and ISE [18] offer volume discounts and/or fee caps for market makers transacting business on their exchanges. The Exchange believes that the proposed increase in the amount of the fee cap is reasonable because of the additional costs being incurred by the Exchange in enhancing its systems to provide our market makers with the increased bandwidth needed to quote competitively, given the growth in overall industry volumes and resultant increased volume on the Exchange. The Exchange notes further that even at the newly proposed $350,000 level, the market maker fee cap would be substantially less than similar caps on PHLX (which offers a cap of $550,000 per month including only certain symbols) [19] and CBOE (which requires a $8,446,400 annual prepayment, equivalent to over $700,000 per month, in order to attain a rate of $0.03 per contract).[20]

For the reasons noted above, the Exchange believes that the proposed fees are fair, equitable and not unfairly discriminatory.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

[14] *See supra* note 6 (describing the operation of the ISE service fee).

[15] *See supra* note 13 (describing the operation of the $.01 incremental charge).

[16] *See* CBOE Fees Schedule—Liquidity Provider Scale on page 2 of 15 and related footnote 10 on page 4 of 15.

[17] *See* PHLX Fee Schedule—Section II (Equity Options Fees) on page 8 of 42.

[18] *See* ISE Schedule of Fees—ISE Market Maker sliding scale on page 4 of 17.

[19] *See supra* note 17.

[20] *See supra* note 16, footnote 10 on page 4 of 15.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [21] of the Act and subparagraph (f)(2) of Rule 19b–4 [22] thereunder, because it establishes a due, fee, or other charge imposed by NYSE Amex.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NYSEAmex–2011–36 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAmex–2011–36. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEAmex–2011–36 and should be submitted on or before July 8, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

Cathy H. Ahn,

Deputy Secretary.

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[21] 15 U.S.C. 78s(b)(3)(A).

[22] 17 CFR 240.19b–4(f)(2).

[23] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–64655; File No. SR–NYSEAmex–2011–37]

Self-Regulatory Organizations; NYSE Amex LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending the NYSE Amex Options Fee Schedule To Establish a New Fee Designed To Encourage Efficient Use of Bandwidth by ATP Firms and To Rename a Related Existing Fee

June 13, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that, on June 1, 2011, NYSE Amex LLC (the ''Exchange'' or ''NYSE Amex'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Options Fee Schedule (the ''Schedule'') by renaming an existing fee to better reflect the nature of the fee and introducing a new fee designed to encourage efficient use of bandwidth by both order sending and quote sending ATP firms. The proposed changes will be operative on June 1, 2011. The text of the proposed rule change is available at the Exchange, the Commission's Public Reference Room, and *http://www.nyse.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposal is to encourage efficient usage of systems capacity by all ATP firms. The Exchange feels that it is in the best interests of all ATP firms and investors who access our markets to encourage efficient usage of capacity.

The first change proposed is simply a name change to an existing fee, the Ratio Threshold Fee, which measures monthly order to trade ratios. This fee is being renamed the Order to Trade Ratio Fee to better reflect what the fee is based on.

At the same time, the Exchange proposes the introduction of a new fee designed to further encourage efficient systems usage (''Messages to Contracts Traded Ratio Fee''). This fee will take into consideration quotes as well as orders entered and will look at the number of contracts traded as a result. ATP firms that enter excessive amounts of orders and quotes that produce little or no volume will be assessed this fee based on the ratio of quotes and orders to contracts traded. The Exchange recognizes that there can be problems at the level of either an ATP firm or its vendor or at the Exchange that can cause inadvertent bursts of quotes and/or orders. For that reason, the Exchange proposes to only consider those ATP firms who exceed 1 billion quotes and/or orders (collectively, ''messages'') in a given month in determining whether inefficient utilization of systems capacity has occurred. For those ATP firms exceeding 1 billion messages in a month, the Exchange proposes to assess a fee for those ATP firms that do not execute at least one (1) contract for every 1,500 messages entered. An ATP firm failing to meet that execution ratio will be charged $.01 for every 1,000 messages in excess of 1 billion messages.

For example, assume an ATP firm enters a combination of quotes and orders in a given month that sum to 1,500,100,000. Assume that same ATP firm also traded 1,000,000 contracts that month. Having traded 1,000,000 contracts, that ATP firm would need to have sent fewer than 1,500,000,000 messages to stay within the execution ratio of 1 contract per 1,500 messages. In this case, the ATP firm sent 100,000 messages in excess of what is permitted under the 1 to 1,500 execution ratio. This would result in a charge of $.01 per 1,000 messages in excess of 1,000,000,000, in this case a charge of $5,001 (500,100,000 quotes/orders in excess of 1,000,000,000 or 500,100 groups of 1,000 messages times $.01 per message group).

The need for the new fee based on the messages to contracts traded ratio is based on the fact that the existing Ratio Threshold Fee (to be renamed the Order to Trade Ratio Fee) only counts orders, not market maker quotes. The proposed Messages to Contracts Traded Ratio Fee incorporates market maker quotes, which the Exchange believes to be appropriate given that market maker quote traffic represents a substantial portion of the total message load that must be processed by Exchange systems each day. This proposed new fee will never be triggered unless a very high level of traffic is generated by a market maker (*i.e.*, over one billion quotes and orders per month); no such minimum exists for the Order to Trade Ratio Fee. Therefore, by preserving the existing fee and also adding the Messages to Contracts Traded Ratio Fee, the Exchange hopes to maintain its existing, well-understood incentives for order-sending firms to use bandwidth efficiently, while ensuring that market makers also have such incentives but with a higher level of traffic permitted before the fee takes effect. The Exchange feels that this higher level of free message traffic is appropriate due to the quoting obligations incurred by market makers and their importance as liquidity providers in the options market.

The Exchange proposes that all ATP firms that send quotes and/or orders will be subject to the proposed Messages to Contracts Traded Ratio Fee as well as to the existing and renamed Order to Trade Ratio Fee, which will be referred to collectively as Excessive Bandwidth Utilization Fees on the Schedule. In the event that an ATP firm is liable for either or both of the Excessive Bandwidth Utilization Fees and/or for charges pursuant to the Cancellation Fee in a given month, that firm would only be charged the largest one of those three fees for the month.[3] For example, if the fee calculated under the Order to Trade Ratio Fee is $10,000, the fee calculated under the Messages to Contracts Traded Ratio Fee is $5,001, and the charges calculated pursuant to the Cancellation Fee are $6,000, the ATP firm would be billed $10,000 for that month.[4]

Unlike the Order to Trade Ratio Fee, the Exchange is not proposing to exclude market-improving quotes or orders from the calculation of the Messages to Contracts Traded Ratio Fee. Due to the much larger amount of traffic generated by market makers, who are potentially included in this fee, addressing market-improving quotes or orders separately for billing purposes would greatly complicate the computation of this fee. In addition, because the parameters of this fee, including the exemption of the first 1 billion messages per calendar month, allow for a large amount of message traffic before the fee is triggered, the Exchange does not believe that including an additional exemption for market-improving quotes is necessary.

The Exchange also proposes to correct certain incorrect footnote references under ''Trade-Related Charges'' in the Schedule by (i) Eliminating a footnote reference under ''Limit of Fees on Options Strategy Executions'' that is not

[3] Currently, ATP Holders are not charged the Ratio Threshold Fee if they incur charges on a monthly basis pursuant to the Cancellation Fee. This provision is being deleted from footnote 12 of the Schedule and being replaced with a new provision stating that the Exchange will now look at a firm's liability under the two Excess Bandwidth Utilization Fees and the Cancellation Fee and only require the firm to pay the largest one of these three fees for the month.

[4] In calculating the Messages to Contracts Traded Ratio Fee, the Exchange will aggregate routing and market making activity in the case of an ATP firm that has both a routing and a market making arm affiliated with its operation. For purposes of determining whether the routing and market making arm are ''affiliated'' with the ATP firm, the Exchange will apply a 70% common ownership test as the criterion for affiliation.

applicable and (ii) adding an additional reference to a footnote on marketing charges under both ''Electronic Complex Order Executions'' and under ''Marketing Charge.'' These error corrections are of a cleanup nature and do not represent changes to any of the Exchange's current fees or the way that they are calculated and applied.

The proposed changes will be operative on June 1, 2011.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Securities Exchange Act of 1934 (the ''Act''),[5] in general, and Section 6(b)(4) of the Act,[6] in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among its members and other persons using its facilities. The Exchange also believes that the proposed rule change furthers the objectives of Section 6(b)(5) of the Act[7] in that it is designed to promote just and equitable principles of trade, remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest by ensuring that systems capacity is utilized efficiently.

More specifically, the Exchange believes that the proposed Excessive Bandwidth Utilization Fees are equitable and not unfairly discriminatory since they will apply equally to all members who send quotes and/or orders. Additionally, the proposed Excessive Bandwidth Utilization Fees are reasonable and justified because they will encourage efficient utilization of system bandwidth, and unfettered growth in bandwidth consumption can have a detrimental effect on all participants who are potentially compelled to upgrade capacity as a result of the profligate ways of other participants.

The Exchange believes that the higher level of free message traffic permitted before the proposed new Messages to Contracts Traded Ratio Fee is triggered, even though the Order to Trade Ratio Fee has no such minimum trigger, is not unfairly discriminatory due to the substantial message load that exists from normal market maker quote traffic as well as the quoting obligations incurred by market makers and their importance as liquidity providers in the options market. In addition, the inclusion of market-improving quotes and orders in the calculation of the Messages to Contracts Traded Ratio Fee (which orders are excluded from the calculation of the Order to Trade Ratio Fee) is not unfairly discriminatory because of the very high level of message traffic allowed before the fee is triggered (even with the inclusion of market-improving quotes and orders), as well as the computation complications from excluding such quotes and orders that would exist as a result of the much larger amount of quote traffic generated by market makers.

Finally, the fact that only one of the three related fees (the two Excessive Bandwidth Utilization Fees and the Cancellation Fee), whichever is the highest, will be charged to an ATP firm in a given month is an additional factor assuring that the application of these fees will be reasonable, equitable and not unfairly discriminatory.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[8] of the Act and subparagraph (f)(2) of Rule 19b–4[9] thereunder, because it establishes a due, fee, or other charge imposed by NYSE Amex.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NYSEAmex–2011–37 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAmex–2011–37. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEAmex–2011–37 and should be submitted on or before July 8, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–15040 Filed 6–16–11; 8:45 am]

BILLING CODE 8011–01–P

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(4).

[7] 15 U.S.C. 78f(b)(5).

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(2).

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–64652; File No. SR–NASDAQ–2011–075]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Regarding BONO SM and ITTO Market Data

June 13, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 31, 2011, The NASDAQ Stock Market LLC (''NASDAQ'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by NASDAQ. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

NASDAQ proposes changes to add new Rule 7054 (NASDAQ Options Market Data Distributor Fees) setting forth the fees for options market data feeds known as Best of NASDAQ Options and NASDAQ ITCH to Trade Options.

While the proposed fee changes are effective upon filing, the Exchange has designated these changes to be operative on July 1, 2011.

The text of the proposed rule change is available at *http://www.nasdaq.cchwallstreet.com,* at NASDAQ's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NASDAQ included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. NASDAQ has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to add new Rule 7054 setting forth the fees for options market data feeds known as Best of NASDAQ Options (''BONO SM'') and NASDAQ ITCH to Trade Options (''ITTO'').

Background

The Exchange recently modified Chapter VI, Section 1(a)(3) of the NASDAQ Options Market (''NOM'') Rules to specify the names and content of the two data feeds that are the subject of this filing, BONO SM and ITTO.[3]

ITTO is currently described in the Exchange's option rules at subsection (a)(3)(B) of Chapter VI, Section 1 as a data feed that provides quotation information for individual orders on the NOM book, last sale information for trades executed on NOM, and Order Imbalance Information as set forth in NOM Rules Chapter VI, Section 8. ITTO is the options equivalent of the NASDAQ TotalView/ITCH data feed that NASDAQ offers under NASDAQ Rule 7023 with respect to equities traded on NASDAQ. As with TotalView, members use ITTO to ''build'' their view of the NOM book by adding individual orders that appear on the feed, and subtracting individual orders that are executed.

BONO SM is currently described in subsection (a)(3)(A) of Chapter VI, Section 1 as a data feed that provides the NOM Best Bid and Offer (''NBBO'') and last sale information for trades executed on NOM. The NBBO and last sale information are identical to the information that NOM sends the Options Price Regulatory Authority (''OPRA'') and which OPRA disseminates via the consolidated data feed for options. BONO is the options equivalent of the NASDAQ Basic data feed offered for equities under NASDAQ Rule 7047.

[3] Securities Exchange Act Release No. 63983 (February 25, 2011), 76 FR 12178 (March 4, 2011) (SR–NASDAQ–2011–032) (notice of filing and immediate effectiveness to offer, among other things, BONO SM and ITTO market data for free). The filing also offered NASDAQ Options Depth at Price (DAP) and NASDAQ Options Net Order Imbalance (NOIView) for free; this proposal does not affect the DAP and NOIView data feeds. Chapter VI, Section 1(a)(3) states generally that the NOM trading system includes data feeds that can be used to display without attribution to Participants' MPIDs Displayed Orders on both the bid and offer side of the market for price levels then within the NASDAQ Options Market using the minimum price variation applicable to that security.

The Proposal

The Exchange has been offering the BONO SM and ITTO options market data feeds free of charge. The Exchange now proposes to institute Rule 7054 setting forth fees for recipients of BONO SM and ITTO data, with a free trial offer for certain data recipients.

The definitions of BONO SM and ITTO are established in new Rule 7054. Proposed Rule 7054(d) states that BONO SM is a data feed that provides the NBBO and last sale information for trades executed on NOM. Proposed Rule 7054(e) states that ITTO is a data feed that provides quotation information for individual orders on the NOM book, last sale information for trades executed on NOM, and Order Imbalance Information as set forth in NOM Rules Chapter VI, Section 8.[4]

Using elements of the current fee structure for recipients of NASDAQ TotalView and NASDAQ Basic,[5] which are similar on the equities side to BONO SM and ITTO, the Exchange proposes to charge monthly fees for firms that are distributors of BONO SM and ITTO market data. Proposed Rule 7054(b) states that a ''distributor'' of NASDAQ options market data is any entity that receives a feed or data file of NASDAQ data directly from NASDAQ or indirectly through another entity and then distributes the data either internally (within that entity) or externally (outside that entity). Proposed subsection (b) also states that all distributors would be required to execute a NASDAQ distributor agreement. The amount of the monthly fees would depend on whether a distributor is an ''Internal Distributor'' or ''External Distributor.''[6]

An Internal Distributor is a firm that is permitted by agreement with the Exchange to provide BONO SM and ITTO data to internal users (*i.e.,* users within their own organization). Under the proposal, Internal Distributors of BONO SM and ITTO data would be charged a monthly fee of $1,500 per firm.

An External Distributor is a firm that is permitted by agreement with the Exchange to provide BONO SM and ITTO data to both internal users and to external users (*i.e.,* users outside of their own organization). External Distributors would be charged a monthly fee of $2,000 per firm. The fee paid by an

[4] The language of subsections (d) and (e) within Rule 7054 is identical to the language that describes BONO SM and ITTO in NOM option rules at Chapter VI, Section 1(a)(3)(A) and (B).

[5] *See* Rules 7023 and 7047.

[6] Thus, a distributor may pay either ''Internal Distributor'' or ''External Distributor'' fees.

External Distributor includes the Internal Distributor Fee. The fee paid by an Internal Distributor or an External Distributor would allow access to both the BONO SM and ITTO data feeds.

The Exchange also proposes to assess user fees for BONO SM and ITTO data on a per-user basis.[7] These fees would vary based on whether they are for Professional users or Non-Professional users. Proposed Rule 7054 (f) states that the term ''Non-Professional'' shall have the same meaning as in NASDAQ Rule 7011(b)(2). Rule 7011(b)(2) defines a ''Non-Professional'' as a natural person who is neither: (A) Registered or qualified in any capacity with the Commission, the Commodities Futures Trading Commission, any state securities agency, any securities exchange or association, or any commodities or futures contract market or association; (B) engaged as an ''investment adviser'' as that term is defined in Section 201(11) of the Investment Advisors Act of 1940 (whether or not registered or qualified under that Act); nor (C) employed by a bank or other organization exempt from registration under federal or state securities laws to perform functions that would require registration or qualification if such functions were performed for an organization not so exempt.[8] A Professional user is any user that is not a Non-Professional.

For BONO SM data, the proposed per-user fees are $5 per Professional user; and $1 per Non-Professional user. For ITTO data, the proposed per-user fees are $10 per Professional user; and $1 per Non-Professional user.

The Exchange notes that for many years, exchanges have engaged in and the Commission has accepted the practice of price differentiation, both in the context of market data as well as in the context of executions. With respect to market data, NASDAQ and NYSE Euronext (''NYSE'') in their capacities as network processors and exchanges have differentiated in pricing between Professional and Non-Professional market data users, often charging Professionals many times more than Non-Professionals for using the same data. For example, NASDAQ currently charges Non-Professional users (subscribers) $60 a month for NASDAQ Depth Data received via a Managed Depth Solution and Professional users $300 a month.[9] Also, NASDAQ currently charges Non-Professionals $15 per terminal for its NASDAQ Depth Data via a standalone terminal, while Professional investors pay roughly five times the Non-Professional rate.[10] This reflects the value of the service to various constituencies (*i.e.,* lower prices are charged to consumers with more elastic demand) and allows both types of investors to contribute to the high fixed costs of operating an exchange platform. The Exchange believes that this differentiation for Professional and Non-Professional data usage, as the differentiation for Professional and Non-Professional users proposed in this filing, is completely consistent with past Commission precedent and economic theory.[11]

The Exchange also proposes to assess a monthly non-display enterprise license fee. Proposed Rule 7054(c) states that an ''enterprise license'' entitles a distributor to provide BONO SM or ITTO market data pursuant to this rule to an unlimited number of non-display devices [12] within the firm without any per user charge. Under the proposal, distributors of BONO SM and ITTO data may, if they choose to subscribe to a non-display enterprise license, be charged a monthly enterprise license fee or $2,500.

The non-display enterprise license is in addition to other distributor fees. Thus, a firm that has a non-display enterprise license could pay an Internal Distributor fee and distribute data to limitless number of non-user display devices (devices within the firm) pursuant to the license without incurring further fees for each internal user. However, the enterprise license does not allow external distribution without incurring an External Distributor fee and external per user fees, if applicable under the circumstances.

Finally, the Exchange proposes a 30-Day Free Trial Offer in subsection (g) of Rule 7054.[13] In particular, the 30-day waiver of the user fees for NASDAQ options market data pursuant to the rule extends to all new individual (non-firm) users (subscribers) and potential new individual users. This fee waiver period will be applied on a rolling basis, determined by the date on which a new individual (non-distributor or firm) user or potential individual user is first entitled by a distributor to receive access to NASDAQ options market data. Subsection (g) provides that a distributor may only provide this waiver to a specific individual user one time.

The Exchange notes that the categories of BONO SM and ITTO market data and fees compare favorably with similar products offered by other markets such as International Stock Exchange (''ISE''), NYSE, NASDAQ OMX PHLX (''Phlx''), and Chicago Board Options Exchange (''CBOE''). For example, ISE offers market data products that are similar to BONO SM: a data feed that shows the top of the market entitled TOP Quote Feed,[14] and a data feed that shows the top five price levels entitled Depth of Market.[15] NYSE offers a market data product for Arca and Amex that is similar to BONO SM and ITTO: a feed that shows top of book, last sale, and depth of quote and is entitled NYSE Arca Book for Options.[16] Phlx offers a market data feed entitled TOPO that is similar to BONO SM and shows orders and quotes at the top of the market, as well as trades; and a TOPO Plus Orders feed that is similar to ITTO and shows the data in the TOPO data feed as well as the depth of orders.[17] A subsidiary of CBOE for

[7] While the user fees would be paid by firms (Internal Distributors and External Distributors), some portion of the fees may be passed through to users inside or outside the firms (that is, to internal or external users).

[8] The Exchange believes that Non-Professional users of market data, in contrast to Professional data users and distributors, often tend to be individual consumers, smaller retail investors, and public customers.

[9] *See* Rule 7026.

[10] *See* Rule 7023.

[11] In economic terms, charging lower fees to non-professional consumers increases overall economic welfare by increasing output—in this case, providing more data to more investors—and avoids two equally undesirable alternatives: (i) requiring the firm to charge uniformly high prices that constrict demand, or (ii) insisting on uniformly low prices at marginal cost (potentially zero or close to zero) that do not allow the firm to cover its fixed costs and thereby lead to bankruptcy.

[12] Non-display devices do not graphically show (display) BONO SM or ITTO market data but instead use the data for performance of analytic or calculative functions (*e.g.* algorithms).

[13] For other Exchange data products that offer a 30-day free trial, *see* Rules 7023, 7044 and 7036. *See also* Rules 7049 and 7055.

[14] The ISE TOP Quote Feed has a monthly base access fee of $5,000 applicable to professionals and non-professionals plus a $10 variable device fee for professionals and a no device fee for internal use professionals; or a flat fixed enterprise fee of $2,500 for professionals and a $2,000 fee for internal use professionals. The Exchange notes that the monthly fees for the ISE TOP Quote Feed are higher than those proposed in this filing.

[15] The ISE Depth of Market Feed has a monthly base access fee of $5,000 applicable to professionals and non-professionals plus a $50 variable device fee for professionals and a $5 per device fee for external distribution non-professionals; or a flat fixed enterprise fee of $7,500 for internal use professionals, $12,500 for external use professionals, and $10,000 for non-professionals. The Exchange notes that the monthly fees for ISE Depth of Market are higher than those proposed in this filing for a more robust product.

[16] The fee for NYSE Arca Book for Options is $750 per month.

[17] TOPO Plus Orders has a monthly fee of $4,000 for internal distributors or $5,000 for external distributors plus a monthly fee of $1 per non-professional subscribers (users) and $20 for professional subscribers. The Exchange notes that

Continued

which CBOE charges fees offers a market data feed that is similar to BONO SM and shows BBO, last sale, and top of book data.[18] And BATS offers Multicast PITCH, which is their depth of market and last sale feed similar to ITTO.[19]

The Exchange believes that the continued availability of BONOSM and ITTO data feeds enhances transparency, fosters competition among orders and markets, and enables buyers and sellers to obtain better prices.

2. Statutory Basis

NASDAQ believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[20] in general and with Sections 6(b)(5) of the Act,[21] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

In adopting Regulation NMS, the Commission granted self-regulatory organizations like NASDAQ and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data. NASDAQ believes that this proposal is in keeping with those principles by promoting increased transparency through the dissemination of more useful proprietary data and also by clarifying its availability to various market participants.

Additionally, NASDAQ has made a voluntary decision to make this market data available. NASDAQ is not required by the Exchange Act in the first instance to make the data available, unlike the best bid and offer which must be made available under the Act. NASDAQ has chosen to make the noted data available to improve market quality, to attract order flow, and to increase transparency; and will continue to make the data available until such time as NASDAQ changes its rule.

NASDAQ believes that its ITTO and BONO,SM which includes the NBBO and last sale information for trades executed on NOM in BONO,SM are precisely the sort of market data products that the Commission envisioned when it adopted Regulation NMS. The Commission concluded that Regulation NMS—by lessening regulation of the market in proprietary data—would itself further the Act's goals of facilitating efficiency and competition:

> [E]fficiency is promoted when broker-dealers who do not need the data beyond the prices, sizes, market center identifications of the NBBO and consolidated last sale information are not required to receive (and pay for) such data. The Commission also believes that efficiency is promoted when broker-dealers may choose to receive (and pay for) additional market data based on their own internal analysis of the need for such data.[22]

By removing ''unnecessary regulatory restrictions'' on the ability of exchanges to sell their own data, Regulation NMS advanced the goals of the Act and the principles reflected in its legislative history. If the free market should determine whether proprietary data is sold to broker-dealers at all, it follows that the price at which such data is sold should be set by the market as well.

The recent decision of the United States Court of Appeals for the District of Columbia Circuit in *NetCoaliton* v. *SEC,* No. 09–1042 (D.C. Cir. 2010) upheld the Commission's reliance upon competitive markets to set reasonable and equitably allocated fees for market data. ''In fact, the legislative history indicates that the Congress intended that the market system 'evolve through the interplay of competitive forces as unnecessary regulatory restrictions are removed' and that the SEC wield its regulatory power 'in those situations where competition may not be sufficient,' such as in the creation of a 'consolidated transactional reporting system.' *NetCoaltion,* at 15 (quoting H.R. Rep. No. 94–229, at 92 (1975), *as reprinted in* 1975 U.S.C.C.A.N. 321, 323).

The court agreed with the Commission's conclusion that ''Congress intended that 'competitive forces should dictate the services and practices that constitute the U.S. national market system for trading equity securities.' ''[23]

The Court in *NetCoalition,* although upholding the Commission's conclusion that competitive forces may be relied upon to establish the fairness of prices, nevertheless concluded that the record *in that case* did not adequately support the Commission's conclusions as to the competitive nature of the market for NYSEArca's data product at issue in that case. As discussed previously and explained below in NASDAQ's Statement on Burden on Competition, however, NASDAQ believes that there is substantial evidence of competition in the marketplace for data that was not in the record in the *NetCoalition* case, and that the Commission is entitled to rely upon such evidence in concluding that the fees established in this filing are the product of competition, and therefore in accordance with the relevant statutory standards.[24]

Competitive products similar to BONO SM and ITTO are, as previously discussed, offered by other exchanges, albeit sometimes at higher prices. ISE offers two data products similar to BONO SM that are called TOP Quote Feed, Depth of Market and have fees higher that those proposed in this filing.[25] NYSE offers a market data product similar to BONO SM and ITTO called NYSE Arca Book of Options that has market data for NYSE Arca and NYAE Amex. Phlx offers a market data product that is similar to ITTO.[26] CBOE offers a market data product that is similar to BONO.SM [27] BATS offers a market data product similar to ITTO.

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the monthly fees for TOPO Plus Orders are higher than those proposed in this filing. *See* Securities Exchange Act Release No. 62194 (May 28, 2010), 75 FR 31830 (June 4, 2010) (SR–Phlx–2010–48)(order approving proposal related to TOPO Plus Orders market data fees).

[18] The subsidiary is identified as Market Data Express, LLC (''MDX'') by CBOE, which indicates that the feed will also provide data regarding contingency orders and complex strategies. The monthly fee charged by CBOE for the data is $3,500 plus a $25 per user or device fee. *See* Securities Exchange Act Release No. 63997 (March 1, 2011), 76 FR 12388 (March 7, 2011) (SR–CBOE–2011–014) (notice of filing and immediate effectiveness). In the filing, CBOE specifically references as similar products the Phlx TOPO Plus Orders feed and the ISE Depth of Market Feed.

[19] BATS offers Multicast PITCH without charge ostensibly to attract order flow to that exchange.

[20] 15 U.S.C. 78f.

[21] 15 U.S.C. 78f(b)(5).

[22] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005).

[23] *NetCoaliton* v. *SEC* at p. 16.

[24] It should also be noted that Section 916 of Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (''Dodd-Frank Act'') has amended paragraph (A) of Section 19(b)(3) of the Act, 15 U.S.C. 78s(b)(3) to make it clear that all exchange fees, including fees for market data, may be filed by exchanges on an immediately effective basis. Although this change in the law does not alter the Commission's authority to evaluate and ultimately disapprove exchange rules if it concludes that they are not consistent with the Act, it unambiguously reflects a conclusion that market data fee changes do not require prior Commission review before taking effect, and that a formal proceeding with regard to a particular fee change is required only if the Commission determines that it is necessary or appropriate to suspend the fee and institute such a proceeding.

[25] For the fees related to ISE TOP Quote Feed and Depth of Market, *see supra* notes 14 and 15.

[26] For the fees related to NYSE Arca Book of Options and Phlx TOPO Plus Orders, *see supra* notes 16 and 17.

[27] For the fees related to the CBOE market data product, *see supra* note 18.

Moreover, the Exchange notes that, as a substitute for exchange data, consolidated market data (*e.g.* last sale, NBBO, current quotes) are also available from securities information processors such as OPRA.

B. Self-Regulatory Organization's Statement on Burden on Competition

NASDAQ does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. NASDAQ's ability to price its BONO SM and ITTO products is constrained by (1) Competition between exchanges and other trading platforms that compete with each other in a variety of dimensions; (2) the existence of inexpensive real-time consolidated data and free delayed consolidated data; and (3) the inherent contestability of the market for proprietary last sale data. NASDAQ believes that the Dodd-Frank Act amendments to Section 19 materially alter the scope of the Commission's review of future market data filings, by creating a presumption that all fees may take effect immediately, without prior analysis by the Commission of the competitive environment. Even in the absence of this important statutory change, however, NASDAQ believes that a record may readily be established to demonstrate the competitive nature of the market in question.

The market for market data products is competitive and inherently contestable because there is fierce competition for the inputs necessary to the creation of proprietary data and strict pricing discipline for the proprietary products themselves. Numerous exchanges compete with each other for listings, trades, and market data itself, providing virtually limitless opportunities for entrepreneurs who wish to produce and distribute their own market data. This proprietary data is produced by each individual exchange, as well as other entities, in a vigorously competitive market. Broker-dealers currently have numerous alternative venues for their order flow, including ten self-regulatory organization (''SRO'') markets, as well as internalizing broker-dealers (''BDs'') and various forms of alternative trading systems (''ATSs'') and electronic communication networks (''ECNs''). For example, the Exchange has noted that numerous other U.S. options exchanges offer market data products that are substantially similar to the ITTO and BONO SM products, which the Exchange must consider in its pricing discipline in order to compete for listings, trades, and the market data itself.

The large number of SROs, BDs, and ATSs that currently produce proprietary data or are currently capable of producing it provides further pricing discipline for proprietary data products. Each SRO, ATS, and BD is currently permitted to produce proprietary data products, and many currently do or have announced plans to do so, including ISE, CBOE, NYSE (NYSE Amex and NYSE Arca), Phlx, and BATS. Indeed, the Exchange has discussed a host of products that are similar to ITTO and BONO,SM including: ISE's TOP Quote Feed and Depth of Market feed; NYSE's Arca Book of Options feed; Phlx's TOPO Plus Orders feed; BATS' Multicast PITCH feed; and CBOE's recently fee liable data feed through MDX.

Furthermore, any ATS or BD can combine with any other ATS, BD, or multiple ATSs or BDs to produce joint proprietary data products. Additionally, order routers and market data vendors can facilitate single or multiple broker-dealers' production of proprietary data products. The potential sources of proprietary products are virtually limitless.

The fact that proprietary data from ATSs, BDs, and vendors can by-pass SROs is significant in two respects. First, non-SROs can compete directly with SROs for the production and sale of proprietary data products, as BATS and Arca did before registering as exchanges by publishing proprietary book data on the Internet. Second, because a single order or transaction report can appear in an SRO proprietary product, a non-SRO proprietary product, or both, the data available in proprietary products is exponentially greater than the actual number of orders and transaction reports that exist in the marketplace.

Market data vendors provide another form of price discipline for proprietary data products because they control the primary means of access to end users. Vendors impose price restraints based upon their business models. For example, vendors such as Bloomberg and Reuters that assess a surcharge on data they sell may refuse to offer proprietary products that end users will not purchase in sufficient numbers. Internet portals, such as Yahoo, impose a discipline by providing only data that will enable them to attract ''eyeballs'' that contribute to their advertising revenue. Retail broker-dealers, such as Schwab and Fidelity, offer their customers proprietary data only if it promotes trading and generates sufficient commission revenue. Although the business models may differ, these vendors' pricing discipline is the same: They can simply refuse to purchase any proprietary data product that fails to provide sufficient value. NASDAQ and other producers of proprietary data products must understand and respond to these varying business models and pricing disciplines in order to market proprietary data products successfully.

In addition to the competition and price discipline described above, the market for proprietary data products is also highly contestable because market entry is rapid, inexpensive, and profitable. The history of electronic trading is replete with examples of entrants that swiftly grew into some of the largest electronic trading platforms and proprietary data producers: Archipelago, Bloomberg Tradebook, Island, RediBook, Attain, TracECN, BATS Trading and Direct Edge. A proliferation of ATSs operate profitably with fragmentary shares of consolidated market volume.

Regulation NMS, by deregulating the market for proprietary data, has increased the contestability of that market. While broker-dealers have previously published their proprietary data individually, Regulation NMS encourages market data vendors and broker-dealers to produce proprietary products cooperatively in a manner never before possible. Multiple market data vendors already have the capability to aggregate data and disseminate it on a profitable scale, including Bloomberg, and Thomson-Reuters.

The court in *NetCoalition* concluded that the Commission had failed to demonstrate that the market for market data was competitive based on the reasoning of the Commission's *NetCoalition* order because, in the court's view, the Commission had not adequately demonstrated that the depth-of-book data at issue in the case is used to attract order flow. NASDAQ believes, however, that evidence not before the court clearly demonstrates that availability of depth data attracts order flow.

Competition among platforms has driven NASDAQ continually to improve its platform data offerings and to cater to customers' data needs. For example, NASDAQ has been offering front end applications such as its NetView and ITCH equity data products and ITTO and BONO SM options data products to help customers utilize data. Yet another example of the continuous effort by exchanges to improve platform data is Phlx's TOPO Plus Orders and TOPO data products.

Moreover, the Exchange believes that the decision whether and on which platform to post an order will depend on the attributes of the platform where the order can be posted, including the execution fees, data quality and price and distribution of its data products. Without trade executions, exchange data products cannot exist. Data products are valuable to many end users only insofar as they provide information that end users expect will assist them or their customers in making trading decisions.

In the recent filing approving the aforementioned Phlx TOPO Plus Orders data feed,[28] the Commission recognized the intense competition among exchanges, particularly as related to options market data, stating:

Phlx currently competes with seven other options exchanges for order flow. Attracting order flow is an essential part of Phlx's competitive success. If Phlx cannot attract order flow to its market, it will not be able to execute transactions. If Phlx cannot execute transactions on its market, it will not generate transaction revenue. If Phlx cannot attract orders or execute transactions on its market, it will not have market data to distribute, for a fee or otherwise, and will not earn market data revenue and thus not be competitive with other exchanges that have this ability. This compelling need to attract order flow imposes significant pressure on Phlx to act reasonably in setting its fees for Phlx market data, particularly given that the market participants that will pay such fees often will be the same market participants from whom Phlx must attract order flow. These market participants include broker-dealers that control the handling of a large volume of customer and proprietary order flow. Given the portability of order flow from one exchange to another, any exchange that sought to charge unreasonably high data fees would risk alienating many of the same customers on whose orders it depends for competitive survival.

The primary competition and anti-trust regulator in the U.S., the Antitrust Division of the U.S. Department of Justice (the ''Antitrust Division''), has recognized the intensely competitive nature of exchange market data. When analyzing competition among exchanges, Assistant Attorney General Christine Varney recently stated:

If the acquisition [of NYSE by NASDAQ and ICE] proceeded, it would have eliminated substantial competition in the following ways * * * NASDAQ and NYSE also compete head to head to offer real-time equity data products. These data products include the best bid and offer of every exchange and information on each equity trade, including the last sale. Post-merger, the [new] firm would have the ability to raise the cost of real-time proprietary equity data and the firm would be less likely to develop new, innovative, real-time data products.[29]

In establishing the price for the BONO SM and ITTO products, NASDAQ considered the competitiveness of the market for data and all of the implications of that competition. NASDAQ believes that it has considered all relevant factors and has not considered irrelevant factors in order to establish a fair, reasonable, and not unreasonably discriminatory fees and an equitable allocation of fees among all users. The existence of alternatives to ITTO and BONO,SM including noted competitive products by other exchanges and real-time consolidated last sale and NBBO data, free delayed consolidated data, and even proprietary data from other sources, ensures that NASDAQ cannot set unreasonable fees, or fees that are unreasonably discriminatory, without losing business to these alternatives.[30] NASDAQ believes that this demonstrates the consistency of these fees with applicable statutory standards.

Accordingly, NASDAQ does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[31] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2011–075 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2011–075. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro/shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal

[28] *See* Securities Exchange Act Release No. 62194 (May 28, 2010), 75 FR 31830 (June 4, 2010) (SR–Phlx–2010–48) (order approving proposal related to TOPO Plus Orders market data fees).

[29] *See* Remarks as Prepared for Delivery by Assistant Attorney General Christine Varney Regarding NASDAQ OMX Group Inc. and Intercontinental Exchange Inc. Abandoning Their Bid for NYSE Euronext (May 16, 2011).

[30] The Exchange notes also that competitiveness in the market data field (as in other areas such as, for example, securities offerings and pricing) encourages—and often requires—exchanges to be innovative and forward-thinking in terms of market data product offerings.

[31] 15 U.S.C. 78s(b)(3)(A)(ii).

identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–NASDAQ–2011–075 and should be submitted on or before July 8, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[32]

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–15015 Filed 6–16–11; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–64654; File No. SR–CBOE–2011–039]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing of Proposed Rule Change To Trade Single Stock Dividend Options

June 13, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 31, 2011, the Chicago Board Options Exchange, Incorporated (''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Chicago Board Options Exchange, Incorporated (''CBOE'' or ''Exchange'') proposes to amend certain of its rules to provide for the listing and trading of options that overlie the ordinary cash dividends paid by an issuer over an annual, semi-annual, or quarterly ''accrual period.'' The options will be cash-settled, have European-style exercise and be P.M.-settled. The text of the rule proposal is available on the Exchange's Web site (*http://www.cboe.org/legal*), at the Exchange's Office of the Secretary and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to permit the Exchange to list and trade options that overlie the ordinary cash dividends paid by an issuer over an annual accrual period. The Exchange may also list series of SSDOs with an accrual period of less than a year, but in no event less than one quarter of a year. SSDOs will be cash-settled, have European-style exercise and be P.M.-settled.

Product Design

Each SSDO represents the accumulated ordinary dividend amounts paid by a specific issuer over a specified accrual period. For purposes of SSDOs, dividends are deemed to be ''paid'' on the ex-dividend date. Each annual accrual period will run from the business day after the third Friday of December through the third Friday of the following December. For an SSDO with an accrual period of less than a year, the accrual period runs from the business day after the third Friday of the month beginning the accrual period through the third Friday of the month ending the accrual period.[3] An example of a quarterly accrual period is one that will run from Monday, March 21, 2011 through Friday, June 17, 2011.

The underlying value for SSDOs will be equal to ten (10) times the ex-dividend amounts of an issuer accumulated over the specified accrual period. Each day, CBOE will calculate the aggregate daily dividend totals for the specific issuer, which are summed up over any given accrual period (*e.g.,* quarterly, semi-annually, annually). During each business day, CBOE will disseminate the underlying SSDO value, multiplied by ten (10), through the Options Price Reporting Authority (''OPRA''), the Consolidated Tape Association (''CTA'') tape and/or the Market Data Index (''MDI'') feed.

Options Trading

Each SSDO will be quoted in decimals and one point will be equal to $100. The minimum price variation shall be established on a class-by-class basis by the Exchange and shall not be less than $0.01. Exhibit 3 presents proposed contract specifications for SSDOs.

The Exchange expects that the underlying index values for SSDOs will be relatively low. As a result, the proposal permits the Exchange to designate $0.01 as the minimum price variation for quotes and believes that granular pricing will result in more pricing points. The availability of more pricing points creates tighter spreads between quotes, which in turn benefits investors.

Similarly, the Exchange is proposing to list series at 1 point ($1.00) or greater strike price intervals if the strike price is equal to or less than $200 and 2.5 points ($2.50) or greater strike price intervals if the strike price exceeds $200. Because the underlying value of an SSDO will fluctuate around a limited expected dividend value range, the Exchange believes that a granular strike price increment will provide investors with greater flexibility by allowing them to establish positions that are better tailored to meet their investment objectives. Below are examples of values underlying SSDOs using past ordinary dividend payouts over varying accrual periods:

Ex-dividend date	Ex-dividend amount	Cumulative dividend	SSDO Index value
Example: Annual Accrual Period December 21, 2009 through December 17, 2010			
Exxon Mobil Corporation (XOM):			

[32] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange will assign separate trading symbols to SSDOs overlying the accumulated ex-dividends of the same issuer that have different accrual periods.

Ex-dividend date	Ex-dividend amount	Cumulative dividend	SSDO Index value
2/8/2010	$0.42	$0.42	4.20
5/11/2010	$0.42	$0.84	8.40
8/11/2010	$0.42	$1.26	12.60
11/9/2010	$0.44	$1.70	17.00
General Electric Company (GE):			
12/23/2009	$0.10	$0.10	1.00
2/25/2010	$0.10	$0.20	2.00
6/17/2010	$0.10	$0.30	3.00
9/16/2010	$0.12	$0.42	4.20
12/22/2010	$0.14	Not Included	
Example: Semi-Annual Accrual Period June 21, 2010 through December 17, 2010			
ONEOK Partners, L.P. (OKS):			
1/27/2010	$1.11	Not Included	
4/28/2010	$1.12	Not Included	
7/28/2010	$1.13	$1.13	11.30
10/27/2010	$1.14	$2.27	22.70
Caterpillar Inc. (CAT):			
1/15/2010	$0.42	Not Included	
4/22/2010	$0.42	Not Included	
7/16/2010	$0.44	$0.44	4.40
10/21/2010	$0.44	$0.88	8.80
Example: Quarterly Accrual Period December 21, 2010 through March 19, 2010 [sic]			
International Business Machines Corporation (IBM):			
2/8/2010 [sic]	$0.55	$0.55	5.50
5/16/2010 [sic]	$0.65	Not Included	
8/6/2010 [sic]	$0.65	Not Included	
11/8/2010 [sic]	$0.65	Not Included	
Altria Group, Inc. (MO):			
3/11/2010 [sic]	$0.35	$0.35	3.50
6/11/2010 [sic]	$0.35	Not Included	
9/13/2010 [sic]	$0.38	Not Included	
12/23/2010 [sic]	$0.38	Not Included	

Initially, the Exchange will list in-, at- and out-of-the-money strike prices and may open for trading up to five annual contract months expiring in December for any single stock underlying an SSDO and up to ten contract months for accrual periods of less than a year. The Exchange is proposing to use the expected dividend (*i.e.,* the aggregate value of dividends that are expected to be paid by the issuer over a given accrual period) amount for setting the initial strikes. Near-term SSDOs will reflect dividends accumulating in the then-current accrual period. All other SSDO options (*i.e.,* contracts listed for trading that are not in the then-current accrual period) will reflect dividends expected in comparable accrual periods beyond the current accrual period.

The Exchange may open for trading additional series, either in response to customer demand or as the price of the expected dividends for an issuer changes.

The Exchange is proposing to permit the listing of up to five annual contract months that expire in December in different years for any single stock underlying an SSDO. For example, the Exchange would be permitted to list the following annual XOM contracts: December 2011, December 2012, December 2013, December 2014 and December 2015. As shown in the following table, each annual XOM SSDO contract features a one-year accrual period that begins on the first business day following the third Friday in December and ends on the respective XOM SSDO expiration date. As of May 17, 2011, near-term XOM SSDO prices would reflect a combination of actual dividend payouts of $0.91 ($0.44 on the ex-dividend date of February 8, 2011 and $0.47 on the ex-dividend date of May 11, 2011), plus any ordinary cash dividends expected to be paid (estimated to be $0.94—$0.47 on two expected ex-dividend dates) through December 16, 2011. Since the accrual periods for longer-dated SSDOs expiring in December 2012, December 2013, December 2014 and December 2015 have not yet begun, longer-dated SSDO prices would reflect dividends that are expected to be paid during their respective one-year accrual periods. The expected dividends for longer-dated SSDOs listed in the table reflect an assumption of 5% dividend growth annually through December 2015. In-, at- and out-of-the-money SSDO strike prices would be listed relative to the Expected SSDO Index level equal to ten

times the dividends expected during the relevant accrual period.

Accrual period start date	Accrual period end date (SSDO expiration date)	Actual dividends	Expected dividends	Actual + expected dividends	Expected SSDO index level	SSDO strikes
December 20, 2010	December 16, 2011	$0.91	$0.94	$1.85	$18.50	16, 17, 18, 19, 20
December 19, 2011	December 21, 2012	.....	1.94	1.94	19.40	17, 18, 19, 20, 21
December 24, 2012	December 20, 2013	.....	2.04	2.04	20.40	19, 20, 21, 22, 23
December 23, 2013	December 19, 2014	.....	2.14	2.14	21.40	20, 21, 22, 23, 24
December 22, 2014	December 18, 2015	.....	2.25	2.25	22.50	21, 22, 23, 24, 25

In addition, the Exchange is proposing to permit the listing of up to ten contract months for accrual periods of less than a year. Near-term SSDOs with accrual periods of less than a year will reflect dividends accumulating in the then-current accrual period. All other SSDOs will reflect dividends expected in comparable accrual periods beyond the current accrual period.

Exercise and Settlement

The proposed options will expire on the Saturday following the third Friday of the expiring month. Trading in the expiring contract month will normally cease at 3 p.m. Chicago time on the last day of trading (ordinarily the Friday before expiration Saturday, unless there is an intervening holiday). When the last trading day is moved because of an Exchange holiday (such as when CBOE is closed on the Friday before expiration), the last trading day for expiring options will be Thursday.

Exercise will result in delivery of cash on the business day following expiration. SSDOs will be P.M.-settled. The Exchange is proposing P.M.-settlement for SSDOs because options trading on individual stocks are P.M. settled. As a result, the Exchange is proposing to match the expiration style for SSDOs to individual stock option exercise. The exercise-settlement amount will be equal [sic] ten times the ordinary cash dividends paid by the issuer over the accrual period. The exercise settlement amount is equal to the difference between the exercise-settlement value and the exercise price of the option, multiplied by the contract multiplier ($100).

If the exercise settlement value is not available or the normal settlement procedure cannot be utilized due to a trading disruption or other unusual circumstance, the settlement value will be determined in accordance with the rules and bylaws of the OCC.

Surveillance

The Exchange will use the same surveillance procedures currently utilized for each of the Exchange's other single stock options to monitor trading in SSDOs. Such procedures include for example monitoring dividend announcements. CBOE is confident that it has adequate tools in place to surveil for market manipulation. The Exchange represents that these surveillance procedures shall be adequate to monitor trading in options on these option products. For surveillance purposes, the Exchange will have complete access to information regarding trading activity in the pertinent securities whose dividend payment is the basis for particular SSDOs. Specifically, as a member of the Intermarket Surveillance Group (''ISG''), the Exchange is able to obtain this information from the exchanges listing the securities whose dividend payment is the basis for particular SSDOs. CBOE's access to information from the ISG and tools such as the Exchange's large options positions reports should prove more than sufficient for surveillance of market manipulation.

Position Limits

Position and exercise limits for SSDOs will be the same as those for standard options overlying the same security. While positions in SSDOs will be aggregated with longer-dated positions in SSDOs with the same underlying stock for position and exercise limits purposes, they will not be aggregated with positions in the ordinary options overlying the stock of the issuer paying the dividends underlying the SSDO. The reason for not aggregating positions with ordinary options is that SSDOs are based solely on expected dividends for an issuer and will reflect the forward value of that expectation. In contrast, the value of ordinary stock options reflect a variety of factors, of which expected dividends is only one. Hence the pricing of ordinary options versus SSDOs will differ dramatically and there is no need to aggregate positions to prevent manipulative practices involving the underlying.

Exchange Rules Applicable

A new Rule 5.9 is proposed to govern the listing and trading of SSDOs. In addition, SSDOs will be margined in the same manner as single stock options under Exchange Rule 12.3. Purchasers of puts or calls, however, must be paid in full, even if there remains longer than nine months until expiration for the position. For SSDOs, the aggregate contract value on which the margin amount will be calculated will be the product of the forward expected dividend amount for the accrual period (as adjusted for any contract scaling factor) and the applicable multiplier ($100).

The Exchange hereby designates SSDO options as eligible for trading as Flexible Exchange Options as provided for in Chapters XXIVA (Flexible Exchange Options) and XXIVB (FLEX Hybrid Trading System).

Capacity

CBOE has analyzed its capacity and represents that it believes the Exchange and OPRA have the necessary systems capacity to handle the additional traffic associated with the listing of new series that will result from the introduction of SSDOs. This is particularly the case since the value of SSDOs are predicated on expected dividend payments, which are generally much less volatile than share prices. Hence, there is less need to list numerous strike prices for each expiration date of an SSDO or to have to add many new strikes over the life of an SSDO.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with Section 6(b)[4] of the Act, in general, and furthers the objectives of Section 6(b)(5)[5] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanisms of a free and open market in a manner consistent with the

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

protection of investors and the public interest. The Exchange believes that the introduction of SSDOs will provide investors with the ability to invest in options that settle to a value that represents the accumulated dividend amounts paid by a specific issuer over a specified accrual period. This will protect investors and the public interest by allowing market participants to hedge against potential declines in dividend income from long positions in the underlying stocks, which can be significant over long holding periods. In addition, the Exchange understands that dividend options trade in the other-the-counter [sic] marketplace and believes that the introduction of SSDOs will attract order flow to the Exchange, increase the variety of listed options to investors, and provide a valuable hedging tool to investors. Similarly, the proposed rule change will permit market participants to trade SSDOs in an environment subject to exchange-based rules that provides price transparency and eliminates contra-party risk through the role of the OCC as issuer, thus removing impediments to a free and open market consistent with the Act. Finally, SSDOs will be subject to CBOE's rules, regulations and oversight, which provide enhanced investor protection and market surveillance.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) As the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2011–039 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2011–039. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make publicly available. All submissions should refer to File Number SR–CBOE–2011–039 and should be submitted on or before July 8, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–15039 Filed 6–16–11; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

Voice One Corp.; Order of Suspension of Trading

June 15, 2011.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Voice One Corp. because of questions regarding the accuracy of assertions by Voice One Corp., and by others, in public statements concerning, among other things: (1) The company's management and (2) financing provided by related parties.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of Voice One Corp.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of Voice One Corp. is suspended for the period from 9:30 a.m. EDT on June 15, 2011, through 11:59 p.m. EDT, on June 28, 2011.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2011–15196 Filed 6–15–11; 4:15 pm]

BILLING CODE 8011–01–P

DEPARTMENT OF STATE

[Public Notice 7503]

30-Day Notice of Proposed Information Collection: DS–3035, J–1 Visa Waiver Recommendation Application

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the following information collection request to the Office of Management and Budget (OMB) for approval in accordance with the Paperwork Reduction Act of 1995.

- *Title of Information Collection:* J–1 Visa Waiver Recommendation Application.

[6] 17 CFR 200.30–3(a)(12).

• *OMB Control Number:* 1405–0135.
• *Type of Request:* Extension of a Currently Approved Collection.
• *Originating Office:* Bureau Of Consular Affairs, Department of State (CA/VO).
• *Form Number:* DS–3035.
• *Respondents:* J–1 visa holders applying for a waiver of the two-year foreign residence requirement.
• *Estimated Number of Respondents:* 10,000.
• *Estimated Number of Responses:* 10,000.
• *Average Hours per Response:* 1 hour.
• *Total Estimated Burden:* 10,000 hours.
• *Frequency:* On occasion.
• *Obligation to Respond:* Required to Obtain or Retain a Benefit.

DATES: Submit comments to the Office of Management and Budget (OMB) for up to 30 days from June 17, 2011.

ADDRESSES: Direct comments to the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB). You may submit comments by the following methods:
• *E-mail: oira_submission@omb.eop.gov.* You must include the DS form number, information collection title, and OMB control number in the subject line of your message.
• *Fax:* 202–395–5806. *Attention:* Desk Officer for Department of State.

FOR FURTHER INFORMATION CONTACT: You may obtain copies of the proposed information collection and supporting documents from Stefanie Claus of the Office of Visa Services, U.S. Department of State, 2401 E Street, NW. L–603, Washington, DC 20520, who may be reached at (202) 663–2910.

SUPPLEMENTARY INFORMATION: We are soliciting public comments to permit the Department to:
• Evaluate whether the proposed information collection is necessary to properly perform our functions.
• Evaluate the accuracy of our estimate of the burden of the proposed collection, including the validity of the methodology and assumptions used.
• Enhance the quality, utility, and clarity of the information to be collected.
• Minimize the reporting burden on those who are to respond.

Abstract of Proposed Collection

Form DS–3035 is used to determine the eligibility of a J–1 visa holder for a waiver of the two-year foreign residence requirement.

Methodology

Form DS–3035 will be mailed to the Waiver Review Division of the State Department.

Dated: June 7, 2011.

David T. Donahue,

Deputy Assistant Secretary, Bureau of Consular Affairs, Department of State.

[FR Doc. 2011–15073 Filed 6–16–11; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF STATE

[Public Notice 7504]

Assistance to Southern Sudan and the United States Contribution to the Global Fund To Fight AIDS, Tuberculosis and Malaria (Global Fund) for Fiscal Year 2009

AGENCY: Department of State.

ACTION: Notice of a Waiver Determination under Section 202(d)(4)(A)(ii) of the United States Leadership against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, as amended, for Fiscal Year 2009.

SUMMARY: This is a notice of a waiver determination under Section 202(d)(4)(A)(ii) of the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, as amended by the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008 (the Leadership Act). The Leadership Act requires that the U.S. Global AIDS Coordinator withhold from the U.S. contribution to the Global Fund an amount equal to expenditures by the Global Fund in the previous fiscal year to governments of countries that have been determined to have repeatedly provided support for acts of international terrorism in accordance with section 6(j)(1) of the Export Administration Act of 1979 (50 U.S.C. App. 2405 (j)(1)) (the ''6(j) list'').

The government of the Republic of Sudan is designated on the ''6(j) list.'' Thus, Global Fund expenditures to the Government of the Republic of Sudan trigger a withholding requirement from the U.S. contribution to the Global Fund, subject to the waiver authority provided for Global Fund expenditures in Southern Sudan. During FY 2008, $301,416 was provided to government entities in Southern Sudan under HIV/AIDS grants, thus triggering a potential withholding requirement in this amount from the FY 2009 U.S. contribution to the Global Fund. These funds were used to support State HIV/AIDS Commissions in all ten southern Sudan states, provide needed financial support for project specialists, and meet other incurred expenses under HIV/AIDS grants.

Under the Leadership Act, the President has authority to waive the withholding requirement for assistance overseen by the Southern Sudan Country Coordinating Mechanism (SSCCM) if such an action is justified by the national interest or for humanitarian reasons. This authority has been delegated to the U.S. Global AIDS Coordinator. The United States places a high priority on ensuring appropriate disbursement and expenditure of foreign development and humanitarian funding. Following consultations with the relevant Congressional committees, the U.S. Global AIDS Coordinator has determined waiver of the withholding requirement for assistance by the Global Fund to the Autonomous Government of Southern Sudan through the Global Fund SSCCM is justified for humanitarian reasons. The application of the withholding requirement of Section 202(d)(4)(A)(ii) of the Act is hereby waived with respect to such assistance, allowing for the additional contribution of $301,416 to the Global Fund from the FY 2009 appropriations for the U. S. contribution to the Global Fund. This notice of waiver determination is published in the **Federal Register** in compliance with Section 202(d)(4)(A)(ii) of the Leadership Act.

FOR FURTHER INFORMATION CONTACT: Guinnevere Roberts, Director, Multilateral Diplomacy, Office of the Global AIDS Coordinator, (202) 663–2586

Dated: June 14, 2011.

Eric P. Goosby,

Ambassador, Office of the U.S. Global AIDS, Coordinator, Department of State.

[FR Doc. 2011–15074 Filed 6–16–11; 8:45 am]

BILLING CODE 4710–10–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. FTA–2011–0032]

Notice of Request for the Extension of a Currently Approved Information Collection

AGENCY: Federal Transit Administration, DOT.

ACTION: Notice of request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the Federal Transit Administration (FTA) to

request the Office of Management and Budget (OMB) to extend the following currently approved information collection: Reporting of Technical Activities by FTA Grant Recipients.

DATES: Comments must be submitted before August 16, 2011.

ADDRESSES: To ensure that your comments are not entered more than once into the docket, submit comments identified by the docket number by only one of the following methods:

1. *Web site: http://www.regulations.gov.* Follow the instructions for submitting comments on the U.S. Government electronic docket site. (*Note:* The U.S. Department of Transportation's (DOT's) electronic docket is no longer accepting electronic comments.) All electronic submissions must be made to the U.S. Government electronic docket site at *http://www.regulations.gov.* Commenters should follow the directions below for mailed and hand-delivered comments.

2. *Fax:* 202–493–2251.

3. *Mail:* U.S. Department of Transportation, 1200 New Jersey Avenue, SE., Docket Operations, M–30, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.

4. *Hand Delivery:* U.S. Department of Transportation, 1200 New Jersey Avenue, SE., Docket Operations, M–30, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001 between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays.

Instructions: You must include the agency name and docket number for this notice at the beginning of your comments. Submit two copies of your comments if you submit them by mail. For confirmation that FTA has received your comments, include a self-addressed stamped postcard. Note that all comments received, including any personal information, will be posted and will be available to Internet users, without change, to *http://www.regulations.gov.* You may review DOT's complete Privacy Act Statement in the **Federal Register** published April 11, 2000, (65 FR 19477), or you may visit *http://www.regulations.gov.*

Docket: For access to the docket to read background documents and comments received, go to *http://www.regulations.gov* at any time. Background documents and comments received may also be viewed at the U.S. Department of Transportation, 1200 New Jersey Avenue, SE., Docket Operations, M–30, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001 between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays.

FOR FURTHER INFORMATION CONTACT: Ms. Candace Noonan, Office of Planning and Environment, (202) 366–1648, or e-mail: *CandaceNoonan@dot.gov.*

SUPPLEMENTARY INFORMATION:

Interested parties are invited to send comments regarding any aspect of these information collections, including: (1) The necessity and utility of the information collection for the proper performance of the functions of the FTA; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the collected information; and (4) ways to minimize the collection burden without reducing the quality of the collected information. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection.

Title: Reporting of Technical Activities by FTA Grant Recipients.

(*OMB Number: 2132–0549*).

Background: 49 U.S.C. Section 5305 authorizes the use of federal funds to assist metropolitan planning organizations (MPOs), states, and local public bodies in developing transportation plans and programs to serve future transportation needs of urbanized areas and nonurbanized areas throughout the nation. As part of this effort, MPOs and states are required to consider a wide range of goals and objectives and to analyze alternative transportation system management and investment strategies. These objectives are measured by definable activities such as planning certification reviews and other related activities.

The information collected is used to report annually to Congress, the Secretary, and to the Federal Transit Administrator on how grantees are responding to national emphasis areas and congressional direction, and allows FTA to track grantees' use of Federal planning funds.

Respondents: FTA grant recipients.

Estimated Annual Burden on Respondents: 3 hours for each of the 52 respondents.

Estimated Total Annual Burden: 156 hours.

Frequency: Annual.

Issued: June 13, 2011.

Ann M. Linnertz,

Associate Administrator for Administration.

[FR Doc. 2011–15027 Filed 6–16–11; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35510]

Alabama Southern Railroad, L.L.C.—Temporary Trackage Rights Exemption—Norfolk Southern Railway Company

Norfolk Southern Railway Company (NSR), pursuant to a written trackage rights agreement dated May 13, 2011, has agreed to grant nonexclusive overhead temporary trackage rights to Alabama Southern Railroad, L.L.C. (ABS) over a portion of NSR's line of railroad between milepost 143.6, at Birmingham, Ala., and milepost 198.5, at Tuscaloosa, Ala., a distance of approximately 54.9 miles.[1]

The transaction is scheduled to be consummated on or after July 1, 2011, the effective date of the exemption (30 days after the exemption was filed). The temporary trackage rights are scheduled to expire on November 15, 2011. The purpose of the temporary trackage rights is to allow ABS to operate around its Hurricane Creek Bridge, near Tuscaloosa, which was destroyed by a tornado.

As a condition to this exemption, any employees affected by the acquisition of the temporary trackage rights will be protected by the conditions imposed in *Norfolk & W. Ry.—Trackage Rights—Burlington N., Inc.,* 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Ry.—Lease & Operate—Cal. W. R.R.,* 360 I.C.C. 653 (1980), and any employees affected by the discontinuance of those trackage rights will be protected by the conditions set out in *Oregon Short Line Railroad & The Union Pacific Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979).

This notice is filed under 49 CFR 1180.2(d)(8). If it contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction. Petitions for stay must be filed no later than June 24, 2011 (at least 7 days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD

[1] A redacted, executed trackage rights agreement between NSR and ABS was filed with the notice of exemption. The unredacted version was filed under seal on June 6, 2011, along with a motion for protective order, which will be addressed in a separate decision.

35510, must be filed with the Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Karl Morrell, of Counsel, Ball Janik LLP, Suite 225, 655 Fifteenth Street, NW., Washington, DC 20005.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

Decided: June 13, 2011.

By the Board.

Rachel D. Campbell,

Director, Office of Proceedings.

Andrea Pope-Matheson,

Clearance Clerk.

[FR Doc. 2011–14990 Filed 6–16–11; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 1099–G

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 1099–G, Certain Government Payments.

DATES: Written comments should be received on or before August 16, 2011 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette B. Lawrence, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Evelyn J. Mack, (202) 622–7381, Internal Revenue Service, room 6231, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the internet at *Evelyn.J.Mack@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Certain Government Payments.

OMB Number: 1545–0120.

Form Number: 1099–G.

Abstract: Form 1099–G is used to report government payments such as unemployment compensation, state and local income tax refunds, credits, or offsets, discharges of indebtedness by the Federal Government, taxable grants, subsidy payments from the Department of Agriculture, and qualified state tuition program payments.

Current Actions: Box 9 was added to report market gain on Commodity Credit Corporation loans repaid on or after January 1, 2007. (Notice 2007–63 and Pub. L. 110–234, sec. 15353) At the request of several states, boxes 10a, 10b and 11 were added for reporting withholding of state income taxes due to legislation passed at the state level which requires such withholding on payments of unemployment compensation.

Type of Review: Extension of a currently approved collection.

Affected Public: Federal, state, local or tribal governments.

Estimated Number of Responses: 61,000,000.

Estimated Time per Response: 16 min.

Estimated Total Annual Burden Hours: 17,080,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: June 7, 2011.

Yvette B. Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2011–15035 Filed 6–16–11; 8:45 am]

BILLING CODE 4830–01–P

FEDERAL REGISTER

Vol. 76 Friday,
No. 117 June 17, 2011

Part II

Nuclear Regulatory Commission

10 CFR Parts 20, 30, 40, et al.
Decommissioning Planning; Final Rule

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 20, 30, 40, 50, 70, and 72

[NRC–2008–0030]

RIN 3150–AI55

Decommissioning Planning

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or the Commission) is amending its regulations to improve decommissioning planning and thereby reduce the likelihood that any current operating facility will become a legacy site. The amended regulations require licensees to conduct their operations to minimize the introduction of residual radioactivity into the site, which includes the site's subsurface soil and groundwater. Licensees also may be required to perform site surveys to determine whether residual radioactivity is present in subsurface areas and to keep records of these surveys with records important for decommissioning. The amended regulations require licensees to report additional details in their decommissioning cost estimate (DCE), eliminate the escrow account and line of credit as approved financial assurance mechanisms, and modify other financial assurance requirements. The amended regulations require decommissioning power reactor licensees to report additional information on the costs of decommissioning and spent fuel management.

DATES: The final rule is effective on December 17, 2012. Compliance with the reporting provisions in Title 10 of the Code of Federal Regulations (10 CFR) 50.82(a)(8)(v) and (vii) is required by March 31, 2013.

ADDRESSES: You can access publicly available documents related to this document using the following methods:

• *NRC's Public Document Room (PDR):* The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* Publicly available documents created or received at the NRC are available online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* From this page, the public can gain entry into ADAMS, which provides text and image files of the NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr.resource@nrc.gov*.

• *Federal Rulemaking Web Site:* Public comments and supporting materials related to this final rule can be found at *http://www.regulations.gov* by searching on Docket ID NRC–2008–0030. Address questions about NRC dockets to Carol Gallagher, telephone: 301–492–3668; e-mail: *Carol.Gallagher@nrc.gov*.

FOR FURTHER INFORMATION CONTACT: Robert D. MacDougall, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–5175; e-mail: *Robert.MacDougall@nrc.gov,* or Kevin O'Sullivan, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–8112; e-mail: *Kevin.OSullivan@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The NRC issued comprehensive and risk informed decommissioning regulations in 1997 as Subpart E of 10 CFR part 20 (62 FR 39058; July 21, 1997). This set of requirements is known as the License Termination Rule (LTR). The LTR is based on calculated doses, and it established specific radiological criteria for remediation of lands and structures to complete site decommissioning and successfully terminate the license. The LTR provides an overall approach for license termination for two different site conditions: unrestricted use and restricted conditions for use after license termination. The LTR applies to the decommissioning of facilities licensed under the regulations in 10 CFR parts 30, 40, 50, 60, 61, 63, 70, and 72. In the 1997 LTR final rule, in response to a public comment that the requirements of then-proposed regulations in 10 CFR 20.1406 should apply to all licensees rather than only to applicants for new licenses, the Commission stated:

> Applicants and existing licensees, including those making license renewals, are already required by 10 CFR part 20 to have radiation protection programs aimed towards reducing exposure and minimizing waste. In particular, § 20.1101(a) requires development and implementation of a radiation protection plan commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR part 20. Section 20.1101(b) requires licensees to use, to the extent practicable, procedures and engineered controls to achieve public doses that are [as low as reasonably achievable] ALARA. In addition, lessons learned and documented in reports such as NUREG–1444 [ML080860275 and ML080860308] have focused attention on the need to minimize and control waste generation during operations as part of development of the required radiation protection plans. Furthermore, the financial assurance requirements issued in the January 27, 1988 (53 FR 24018), rule on planning for decommissioning require licensees to provide adequate funding for decommissioning. These funding

requirements create great incentive to minimize contamination and the amount of funds set aside and expended on cleanup. (62 FR 39082; July 21, 1997).

Current 10 CFR 20.1101(a) requires each licensee to implement a radiation protection program to ensure compliance with the regulations in 10 CFR part 20. Current § 20.1101(b) requires each licensee to use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA. To achieve doses that are ALARA, licensees are already required to apply operating procedures and controls to evaluate potential radiological hazards and methods to minimize and control waste generation during facility operations.

In a Staff Requirements Memorandum (SRM) for SECY–01–0194, dated June 18, 2002 (NRC ADAMS Accession Number ML021690563), the Commission directed the staff to conduct an analysis of LTR issues. The staff conducted the analysis and presented results and recommendations to the Commission in SECY–03–0069 (ML030800158), dated May 2, 2003, and known as the LTR Analysis. One of the recommendations was a set of ''measures to prevent future legacy sites.'' A legacy site is a facility that is in decommissioning status with complex issues and an owner who cannot complete the decommissioning work for technical or financial reasons (as discussed further in Section II.E of this document). The set of measures to prevent future legacy sites had two distinct parts: (1) The need for timely reporting during facility operations of subsurface contamination that has a potential to complicate future decommissioning efforts; and (2) The need for more detailed reporting of licensee financial assurance mechanisms to fund site decommissioning activities and protection of the committed funds in cases of financial distress. The need for timely reporting of subsurface contamination during facility operations was explained in Attachment 8 to SECY–03–0069 (ML030870186). Attachment 8, under the heading ''chronic releases,'' recommended revising the regulations in 10 CFR 20.1406 to extend its minimization of contamination requirements to cover licensees in addition to license applicants. Recommendations for more detailed decommissioning financial assurance requirements are set forth in Attachment 7 to SECY–03–0069 (ML030870180).

In the SRM for SECY–03–0069 (ML033210595), the Commission approved the staff's recommendations and authorized development of a technical basis to support a proposed rule. As pertinent to the then-proposed regulations in 10 CFR 20.1406 and 10 CFR 20.1501 revisions, the Commission's SRM states as follows:

> The Commission has approved the staff's recommendation related to changes in licensee operations as described in attachment 8. However, in addition to incorporating risk-informed approaches, the staff should ensure that they are performance-based. The staff will have to be very careful when crafting the guidance documents so that it is clear to the licensees and to the staff how much characterization information is enough. The staff should only ask for limited information. Licensees should not be required to submit the equivalent of a full scale MARSSIM [Multi-Agency Radiation Survey and Site Investigation Manual (ML082470583)] survey every year.

During 2003 and 2004, the NRC staff evaluated the decommissioning program and assessed the effectiveness of other improvements to protect public health and safety beyond those identified in the LTR Analysis. To integrate and track regulatory improvements resulting from the LTR Analysis and the further evaluation of the decommissioning program, the NRC adopted an Integrated Decommissioning Improvement Plan (IDIP) for activities during FY 2004 through 2007 (ML050890051). Among other actions, the IDIP called for publication of the Decommissioning Planning proposed rule and written guidance describing changes in the regulations to prevent future legacy sites.

In 2005 and 2006, the operators of several nuclear power plants reported that inadvertent and unmonitored radioactive liquid releases, primarily tritium contained in water, had occurred. In some instances, the release of radioactive liquid was not recognized by the licensee until years after the release had apparently started. The NRC Executive Director for Operations chartered a Task Force to conduct a lessons-learned review of these incidents. The Task Force final report (ML062650312) dated September 1, 2006, concluded that the levels of tritium and other radionuclides measured thus far do not present a health hazard to the public and presented a list of findings and recommendations that the Task Force believed would improve plant operations and public confidence in nuclear plant operations. The findings and recommendations in the Task Force report identified the need to clarify existing licensee requirements to demonstrate that they have achieved public and occupational exposures that are ALARA during the life cycle of the facility, which includes the decommissioning phase.

In April 2005, the NRC conducted a 2-day public workshop to solicit public comments on the technical basis for the proposed rule, covering changes in licensee operations and financial assurance. A 1-day public roundtable meeting was held in January 2007 to solicit public comments on specific topics in the technical basis for the proposed rule.

SECY–07–0177 (ML072390153), dated October 3, 2007, requested Commission approval to publish a proposed rule consistent with the recommendations approved in SRM–SECY–03–0069 and the public comments from the workshop and roundtable meeting noted previously. The Commission approved staff's request in SRM–SECY–07–0177 (ML073440549), dated December 10, 2007, and accordingly, the proposed rule was published for comment in the **Federal Register** on January 22, 2008 (73 FR 3812).

II. Discussion

A. What action is the NRC taking?

The NRC is amending its regulations to improve decommissioning planning and thereby reduce the likelihood that facilities under its jurisdiction will become legacy sites. To help achieve this goal, one set of complementary amendments revises 10 CFR 20.1406 to make it applicable to licensees with operating facilities as well as to license applicants and revises 10 CFR 20.1501(a) by replacing its undefined term ''radioactive material'' with ''residual radioactivity,'' a term already defined in 10 CFR part 20. This defined term includes subsurface contamination within its scope. Both new 10 CFR 20.1406(c) and amended 10 CFR 20.1501(a) are worded to include subsurface contamination within their scope by using the term ''residual radioactivity.'' These changes serve to reinforce the intended linkage between these provisions, and are consistent with NRC policy that licensees conduct operations to minimize the generation of waste to facilitate later facility decommissioning. A second set of amendments improves decommissioning planning by requiring more detailed reporting of DCEs and tighter control of financial instruments used to provide decommissioning financial assurance.

The new 10 CFR 20.1406(c) states as follows:

(c) Licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing radiation protection requirements in Subpart B of this part and radiological criteria for license termination in Subpart E of this part.

The amended 10 CFR 20.1501(a) and (b) state as follows:

(a) Each licensee shall make or cause to be made, surveys of areas, including the subsurface, that—

(1) May be necessary for the licensee to comply with the regulations in this part; and

(2) Are reasonable under the circumstances to evaluate—

(i) The magnitude and extent of radiation levels; and

(ii) Concentrations or quantities of residual radioactivity; and

(iii) The potential radiological hazards of the radiation levels and residual radioactivity detected.

(b) Notwithstanding § 20.2103(a) of this part, records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning, and such records must be retained in accordance with §§ 30.35(g), 40.36(f), 50.75(g), 70.25(g), or 72.30(d), as applicable.

As indicated, use of the term ''residual radioactivity'' is a key component of the amendments, and this term is discussed below. It is also discussed in the response to comment G.19 in section III of this document.

1. Residual Radioactivity

As set forth in 10 CFR 20.1003:

Residual radioactivity means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of 10 CFR part 20.

Certain operational events (*e.g.,* slow, long-term leaks), particularly those that cause subsurface soil and ground-water contamination, can significantly increase the cost of decommissioning. To adequately assure that a decommissioning fund will cover the costs of decommissioning, the owner of a facility must have a reasonably accurate estimate of the extent to which residual radioactivity is present at the facility, particularly in the subsurface soil and groundwater. As reflected previously, the new 10 CFR 20.1406(c) requires that licensees conduct their operations in a manner that will minimize the introduction of residual radioactivity into the site.

Section 20.1501(a) has been revised by replacing its undefined term ''radioactive material'' with ''residual radioactivity.'' For some, the phrase ''residual radioactivity'' may have a connotation implying radioactive material that is ''left over'' after operations. This is not the meaning. As reflected in the previously stated definition, the term ''residual radioactivity'' includes everything that the term ''radioactive material'' implies in this section of the current regulations plus other radioactive material resulting from activities under the licensee's control, such as contamination in the subsurface. The use of the term ''residual radioactivity'' in § 20.1501(a) also is intended to provide a link with new § 20.1406(c). The amended § 20.1501(a) retains previous survey requirements, with the addition that such requirements include consideration of waste in the form of residual radioactivity. Together, the amended § 20.1501(a) and the new § 20.1406(c) specify that compliance with 10 CFR part 20 requirements is a necessary part of effectively planning for decommissioning. The §§ 20.1406(c) and 20.1501(a) provisions are discussed further in Sections II.I and J of this document. These activities, undertaken during facility operations, will provide a technical basis for licensees and NRC to understand the effects of significant residual radioactivity on decommissioning costs, and will help to determine whether existing financial assurance provided for site-specific decommissioning is adequate. By using the term ''residual radioactivity,'' the new § 20.1406(c) and amended § 20.1501(a) cover any licensed and unlicensed radioactive material that have been introduced to the site by licensee activities.

New paragraph 10 CFR 20.1501(b) requires licensees to keep records of surveys of subsurface residual radioactivity identified at the site with the records important for decommissioning. To remove any ambiguity about the applicability of record retention requirements, this paragraph also clarifies that such records must be retained in accordance with §§ 30.35(g), 40.36(f), 50.75(g), 70.25(g), or 72.30(d), as applicable. These provisions specify certain types of information important to decommissioning and require licensees to keep records with this information in an identified location until the site is released for unrestricted use, or in the case of reactors, until the license is terminated. These decommissioning-related record retention requirements supersede those of § 20.2103(a), which generically requires that records of the results of such radiological dose assessment activities as surveys, air sampling, bioassays, and calibrations be retained for 3 years after the record is made.

During operations, residual radioactivity that would be significant for decommissioning planning would be a quantity of radioactive material that would later require remediation during decommissioning to meet the unrestricted use criteria of 10 CFR 20.1402. As stated in the proposed rule, significant residual radioactivity in subsurface media, such as soil, is a component of waste, because it must be removed and disposed of to meet unrestricted use criteria in 10 CFR 20.1402 (73 FR 3815; January 22, 2008).

During decommissioning, the licensee must evaluate dose from all residual radioactivity surveyed at its site using the radiological criteria in Subpart E to 10 CFR part 20. For contamination migrating offsite from previous leaks and spills into the subsurface, a licensee must comply with the applicable license conditions for its facility. Such offsite contamination, released as an effluent in quantities below annual regulatory limits, has been a factor in the decommissioning of a few NRC and Agreement State sites. However, the scope of this rulemaking does not include offsite contamination discovered during decommissioning.

The NRC's technical basis for the effect that significant residual radioactivity in the subsurface has on decommissioning costs is based on a 2005 NRC staff study, ''General Guidance for Inspections and Enforcement to Prevent Future Legacy Sites and Indicators of Higher Risk of Subsurface Contamination'' (ML052630421). The purpose of this study was to evaluate experience at sites that have undergone, or were undergoing, decommissioning to identify the types of events that have caused subsurface contamination. Associating these events with knowledge of currently operating sites provided a means for NRC staff to evaluate the potential for future subsurface contamination at currently operating facilities. This risk-informed approach concluded that the sites with a higher likelihood of becoming legacy sites shared the following characteristics: relatively large volumes of low specific activity radioactively contaminated liquids, large volumes of long-lived radionuclides, large throughput, liquid processes, or processes that involve large quantities of solid radioactive material stored

outdoors. The study identified a number of events that could increase decommissioning costs by increasing the possibility of soil or ground-water contamination and concluded that these events should cause the licensee to reevaluate its DCE. Additional discussion on this topic is in Sections II.G and II.H of this document.

The changes to 10 CFR 20.1406 and 20.1501 are consistent with existing NRC policy for operating facilities. Under 10 CFR 20.1101(b), licensees must use procedures and engineering controls to achieve occupational doses and doses to members of the public that are ALARA, during operations and during decommissioning. To accomplish this, licensees must be able to demonstrate their knowledge of residual radioactivity in the subsurface, including soil and ground-water contamination, particularly if the subsurface contamination is a significant amount that would require remediation during decommissioning to meet the unrestricted use criteria of 10 CFR 20.1402. This is an extension of the requirements promulgated in the 1997 LTR that were applicable only to license applicants. This action is needed, because significant subsurface residual radioactivity at current operating facilities may be a potential radiological hazard. Such a hazard, if left undetected, could potentially result in a failure to fully fund decommissioning while the facility is still operating. The revised requirements implement existing NRC policy by helping licensees to continue achieving doses that are ALARA and within dose limits, and helping them to more effectively plan for decommissioning.

2. Financial Assurance

This final rule (amending §§ 30.35, 40.36, 70.25, and 72.30, and Criterion 9 of Appendix A to Part 40) codifies certain aspects of existing regulatory guidance to improve the quality of the DFP and applies NRC experience to increase the likelihood that adequate funds will be available when needed to complete the decommissioning process. This final rule allows materials licensees to base their financial assurance for decommissioning on a ''certification amount'' only if the licensee's site surveys do not indicate the presence of residual radioactivity in amounts that would prevent the site from meeting the unrestricted use criteria in § 20.1402. This final rule addresses the potential vulnerability of the parent company guarantee and the self-guarantee as the financial mechanism for providing decommissioning funding assurance, in cases where the guarantor falls into financial distress. This final rule requires all reactor and materials licensees who use these guarantee mechanisms to establish a standby trust fund to receive the guaranteed financial assurance amount should that amount become immediately due and payable.

For licensees with reactors in a decommissioning status, this final rule institutes additional reporting requirements for decommissioning fund status, spent fuel management costs, and estimated decommissioning costs. These new reporting requirements, in part, modify the existing Post Shutdown Decommissioning Activities Report (PSDAR) requirements set forth in 10 CFR 50.82(a)(4)(i). Additional reporting requirements specify that each power reactor licensee undergoing decommissioning must submit an annual financial assurance status report, as set forth in new paragraphs 10 CFR 50.82(a)(8)(v) through (a)(8)(vii).

Under this final rule, all licensees decommissioning their facilities pursuant to 10 CFR 20.1403 restricted release criteria are required to use a trust fund to meet the financial assurance requirements. A trust fund is the only financial assurance mechanism allowed for the long-term maintenance and surveillance of restricted release sites, unless a government organization either provides a guarantee of funds or assumes custody and ownership of the site. This topic is discussed further in Section II.N of this final rule.

B. Whom does this action affect?

By the effective date of this final rule, the NRC believes that the changes to 10 CFR part 20 will affect a small number of licensees, and that the changes to financial assurance regulations will affect several hundred NRC licensees.

Based on the regulatory analysis for the final rule, NRC believes a small number of materials licensees (a total of about five NRC and Agreement State licensees) will need to perform additional site surveys due to the presence of significant residual radioactivity. The licensees who will need to perform additional surveys were modeled in the regulatory analysis as rare metal (*i.e.,* rare earth) extraction facilities with uranium as a soil contaminant. Although the number of licensees affected by rule changes to 10 CFR part 20 is small, the cost to States or the Federal Government to enforce and then fully decommission a single legacy site is much higher than the cost to prevent the occurrence of a legacy site through amended regulations.

Uranium recovery licensees and applicants will not be subject to the new 10 CFR 20.1406(c) requirements, just as they are not subject to the existing 10 CFR 20.1406 requirements. As stated in existing 10 CFR 20.1401(a), uranium and thorium recovery facilities, and uranium solution extraction facilities, are not subject to the regulations in 10 CFR part 20, Subpart E. Such facilities are and will continue to be subject to the regulations in the other 10 CFR part 20 subparts, and the revised survey and monitoring requirements in 10 CFR 20.1501(a) and new 10 CFR 20.1501(b) will thus be applicable to them. Uranium recovery licensees are additionally subject to existing monitoring requirements pertaining to soil and groundwater contamination in Appendix A to 10 CFR part 40. The above issues are discussed further in the response to Comment G.14 in Section III of this document.

For NRC licensees who have subsurface soil contamination but no groundwater contamination, a minimal, routine monitoring plan may remain in effect through license termination. The routine monitoring plan will be described in DG–4014. Application of a minimal, routine monitoring plan at sites with no groundwater contamination is meant to improve licensee decommissioning planning and the basis used for DCEs.

The large majority of NRC and Agreement State licensees are not expected to have residual radioactivity in soil or groundwater, because they possess small amounts of short-lived byproduct material or byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material (*i.e.,* a sealed source). This set of licensees is expected to include the non-fuel-cycle nuclear facilities, which either have no significant residual radioactive contamination to be cleaned up, or, if there is contamination, it is localized or will be quickly reduced to low levels by radioactive decay. Licensees who do not have residual radioactivity in soil or groundwater, and who do not have an obligation to set aside funds for decommissioning financial assurance, are not affected by this final rule.

Approximately 300 NRC materials licensees and over 1,000 Agreement State licensees have an obligation to set aside funds for decommissioning financial assurance. Of the NRC licensees, approximately 50 percent use a certified amount, specified in regulations, with the remaining 50 percent using a site-specific DFP or License Termination Plan (LTP) to meet the decommissioning financial assurance requirements. If there is significant residual radioactivity at the

site, the final rule changes in §§ 30.35, 40.36, 70.25, and 72.30 require a licensee to switch out of its certified funding amount and replace the certified amount with a DFP. At this time, the NRC staff is not aware of any licensees using certified amounts for decommissioning that need to switch to a DFP because of significant residual radioactivity.

Licensees using a site-specific DFP or License Termination Plan to meet decommissioning financial assurance requirements will have additional reporting requirements based on final rule changes in §§ 30.35, 40.36, 50.82, 70.25, and 72.30. The materials licensees under 10 CFR parts 30, 40, 70, and 72 will need to provide more details to support their DCEs, such as the assumed cost of an independent contractor to perform all decommissioning activities.

Final rule changes to 10 CFR 50.82(a) affect the 12 power reactor licensees undergoing decommissioning. Such licensees will need to provide more details regarding their DCEs and will need to provide cost estimates for managing irradiated fuel. More specifically, licensees who have submitted a certification of permanent cessation of operations under 10 CFR 50.82(a) are subject to annual financial assurance reporting requirements similar to those imposed on operating reactors under existing 10 CFR 50.75(f). The annual reports must identify yearly decommissioning expenditures, the remaining balance of decommissioning funds, and a cost estimate to complete decommissioning. Similar to the one-time reports required by 10 CFR 50.54(bb), the annual reports required under 10 CFR 50.82(a)(8) must identify the amount of funds accumulated to manage irradiated fuel and the projected cost of managing the irradiated fuel until title and possession is transferred to the Secretary of Energy.

Approximately 20 NRC licensees use an escrow account as a prepayment financial mechanism and will be affected by final rule changes in §§ 30.35, 40.36, 70.25, and 72.30 (which eliminate the escrow account as a prepayment financial assurance method). No NRC licensees are using a line of credit (which is being eliminated as an acceptable financial assurance instrument) to provide financial assurance.

Approximately 45 NRC licensees use a parent company guarantee or self-guarantee as a financial assurance mechanism. These licensees will be affected by final rule changes in 10 CFR part 30, Appendices A, C, D, and E, which require establishment of a standby trust fund before the guarantee becomes effective, and which contain other new requirements. The standby trust fund is to be set up for receipt of funds in the case of financial distress by the guarantor. In the regulatory analysis and Paperwork Reduction Act burden estimate, NRC assumed that a total of 25 of these 45 licensees will need to establish a trust fund to comply with the amended regulations, while the other 20 already have an established trust fund.

The regulatory analysis for this final rule, referenced in Section X of this document, has detailed cost-benefit estimates regarding the licensees who will be affected by the amended regulations.

C. What steps did NRC take to prepare for this rulemaking?

The NRC took several initiatives to enhance stakeholder involvement and to improve efficiency during the rulemaking process. On May 28, 2004, the NRC staff issued Regulatory Information Summary (RIS) 2004–08, ''Results of the License Termination Rule Analysis'' (ML041460385). This RIS was the first follow-up action taken in response to the SRM for SECY–03–0069. The purpose of the RIS was to inform licensees and stakeholders of NRC's analysis of the issues associated with implementing the LTR, the Commission's direction to resolve these issues, the schedule for future actions, and opportunities for stakeholder comment. The RIS noted that stakeholder involvement would be an important part of developing the planned rulemaking and guidance.

In April 2005, the NRC conducted a 2-day decommissioning workshop examining a number of LTR topics, including potential changes in facility operating requirements and changes to financial assurance to prevent legacy sites. Stakeholders addressed the issues and potential resolutions that could be accomplished through rulemaking. Since then, NRC has maintained a Web page (*http://www.nrc.gov/about-nrc/regulatory/decommissioning.html*) with information including draft guidance documents, Commission papers, and a variety of decommissioning program documents. The NRC presented papers on the technical basis scope of the rulemaking at American Nuclear Society conferences in 2004, 2005, and 2006, and other stakeholder forums.

In June 2006, the NRC formed a proposed rule Working Group of NRC staff and one Agreement State representative from the Organization of Agreement States (OAS). The NRC has held discussions with State and Federal agencies on their experience with trust funds for long-term financial assurance, including a discussion with the U.S. Environmental Protection Agency (EPA) on October 6, 2006.

In January 2007, the NRC held a public roundtable meeting that was attended by about 40 stakeholders. The meeting was held to solicit input from stakeholders and interested members of the public regarding the issues of licensee control and identification of subsurface residual radioactivity and changes that were being considered in decommissioning financial assurance requirements. The Summary Notes and transcript of this public meeting are posted on: *http://www.nrc.gov/about-nrc/regulatory/decommissioning/public-involve.html*.

D. What alternatives did NRC consider?

The proposed rule Working Group considered three different alternatives for the rule. Each was evaluated in the environmental assessment (see Section VIII of this document) and the regulatory analysis (see Section X of this document). Alternative 2, comprised of the amendments in this final rule, was assessed to be superior compared to the other alternatives.

E. What is a legacy site?

A legacy site is a facility that is decommissioning and has an owner who cannot complete the decommissioning work for technical or financial reasons. These sites have been materials facilities, not reactor facilities.

The purpose of this final rule is to improve decommissioning planning and thereby reduce the likelihood that a site will become a legacy site, thus avoiding unnecessary expense and promoting more timely return of licensed sites to other productive uses.

NRC terminates several hundred materials licenses each year. Most of these are routine actions, and the sites require little, if any, remediation to meet NRC's unrestricted use criteria. There are other sites where more complex decommissioning actions are needed. These complex decommissioning sites are described, along with the objectives of NRC decommissioning activities, in the ''Status of Decommissioning Program 2006 Annual Report'' available at: *http://www.nrc.gov/about-nrc/regulatory/decommissioning/program-docs.html*. This report identifies and describes the status of 32 complex materials sites undergoing decommissioning. Of the total 32 complex sites, the NRC considered 8 of these to be legacy sites as of December 31, 2006. At the end of 2010, there were 6 legacy sites among the complex

materials sites undergoing decommissioning.

F. What are financial assurances?

Financial assurances are financial arrangements provided by a licensee, whereby funds for decommissioning will be available when needed. Each NRC licensee has a regulatory obligation to properly decommission its facility. However, only licensees whose decommissioning cost is likely to exceed a threshold amount must provide financial assurance. All nuclear power reactors and about 7 percent of NRC materials licensees must provide decommissioning financial assurance. This financial assurance may be funds set aside by the licensee or a guarantee that funds will be available when needed. The guarantee may be provided by a qualified third party or upon passage of a financial test by the licensee. The third party may be the parent company of the licensee, which is the case for about 10 percent of the NRC materials licensees that are obligated to have decommissioning financial assurance.

Nuclear power reactors have financial assurance obligations that are different from materials licensees. The minimum amount of financial assurance for reactors is defined in 10 CFR 50.75, and this rulemaking does not change this required minimum amount. Acceptable financial assurance mechanisms for power reactors are defined in § 50.75(e)(1). An external sinking fund is used to provide financial assurance for about 90 percent of the reactors. The remaining 10 percent of reactors have assurance through prepaid funds and/or guarantees.

As of December 31, 2006, there were about 300 NRC materials licensees that had a regulatory obligation to provide approved financial assurance mechanisms. An acceptable financial assurance mechanism for unrestricted use decommissioning is any of the following four types of financial instruments:

- A prepayment of the applicable decommissioning costs;
- A guarantee to pay the decommissioning costs issued by a qualified third party or the licensee;
- A statement of intent from a Federal, State or local government licensee; or
- An external sinking fund.

The prepayment method is full payment in advance of decommissioning using an account segregated from licensee assets and outside the licensee's administrative control. About 11 percent of current financial assurance mechanisms for materials licensees are prepayment methods, with most of these being escrow accounts. Currently accepted prepayment mechanisms include escrow accounts (8 percent), trust funds (2 percent), certificates of deposit (1 percent), government funds (0 percent), and deposits of government securities (0 percent). This final rule eliminates all prepayment mechanisms except the trust fund, for reasons discussed under Section II.N.2 of this document.

The guarantee method can be used by licensees that demonstrate adequate financial strength through their annual completion of financial tests contained in Appendices A, C, D, and E of 10 CFR part 30. About 51 percent of current financial assurance mechanisms for materials licensees are guarantee methods. Currently accepted guarantee mechanisms include letters of credit (28 percent), parent company guarantees (8 percent), licensee self-guarantees (7 percent), surety bonds (8 percent), lines of credit (0 percent), and insurance policies (0 percent). This final rule eliminates the line of credit as an acceptable mechanism, for reasons discussed under Section II.N.10 of this document.

The statement of intent is a commitment from a Federal, State or local government licensee that it will request and obtain decommissioning funds from its funding body, when necessary for decommissioning an NRC licensed site. It is available for use only by governmental entities. Approximately 38 percent of the NRC materials licensees who are required to provide financial assurance use the statement of intent as a means to provide financial assurance.

The external sinking fund is an approved financial assurance method that allows an NRC licensee to gradually prepay the DCE, but no NRC materials licensees who have an obligation to provide decommissioning financial assurance use this option. Before this rulemaking, materials licensees choosing this option would have to cover amounts that were not prepaid by a surety mechanism or insurance. The same requirements apply to power reactor licensees, except that the amounts that are not prepaid can be covered by a guarantee method as well as by surety or insurance. This rulemaking provides materials licensees opting to use the external sinking fund with the same degree of flexibility that power reactor licensees have had since 1998 (in a final rulemaking for power reactor financial assurance, the NRC allowed use of a parent company guarantee or self-guarantee with an external sinking fund (63 FR 50465; September 22, 1998)). This final rule makes conforming changes in the financial assurance requirements for materials licensees (10 CFR 30.35, 40.36, 70.25, and 72.30) to provide greater consistency with the 10 CFR part 50 regulations.

This discussion of financial assurance to decommission a site pertains only to unrestricted use under 10 CFR 20.1402. If a licensee can demonstrate its ability to meet the provisions of 10 CFR 20.1403 for restricted use, financial assurance for long-term surveillance and control may be provided by a trust fund or by a government entity assuming ownership and custody of the site.

G. Why might some materials licensees not have funds to decommission their facility?

In SECY–03–0069, the NRC evaluated licensee decommissioning experience and identified the following five reasons why some licensees may not have enough funds to complete their decommissioning activities.

1. Licensees at complex sites may underestimate decommissioning costs, if the assumption that the site will qualify for a restricted release proves incorrect. The cost for a restricted release is usually significantly lower than unrestricted release given the high offsite disposal costs of licensed material when compared to the cost of onsite controls. If it turns out that the licensee cannot meet the 10 CFR 20.1403 criteria for restricted conditions, the licensee may then not be able to meet its decommissioning financial obligations. To address this problem, this final rule amends 10 CFR 30.35, 40.36, 70.25, and 72.30 to require licensees to obtain NRC approval of their DFP based on a DCE for unrestricted release, unless the ability to meet the restricted release criteria can be adequately shown.

2. Certain operational events, particularly those that cause soil or ground-water contamination, can increase decommissioning costs if not addressed during the life of the facility. If the licensee does not identify these events, assess the problem in a timely manner, and update its DCE based on new conditions, the licensee may find it difficult to later meet its decommissioning obligations. To address this problem, this final rule amends 10 CFR 20.1406 as discussed previously in Section II.A of this document. Licensees also are required, in amendments to 10 CFR 30.35, 40.36, 70.25, and 72.30, to factor in residual radioactivity information in arriving at DCEs.

3. Certain financial assurance methods may not be effective in bankruptcy situations, given that funds held in them may be accessible to creditors. For example, title to property held in escrow remains with the licensee, making the property potentially vulnerable to claims by creditors. Another example is the parent and self-guarantees. The guarantees promise performance rather than payment. In the past, two companies used corporate reorganization to isolate the decommissioning obligations with the subsidiary company, but with insufficient funds to perform the work. In one case, the parent company reorganized without NRC approval and transferred to the subsidiary few assets and low levels of operating profits, so that the subsidiary was able to fund only a small portion of its decommissioning costs. In the second case, the parent company purchased the licensee before the financial assurance regulations went into in effect. The licensee was permanently shut down after the purchase and was unable to provide full financial assurance. To address this problem, this final rule amends 10 CFR 30.35, 40.36, 70.25, 72.30, and 10 CFR part 30, Appendices A, C, D, and E by eliminating the use of an escrow account as a financial assurance option, and requiring a guarantor, as a condition of using the parent company guarantee and self-guarantee financial assurance options, to establish a standby trust fund and to submit to a Commission order, if the guarantor is in financial distress, to immediately pay the guaranteed funds into the standby trust.

4. The funds set aside by licensees to carry out decommissioning may decline in value over time. To address this problem, this final rule amends 10 CFR 30.35(h), 40.36(f), 70.25(h), and 72.30(g) to require that a licensee monitor the status of its decommissioning funds and, if necessary, add funds if the balance falls below the estimated cost of decommissioning.

5. The initial funding of a trust fund to cover the recurring costs of long-term surveillance and control for license termination under restricted release criteria may be inadequate if it assumes a high rate of return for the trust fund. To address this problem, this final rule amends 10 CFR 20.1403 to require that licensees assume only a 1 percent real rate of return in establishing the initial funding amount.

H. Why Is 10 CFR 50.82 being amended?

Several power reactor licensees have successfully decommissioned their reactor sites consistent with 10 CFR part 20 requirements. In some cases, reactor decommissioning costs have exceeded the initial DCE. For example, the Connecticut Yankee Nuclear Plant experienced higher decommissioning costs than planned, due in part to a larger volume of contaminated soil than was identified in the initial site characterization.

In the past, the NRC has not required licensees to submit details of decommissioning costs on the grounds that the typical reactor licensee was part of a public utility with access to substantial assets and revenues and that the minimum required amount for decommissioning financial assurance was adequate. A licensee's status as a regulated public utility provided access to cost of service rate recovery to help provide additional funds. A public utility had access to sales revenues to fund its obligations, even if rate recovery was limited.

Deregulation of the electric industry now permits a reactor licensee to operate as a merchant plant not subject to rate regulation or rate recovery of costs of service. When it ceases operation, it may have no sales revenues. The licensee may be organized as a separate company or a subsidiary of a holding company to isolate the risks and rewards of selling electricity on the open market. Without access to rate relief, with no sales revenues, and with the licensee's owner protected by limited liability, shortfalls in decommissioning funding may jeopardize timely completion of decommissioning. This final rule provides NRC regulatory authority to perform oversight to assure that the licensee anticipates potential shortfalls and takes steps to control costs to stay within its budget or obtain additional funds.

I. What changes are being made to 10 CFR 20.1406?

New 10 CFR 20.1406(c) states as follows:

> (c) Licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing radiation protection requirements in Subpart B of this part and radiological criteria for license termination in Subpart E of this part.

The term ''to the extent practical'' is intended to limit the scope of this provision to actions that are already manifested in practice or action. The same phrase is used in existing 10 CFR 20.1101(b), which requires that licensees keep occupational and public radiological doses to ALARA levels. This final rule requires licensees to conduct their operations to minimize the introduction of residual radioactivity into the site, including the subsurface, to achieve effective decommissioning planning. For operating facilities, significant residual radioactivity is a quantity that would later require remediation during decommissioning to meet the unrestricted use criteria of 10 CFR 20.1402.

The current 10 CFR 20.1101 requirements are related to those in new 10 CFR 20.1406(c). Section 20.1101(a) requires each licensee to implement a radiation protection program to ensure compliance with the regulations in 10 CFR part 20. The current 10 CFR 20.1101(b) requires each licensee to use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA. To achieve doses that are ALARA during facility operations and decommissioning, the § 20.1101(b) operating procedures and controls must apply to potential radiological hazards and to methods used by the licensee to minimize and control waste generation.

In furtherance of these existing requirements, new 10 CFR 20.1406(c) includes the term ''residual radioactivity,'' as discussed previously in Section II.A of this document. This new section applies to current licensee operations, in contrast to the § 20.1406(a) and (b) requirements which are imposed on license applicants. Residual radioactivity excludes background radiation. The licensees of large nuclear facilities will have performed an assessment of background radioactivity at their site as part of an Environmental Impact Statement required during the license application process. As a matter of standard operating practice, licensees will document the background level of radioactivity when a survey is performed at the site. Residual radioactivity, as defined in 10 CFR 20.1003, is not ''residual radioactive material'' as defined in 10 CFR 40.4, which is used only with respect to materials at sites subject to remediation under Title I of the Uranium Mill Tailings Radiation Control Act of 1978, as amended.

The final rule's use of the term ''subsurface'' designates the area below the surface by at least 15 centimeters, as defined in NUREG–1575, ''Multi-Agency Radiation Survey and Site Investigation Manual'' (ML070110228). Under this final rule, licensees must conduct their operations to minimize residual radioactivity that enters the

subsurface at the site. If there are pathways that would allow the contamination to migrate, the licensee may need to monitor the groundwater onsite for contamination based on site specific conditions. Based on past NRC experience, significant concentrations or quantities of undetected and unmonitored contamination, caused primarily by subsurface migration of groundwater, have been a major contributor to a site's becoming a legacy site and a potential radiological hazard.

Several hundred NRC materials licensees possess radioactive material and have liquid processes that could cause subsurface contamination. These licensees generally are compliant with regulations that limit effluent release to the environment over a specified time. Some of these licensees may not have documented onsite residual radioactivity, such as spills, leaks and onsite burials that may be costly to remediate during decommissioning and should be considered in arriving at an accurate DCE. There have been instances of previously unidentified soil and ground-water contamination at uranium recovery and rare earth metal recovery sites undergoing decommissioning in several states, notably Colorado and Pennsylvania. Two contributing factors to the accumulation of unidentified subsurface contamination are: (1) Reluctance among some licensees to spend funds during operations to perform surveys and document spills and leaks that may affect site characterization; and (2) reluctance to implement procedures for waste minimization.

The vast majority of NRC materials licensees do not have processes that would cause subsurface contamination. NRC's expectation is that these licensees, including those that release and monitor effluents of short-lived radionuclides to municipal sewer systems, will not be impacted by new 10 CFR 20.1406(c). The accumulation of radionuclides at municipal waste treatment facilities was the subject of an Interagency Steering Committee on Radiation Standards (ISCORS) study (NUREG–1775, November 2003, ML033140171), which concluded that, in general, these facilities do not have significant concentrations of long-lived radionuclides. Other classes of licensees that are, in general, not expected to introduce significant residual radioactivity into the subsurface include broad scope academic, broad scope medical, and small research and test reactors. The DG–4014 proposes an acceptable method for these licensees to evaluate the subsurface residual radioactivity.

Power reactor licensees have exhibited a high level of ALARA discipline with respect to effluent release and known spills and leaks. Current NRC regulations in §§ 20.1301, 20.1302, and 50.36a ensure that power reactor licensees maintain adequate monitoring and surveys of radioactive effluent discharges, with annual reporting requirements outlined in § 50.36a(2) that are made available to the public on the NRC Web site. Several nuclear power plants have reported abnormal releases of liquid tritium, which resulted in ground-water contamination. On May 5, 2006, the NRC staff issued a revised baseline inspection module (Procedure 71122.01, ML053490179) used to inspect leaks and spills at power reactor sites. To further address this issue, the Nuclear Energy Institute (NEI) developed voluntary guidance for licensees in the Industry Ground Water Protection Initiative (GPI) (ML072600295). The voluntary GPI, implemented by all licensed power reactors as of September 2008, is a site-specific groundwater protection program to manage situations involving inadvertent releases of licensed material to groundwater and to provide informal communication to appropriate State/Local officials, with follow-up notification to the NRC as appropriate.

J. What surveys are required under amended 10 CFR 20.1501(a)?

Before this final rule, § 20.1501(a) required licensees to perform surveys necessary to comply with Part 20 requirements, including surveys reasonable under the circumstances to evaluate potential radiological hazards. This final rule requires radiological surveys, reasonable under the circumstances (such as scoping surveys), sufficient to understand the extent of significant residual radioactivity, including the subsurface. This final rule does not add any new requirements regarding extensive site characterization. Slow and long-lasting leaks of radioactive material into the onsite subsurface may eventually produce radiological hazards and pose a risk for creation of a legacy site if contaminant characteristics are not identified when the facility is operating. The staff views radiological hazards as including those resulting from subsurface contaminating events, when these events produce significant residual radioactivity that would later require remediation during decommissioning to meet the unrestricted use criteria of 10 CFR 20.1402. An effective approach to understand the extent of subsurface residual radioactivity is through the use of radiological surveys.

Appropriate surveys are essential for determining the adequacy of financial assurance for materials licensees, and need to be done periodically on a limited basis during operations when the DFP and financial assurance can be adjusted while the licensee is still generating revenue. This is far superior to the current practice at some facilities of delaying even limited survey work at the site until after the facility has been shut down.

Facilities that process large quantities of licensed material, especially in fluid form, have the potential for causing significant environmental contamination. Leaks from these facilities can lead to large amounts of radioactive contamination entering the subsurface environment over an extended time. The estimated doses from this contamination are below the limits in 10 CFR part 20 that would initiate immediate regulatory action. Another factor the staff considered in preparing this final rule is the high cost to dispose of radioactive materials offsite. These costs are a concern, even when the material contains relatively low concentrations of radioactivity. A continued trend of high disposal costs could increase the number of environmental contamination incidents at operating facilities, resulting in higher decommissioning costs. A third factor that may contribute to future legacy sites is the delayed identification of contamination on the site. Over a long time, contamination that migrates in subsurface soil or groundwater does not cause immediate exposure to either workers or the public that approaches the limits specified in 10 CFR part 20. It is only after operations have ceased when the possible results of unlimited access to the site, and associated exposure pathways (*i.e.,* ingestion and inhalation) are being evaluated, that the volume of contamination becomes apparent.

As discussed previously in Section II.A of this document, amended 10 CFR 20.1501(a) requires licensees to perform contamination surveys to comply with current 10 CFR part 20 requirements and the new § 20.1406(c), if there is a history of leaks or spills to the subsurface at the site. The magnitude and extent of radiation levels are typically defined in units of radioactivity measurement, such as in micro-rem per hour (μrem/hr). The concentrations or quantities of residual radioactivity are typically defined in units of radioactivity associated with a specific radionuclide, for example

picocuries per liter of tritium (pCi/L of H–3).

The amended § 20.1501(a) retains previous survey requirements and specifies that such requirements include consideration of subsurface residual radioactivity. Survey requirements may include ground-water monitoring if reasonable under the site specific conditions. Soil sampling also may be warranted based on site-specific conditions—for example, if there is no ground-water monitoring at the site or if known subsurface contamination has not migrated to the groundwater. The DG–4014 proposes a variety of acceptable methods to evaluate subsurface characteristics. The NRC recognizes that ground-water monitoring may be a surrogate for subsurface monitoring at some sites, that soil sampling may be appropriate at other sites, and that there are sites with no subsurface residual radioactivity where the existing monitoring method is appropriate. Also, the NRC recognizes that an area within the footprint of a building, during licensed operations, may not be a suitable area for subsurface residual radioactivity surveys if the process of sampling would have an adverse impact on facility operations. The decision to perform subsurface residual radioactivity sampling in a particular area should be balanced against the potential to jeopardize the safe operation of the facility. The purpose of amended 10 CFR 20.1501(a) and new 10 CFR 20.1406(c) is to specify that compliance with 10 CFR part 20 survey and recordkeeping requirements is necessary to demonstrate compliance with existing regulations and to plan effectively for decommissioning, including effects from subsurface contamination.

Final rule amendments to 10 CFR 30.35(e)(2), 40.36(d)(2), 70.25(e)(2), and 72.30(c) require licensees who have a DFP or a LTP to factor in the results of surveys, performed under § 20.1501(a), in estimating decommissioning costs. This requirement applies only to materials licensees who are required to have a DFP and assures that these licensees properly consider the extent of subsurface residual radioactivity in their DCEs, thus improving decommissioning planning and helping to reduce the likelihood of future legacy sites.

For the materials licensees with a certified amount as decommissioning financial assurance, the NRC assumes their current monitoring methods are adequate. If these licensees detect onsite contamination that would later require remediation during decommissioning to meet the unrestricted use criteria of 10 CFR 20.1402, then the licensees are required to submit for approval by the NRC a DFP with a DCE.

Some materials licensees are not required to have financial assurance for decommissioning based on a license possession limit that is below the financial assurance threshold values in Appendix B of 10 CFR part 30. For these licensees, the NRC's expectation is that the monitoring performed under amended § 20.1501(a) would be of a simple form, as will be discussed in DG–4014. Simple form monitoring is a method that confirms the absence of leaks or spills to the subsurface. The risk is low that any of these sites would cause contamination to create a potential radiological hazard or a future legacy site.

On the effective date of this final rule, NRC's expectation is that no additional surveys will be required of power reactor licensees and fuel cycle facilities. For power reactors, NRC staff concludes that the monitoring and survey processes and related reports prepared at power reactor sites will likely contain sufficient information to satisfy new § 20.1406(c) and amended § 20.1501 requirements. The NRC is not requiring licensees to submit reports, but the information must be kept onsite in records that are available for review. It is not expected that power reactor licensees will need to immediately install additional monitoring equipment or modify existing operating procedures to satisfy the amended § 20.1501(a) requirements. It may be necessary, however, for such licensees to take these actions if, for example, significant residual radioactivity is identified at a power reactor site at a level higher than had been previously identified. In any such situations, the need for additional monitoring will be determined on a case-by-case basis.

Fuel cycle facilities, such as uranium fuel fabrication plants, the gaseous diffusion enrichment plants, and the dry process natural uranium conversion/de-conversion facility, also perform surveys to detect radioactive releases to the groundwater. NRC staff concludes that the monitoring and survey processes and related reports prepared at these facilities would likely contain sufficient information to satisfy § 20.1406(c) and § 20.1501 requirements. A high level of ALARA discipline for onsite spills and leaks is expected of the centrifuge enrichment plants and mixed oxide fabrication plant based on the information in their license applications (these facilities have not begun operations).

K. What information must the licensee collect under amended 10 CFR 20.1501?

For facilities having significant subsurface contamination, NRC is requiring licensee documentation of contaminating events and survey results, including groundwater monitoring surveys, and the retention of survey records until license termination, to facilitate later decommissioning of the facility.

Licensees must be able to demonstrate compliance with the regulations in 10 CFR part 20 through surveys that evaluate the magnitude and extent of site radiation levels, including significant concentrations or quantities of residual radioactivity in the subsurface. Such surveys would evaluate any potential radiation hazards of the radiation levels and residual radioactivity detected. The sampling results should include the date, time, location, contaminants of interest and contamination levels, and the concentrations at which action is required to comply with regulations. The contaminants of interest are those used within the facility with half-lives long enough that they would require remediation during decommissioning to meet the unrestricted use criteria under 10 CFR 20.1402. Contaminants may include both chemicals and radionuclides in the groundwater from sources upstream of the NRC-licensed site because of the potential for interaction with releases from other sites. When groundwater is being monitored, the surveys conducted by the licensee should include hydro-geologic evaluations that lead to a determination of effective sampling and analysis, including accurate placement and installation of the wells, and well locations to determine the nominal groundwater flow direction and preferential flow paths for each ''aquifer'' underlying the site. Licensees may need to perform surveys to demonstrate compliance with the new 10 CFR 20.1406(c).

Under the requirements of §§ 30.35(g), 40.36(f), 50.75(g), 70.25(g), and 72.30(d), licensees must designate the records from 10 CFR 20.1501(b) surveys of subsurface residual radioactivity at the site as records important for decommissioning. Significant residual radioactivity that must be documented in these records would include onsite subsurface residual radioactivity that would later require remediation during decommissioning to meet the unrestricted use criteria of 10 CFR 20.1402 (73 FR 3815; January 22, 2008). These records can be as simple as a description of the contaminating event,

to include date, time, location, and the estimated quantities and activity levels of radioactive materials that were spilled or leaked. The documentation may describe the activation of a moisture alarm system used to indicate the presence of liquid in an area that is supposed to be dry. Contamination survey results must be included in these records if the surveys are considered important for decommissioning planning.

L. How will licensees report required information to the NRC?

There are no reporting requirements for licensees under amendments to 10 CFR 20.1406(c) and 20.1501.

Instead, the NRC requires licensees to collect information and to have that information available for review. The information must be retained by licensees in records important for decommissioning under §§ 30.35(g), 40.36(f), 50.75(g), 70.25(g), and 72.30(d).

Under amendments to financial assurance regulations, under § 30.35(e), § 40.36(d), 10 Part 40 Appendix A Criterion 9(b), § 70.25(e), and § 72.30, reporting requirements would increase for materials licensees who must prepare a detailed cost estimate for decommissioning. Reporting requirements also increase based on amended § 50.82(a) for power reactor licensees who prepare a post-shutdown decommissioning activities report (PSDAR) or an annual financial assurance status report.

Under amendments to 10 CFR part 30, Appendix A, licensees who use the parent company guarantee as financial assurance for decommissioning will have increased reporting requirements. Increased reporting requirements will include reporting of off-balance sheet transactions and verification of bond ratings and annual documentation of continuing eligibility to use the parent company guarantee. Licensees who use the self-guarantee as financial assurance for decommissioning under 10 CFR part 30, Appendices C, D, and E, will have similarly increased reporting requirements.

Licensees will continue to submit information to the NRC by certified mail or through approved Electronic Information Exchange (EIE) methods.

M. What financial assurance information must licensees report to the NRC?

Materials licensees with a license possession limit that is below the financial assurance threshold in 10 CFR part 30, Appendix B, are not required to have financial assurance for decommissioning. Licensees under 10 CFR parts 30, 40, and 70 with a license possession limit above the financial assurance threshold in 10 CFR part 30, Appendix B, but below the threshold requiring a DFP, have an option of providing financial assurance based on an amount specified by regulation or based on a DFP with a site-specific cost estimate. Materials licensees with a licensed possession limit above the financial assurance threshold, and all 10 CFR part 72 licenses, must submit at intervals not exceeding 3 years a DFP which includes the following: A site-specific cost estimate, a description of the methods used to assure the funds, and a description of the means of adjusting the cost estimate. The required contents of the DFP are changing as a result of this final rule, as discussed in Section II.P of this document.

Except for 10 CFR part 72 licensees, materials licensees must also provide a signed original of the financial instrument obtained to satisfy the financial assurance requirement.

For materials licensees, Chapter 4 in NUREG–1757, Volume 3, revision 1, ''Consolidated NMSS Decommissioning Guidance,'' provides details on information necessary to satisfy their financial assurance requirements. This document is available on the NRC Web site at: *http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/*. This document is being updated to include new requirements resulting from this final rule.

Power reactor licensees are already required by existing 10 CFR 50.75(f)(1) to report on the status of their decommissioning funds at 2-year intervals. A power reactor licensee that is within 5 years of the end of its projected life, or will close within 5 years (before the end of its licensed life), or has already closed, must submit the report of funds status on an annual basis. These requirements are not being changed.

Applicants for power reactor and non-power reactor licenses and reactor license holders must submit a decommissioning report as required by existing 10 CFR 50.33(k), and this provision is not being changed. The 10 CFR 50.33(k) report is submitted once and contains the following: Information indicating how reasonable assurance will be provided that funds will be available to decommission the facility, the method used to provide funds for decommissioning, and the means for adjusting periodically the amount to be provided. The reporting requirements for reactors being decommissioned are changing as a result of amendments to 10 CFR 50.82, as discussed in Section II.R in this document.

For nuclear power reactor licensees, Chapter 2 in Regulatory Guide 1.159, ''Assuring the Availability of Funds for Decommissioning Nuclear Reactors,'' provides details on the information necessary to satisfy these licensees' financial assurance requirements (ML032790365). This regulatory guide is being revised. The draft guide (DG–1229) is available at ML103400008.

N. What changes are being made to financial assurance regulations?

Most of the final rule amendments are changes to financial assurance regulations for materials licensees. A few changes apply to decommissioning financial assurance for power reactor licensees. The changes to financial assurance regulations are discussed in this section, under the following headings:

N.1 Require a trust fund for decommissioning under restricted release.
N.2 Require a trust fund for the prepayment option.
N.3 Require an upfront standby trust fund for the parent guarantee and self-guarantee options.
N.4 Require parent company to inform NRC of financial distress and submit to an Order.
N.5 Require guarantor payment immediately due to standby trust.
N.6 Allow intangible assets, with an investment grade bond, to meet some financial tests.
N.7 Increase the minimum tangible net worth for the guarantees' financial tests.
N.8 Clarify guarantors' bond ratings and annual demonstration submittals.
N.9 Invalidate the use of certification for financial assurance if there is contamination.
N.10 Other changes to financial assurance regulations.

Many of the financial assurance amendments had been in NRC guidance and are being codified in this final rule. The amendments strengthen and clarify the financial assurance requirements. The NRC seeks to improve decommissioning planning and reduce the number of funding shortfalls caused in the past by—(1) overly optimistic decommissioning assumptions; (2) lack of adequate updating of cost estimates during operation; and (3) licensees' falling into financial distress with financial assurance funds unavailable for decommissioning. The changes increase licensee reporting requirements. The added reporting burden is estimated as part of the Paperwork Reduction Act Statement in Section IX of this document. The costs

and benefits of this final rule are evaluated in the regulatory analysis in Section X of this document.

N.1 Require a Trust Fund for Decommissioning Under Restricted Release

The NRC is amending the regulations related to decommissioning financial assurance applied to planned restricted release sites.

This final rule requires, under § 20.1403(c), that the funds for financial assurance of long-term care and maintenance of a restricted release site must be placed into a trust segregated from the licensee's assets and outside the licensee's administrative control.

This amendment eliminates, as prepayment options, the escrow account, sureties and insurance, and the parent company and self-guarantee methods at restricted release sites. To date, no licensee has chosen to use these financial assurance mechanisms at a restricted release site. These mechanisms were eliminated, because they possess characteristics that make their use inadvisable for the types of long-term care and maintenance situations involved in restricted release sites. The final rule continues to permit government entities to use a statement of intent or to assume custody and ownership of a site.

Escrow accounts are not well suited to the protection of funds over a long term. The purpose normally served by an escrow is to collect or hold funds for an expense to be paid in the relatively near future (*e.g.,* property tax escrows). The EPA concluded that a trust was more protective of funds because, under trust law, the title to property in a trust is transferred to the trustee (46 FR 2802, 2827; January 12, 1981). In an escrow account, title to the property remains with the grantor. Thus, escrow property is more likely to be subject to a creditor's claim than property held in trust. In addition, the law of trusts places obligations on the trustee to act in the interest of the beneficiary. In contrast, an escrow agent is responsible only for what is specified in the escrow agreement. The EPA concluded that it would be extremely difficult to draft an escrow agreement that adequately specifies all the actions that an escrow agent would need to take in all situations to assure the instrument served its intended purpose.

The surety methods and insurance are also not well suited to protect funds over the long term, because they depend on contracts made by the former licensee. There are no actual funds set aside for future costs; rather, the methods are promises made by the issuer to pay at a future time. These methods require renewal to remain effective. They depend on the former licensee continuing to exist to make renewal payments for the surety or insurance instruments. The instrument lapses if the payments are not made. Under the existing rule, the NRC may require the issuer to pay the face amount before the lapse occurs. However, issuers may resist making the payment, which could delay obtaining (and possibly reduce) the amount of funds for long-term care and maintenance. Whether the issuer resists paying or not, when the funds are paid for the face amount, the funds will be placed into a trust account. That is, the response to the non-renewal of a surety is to create a trust to hold funds. The long-term nature of the obligation increases the possibility that circumstances may arise that would require a demand for payment. In view of the potential difficulties and delays and recognizing that a trust fund is the preferred long-term instrument for holding funds, the surety and insurance methods of financial assurance for long-term maintenance and control have been eliminated.

Likewise, the parent company and self-guarantee mechanisms are not well suited for providing financial assurance at restricted release sites, because these were designed to assure funding for the relatively limited time needed to complete most decommissioning projects under 10 CFR 20.1402. The former licensee or its parent must continue to exist to pay for long-term control and maintenance costs. If the former licensee or its parent ceases to exist, the self-guarantee or parent company guarantee has no source of funds to pay the costs. In addition, these guarantees presume the existence of a licensee subject to NRC authority. However, when the license is terminated, the NRC has no regulatory authority over the former licensee. Therefore, the self-guarantee and parent company guarantee have been eliminated as financial assurance options at restricted release sites.

In contrast, the trust fund is best suited as a financial mechanism to assure the necessary long-term care and maintenance at restricted release sites. The trust fund can exist for long periods without need for renewal. It exists independently of the former licensee and can continue to serve the purposes of control and maintenance, even if the former licensee ceases to exist. The trustee has a fiduciary duty to serve the beneficiaries of the trust. The funds placed in the trust become property of the trust and generally cannot be reached by creditors of the former licensee. Trust funds have traditionally been used to provide for the long-term care and maintenance of parks and other public facilities, to care for cemeteries, and for similar purposes. This final rule requires the use of trust funds for the financial assurance for long-term care and maintenance at restricted release sites, unless a government entity provides long-term funding or assumes custody and ownership of the site.

A further change to 10 CFR 20.1403(c)(1) requires that the initial amount of the trust fund established for long-term care and maintenance be based on a 1 percent annual real rate of return on investment. A similar provision is currently contained in 10 CFR part 40, Appendix A, Criterion 10, which provides that if a site-specific evaluation shows that a sum greater than the minimum amount specified in the rule is necessary for long-term surveillance following decontamination and decommissioning of a uranium mill site, the total amount to cover the cost of long-term surveillance must be that amount that would yield interest in an amount sufficient to cover the annual costs of site surveillance, assuming a 1 percent annual real rate of interest.

The NRC concluded that a conservative estimate of the annual real rate of return is justified in the case of financial assurance for long-term care and maintenance under § 20.1403(c)(1). Although the NRC in 10 CFR 50.75(e)(1)(ii) allows a licensee of a nuclear power reactor that is using an external sinking fund to take credit for projected earnings on the external sinking funds (using up to a 2 percent annual real rate of return from the time of the future fund's collection through the decommissioning period), the reactor situation is distinguished by the continuing presence of the reactor licensee, who is obligated to provide additional funds if necessary. Long-term trust funds for surveillance and control are created when license termination relieves the licensee of any further obligation regarding the site. Therefore, no licensee is available to make up shortfalls in the fund, which reduces the likelihood that funds will be available when needed. A long period of low returns could deplete a trust fund so that later higher returns would be insufficient to return the fund to the value needed to permit earnings to cover the recurring long-term costs. Consequently, a conservative rate of return is necessary to assure that funds will be available when needed. From 1975–2005, the annual real rate of return was 1.58 for U.S. Treasury Bills and 4.87 for government bonds. Thus, a

1 percent real rate of return is conservative and appropriate for assuring funds under the amended § 20.1403(c)(1). The actual rate of return may exceed the 1 percent real rate. The trust agreement may contain provisions to return excess funds to the trust grantor if the fund balance significantly exceeds the amount needed to cover the recurring costs at the 1 percent rate.

This final rule adds a new § 20.1404(a)(5) specifying one of the factors that the Commission must consider in determining whether to terminate a license under alternate criteria. The Commission must consider whether the licensee has provided sufficient financial assurance to enable an independent third party (including a government custodian of a site) to assume and carry out responsibilities for any necessary control and maintenance of the site. This new section also explicitly states that the financial assurance be in the form of a trust fund, as in § 20.1403(c).

N.2 Require a Trust Fund for the Prepayment Option

The final rule amends the list of prepayment financial methods that may be used to provide financial assurance for decommissioning to provide that prepayment shall only be in the form of a trust established for decommissioning costs (§§ 30.35(f)(1), 40.36(e)(1), 70.25(f)(1), and 72.30(c)(1)). The final rule eliminates the four other prepayment options that had been listed in those sections of the regulations (*i.e.,* the escrow account, government fund, certificate of deposit, and deposit of government securities). Three of these options (the government fund, certificate of deposit, and deposit of government securities) initially were authorized for use to provide alternatives to licensees that elected not to use a trust fund as their prepayment mechanism, even though the NRC recognized that in the event of the licensee's bankruptcy, they provided somewhat less assurance that the funds would remain available to pay for decommissioning. However, no NRC licensees have elected to use the government fund and deposit of government securities options, and only two have used a certificate of deposit. Because of their relative risk in bankruptcy and their non-use by licensees, the NRC has eliminated them as alternatives for providing financial assurance for decommissioning.

The NRC recognizes that the elimination of the escrow account option will affect some materials licensees who currently use escrows. Approximately 25 escrows are currently in use as a prepayment option for decommissioning financial assurance. Because some materials licensees use more than one escrow, the number of materials licensees using escrows is slightly less than the number of escrows.

The staff reviewed several studies of the situation of escrows in bankruptcy and concluded that the most accurate summary of the various assessments is as follows. The funds contained in escrows that are set up correctly before a licensee's entry into bankruptcy will likely be secure from transfer into the bankruptcy estate as assets of the debtor, and they will not be reachable by the bankruptcy trustee using doctrines of fraudulent conveyance or voidable preference. However, correctly setting up an escrow is difficult, as noted in Section II.N.1 of this document. The NRC is also concerned that a determination of the legal status of an escrow may be subject to considerable delay. In addition to the time necessary to carry out a legal standing analysis, a bankruptcy trustee could attempt to use the automatic stay provisions of the bankruptcy code to stop payment by an escrow agent under the escrow, if that payment is occurring following the commencement of the bankruptcy action. While this attempt may fail, it could postpone the NRC's access to the funds held in the escrow and thereby preclude the prompt commencement of decommissioning. Finally, the administrative costs of a trust fund are comparable to an escrow, so there is little economic benefit to using the escrow.

Elimination of the use of escrow accounts by materials facilities was discussed at the public stakeholder meeting held January 10, 2007. No stakeholders objected to the elimination of the escrow as a financial assurance method. Two comments on this topic were received during the proposed rule public comment period. Both comments disagreed with the NRC's elimination of the use of escrow accounts for financial assurance. For reasons discussed previously, the NRC disagrees with these comments and has eliminated the escrow as an approved method for materials licensees to provide financial assurance. The escrow account may continue to be used by power reactor licensees, pursuant to 10 CFR 50.75. The technical basis for the Decommissioning Planning proposed rule did not include removal of the escrow account from 10 CFR 50.75, so this change was not made during this rulemaking.

N.3 Require an Upfront Standby Trust Fund for the Parent Guarantee and Self-Guarantee Options

The final rule amends Appendices A, C, D, and E to 10 CFR part 30 (amends Section III.D of Appendix A; amends Section III.F and adds a new Section III.G to Appendix C; amends Section III.D and adds a new Section III.E to Appendix D; and adds a new Section III.F to Appendix E). The amendments require a parent company providing a parent company guarantee and a licensee providing a self-guarantee to—(1) set up a standby trust before it may rely on the guarantee for financial assurance, and (2) specify criteria for selecting an acceptable trustee.

Under current regulations, the guarantor was not required to establish a standby trust before providing a parent company or self-guarantee. Instead, a standby trust would be established and used to hold funds for decommissioning only if the NRC required the guarantor to provide such funding for decommissioning. Setting up a standby trust at the time that the guarantee is drawn upon could lead to a significant delay. Therefore, regulatory guidance recommended the creation of a standby trust at the commencement of the guarantee. A standby trust is necessary, because the NRC cannot accept decommissioning funds directly. Under the ''miscellaneous receipts'' statute (31 U.S.C. 3302(b)), the NRC must turn over all payments received to the U.S. Treasury. Therefore, a standby trust is necessary to receive funds if the NRC requires the guarantor to put the funds into a segregated account. Creating a standby trust before the guarantee is provided avoids potential delays in initiating decommissioning. In addition, the use of a trust protects the funds from creditors' claims, which may be necessary if the guarantor faces financial distress. Therefore, the final rule requires that the guarantor set up a standby trust. In addition, the final rule provides that the Commission has the right to change the trustee of the trust. That power is necessary to assure that the trustee will faithfully execute its duties. Finally, to assure that the trust agreement is adequate, the final rule specifies that an acceptable trust is one that meets the regulatory requirements of the Commission.

N.4 Require Parent Company to Inform NRC of Financial Distress and Submit to an Order

Because a parent company is not usually an NRC licensee subject to the NRC's authority, 10 CFR part 30, Appendix A, Section III.E (published as

10 CFR part 30, Appendix A, Section III.F in the proposed rule) is added to specify that the parent company guarantee option must include a contractual agreement by the parent company to submit to NRC payment orders.

Before this final rule, the parent company had no requirement to inform the NRC of financial distress that may adversely affect its ability to meet its guarantee obligations. Because the NRC needs to know if the parent guarantor is in financial distress to take steps to protect the funds guaranteed for decommissioning, the final rule requires the parent guarantor to notify the NRC in case of its financial distress, and its plan to transfer the guaranteed amount to the standby trust. In these situations, payments from the parent company are immediately due and payable to the standby trust pursuant to an acceleration clause, discussed in Section II.N.5 of this document. A similar notification requirement is not necessary for a licensee guarantor because NRC regulations under 10 CFR 30.34(h), 40.41(f), 70.32(a)(9), and 72.44(a)(6) already require licensees to notify NRC of bankruptcy proceedings.

N.5 Require Guarantor Payment Immediately Due to Standby Trust

Before this final rule, the regulations did not address the possibility that the guarantor of the parent guarantee or self-guarantee may be in financial distress when it is required to provide alternate financial assurance. When decommissioning is not being conducted at the time of an insolvency proceeding, creditors could argue that the debtor owes performance of decommissioning in the future, not money at the present time. That argument could potentially support a finding that no payment is owed to the standby trust. In that event, a division of assets to satisfy creditors' claims may not adequately protect resources needed to fund decommissioning. To provide a money claim on the assets of the guarantor that would cover the cost of decommissioning at the time of a division of assets, the final rule authorizes the Commission to make the amount guaranteed immediately due and payable to the standby trust (*i.e.,* an acceleration clause).

N.6 Allow Intangible Assets, With an Investment Grade Bond, To Meet Some Financial Tests

The NRC regulations allow guarantees to be used as financial assurance for decommissioning by companies whose financial statements demonstrate a low risk of default for corporate obligations. A set of financial tests are prescribed in 10 CFR part 30, Appendices A, C, D, and E for companies who may qualify to use the guarantee methods. Licensees who desire to use the parent company guarantee or self-guarantee as a financial assurance option must pass the tests on an annual basis. Some of the financial tests in 10 CFR part 30, Appendices A, C, and E involve bond valuations. In the past, only tangible assets were considered within the calculations performed under the financial tests. In response to an inquiry during the public stakeholder meeting on January 10, 2007, the NRC staff considered whether allowing the use of intangible assets would materially increase the risk of a shortfall in decommissioning funds. The NRC concluded that if a licensee can meet a minimum tangible net worth requirement, then allowing that licensee to use intangible assets to meet a total net worth requirement beyond the minimum tangible net worth amount, in conjunction with certain bond valuations of the guarantor, would not materially decrease the ability of the licensee to provide assurance that it will have the requisite decommissioning funding.

Although the use of a company's bond rating remains a joint criterion with the use of intangible assets in some of the financial tests, the NRC is making other changes so that licensees that pass the tests will have an increased likelihood of providing financial assurance. Recent data suggests that regulators should not rely on a bond rating by itself to provide financial assurance, as discussed in paragraph N.7 of this section. However, an investment grade bond rating coupled with a minimum amount of tangible net worth does provide an additional level of assurance. In a 1982 revised interim final rule, the EPA provided several reasons for accepting a minimum tangible net worth requirement, which are discussed in Paragraph N.7 of this section. Once these other components of the financial tests are met, licensees can use intangible assets for a total net worth requirement beyond the minimum tangible net worth requirement. Because bond rating agencies include intangible assets in their evaluation of the financial stability of a company's bonds, these companies are already given credit for their intangible assets in the bond rating component of the test. The minimum tangible net worth component prevents the NRC from relying too heavily on intangible assets. To further assure the efficacy of a company's current bond rating, amendments in the final rule specify that the bond must be uninsured, uncollateralized, and unencumbered to be used in the financial test. Moreover, the value of the nuclear facilities, both as tangible and intangible assets, is excluded from the calculation of net worth, because those assets would not be available to produce funds for decommissioning after the facility is shut down. The staff concluded that permitting the use of intangible assets after the minimum tangible net worth requirement is met, in conjunction with an investment grade bond rating, would not materially decrease the ability of the licensee to provide assurance that it will have adequate decommissioning funding.

With the financial tests required by 10 CFR part 30, Appendices A, C, and E, the NRC has a greater level of assurance that these companies will not default on their decommissioning obligations. In addition, the guarantee methods require annual re-passage of the test. Because a company that satisfies the minimum tangible net worth criterion and has an investment grade bond rating is less likely to default in a one-year period, the annual re-passage requirement will normally provide adequate time for the guarantor to obtain alternative financial assurance. In rare cases in which a default may occur in a short time, the acceleration clause, discussed in paragraphs N.4 and N.5 of this section, will provide a method to obtain funds in situations of financial distress.

Therefore, after the minimum tangible net worth requirement is met, this final rule will allow the use of intangible assets, in conjunction with an investment grade bond rating, to meet specified criteria in the financial tests for parent company and self-guarantees.

N.7 Increase the Minimum Tangible Net Worth for the Guarantees' Financial Tests

Before this final rule, the financial tests in Appendices A and D to 10 CFR part 30 each require the entity seeking to pass the relevant financial test to have a tangible net worth of at least $10 million. The financial test in the current Appendix C to 10 CFR part 30 requires the applicant or licensee to have a tangible net worth at least 10 times the current DCE or certification amount for decommissioning. The final rule amendments require a tangible net worth of at least $21 million in each of the financial tests in Appendices A, C, and D to 10 CFR part 30.

The $10 million in tangible net worth requirement was first adopted by the EPA in 1981, and the financial test adopted by the NRC in 1988 used the same criterion. The NRC believes that the criterion should be adjusted to

represent the value in current dollars of $10 million in 1981. For the proposed rule, the NRC calculated a new tangible net worth amount using the 2005 Implicit Price Deflator for Gross Domestic Product published by the U.S. Department of Commerce in its Survey of Current business, and the equivalent Implicit Price Deflator for 1981, to arrive at a value of $19 million to represent the $10 million value (1981 dollars) in 2005 dollars. The NRC agrees with a comment submitted on the proposed rule to escalate the 1981 dollars to 2007 dollars. This calculation, rounded up in units of one million dollars, equals $21 million.

The final rule adds a requirement in Section II.A.(1) of Appendix C to 10 CFR part 30 for applicants or licensees to have a tangible net worth of at least $21 million. Before this final rule, that component of the financial test for self-guarantee specified only that the applicant or licensee must have a tangible net worth at least 10 times the current DCE or certification amount. The additional requirement has been added as recent events indicate that the existing requirement in Section II.A.(3) of Appendix C—that the applicant or licensee must have a current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard & Poor's (S&P), or Aaa, Aa, or A as issued by Moody's —may not be adequate. The NRC has historically relied on the bond rating component to provide greater assurance that a company with a qualifying rating will be less likely to fall into bankruptcy within a one year time period; hence, the regulations require a licensee to repeat passage of the financial test on an annual basis. Recent trends suggest that a bond rating may not provide the additional assurance that the NRC is seeking. For example, companies that provide bond ratings may be reluctant to downgrade, because a downgrade can have such an adverse effect on a rated sovereign or corporate issuer that it can destabilize the issuer or the market for its securities (*e.g.,* AIG) (Katz, J., Salinas, E., & Stephanou, C., ''Credit Rating Agencies: No Easy Regulatory Solution,'' *Crisis Response: Public Policy for the Private Sector, Note Number 8,* 4–5 (October 2009), *http://rru.worldbank.org/documents/CrisisResponse/Note8.pdf*). Credit ratings can also be slow indicators of an entities' financial health (*e.g.,* Enron, Worldcom, Parmalat, Lehman Brothers) (Katz; O'Brien, B., ''Fitch Fells Berkshire's Credit Rating,'' Barron's (March 13, 2009), *http://blogs.barrons.com/stockstowatchtoday/2009/03/13/fitch-fells-berkshires-credit-rating/*).

Because recent events and trends cause the NRC to question the adequacy of the bond rating requirement to provide financial assurance, the NRC concludes that the bond rating requirement in appendix C to 10 CFR part 30 should be coupled with another requirement. The NRC determined that the tangible net worth requirement found in appendix A and appendix D to 10 CFR part 30 is an adequate accompaniment. The basis of this finding is rooted in a 1982 EPA revised interim final rule (47 FR 15032; April 7, 1982), which provided several reasons for choosing $10 million in tangible net worth in 1982 dollars as a financial test. The EPA recognized that the business failure rate for firms with $10 million (1982 dollars) or more in net worth was significantly lower than for firms overall. (47 FR 15035; April 7, 1982). Because firms with $10 million or more in net worth were more stable than companies with less net worth, these larger firms were less likely to abandon facilities or otherwise avoid closure or post-closure responsibilities. (47 FR 15035; April 7, 1982). EPA ''furthermore believes that retaining the $10 million requirement will keep the burden of administering this new financial assurance mechanism at manageable levels; monitoring the use of the financial test by less stable firms can be expected to be more time-consuming and a greater administrative burden.'' (47 15035; April 7, 1982). Because ''[a]ssets of firms often include intangibles such as goodwill, patents, and trademarks which may be difficult to convert into cash to pay for closure or post-closure costs,'' *the EPA concluded that only tangible net worth could be used to meet its net worth requirements.* (47 FR 15035; April 7, 1982).

The data suggests that a high bond rating by itself does not necessarily signal financial strength. Also, the risk of a shortfall is expected to be lower for licensees that pass these qualifying tests than for licensees that do not. Therefore, the NRC has determined that licensees that can satisfy the $21 million tangible net worth minimum, together with the other financial tests, will have an increased likelihood of providing reasonable assurance that the necessary decommissioning funding will be available when it is needed.

N.8 Clarify Guarantees' Bond Ratings and Annual Demonstration Submittals

The final rule amendments specify that the current rating of the most recent bond issuance of AAA, AA, or A by Standard and Poor's could include adjustments of + or − (*i.e.,* AAA+, AA+, or A+ and AAA−, AA−, and A− would meet the criterion) and the current rating of Aaa, Aa, or A by Moody's could include adjustments of 1, 2, or 3.

Standard and Poor's and Moody's have introduced the plus or minus and numerical adjustments to refine the precision of their ratings. As a result, licensees have been uncertain whether a rating that includes these adjustments, and in particular ratings that might be considered below the unadjusted ratings specified in the appendices (*e.g.,* A−) could be used. Based on the minimal difference in default rate associated with the qualifiers, the final rule states that all the bonds within a specified rating level meet the regulatory standard.

In addition, the final rule amends Section II.A.(2)(i) of Appendix A to 10 CFR part 30 and Section II.A.(3) of Appendix C to 10 CFR part 30 to require the bond to be the most recent ''uninsured, uncollateralized, and unencumbered'' bond issuance. This amendment makes the bond criterion in Appendix A to 10 CFR part 30 and Appendix C to 10 CFR part 30 consistent with the bond criterion in Appendix E to 10 CFR part 30. As explained in NUREG/CR–6514, when a rated bond has insurance or pledged assets to provide additional security, the bond rating may not directly reflect the creditworthiness of the bond issuer. Therefore, the final rule adds the requirement that the bond rating used to pass the financial test must be uninsured, uncollateralized, and unencumbered.

The final rule makes a conforming change in Section III.E. of Appendix E to 10 CFR part 30 to provide that if, at any time, the licensee's most recent bond issuance ceases to be rated in any category of ''A−'' and above by Standard and Poor's or in any category of ''A3'' and above by Moody's, the licensee no longer meets the requirements of the financial test.

The final rule amendments to the bond rating criterion in Appendices A and C to 10 CFR part 30 are intended to clarify the intent of the rule, eliminate an unintended apparent inconsistency among the different financial tests that may be used, and to make administration of the financial assurance requirements more efficient by eliminating recurring questions.

The final rule requires a certified public accountant to verify that a bond rating, if used to demonstrate passage of the financial test, meets the requirements. Some financial tests

received by the NRC did not apply the requirement correctly. Requiring an audit of the bond rating will minimize the potential that an error is made in verification of the bond rating.

Before this final rule, the regulations required the licensee to repeat passage of the financial test each year, but the regulations did not explicitly state that the licensee must annually submit documentation to the NRC to verify its passage of the test. However, the parent company and self-guarantee agreements illustrated in regulatory guidance include a provision that the licensee will annually submit to the NRC revised financial statements, financial test data, and an auditor's special report. Submittal of the documents permits the NRC to verify the licensee's continuing eligibility to use the parent company guarantee without incurring the expense of an onsite inspection. Therefore, the final rule codifies the regulatory guidance to require annual submittal of documentation that the guarantor passed the financial test.

Before this final rule, the regulations were unclear about whether the parent company guarantee and financial test are to remain in effect until the license is terminated. The final rule clarifies that the NRC's written acceptance of an alternate financial assurance by the parent company or licensee allows the guarantee and financial test to lapse.

N.9 Invalidate the Use of Certification for Financial Assurance if There Is Contamination

This final rule amends regulations to add new requirements related to decommissioning financial assurance as applied to certifications. The changes affect §§ 30.35(c)(6), 40.36(c)(5), and 70.25(c)(5).

Before this final rule, the regulations prescribed specific amounts of financial assurance for licensees that are authorized to possess relatively small amounts of radioactive material. Licensees authorized to possess radioactive materials in higher amounts must submit a DFP, which includes a site-specific cost estimate for decommissioning. The site-specific cost estimate is almost always higher than the prescribed certification amounts.

This final rule requires licensees who qualify to use the certification amounts to submit a DFP in the event that survey results detect significant residual radioactivity within the site boundary, including the subsurface. A significant amount would be residual radioactivity that would, if left uncorrected, prevent the site from meeting the criteria for unrestricted use. Remediating subsurface contamination can be very expensive. However, licensees that qualify to use the certification amounts have no regulatory requirement to increase the amount of financial assurance to cover subsurface remediation costs. In the event subsurface contamination occurs at such a site, this final rule provides the regulatory basis to require these licensees to cover the full cost, not just the certification amount.

N.10 Other Changes to Financial Assurance Regulations

This final rule eliminates the line of credit option from 10 CFR 30.35(f), 40.36(e), 50.75(e)(1)(iii)(A), 70.25(f), and 72.30(e) from the list of surety, insurance, or other guarantee methods that may be used to provide financial assurance for decommissioning. Although the line of credit was initially authorized for use to provide an alternative to licensees that elected not to use a surety or letter of credit, the NRC recognized that it posed a greater risk than the other two surety methods, because it might be subject to underlying loan covenants that could make it more vulnerable to cancellation if the licensee experienced financial difficulties. However, since 1988, no NRC licensees have elected to use a line of credit to provide financial assurance for decommissioning. Because of its greater risk of cancellation and its non-use by licensees, the NRC has decided to eliminate the line of credit as an alternative for providing financial assurance for decommissioning.

The final rule excludes, in the financial tests for the parent guarantee and self-guarantee, the net book value of the nuclear facility and site from the calculation of tangible net worth. Before this final rule, the regulations required that the calculation of tangible net worth must exclude the book value of the ''nuclear units.'' That requirement leads to confusion, because some interpreted it to apply to nuclear reactor units and not other kinds of nuclear facilities. However, other kinds of nuclear facilities should be excluded from the tangible net worth calculation, because they are unlikely to provide funds for decommissioning. The existing rule does not specify whether the nuclear site, as distinguished from the facility, may be included in the calculation of tangible net worth. The value of the site is likely to depend on the probability that the decommissioning will be completed, and is subject to some degree of uncertainty. Therefore, the calculation of tangible net worth has been changed to exclude the net book value of the nuclear facility and site.

The final rule requires a certified public accountant to include an evaluation of off-balance sheet transactions, for the parent guarantee and self-guarantee. Generally accepted accounting principles (GAAP) permit certain kinds of transactions to be accounted for off the company's balance sheet. Many companies, as a means of managing risk and/or taking advantage of legitimate tax minimization opportunities, create off-balance-sheet transactions. It is important to understand the nature and the reason for each off-balance-sheet item and ensure that any such relationships are adequately disclosed. (*Off-Balance Sheet Arrangements and Other Disclosures,* American Institute of Certified Public Accountants, *http://www.aicpa.org/ForThePublic/AuditCommitteeEffectiveness/AuditCommitteeBrief/DownloadableDocuments/Off%20Balance%20Sheet%20Arrangements.pdf,* last visited May 9, 2011). The volume and risk of the off-balance-sheet activities need to be considered (Risk Management Manual of Examination Policies, Federal Deposit Insurance Corporation, *http://www.fdic.gov/regulations/safety/manual/section3–8.pdf,* last visited December 20, 2010). Before this final rule, the regulations did not require the independent certified public accountant's special report to examine off-balance sheet transactions. However, these transactions have the potential to materially affect the guarantor's ability to fund decommissioning obligations. Therefore, the final rule requires the auditor to include an evaluation of off-balance sheet transactions.

O. Will some licensees who currently do not have financial assurance need to get financial assurance?

No. Licensees who are not required to provide financial assurance for decommissioning will not have to obtain financial assurance as a result of amendments in this final rule.

The decommissioning planning and financial assurance amendments in this final rule only apply to licensees who are or will be subject to the decommissioning financial assurance requirements under 10 CFR 30.35, 40.36, 50.75, 70.25, and 72.30.

All operating power reactor licensees are required to have financial assurance, consistent with 10 CFR 50.75(c), and all licensees with an independent spent fuel storage installation (ISFSI) regulated under 10 CFR part 72 must have financial assurance for decommissioning in accordance with 10 CFR 72.30(c).

P. What changes are being made with respect to materials facilities' decommissioning funding plan (DFP) and DCE?

This final rule requires certain licensees under 10 CFR part 72 to adjust their DCEs within 3 years of the previous DCE. This was done by final rule on October 3, 2003 (68 FR 57327) for licensees under 10 CFR parts 30, 40, and 70. This provision in the final rule makes the timing basis for DCE adjustments consistent among all materials facilities.

Regarding DFPs, §§ 30.35(e), 40.36(d), 70.25(e), and 72.30(b) are amended to require additional information from licensees. The NRC's experience indicates that underestimation of decommissioning costs can occur when the licensee assumes it will qualify for a restricted site release by meeting all of the 10 CFR 20.1403 requirements. If it turns out that these requirements cannot be met, and that an unrestricted site release under 10 CFR 20.1402 will be required, the licensee may not have the ability to fund a potentially more expensive cleanup. For example, if instead of leaving large volumes of slightly contaminated soil onsite in a restricted release decommissioning, the licensee must ship this material offsite for disposal to support an unrestricted site release, then the decommissioning will typically be much more expensive due to high offsite disposal costs. Therefore, the final rule requires the licensee to estimate and cover the costs to decommission the facility to meet unrestricted use criteria. The option of meeting the 10 CFR 20.1403 restricted release requirements will be available, but the licensee would have to demonstrate that it can meet those criteria before a cost estimate based on that assumption would be acceptable.

In addition, certain operational events can increase decommissioning costs above the original estimate. These events include spills, increases in onsite waste inventory, increases in waste disposal costs, facility modifications, changes in authorized possession limits, actual remediation costs that exceed the initial cost estimate, onsite disposal, and use of settling ponds. The final rule amends 10 CFR 30.35(e)(2), 40.36(d)(2), 70.25(e)(2), and 72.30(b) to require the 3-year update of the DFP to consider these events for the effect, if any, they may have on the estimated cost of decommissioning. Subsurface contamination can be very expensive to remediate. The new regulations require the licensee to estimate the volume of contaminated subsurface material that would require remediation, and provide financial assurance for the estimated cost of remediation. Early consideration and funding arrangements to cover increased costs will improve decommissioning planning and increase the likelihood that funds will be available when needed for site decommissioning.

Existing regulatory guidance identifies recommended methods for arriving at DCEs. The NRC is codifying some of these recommended methods in this final rule. To assure that funds will be adequate to complete decommissioning in the event the licensee is unable to do so, cost estimates are required to include contractor overhead and profit. An adequate contingency factor is necessary to cover unanticipated costs that can arise after the decommissioning project begins. The key assumptions underlying the cost estimate would have to be identified to aid the staff in evaluating the adequacy of the estimate. Codification of these recommendations will improve the quality of DFP submittals, facilitate the staff's review of these submittals, and result in regulatory efficiencies.

The NRC is aware of the records important for decommissioning reporting requirements that licensees have under §§ 30.36(g)(1), 40.36(f)(1), 50.75(g)(1), 70.25(g)(1), and 72.30(d)(1). The additional reporting requirements in this final rule are designed to foster a better understanding of the impact the spill or contaminating event has on the DCE.

Q. What changes are being made with respect to license transfer regulations for materials licensees?

This final rule makes a set of parallel changes to §§ 30.34(b)(2), 40.46(a)(2), and 70.36(a)(2). These changes codify NRC regulatory guidance to require the licensee to do the following: (1) Provide information on the proposed transferee's technical and financial qualifications, and (2) to provide decommissioning financial assurance as a condition for approval of the transfer if the licensee is required to have financial assurance. The information and financial assurance are necessary to evaluate the adequacy of the proposed transferee. Placing these provisions in the regulation, rather than keeping them in regulatory guidance, will improve regulatory efficiency by improving the quality of license transfer requests. It also will ensure that a prospective license transferee provides to the NRC the information necessary to determine that public health and safety are not compromised by the transfer and that the radiation safety aspects of the program are not degraded.

R. What changes are being made with respect to permanently shutdown reactor decommissioning fund status and spent fuel management plan reporting?

The final rule amends § 50.82(a)(4)(i) and adds three new provisions to § 50.82(a)(8) in Paragraphs (a)(8)(v) through (a)(8)(vii). The revised § 50.82(a)(4)(i) requires that the PSDAR include, if applicable, a cost estimate for managing irradiated fuel, pursuant to § 50.54(bb). Before this final rule, the PSDAR was required to include a description of the planned decommissioning activities, a schedule for their accomplishment, and an estimate of expected costs.

The amendments to § 50.82(a)(8) require each power reactor licensee undergoing decommissioning to submit, in the form of an annual financial assurance status report, information (specified further in this section) regarding its decommissioning funds. Currently, under § 50.75(f)(1), the information reported to the NRC by power reactor licensees is focused on collection of funds before permanent shutdown and does not require information on the actual funds spent. To assess the adequacy of power reactor decommissioning funding after permanent shutdown, the NRC needs to know the actual costs being incurred at decommissioned facilities. To obtain this information, the annual report is now required to include, among other things, the amount spent on decommissioning over the previous calendar year, the remaining balance of any decommissioning funds, and an estimate of the costs to complete decommissioning. If the annual report reveals a projected funding shortfall, additional financial assurance to cover the cost to complete decommissioning must be provided. These changes will improve NRC oversight of decommissioning planning and increase the likelihood that funds for decommissioning will be available when needed.

Under new § 50.82(a)(8)(vii), the annual financial assurance status report must also include the status of funds to manage irradiated fuel. Due to the cessation of operating revenues, spent fuel management and related funding are a concern after the reactor is permanently shut down. Therefore, the final rule requires the following: (1) That the amount of funds accumulated to cover the cost of managing the spent fuel be specified; (2) that an estimate of the projected costs of spent fuel management, until the Department of Energy takes title to the spent fuel, be

provided; and (3) that a plan to obtain additional funds if the accumulated funds do not cover the projected cost be identified. These changes will increase the likelihood that funds for spent fuel management will be available when needed.

S. When do these actions become effective?

The effective date of the Decommissioning Planning final rule is eighteen months after publication of the final rule in the **Federal Register.** The NRC considers this an adequate time for licensees to implement the requirements in the final rule. The 18-month period will provide licensees sufficient time if there is a need on their part to review their current methods for radiological surveys and monitoring in relation to new 10 CFR 20.1406(c) and modified 10 CFR 20.1501(a) and (b). Also, the 18-month implementation period will accommodate the time needed to prepare and publish a final version of DG–4014. The DG–4014 contains changes made as a result of public comments received on the draft guidance released with the Decommissioning Planning proposed rule. The NRC considered revising Regulatory Guide 4.21, ''Minimization of Contamination and Radioactive Waste Generation: Life-Cycle Planning,'' dated June 2008, but considered this inappropriate because Regulatory Guide 4.21 applies only to certain licensees who submitted their initial license application after August 20, 1997. The DG–4014 applies to licensees who submitted their initial license application on or before August 20, 1997, and who were not required to consider in the early planning stages of the facility specific design features for contaminant management. Additionally, the 18-month implementation period will provide sufficient time to licensees who need to—(1) Switch out of their escrow account into a different financial assurance mechanism; (2) examine their continued use of a parent guarantee or self-guarantee as decommissioning financial assurance; or (3) prepare more detailed information in their DCE or surety supporting their DFP. Power reactor licensees who are in a shutdown status will need to submit a report on the status of funding for managing irradiated fuel by March 31, 2013.

T. Has NRC prepared a cost-benefit analysis of the final rule?

Yes, the NRC staff prepared a draft regulatory analysis for the proposed rule. Public comments were received on the draft regulatory analysis and are discussed in Section III.D of this document. The regulatory analysis was revised for this final rule. Single copies of the regulatory analysis are available as discussed in Section X of this document.

The implementation of the final rule by industry, NRC, and Agreement States was analyzed to cost about $43 million (2007$) over a 15-year analysis period at a 3 percent discount rate. NRC licensee costs are about $6 million, and NRC costs are about $3 million. Agreement State licensee costs are about $22 million, and Agreement State costs are about $12 million. Two alternatives were considered, each with estimated total costs that were higher than implementation of this final rule. The primary benefits of the final rule are due to reduction in the number of legacy sites and higher reliability of obtaining sufficient funds pledged for decommissioning financial assurance to complete the decommissioning work through license termination.

U. Has NRC evaluated the additional paperwork burden to licensees?

This final rule contains new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The NRC staff has estimated the impact this final rule will have on reporting and recordkeeping requirements of NRC and Agreement State licensees. More information on this subject is in Sections III.J and IX of this document.

III. Summary and Analysis of Public Comments on the Proposed Rule

The proposed rule on Decommissioning Planning was published on January 22, 2008 (73 FR 3812), for a 75-day public comment period. The NEI and several other stakeholders requested an extension of 90 days to provide review of issues raised in the proposed rule. The NRC extended the comment period by 30 days, until May 8, 2008 (73 FR 14946). The NRC received 35 comment letters on the proposed rule. Commenters on the proposed rule included states, licensees, industry organizations, environmental advocacy organizations, and one individual.

The comments and responses have been grouped into 11 areas. The NRC specifically sought comments on the first five areas: (A) The use of fee incentives to induce licensees to characterize subsurface residual radioactivity while their facility is operating; (B) licensees' use of a secure Web site to submit and update decommissioning reporting and financial assurance requirements; (C) the extent of proprietary data in the details submitted under new requirements in 10 CFR 50.82(a)(4)(i) and 50.82(a)(8)(v); (D) the accuracy of input assumptions and methodology in the regulatory analysis and environmental assessment; and (E) information regarding significant amounts of radium-226 at sites that could be considered legacy sites in the regulatory analysis. The other comment areas are: (F) backfit considerations; (G) need for 10 CFR 20.1403, 20.1406 and 20.1501 amendments; (H) financial assurance mechanisms and reporting; (I) draft regulatory guidance, (J) OMB Supporting Statement; and (K) Agreement State compatibility table. To the extent possible, all of the comments on a particular subject are grouped together. A discussion of the comments and the NRC staff's responses follow.

A. Fee Incentives

Comment: In the proposed rule, the NRC specifically invited comment on whether fee incentives, as permitted in 10 CFR 171.11(b), would be effective as a means to induce licensees to perform site characterization work during operations instead of waiting until the facility is shut down.

Six commenters responded to this topic, and all argued against the adoption of fee incentives. Some said the concept had not been clearly explained. Several commenters argued that any incentive should not reduce financial assurance amounts. Some thought that incentives would have the effect of transferring the financial burden of meeting the proposed requirements from licensees who have subsurface residual radioactivity to those who do not. Monitoring of environmental impacts during operations, one said, is an essential part of doing business that should not require incentives. Three commenters thought that the exemption of annual fees as a ''fee incentive'' to conduct monitoring during facility operations would be contrary to Congress' requirement that the NRC collect user fees and would not fit into the narrow range of exemptions contemplated in 10 CFR 171.11. One commenter said that the NRC should not give a blanket exemption to all power reactor licensees under 10 CFR part 171 by characterizing it as a ''fee incentive'' for complying with a proposed regulation or a volunteer monitoring program.

Response: The Commission agrees with the commenters that no fee incentives should be provided as part of this final rule. For any subsurface monitoring and modeling activities that may be required as a result of this final

rule, licensees should fund such activities as an operating and maintenance expense to help achieve occupational and public doses that are ALARA.

B. Secure Web Site

Comment: The NRC specifically invited comment on licensees' use of a secure Web site to submit and update the following: (1) Decommissioning reporting requirements, and (2) information submitted to support passing the financial tests in the parent guarantee and self-guarantee. The NRC received input on this issue from two states and the Conference of Radiation Control Program Directors, Inc. (CRCPD). The commenters were not clear on the implementation of the Web site because this topic was not discussed in the proposed rule. One commenter supported the concept of using a Web site but questioned whether states would have access to the information, whether notifications would be sent electronically when information was updated, and whether the Web site would be a data transfer tool or would also contain algorithms for decision logic. One of the state commenters supported the concept only if the information would be publicly available.

Response: Public comments were solicited on this topic to provide initial information regarding the scope of functions for a Web site to allow materials licensees to submit, revise and update the following: (1) Information in their DFP, (2) DCEs, (3) information in the financial tests for the parent company guarantee and self-guarantees, and (4) decommissioning power reactor annual financial assurance status reports. For the licensees whose companies are publicly traded, there appears to be no sensitive or proprietary data in the financial information reported to support use of the parent guarantee and the self-guarantee, as much of this information can be obtained in the public domain. Licensees may request that information submitted to the NRC be withheld from public disclosure in accordance with 10 CFR 2.390(b). The NRC thanks commenters for responding to this question and will factor their comments into any plans to modernize the processing of this information. Currently, there are no plans to develop such a Web site.

C. Proprietary Data

Comment: NRC specifically invited comment on whether additional details in new reporting requirements of licensees with a power reactor in a shut down status would be considered proprietary to the licensees reporting the information. These new reporting requirements are in 10 CFR 50.82(a)(4)(i) and 50.82(a)(8)(v). One commenter responded to this question, stating that making more information available for public review will facilitate better analysis of work scope and cost for decommissioning planning.

Response: The NRC staff agrees with this comment. The information required by the new reporting requirements can be conveyed by licensees in their PSDAR and in their annual financial assurance status report, with little additional burden. The PSDAR information is publicly available. The annual financial assurance status report information submitted to the NRC under revised 10 CFR 50.82(a)(8)(v) and (8)(vii) will be publicly available, unless the licensee submitting the information shows that the information should be withheld from public disclosure in accordance with the regulations in 10 CFR 2.390(b).

D. Regulatory Analysis and the Environmental Assessment

The NRC specifically invited comment on the input assumptions, methodology, and results of the draft regulatory analysis, including the backfit analysis, and the environmental assessment. Comments were received and are discussed below. Comments on the backfit analysis are discussed in Section III.F of this document.

Comment D.1: The need to install new capital or modify procedures is not expected.

Several commenters objected to the following statement made by the NRC in the Executive Summary and again in Section 2 of the regulatory analysis: ''It is not expected that (power reactor and uranium fuel fabrication) licensees will need to install new capital or modify existing operating procedures to satisfy the proposed amendments to 10 CFR 20.1406(c) and 20.1501.'' The commenters interpreted the statement to mean that those licensees would never need to install new equipment or modify procedures in order to comply with the new requirements.

Response: The previous statement was made in the context of anticipated changes that licensees would need to make by the effective date of the final rule, given information about onsite leaks and spills known to the NRC when the proposed rule was published. Licensees must be allowed time to perform scoping surveys and preliminary characterization of site contamination to determine if their site contains significant residual radioactivity. Based on the evaluation of these surveys, additional monitoring and modeling may be required based on site specific conditions. Page 41 of the draft regulatory analysis released with the proposed rule states this position by the NRC: ''It may be necessary for licensees at a time after the effective date of the final rule to install additional monitoring equipment under some circumstances. * * * The need for additional monitoring equipment would be determined on a case-by-case basis by either licensee activities or after NRC inspection activities.''

Comment D.2: Costs to uranium recovery licensees.

Several commenters stated that the regulatory analysis did not properly analyze the costs to retrofit and upgrade uranium recovery facilities.

Response: As discussed in the response to Comment G.14 below, the NRC has concluded that a uranium recovery licensee's program that complies with the 10 CFR part 40, Appendix A site remediation criteria would not be impacted by the revised survey requirements in § 20.1501(a), and such programs would not become more complex or expensive as a result of this rulemaking. Thus, survey and monitoring costs at uranium recovery facilities are not expected to change, and there is no need to revise the regulatory analysis in this regard.

Comment D.3: 10 CFR part 20 changes could affect hundreds, and costs are underestimated.

Several commenters argued that the proposed changes to 10 CFR part 20 and draft guidance for survey and monitoring could affect hundreds of licensees, and that the costs of the regulation were underestimated both for materials licensees and for power reactor licensees. One commenter stated that the NRC has grossly underestimated the cost to licensees of achieving compliance. One commenter believes that the proposed regulations and draft guidance documents appear to leave no options other than installation of a complicated subsurface monitoring system to prove that a subsurface monitoring system is not needed. The commenter stated that industry experience shows that these monitoring systems can cost from $500,000 to well over $1,000,000. Another commenter argued that the scope of the proposed rule and guidance is far more extensive than warranted by the circumstances and is inconsistent with the NRC's own finding that none of the instances of inadvertent releases to the environment presented a threat to public health and safety.

Response: Section II.B of this document discusses why very few licensees will be affected by the changes being made to new 10 CFR 20.1406(c) and amended 20.1501. For those licensees who are affected by the change in 10 CFR part 20 regulations, the revisions made to their existing monitoring methods will be site-specific and may not require the installation of a subsurface monitoring system. For example, if a site contains significant residual radioactivity in the soil, the monitoring plan likely will require only the specification of sampling locations and sampling methodology. If the significant residual radioactivity in the soil has migrated to a groundwater pathway, then a groundwater monitoring plan will be required that is appropriate for the affected site. As stated in the preamble to the proposed rule (73 FR 3821; January 22, 2008), the licensees of power reactors and fuel cycle facilities already perform surveys to detect radioactive releases to the groundwater or will be performing groundwater surveys by the effective date of this final rule. It is likely that these surveys will contain sufficient information to satisfy the final rule requirements in new 10 CFR 20.1406(c) and amended 20.1501.

The NRC revised the regulatory analysis for this final rule to include a one-time cost for 500 NRC licensees and 1,000 Agreement State licensees to do the following: (1) Read the final rule changes in new 10 CFR 20.1406(c) and amended 20.1501 and DG–4014, and (2) to determine if the licensees are affected by the final rule. The NRC assumed that these licensees would need 90 minutes each to read the changes to 10 CFR part 20 and DG–4014. This increased the cost estimate in the regulatory analysis by $270,000 for the preferred alternative but did not affect the decision rationale that implementation of the final rule is preferred compared to the other two alternatives.

Comment D.4: Impact of requirements on existing facilities.

One commenter stated that the proposed rule could significantly affect the existing design of systems, monitoring, surveys, site characterization, and recordkeeping that are performed to meet existing regulations. The proposed rules could also ultimately affect the site release alternatives available at decommissioning. One commenter argued that for some licensees, such as research and test reactors, the consequence would be to severely limit or entirely eliminate the ability of these facilities to perform their mission of research and education. Another commenter disagreed with the NRC staff's conclusion that currently operating power reactor licensees' voluntary adherence to the NEI GPI is sufficient to comply with the proposed amendments to 10 CFR 20.1406 and 20.1501. One commenter representing several States disagreed with the NRC's statement that survey and monitoring activities are already taking place, finding it unlikely that groundwater or subsurface surveys have been an integral part of the past radiation monitoring programs at facilities. The commenter also disagreed that adequate current information exists on the spatial bounds and concentrations of residual radioactivity at sites to enable decisions to be made about which sites will require remediation.

Response: For the reasons discussed in the response to comment D.3, and in Section II.B of this document, the NRC believes that very few licensees will be affected by changes to new 10 CFR 20.1406(c) and amended 20.1501 by the effective date of the final rule. After the effective date, as modeled in the regulatory analysis, the NRC believes licensees of a small number of materials facilities will need to perform additional monitoring compared to their current practices because of significant residual radioactivity at their sites. With respect to information collected by power reactor licensees as part of the NEI GPI, the NRC will begin to inspect the activities performed by power reactor licensees compared to their public commitments in the GPI. The NRC's Temporary Instruction 2515/173 (ML072950622) will be used by inspectors to assess if licensees have completed the voluntary industry GPI. The Temporary Instruction includes inspection of licensees' Annual Reporting whereby the power reactor licensees will have documented onsite groundwater sample results for each calendar year in the Annual Radiological Environmental Operating Report (AREOR) or the Annual Radiological Effluent Release Report (ARERR), as part of their annual environmental and effluent reports. This information is publicly available in ADAMS. The NRC agrees with the commenter representing several States that groundwater or subsurface surveys are not expected to be performed by materials licensees as an integral part of their current radiation monitoring programs if there is no evidence at the site of significant subsurface residual radioactivity. The 10 CFR part 20 changes in this final rule aim to improve licensee understanding of spatial bounds and concentrations of significant residual radioactivity at sites during active facility operations.

Comment D.5: Analysis of Voluntary Industry Actions.

One commenter, supported by two other commenters, stated that the NRC did not properly assess the impact of the rule against current regulatory requirements. In an apparent reference to the GPI, the commenter stated that the proposed rule was being improperly analyzed against a more stringent set of voluntary licensee actions. This approach is said to have policy implications in that it could have a chilling effect on licensees' willingness in the future to undertake voluntary initiatives.

Response: The NRC disagrees with this comment. The NRC staff evaluated the GPI consistent with the 2004 guidance in NUREG/BR–0058, ''Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,'' Revision 4 (*http://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0058*). Section 4.3.1 of NUREG/BR–0058 describes an acceptable method to analyze voluntary industry initiatives in estimating values and impacts. Values are benefits, and impacts are costs. A 1999 staff requirements memorandum (''Treatment of Voluntary Initiatives in Regulatory Analyses,'' (ML003752222)) had directed the NRC staff to ensure that NUREG/BR–0058 was revised to facilitate consistent and predictable treatment of voluntary initiatives in regulatory analyses. In accordance with NUREG/BR–0058, the regulatory analysis, in estimating values and impacts of the GPI, considered two cases: Giving ''no credit'' for the voluntary GPI, and giving ''full credit'' for the voluntary GPI.

In the regulatory analysis, a ''Baseline'' of No-Action was modeled as Alternative 1. Alternative 2 was modeled as the preferred Alternative, consistent with the amendments in this rulemaking. Alternative 3 was the same as Alternative 2 but added a security interest in collateral for licensees who use a parent guarantee or a self guarantee. Table 5–1 in the regulatory analysis itemized the net impacts of Alternatives 1, 2, and 3. The net impact over a 15-year analysis period of Alternative 2 was $70 million less than Alternative 1, and the net impact of Alternative 2 was $260 million less than Alternative 3. These results provided ''no credit'' for the voluntary activities performed by power reactor licensees under the GPI.

Section 6 of the regulatory analysis provided a description of the GPI, with Section 6.1 on page 42 identifying the incremental impact of the voluntary GPI

based on cost assumptions in Appendix D of the regulatory analysis. No comments were received during the proposed rule public comment period regarding the NRC's cost estimates of the GPI. The NRC estimated the costs of 10 CFR part 50 licensees to implement the GPI over the 15-year analysis period to be about $105 million (2007$) at a 3 percent discount rate. ''No credit'' was given for these activities, because these costs are incurred regardless of the eventual promulgation of this final rule. The GPI has different objectives than the amendments in this final rule, and the voluntary activities by power reactor licensees were undertaken before development of this rulemaking.

If, instead, ''full credit'' was given for the expected costs under the GPI, the results for Alternative 2 would not change, because no additional survey and monitoring activities were modeled in any of the Alternatives for power reactors that are implementing the voluntary GPI. Based upon the NRC's review of power reactor licensee reports and information known to the NRC about current conditions at power reactor sites, the NRC does not believe that any current power reactor licensee has contamination at its site which exceeds the threshold in the final rule that would require additional monitoring. Therefore, the regulatory analysis did not identify any additional costs or benefits associated with the final rule's survey and monitoring requirements as applied to current power reactor licensees. Following promulgation of this final rule, there may be an increase in survey and monitoring activities at some power reactors and a decrease in activities at other power reactors. The results for Alternative 2 in the regulatory analysis show that early detection of significant subsurface contamination through surveys and monitoring and appropriate response by the licensee become the preferred approach when the regulatory objective is to ensure the licensee and the NRC are aware of contamination that may create conditions that would complicate decommissioning, and possibly create a legacy site.

The NRC does not agree with the commenter that a ''chilling effect'' on future voluntary industry initiatives will occur if the NRC adopts the final survey requirements by rule. As discussed in the regulatory analysis, the GPI was initiated by power reactor licensees independent of this rulemaking. The industry operates in an environment in which there are many factors other than the possibility of NRC rulemaking that may influence the industry's decision to voluntarily undertake action. The NRC does not believe it is reasonable to assume that a rulemaking which overlaps an area of voluntary industry action will inhibit future voluntary industry initiatives. Moreover, the NRC believes that any possible disincentive to industry to undertake such voluntary actions is removed by the NRC performing a regulatory analysis using two different baselines to account for the industry's voluntary actions, consistent with the guidance in NUREG/BR–0058.

Comment D.6: Cost of characterization.

Several commenters stated that the cost would be large to perform site characterization, if required under the proposed rule in 10 CFR 20.1501(a). According to one cost estimate prepared for a 10 CFR part 40 facility, setting up the initial near-surface soil characterization and installing the necessary monitoring equipment would cost between $30,000 and $50,000 for a site with a relatively small footprint. This cost would include obtaining the necessary samples and conducting the associated laboratory work. Additionally, requiring maintenance and ongoing monitoring would result in annual expenditures of approximately $10,000/year. One commenter believed the NRC's estimate of the cost was too low, and that therefore its cost-benefit analysis was flawed.

Response: The NRC's estimates of one-time monitoring equipment and annual maintenance costs were almost identical to those cited previously by the commenter. On page 54 of the regulatory analysis released with the proposed rule, the one-time capital cost for a groundwater monitoring system was estimated at $46,000, and the annual cost for inspection, leak detection and groundwater monitoring was estimated at $9,500 per year, for the few facilities that were analyzed to need such monitoring. The actual scope of work that will be performed by licensees as a result of amended 10 CFR 20.1501(a) in this final rule covers a broad range of activities, with a broad range of expected costs. This final rule requires radiological surveys, reasonable under the circumstances (such as scoping surveys), sufficient to understand the extent of significant residual radioactivity, including the subsurface. This final rule does not add any new requirements regarding extensive site characterization.

Comment D.7: Regulatory analysis examples cannot be generalized to broad classes of licensees.

One commenter believes that the examples in the regulatory analysis relate to unusual factual and financial circumstances which cannot be generalized to broad classes of NRC licensees.

Response: The Commission disagrees with this statement. The legacy sites modeled in the regulatory analysis were assumed to be rare earth extraction facilities holding contaminated material in areas of 200 square meters at 0.6 meters depth. This is viewed as being an acceptably conservative representation of a legacy site for purposes of performing the regulatory analysis. Without effective regulation, the technical and financial conditions that contributed to the creation of legacy sites in the past could occur in the future at sites that are licensed under 10 CFR parts 30, 40, 50, 70, and 72, especially those with radioactive material possession limits high enough to require decommissioning financial assurance.

Comment D.8: Environmental assessment.

One comment received on the environmental assessment agreed that monitoring wells, if required at licensed sites, will result in small environmental impacts. Another commenter, a state, disagreed strongly with the finding in the proposed rule of no significant environmental impact and stated that such a finding violates the National Environmental Policy Act (NEPA). The commenter believes that the NRC must perform additional environmental analyses, because the final rule does not go far enough in requiring prompt remediation of spills and leaks during facility operations, and that during any cleanup delays contamination could spread, resulting in larger impacts on environmental resources, nearby properties, and public health.

Response: The NRC agrees that the procedures necessary to detect and monitor subsurface contamination will not have a significant environmental impact. The initial licensee investigation may involve only the review of records of past leaks and spills (if any) and facility inspections to identify potential release points. Physical sampling, if any, will take place within the boundaries of the site and will involve small amounts of drilling and analysis. The wastes generated from sampling and from laboratory analysis of the samples will be managed according to existing environmental requirements that have been designed to avoid impacts on the environment. The environmental impacts of remediation, if it occurs, have already been reviewed in connection with the LTR (62 FR 39057; July 21, 1997). In that final rule, a generic Environmental Impact

Statement evaluated ''the environmental impacts associated with the remediation of several types of NRC-licensed facilities to a range of residual radioactivity levels'' (62 FR 39086; July 21, 1997).

The NRC does not agree that absent immediate remediation of all subsurface contamination there will be a significant impact on the environment; nor does the NRC agree that the environmental assessment's finding of no significant impact is incorrect. This final rule allows a licensee who detects subsurface contamination either to conduct immediate remediation or to plan for and provide funds in the form of financial assurance to conduct remediation at a later time, including at the time of decommissioning. Thus, this final rule creates a potential incentive for immediate remediation instead of an increased financial assurance obligation. Whenever the remediation occurs, however, the licensee is required to ensure that at the time of decommissioning the annual 25 millirem license termination standard will be met. This final rule does not change or weaken that requirement.

E. Radium-226

Comment: The NRC invited comments regarding the description of sites that are known to have significant amounts of radium-226 contamination from past practices or operations, and whether the information of these sites could be included as legacy sites in the regulatory analysis. Two comments were received on this topic. One comment, from a state, provided limited information on the remediation of radium contamination at two structures in the state. This commenter also noted the difference between discrete radium sources that are considered byproduct material and diffuse radium sources which are not regulated by the NRC. A second comment, from an organization representing states, noted that legacy sites exist where discrete radium was manufactured and that these types of sites should be included in the regulatory analysis, but no specific information was provided for use in the regulatory analysis.

Response: The NRC appreciates the comments from states with qualitative information about radium-226 contaminated sites. No changes were made in the quantitative results of the regulatory analysis to include costs and benefits from radium sites, but the analysis was revised with the qualitative descriptions from these commenters.

F. Backfit Considerations

Comment F.1: Proposed rule and guidance will have substantial impacts on facilities and procedures.

One commenter (NEI) stated that the proposed rule, coupled with the survey and monitoring draft guidance, will have substantial impacts on licensees' facilities and procedures (*e.g.,* new confinement measures; leak detection equipment; three-dimensional modeling of groundwater contamination) and would require the preparation of a backfit analysis. The commenter stated that the proposed rule would codify in the regulations for power reactor licensees the actions which such licensees have voluntarily agreed to perform under the GPI. The commenter further stated that the new 10 CFR 20.1406(c) and amended 10 CFR 20.1501(a) and (b) are not a ''clarification'' of existing requirements, but rather an effort to impose an expansive regulatory scheme of ''ongoing decommissioning,'' whereby activities that would normally take place at the time of decommissioning would have to occur instead during plant or facility operation. The commenter also stated that the NRC has made no demonstration that there is a substantial increase in the protection of the public health and safety, or that the proposed rule is justified to achieve compliance or ensure adequate protection of the public health and safety, or that a redefinition of the level of protection is necessary.

Response: While the commenter is correct that the findings referenced were not made, these findings are not required here, because the preparation of a backfit analysis of this rulemaking is not required, as discussed further in this section.

The NRC disagrees that the new 10 CFR 20.1406(c) and amended 10 CFR 20.1501(a) and (b) will have substantial impacts on facilities and procedures. As stated in the preamble of the proposed rule, these proposed requirements ''specify that compliance with 10 CFR part 20 requirements is a necessary part of effectively planning for decommissioning,'' and that any actions undertaken by licensees during facility operations to comply with these new requirements would only ''provide a technical basis for licensees and the NRC to understand the effects of significant residual radioactivity on decommissioning costs, and to determine whether existing financial assurance provided for site specific decommissioning is adequate'' (73FR 3814; January 22, 2008). This final rule requires radiological surveys, reasonable under the circumstances (such as scoping surveys), sufficient to understand the extent of significant residual radioactivity, including the subsurface. The term ''residual radioactivity'' includes radioactivity in soils and groundwater, which should already be the focus of licensee survey and monitoring efforts, and minimization efforts, to prevent the subsurface accumulation of radioactive material that could be a potential radiological hazard.

Whether significant residual radioactivity exists at a given site is a complex site-specific issue, and the NRC received no information during the proposed rule public comment period that any site now has residual radioactivity at levels that would exceed the 10 CFR 20.1402 dose criteria at the time of facility decommissioning. For operating facilities, significant residual radioactivity is a quantity of radioactive material that would later require remediation during decommissioning to meet the unrestricted use criteria of 10 CFR 20.1402 (73 FR 3835). For example, the sample data from isopleths of subsurface contamination at Indian Point Energy Center (submitted by the State of New York, in Exhibit A of its comment (ML081340325)) does not show that significant levels of residual radioactivity are present there (2008 Indian Point Government to Government Meeting, May 9, 2008 (ML090540162)).

The commenter is correct that the NRC will expect licensees to apply radiological screening values, or other methods recommended in guidance, to determine if residual radioactivity at the site has accumulated or is in groundwater at levels that are considered significant. But to the extent that the commenter is relying on the survey and monitoring draft guidance to support its backfit argument, such reliance is misplaced. Guidance documents do not impose regulatory requirements.

Moreover, it has never been a policy of the NRC that significant subsurface contamination may go unmonitored, or that appropriate survey information not be obtained regarding such contamination, just because the contamination does not pose an immediate safety or health hazard. The licensee must have such information to achieve doses that are ALARA during the life cycle of the facility, including during decommissioning. Licensee procedures to comply with the ALARA requirement in 10 CFR 20.1101(b) should be in place at facilities where there is a reasonable risk that such contamination may occur.

Regarding the issue of ''ongoing decommissioning,'' the NRC disagrees that the regulations for this final rule contain such a requirement. Licensees are not required through this final rule to perform any new type of extensive characterization or timely remediation during facility operations. Instead, in DG–4014, the NRC has proposed for licensees—(1) An acceptable method to determine if any changes are needed to existing site monitoring practices, and (2) acceptable approaches to determine the cost-effectiveness of prompt, compared to deferred, cleanup of contamination based on sample analysis. The scope of cleanup activities during facility operations is dependent on site-specific conditions. This final rule does not require that any new remediation action be undertaken by a licensee during operations. Remediation of residual radioactivity at the site may occur during decommissioning, or it may occur during facility operations if the licensee deems it beneficial to perform sooner rather than later. If the decision is to remediate later, then a materials licensee must consider the extent of contamination in its updated DFP.

The final rule does not codify the actions that power reactor licensees are performing voluntarily under the GPI. New 10 CFR 20.1406(c) requires power reactor licensees to conduct their operations, to the extent practical, to minimize the introduction of residual radioactivity into the site, including the subsurface. The GPI does not specify licensee activities to minimize contamination at the site. Revised 10 CFR 20.1501(a) specifies that survey and monitoring requirements must be performed of residual radioactivity in areas, including the subsurface, that are potential radiological hazards. This final rule identifies significant residual radioactivity at the site as a potential radiological hazard. This specification of survey and monitoring requirements is not part of the GPI.

Comment F.2: Immediate remediation.

Three commenters argued that immediate remediation should be required after contamination is discovered. One commenter stated that requiring licensees to immediately remediate the contamination resulting from any unplanned or unauthorized release would protect the environment and the public and reduce the likelihood that the NRC and the Federal taxpayers would be saddled with the responsibility of decontaminating a spreading plume of radionuclides at legacy sites several years down the road. Another commenter urged the NRC to include rules related to the establishment of reclamation milestones. The commenter stated that the NRC in the past has allowed at least one licensee to defer the cleanup of off-site tailings until the final reclamation, even though it was perfectly feasible for the off-site contamination to be cleaned up and placed on the tailings impoundment. The result was that the cost from extensive offsite tailings cleanup was not born by the licensee.

Response: The issue of whether immediate remediation should be required after contamination is discovered is outside the scope of this rulemaking. The focus of this rulemaking is on improving the decommissioning planning process. This rule does not suggest that immediate remediation is being imposed as a new requirement.

Slow, long-term leaks, particularly those that cause subsurface soil and ground-water contamination, can significantly increase the cost of decommissioning (73 FR 3814; January 22, 2008). Such leaks may eventually produce radiological hazards (73 FR 3820). To adequately assure that a decommissioning fund will cover the costs of decommissioning, one must have a reasonably accurate estimate of the extent to which residual radioactivity is present in the subsurface soil and groundwater. Together, the proposed requirements in 10 CFR 20.1406(c) and 10 CFR 20.1501(a) specify that compliance with 10 CFR part 20 requirements is a necessary part of effectively planning for decommissioning (73 FR 3814). These regulatory changes are consistent with existing requirements for operating facilities contained in 10 CFR 20.1101(b), requiring licensees to use procedures and engineering controls to achieve doses to members of the public that are ALARA, both during operations and during decommissioning. To accomplish this, licensees must be able to demonstrate their knowledge of residual radioactivity in the subsurface, including soil and groundwater contamination, particularly if the subsurface contamination is a significant amount that would require remediation during decommissioning to meet the unrestricted use criteria of 10 CFR 20.1402 (73 FR 3815). While leaks from facilities can lead to a large volume of radioactive contamination entering the subsurface environment over an extended time, this does not necessarily mean that estimated doses from this contamination are above the limits in 10 CFR part 20 that would initiate immediate regulatory action (73 FR 3820).

Moreover, even if the comment pertained to issues within the scope of this rulemaking, this final rule does not impose immediate remediation as a regulatory requirement. The NRC's performance-based regulatory framework provides licensees a measure of flexibility to determine for themselves the appropriate response to a contaminating radiological event that does not exceed a regulatory threshold and does not result in a health or safety concern. By providing this discretion to licensees instead of a prescriptive approach, the NRC is encouraging licensees to focus on results and to implement methods that are effective for them and will result in improved outcomes. The types of contaminating events that are the focus of this final rule are not an immediate radiological hazard, but over time they can accumulate in an inaccessible area or migrate to groundwater pathways to form significant residual radioactivity at the time of decommissioning. Licensees are not now required to perform immediate remediation of low-level contaminating events that do not exceed regulatory thresholds, and licensees are not required through this final rule to perform any new type of immediate remediation. If the licensee is aware of significant subsurface contamination through surveys and decides to defer cleanup of that contamination to some future date, then the NRC must ensure that adequate funds are available at the time of decommissioning in order to complete the work. During facility operations, it is the responsibility of the NRC staff to ensure that licensees have adequate decommissioning financial assurance based on specific regulatory requirements, including in many cases site specific DCEs. At the start of and during facility decommissioning, the NRC staff is responsible for ensuring that the DCE is based on reasonable project milestones to complete the activities within a timely schedule, to monitor the progress of the licensee against the milestones, and to require additional decommissioning financial assurance if the schedule is extended.

Comment F.3: The expanded scope of new 10 CFR 20.1406(c).

Regarding the expanded scope of 10 CFR 20.1406 to include existing licensees, several commenters argued that this expansion—(1) had not been adequately analyzed for its impact; (2) was inconsistent with the NRC's own finding in the Liquid Radioactive Release Lessons Learned Task Force Final Report (ML062650312) that the releases were not a threat to public health and safety, and (3) should be evaluated as a backfit.

Response: The expanded scope of 10 CFR 20.1406 was evaluated in the regulatory analysis for the proposed rule. Based on the technical basis in Section 2 of the regulatory analysis, five operating sites with licensed rare earth extraction activities were modeled to have residual radioactivity at a level that would exceed the unrestricted release criteria of 10 CFR 20.1402, at the time of their decommissioning. The one-time costs and annual costs for these licensees were modeled over a 15-year analysis period, including groundwater monitoring, and licensee inspection and leak detection activities at each facility (Regulatory Analysis, September 2007, page 34, ML072390191). The comments offer no specific criticisms of this analysis and thus do not call into question the validity of its findings.

The regulatory analysis for the proposed rule and final rule included discussion of the findings of the Liquid Radioactive Release Lessons Learned Task Force Final Report. The regulatory analysis summarizes the report as having ''identified a large volume of subsurface and ground-water tritium contamination from power reactors due to undetected leaks in spent fuel pools, component cooling water tanks, condensate holding tanks, refueling water storage tanks, borated water storage tanks, buried piping, and ventilation systems,'' as well as having ''identified other radionuclides, including mixed fission products, cobalt-60, cesium-137, and strontium-90, that were inadvertently released into the onsite environment at two power plants'' (Regulatory Analysis, September 2007, page 7, ML072390191). The NRC agrees that one of the conclusions of the Liquid Radioactive Release Lessons Learned Task Force Final Report was that the report did not identify any instances of liquid radioactive release where the health of the public was impacted. However, none of the sites examined in the report are legacy sites. Based on NRC experience, chronic radioactive release to the subsurface is a primary contributing cause to the creation of a legacy site, and a legacy site is a potential radiological hazard that may be a threat to public health and safety. The final rule does not require evaluation of a backfit analysis, because the new or amended regulations in the rule either clarify existing requirements or require the collection and reporting of information using existing equipment and procedures. As such, the new or amended regulations are not regulatory actions that require the performance of a backfit analysis.

Comment F.4: Agreement that a backfit analysis is not required.

One commenter agreed with the position taken by the NRC that a backfit analysis is not required for this proposed rule, because the requirement already exists for licensees to perform waste characterization and minimization during operations.

Response: The NRC agrees that a backfit analysis is not required for this proposed rule. But the NRC cannot respond further to the comment, as it provides no citations to regulatory requirements referenced in the comment.

G. Need for 10 CFR 20.1403, 20.1406, and 20.1501 Amendments

Comment G.1: Support for amended 10 CFR 20.1403.

Commenters from several States expressed support for the proposed criteria in § 20.1403 for license termination under restricted conditions eliminating certain financial assurance methods. Noting that since September 11, 2001, it has become more difficult for materials licensees to get any form of surety, the commenters agreed that while the NRC should be sensitive to this situation, certain financial assurance methods may not be effective in bankruptcy situations.

Response. The NRC agrees that a trust fund is the financial assurance mechanism most suitable for use over the relatively long period required for license termination under restricted conditions. The trust fund should be a less complicated financial instrument to establish and fund decommissioning financial assurance compared to other forms of surety which can be difficult for materials facilities to maintain over long periods.

Comment G.2: Support for amended 10 CFR 20.1406 and 20.1501.

Several commenters supported the new 10 CFR part 20 regulations, arguing that residual radioactivity is a problem that should be addressed promptly. One commenter stated that as time passes, residual radioactivity can spread vertically and laterally driven by downward percolating rainfall and snow melt, increasing the volume of materials requiring excavation. This commenter concluded that licensees should be compelled to conduct thorough subsurface investigations of their sites that include drilling, and should residual radioactivity be found, licensees should be compelled to remediate or otherwise address it promptly. Commenters from several States also support the proposed requirements. One commenter stated that a lack of characterization of subsurface residual radioactivity could lead to a need for additional unforeseen decommissioning activities, and that the cost of removing and disposing of residual radioactivity could overwhelm existing decommissioning funds and lead to the site's becoming a legacy site. Subsurface investigations should take place when it is known that residual radioactivity exists, so that mitigating efforts can be put in place, if necessary, before the situation worsens and revisions to the decommissioning funding calculations can be made. The cost to enforce and fully decommission a single legacy site is much higher than the cost to prevent the occurrence of a legacy site through amended regulations. A commenter representing several States generally supported the proposed § 20.1501 requirements, noting that slow and long-lasting leaks, and leaks from the processing of large quantities of licensed material, especially in liquid form, did pose particular risks. Another commenter asserted that events in the last decade have shown that the key assumptions behind the 1988 and 1998 decommissioning regulations are no longer accurate, and that the NRC has become aware of several unpermitted releases at sites across the country.

Response: The Commission agrees that licensees must have, at a minimum, adequate information about the type and extent of significant residual radioactivity that is present in the subsurface at their facility. The licensees can then make informed decisions about whether to undertake remediation immediately or to plan for remediation at the time of decommissioning, while revising their DCE and decommissioning financial assurance to ensure that they will be able to address effectively the cleanup of the subsurface contamination.

Comment G.3: Support for monitoring and recordkeeping requirements.

One commenter stated that when any subsurface contamination above background is identified, it should be noted in decommissioning records, even if it is not otherwise reportable. This is because such information can be very useful for conducting site characterization for purposes of license termination and to support decisions on the extent of site remediation necessary to meet unrestricted use criteria. It is also useful when planning modifications to a facility. This stems from the logic that if subsurface contamination exists, then it came from some plant system that handles that material; therefore, any physical activity on or near those systems should include provisions for dealing with the source of contamination. One state commenter provided a detailed description of a

situation it had encountered that supported the need for increased monitoring. It stated further that recording recurring leaks or spills in decommissioning records or operational logs is neither onerous nor financially burdensome. Geographic Information Systems (GIS) make documentation of tracking of spills a relatively easy task, and do not pose a paperwork burden. Tracking of these data are critical for an effective Historical Site Assessment under MARSSIM.

Response: The NRC agrees with these comments as they apply to contamination that may be significant for site specific decommissioning planning.

Comment G.4: Cost of required activities compared to potential benefits.

Some commenters argued that the final rule survey and monitoring requirements, particularly as they were interpreted in the draft survey and monitoring guidance released with the proposed rule, would be a tremendous potential financial burden to licensees with no health and safety benefit to the public. Some commenters stated that sites already have sufficient existing survey, monitoring and detection programs in place to assure compliance with current licenses. In addition, the extent of modeling of the hydrology that would be required to meet the draft regulatory guidance does not appear to be warranted at sites that do not have extensive subsurface contamination.

One commenter argued that the scope of the proposed rule and guidance is far more extensive than what is warranted by the circumstances, and that both the proposed rule and the guidance are inconsistent with the NRC's own finding that none of the instances of inadvertent releases to the environment presented a threat to public health and safety.

Response: The commenter is correct that the NRC's conclusion in its Liquid Radioactive Release Lessons Learned Task Force final report dated September 1, 2006, which was focused on inadvertent and unmonitored radioactive liquid releases from power reactors, was that the measured levels of tritium and other radionuclides do not present a health hazard to the public, and this finding was noted in the preamble to the proposed rule (73 FR 3814; January 22, 2008). However, as also noted in the preamble to the proposed rule (73 FR 3820), based on past NRC experience, significant concentrations or quantities of undetected and unmonitored contamination, caused primarily by subsurface migration of groundwater, have been a major contributor to a site becoming a legacy site. A legacy site is a potential radiological hazard and a threat to public health and safety.

As discussed in Section II.B of this document, all power reactor licensees and about 300 NRC and 1,000 Agreement State licensees have an obligation to set aside funds for decommissioning financial assurance. These licensees are subject to the amended regulations in 10 CFR part 20 and are already required to have radiation protection programs aimed toward reducing exposure and minimizing waste at their sites (73 FR 3813). The NRC received no information during the proposed rule public comment period that any operating facility now has subsurface residual radioactivity at levels that would exceed the 10 CFR 20.1402 dose criteria at the time of facility decommissioning. Thus, the NRC believes there is no incremental burden for these licensees as a result of final rule amendments to 10 CFR part 20, except to read and understand the final rule and the survey and monitoring guidance.

If there is a history of subsurface spills at a site, to the extent that a recurrence could result in significant residual radioactivity, then the NRC expects appropriate licensee action to comply with the new survey and monitoring requirements as appropriate for site-specific conditions. The survey and monitoring requirements in 10 CFR part 20 are broad scope requirements that apply to many types of facilities and thus cannot be specific to any one type of facility. Therefore, the extent of compliance with new survey and monitoring requirements and the level of licensee burden is very much a site-specific issue.

Comment G.5: Indian Point Nuclear Power Plant and Breazeale Research Reactor.

The State of New York and Riverkeeper cited in their comments on the proposed rule information about radioactive leaks from the Indian Point Nuclear Power Plant.

Response: The NRC takes this opportunity to discuss survey and monitoring requirements in this final rule by using public information of recent leaks at two nuclear facilities, one at the Indian Point Nuclear Power Plant and the other at a research and test reactor.

A public meeting was held on May 20, 2008, in Cortlandt, New York, to discuss the results of the NRC's inspection of the licensee's performance and the agency's independent assessment of contaminated groundwater conditions that were first detected by the licensee at the Indian Point Energy Center in September 2005. The NRC Inspection Reports Nos. 05000003/2007010 and 05000247/2007010, dated May 13, 2008, were referenced in this report (ML081340425). The groundwater samples contained tritium and strontium-90 that were not previously monitored or detected in groundwater before late 2005. As determined by the licensee's hydro-geological analysis and independently confirmed by the NRC, the contaminated groundwater does not migrate off-site, except directly to the Hudson River. Because there is no current drinking water pathway derived from groundwater or the Hudson River in the vicinity influenced by the Indian Point Energy Center, the primary radiological liquid effluent exposure pathway is through the consumption of aquatic foods such as fish and invertebrates. The licensee's radiological assessment of this pathway, performed in accordance with NRC regulatory requirements and confirmed by NRC inspection, determined that the radiological consequence of groundwater migration to the Hudson River was, and continues to be, negligible with respect to NRC regulatory limits; *i.e.,* the dose consequence to a hypothetical maximally exposed individual is no more than 0.1 percent of the NRC regulatory specification for liquid radiological effluent release.

In view of the potential radiological implications of contaminated groundwater, the NRC initiated enhanced regulatory oversight at Indian Point following the licensee's initial reporting of onsite sample data of groundwater contamination. Subsequently, the licensee initiated a comprehensive investigation of the extent of onsite groundwater contamination which included an extensive hydro-geological site characterization, the installation of several groundwater monitoring wells, comprehensive radiological assessment, and the establishment of a long-term monitoring program. As the NRC reported at the May 20, 2008, public meeting (ML081490020), the NRC independently confirmed the adequacy and acceptability of the licensee's investigation, radiological assessment, and plans for long-term monitoring of the contaminant groundwater conditions. The licensee's remediation approach *(i.e.,* monitored natural attenuation) is considered reasonable by the NRC. Notwithstanding, the licensee's long term monitoring program

will continue to be inspected by the NRC.

The State of New York, in Exhibit A of its comment to the Commission on the proposed rule, cited sample data taken of the contamination concentration levels. Based on the sample data, this level of residual radioactivity is likely to be below the 10 CFR 20.1402 unrestricted release dose criteria at the time of Indian Point decommissioning. On the effective date of the final rule, the licensee must demonstrate that it is conducting operations, to the extent practical, to minimize the introduction of residual radioactivity at the site, including the subsurface (10 CFR 20.1406(c)). The amended 10 CFR 20.1501(a), and the existence of previously undetected groundwater contamination due to leakage from the Units 1 and 2 spent fuel pools, requires the licensee to continue monitoring the condition and evaluate the need for additional monitoring and modeling at the plant in the event of new or additional leaks, spills, data from existing monitoring wells, or other information pertaining to residual radioactivity at the site. The licensee may modify or revise the scope of its monitoring effort at Indian Point based on demonstrated results, supported by analysis of sample and survey data, which indicate that operations and activities are sufficient to minimize the introduction of residual radioactivity at the site. The sample and survey data is planned to be publicly available in ADAMS with the annual effluent and environmental reports.

In October 2007, the Pennsylvania State University Breazeale Research Reactor facility experienced a minor leak of slightly radioactive water from the reactor pool lining. In the following 6 weeks, the NRC performed several inspections at the facility (ML073480163) and determined that the existing environmental monitoring satisfied licensee and regulatory requirements. The licensee reviewed its monitoring and decided to take samples from a nearby water well to assess overall area well quality. Contamination surveys were performed at the site to understand the migration of the residual radioactivity. The NRC inspection concluded that the number and location of survey points were adequate to characterize the radiological conditions. The NRC inspection report noted that the licensee always investigates readings above background levels and ensures that contaminated areas are decontaminated.

Following the effective date of this final rule, this licensee must demonstrate that, to the extent practical, it is conducting operations so as to minimize the introduction of residual radioactivity at the site, including the subsurface. Also, the licensee must perform surveys sufficient to evaluate the need for additional monitoring and modeling at the reactor based on future leaks or spills or other information the licensee has relevant to residual radioactivity at the site.

There have been leaks at other research and test reactors with outcomes that affected decommissioning planning. For example, Cintichem, Inc., of Tuxedo, New York, held two NRC licenses, one for the operation of a 5-megawatt research reactor and another for special nuclear material. In February 1990, the licensee reported an unmonitored release of radioactively contaminated water from the reactor building to an onsite retention pond and a second leak in an onsite concrete vessel (56 FR 23601; May 22, 1991). In May 1990, Cintichem informed the NRC that it had decided to decommission the reactor and related facilities. Over the next several years, Cintichem conducted cleanup activities and dismantled the reactor. The Cintichem licenses were terminated in 1998, with the site having been remediated to levels suitable for unrestricted use (63 FR 45268; August 25, 1998).

Comment G.6: The proposed rule is unnecessary.

One commenter, supported by several additional commenters, stated that existing decommissioning regulations contain appropriate requirements to provide reasonable assurance that legacy sites will be prevented. The programs that NRC licensees already have in place address all aspects of decommissioning planning, including conduct of operations to minimize contamination, monitoring and surveillance, recordkeeping, and financing. These programs are subject to NRC inspection and oversight. Another commenter argued that the reduction of radiological risk associated with the proposed rule is extremely small, yet compliance will be very resource-intensive and costly.

One commenter agreed with the NRC's statement that the vast majority of NRC materials licensees do not have processes that would cause subsurface contamination. This same commenter reasoned that additional surveys should be therefore required only at those limited sites where subsurface contamination may be a concern. This commenter also asserted that the requirements in § 20.1406(c) were unnecessary, because ALARA requirements covered the requirement to conduct operations to minimize subsurface and other residual radioactivity. Current regulations include consideration of subsurface contamination in the DCE, or could be addressed on a case-by-case basis through license conditions and required materials licensees to minimize contamination, survey contamination, and keep records. This commenter believed that the vast majority of licensees would be unlikely to have a reason for, or a means of determining, the volume of onsite subsurface material containing residual radioactivity.

Commenters opposing the rule as unnecessary stated that, at a minimum, the proposed rule and accompanying draft regulatory guidance should be held in abeyance until the issues identified by the commenter have been addressed. The commenter stated that the proposed rule and regulatory guides should be substantially rewritten, and this would require reissuance for public comment. In addition, the commenter encouraged the NRC to hold workshops with the affected stakeholders. Although the commenter believed the rulemaking is unnecessary, issues of importance to the staff might be pursued in these workshops.

Response: The NRC disagrees with these comments concerning the need for rulemaking. The ALARA requirements in existing regulations do not explicitly address subsurface contamination and do not provide adequate assurance that additional legacy sites will be prevented. Before this final rule, the NRC regulations did not explicitly specify licensees' obligations to survey subsurface contamination, nor did the regulations explicitly specify the requirement of licensees to conduct operations to minimize residual radioactivity at the site, including the subsurface. This rulemaking will augment NRC inspection and oversight activities by defining the regulatory basis to mandate particular licensee actions on a timely basis to prevent the creation of more legacy sites. The radiological risk of a legacy site with groundwater contamination may be significant. The NRC will issue DG–4014 to support the survey and monitoring requirements in this final rule and will hold at least one public workshop (details on the public workshop will be available under Docket ID NRC–2011–0103) to refine that guidance for issues of importance to stakeholders.

Comment G.7: The proposed rule is unnecessary because NRC could accomplish its objectives through inspection, oversight, and licensing activities.

Several commenters argued that the decommissioning issues raised in the proposed rule could be better addressed on a case-by-case basis through the licensing, inspection, and enforcement process for the unusual licensee that may have those concerns. This would be much more effective and efficient than attempting to adjust regulations that 23,000 licensees are obliged to read. One commenter stated that the rule seems to be an overly broad response to a narrow problem. If the NRC has concerns regarding the potential for ''legacy sites'' for only five to six licensees, then the more efficient path would be to impose site-specific and license-specific conditions on the limited set of facilities, rather than impose regulations on all licensees with uncertain costs and even more uncertain benefits. Given the limited scope of the problem as defined by the NRC, it does not make sense to introduce a new layer of NRC review and approval of survey and monitoring programs outside of licensing reviews.

Several commenters also recommended that statements should be added that certain categories of licensees currently satisfy the proposed requirements. According to one commenter, the NRC should include an unqualified statement that NRC inspection and oversight programs provide the necessary guidance and license conditions/requirements to regulate activities for uranium mills undergoing decommissioning and remediation. One commenter noted that the issue of controlling or limiting the release of radioactivity in licensed operations is different than the issue of intervention to address residual radioactivity that was previously permitted. In the latter case, no general solutions are available, and a case-by-case analysis will be necessary. This is exactly what has taken place at the existing legacy sites. To the extent that the proposed rule seeks to require intervention to address residual radioactivity resulting from past, permissible activities, the rule is unlikely to have any impact on reducing the cost or complexity of decommissioning. Ultimately, the NRC's licensing and oversight programs are adequate to reduce introduction of residual radioactivity from current practices. Finally, two commenters argued that the proposed rulemaking contradicts the NRC's policy of risk-based regulation. Each affected licensee will be required to spend an enormous amount of resources on monitoring programs to address an issue that by the NRC's own evaluation has no impact on the health and safety of the public. A more reasonable approach would be to address subsurface contamination concerns on a risk-informed basis for individual licensees by means of the existing inspection and licensing process.

Response: The NRC believes that rulemaking is much more effective than relying on existing licensing, inspection, the Reactor Oversight Process and/or enforcement processes to accomplish regulatory objectives that were stated in the technical basis for the proposed rule. A legacy site can occur among a broad range of currently operating licensees. Section II.B in this document identifies the licensees that are affected by this final rule. The NRC agrees with the commenter that case-by-case intervention is not an effective regulatory approach to reduce the cost or complexity of decommissioning. As discussed in the response to comment G–9 and G–13 below, the NRC considers this final rule to be risk-informed.

Comment G.8: The proposed rule is not stringent enough.

Several commenters generally opposed the proposed rules because, they believe that the rules are not stringent enough to protect the environment or promote safety and will not make NRC actions more effective, efficient, and realistic. One commenter believes that the proposed regulations will encourage licensees to postpone the cleanup of radionuclide leaks until some future date, by which time a plume may be more difficult and expensive to decontaminate. This commenter argued that aside from a few modest improvements in limited aspects of the decommissioning process, the proposed rule does not address, in a meaningful way, the deficiencies in facility operations that lead to subsurface contamination, the threats posed by delayed remediation, or the risks of unfunded subsurface decontamination at nuclear power plants. This commenter stated that the final rule should require nuclear power plant owners and other licensees to: (1) Actively prevent subsurface radionuclide leaks, (2) look for contamination under their sites, (3) publicly report what they find, (4) immediately clean up subsurface radionuclide contamination, and (5) increase their decommissioning funds to cover the costs of historical contamination at their plants. The commenter also called for the NRC to create an additional funding requirement when contamination is discovered by requiring licensees to update decommissioning estimates to keep pace with the actual subsurface and surface contamination conditions at their facilities. That is, the NRC should require licensees to set aside ample funds to cover decontamination and decommissioning as if decommissioning were occurring now. Monitoring should be required at least every 2 years.

Response: The NRC agrees that this final rule provides regulatory flexibility to provide licensees discretion in determining the appropriate response to a contaminating event that does not pose an immediate health or safety concern, and licensees may in fact decide to postpone cleanup activities. The NRC disagrees with the commenter that the rule does not address events at operating facilities that lead to subsurface contamination and additional risks later, resulting from unfunded decommissioning activities. As stated in the proposed rule (73 FR 3814; January 22, 2008), the activities that will be undertaken by licensees as a result of this final rule will provide a technical basis for licensees and the NRC to understand the effects of significant residual radioactivity on decommissioning costs, and to determine whether existing financial assurance provided for site-specific decommissioning is adequate. By using the term ''residual radioactivity,'' the new § 20.1406(c) and § 20.1501(a) cover any licensed and unlicensed radioactive material that has been introduced into the site by licensee activities. If operating events are causing significant amounts of residual radioactivity to accumulate onsite, those events will need to be mitigated to comply with the new § 20.1406(c).

This final rule contains provisions in §§ 30.35(e)(2), 40.36(d)(2), 70.25(e)(2), and 72.30(c) to require licensees to update their DFP at least every 3 years to account for changes in costs and the extent of subsurface contamination. A separate set of similar funding update requirements is already applicable to power reactors.

Comment G.9: The proposed rules are not sufficiently precise.

Several commenters opposed the use of the phrase ''to the extent practical'' in proposed 10 CFR 20.1406(c) and the phrase ''reasonable under the circumstances'' in proposed § 20.1501, because the terms were too broad. One commenter stated that these phrases created a loophole that was compounded by use of the term ''minimize,'' as opposed to ''prevent.'' The commenter stated that these words will hamper, if not preclude, effective enforcement actions by the NRC or the U.S. Department of Justice against facilities and operators who release radionuclides to the subsurface area. A

commenter representing several States also stated that use of the term ''to the extent practicable'' in the proposed rule could provide licensees with the leeway to perform very limited sampling or surveys to verify the extent of any subsurface plume, leading to erroneous conclusions regarding no significant hazards. Another commenter said that the survey requirement must be clearly spelled out in the language of the regulation to make it binding upon licensees. The current language is unacceptably vague.

Response: The NRC disagrees that the rule language is vague. The phrases ''to the extent practical'' and ''reasonable under the circumstances'' are already used in 10 CFR part 20 requirements to provide flexibility in support of a risk-informed regulatory approach. The risk-informed approach is more effective at achieving acceptable results and compliance by licensees compared to a prescriptive approach, which is cumbersome for licensees and regulators considering the broad range of licensees using radioactive material. The regulatory analysis in the proposed rule addressed this specific topic as it relates to survey requirements. On Page 45, the regulatory analysis notes that the Commission established a broad regulatory framework when § 20.1501 was added to the regulations in 1991. This final rule adds precision to survey requirements by amending § 20.1501(a) to explicitly include the subsurface at a site as an area that needs to be surveyed if concentrations or quantities of residual radioactivity in the subsurface present a radiological hazard. The proposed rule states, ''The staff views radiological hazards as including those resulting from subsurface contaminating events, when these events produce subsurface residual radioactivity that would later require remediation during decommissioning to meet the unrestricted use criteria of 10 CFR 20.1402'' (73 FR 3820; January 22, 2008).

Comment G.10: The proposed rule is based on historical AEC legacy sites, rather than modern sites.

Several commenters stated that the NRC was basing the proposed rule on past, rather than current, problems. One commenter asserted that the very limited ''examples'' cited by the NRC of licensees for which some concern has existed do not support the broad brush approach proposed by the NRC in this rulemaking. The cited examples generally relate to licensees that had been operating long before the current regulations, comprehensive guidance, discipline in reviewing license applications, contemporary licensee practices and awareness, and current decommissioning funding requirements were in place. The commenter pointed to the example of burial in soil of radiological waste onsite, even if exceeding ''exempt'' regulatory limits at the time of burial, which was permitted for over 20 years without prior agency review. The commenter argued that it was likely that significant changes to the historical regulatory scheme with respect to onsite radiological waste disposal were at least factors in some of the site-specific examples of legacy sites of concern to the NRC, but these examples have been addressed within the current regulatory framework.

Response: The NRC agrees that previous changes to regulations on subsurface burials have reduced the likelihood of legacy sites. The NRC disagrees that the current regulatory framework is sufficient to provide effective oversight of operating facilities to ensure the prevention of more legacy sites.

Comment G.11: The proposed rulemaking is a new regulatory scheme for ongoing decommissioning.

One commenter, supported by several others, argued that the requirements for extensive subsurface soil characterization (or remediation) during an operating facility's lifetime is largely unrealistic. It is not feasible to perform subsurface characterization without risking the breach of barriers that contain radioactivity, disrupting the operationally essential equipment, or exacerbating the migration of contaminants already in the environment. Based on industry decommissioning experience, the majority of subsurface contamination (by volume and concentration) would likely be located directly under structures, systems and components (SSCs) that have leaked, where it cannot be safely or adequately accessed for characterization purposes. Even in the case of a reactor undergoing decommissioning, these areas usually cannot be accessed until late in the decommissioning process, when many of the SSCs and higher levels of contaminant sources have been removed. Another commenter stated that the dust and other materials stirred up during decommissioning could lead to greater exposures for site personnel, thus obviating much of the already small benefit of requiring site cleanup while operations are ongoing. The prospect of ''continual decommissioning'' may also be contrary to the principles of ALARA embodied elsewhere in 10 CFR part 20. One commenter requested that licensees be permitted to evaluate normal construction-related risks associated with any proposed excavation of residual radioactivity, and that should these risks exceed the risks posed by the residual contamination itself, the licensee should not be required to excavate the material.

Response: As indicated in the response to Comment F.2, conducting remediation actions while a facility continues to operate is not required by the proposed rule, even if significant amounts of residual radioactivity are present at a site. Based on the history of radioactive leaks at power reactors, the leaks can generally be attributed to the following SSCs: Fuel transfer systems and spent fuel pools, buried piping, and storage tanks. Existing regulatory requirements may apply to SSCs that have leaked radioactive liquids, but determining which requirements apply to a specific facility requires review of the plant's licensing basis. SSCs that are not safety-related and are not covered by the licensee's quality assurance program generally are subject to less maintenance, testing and inspection than safety-related SSCs. The non-safety related SSCs are more likely to have a radioactive leak without detection, and a significant level of contamination from SSCs can migrate through the subsurface far from the source. One of the findings in the Liquid Radioactive Release Lessons Learned Task Force (73 FR 3814; January 22, 2008) final report was that a majority of leaks at power reactors are from non-safety related SSCs that contain radioactive material.

Comment G.12: Variability in licensee practices in documenting spills and leaks important for decommissioning does not justify new requirements.

Several commenters stated that the proposed rule applies the same requirements to all types of licensees despite the inherent differences in how each type of licensee safely manages radioactive material and/or the financial assurance instruments for decommissioning. Throughout the preamble to the proposed rule, the NRC acknowledges that only a few sites have identified contamination and been faced with hurdles to releasing the site for unrestricted use. To date, all nuclear generating facilities have been successful in their decommissioning for unrestricted use.

Response: The NRC agrees that the 10 CFR part 20 changes in this final rule apply equally to all NRC and Agreement State licensees despite the differences in facility operations and the extent of their radiation safety programs. However, licensees with an obligation to provide decommissioning financial assurance are likely to be affected by

this rulemaking only if they have liquid processes that would contribute to significant subsurface contamination. The commenters are correct that no power reactor sites have become legacy sites.

Comment G.13: The proposed rule is based on unusual factual and economic circumstances that cannot be generalized to broad classes of licensees.

Several commenters noted that throughout the January 22, 2008, proposed rule, the NRC acknowledged that only a few facilities have identified contamination that has resulted in unexpected difficulty in decommissioning the site, and that the regulatory analysis represented these facilities as a certain type of licensee (*i.e.,* rare earth extraction facility). Rather than targeting the proposed rule accordingly, the scope of the proposed rule includes all types of licensees, despite the inherent differences in how each type of licensee controls radioactive material. Another commenter stated that the proposed rule and draft guidance are attempting to apply a ''one-size-fits-all'' approach to all NRC-licensed facilities without regard to the varying processes, radionuclides, and risks at different categories of licensees. For example, uranium mills, conversion facilities, and solution mining facilities have unique attributes making a ''one-size-fits-all'' approach inappropriate.

Response: The NRC used a risk-informed approach in developing the language for the amendments to 10 CFR part 20 in the proposed rule. This final rule is not prescriptive but instead applies a broad and flexible regulatory framework as discussed in the response to Comment G.9. The NRC agrees in part with the comment regarding the unique attributes for uranium mills and solution mining facilities, as discussed further in response to the next comment.

Comment G.14: Applicability to uranium recovery facilities.

Several commenters urged the NRC not to make uranium recovery facilities subject to the new 10 CFR part 20 requirements, because such facilities do not process enriched source material. One commenter stated that the proposed rule should not apply to decommissioning uranium recovery (UR) facilities. Another commenter requested that UR facilities (conventional mills, in-situ uranium recovery facilities and heap leach facilities) be categorically excluded from coverage under the proposed amendments to 10 CFR 20.1406 and 20.1501 in the final rule. A commenter stated that NRC inspection and oversight programs, together with license conditions and existing regulations, adequately regulate uranium mills undergoing decommissioning and remediation, and are protective of the public health and safety and the environment. A commenter stated that the requirements in the proposed rule to address residual radioactivity during UR operations would result in new operational restrictions well beyond those imposed by existing licenses, and that the extreme variability of natural background radionuclide concentrations, and the presence of Technologically Enhanced Naturally-Occurring Radioactive Material (TENORM) and unprocessed ore at a site would introduce new requirements in survey and monitoring methods. Commenters also stated that the ''routine'' monitoring program described in the guidance would require a more complex and expensive program than is presently necessary to adequately characterize contamination or support decommissioning.

Response: The NRC agrees in part with the above comments. In finalizing the license termination rule, which established 10 CFR part 20 Subpart E in 1997, the NRC recognized that there are unique soil contamination issues associated with the decommissioning of UR facilities. For this reason, 10 CFR 20.1401(a) was worded to exclude UR facilities from the scope of 10 CFR part 20 Subpart E, and the NRC requested comments on what radiological criteria should be used in terminating UR facility licenses (62 FR 39093; July 21, 1997). The 10 CFR 20.1401(a) exclusion is not changed by the present rulemaking, and UR licensees and applicants will not be subject to the new requirements in 10 CFR 20.1406(c), just as they were not subject to the existing 10 CFR 20.1406 requirements.

As a result of the 1997 request for comments referenced above, Criterion 6(6) of Appendix A to 10 CFR part 40 was amended in 1999 by adding its second paragraph, which established total effective dose equivalent (TEDE) requirements to address the radionuclides of concern (chiefly uranium and thorium) present in the soils of UR facilities. See 64 FR 17506 et seq. (April 12, 1999). If UR facilities undergoing decommissioning have radioactive contamination in their soils associated with their operations at levels exceeding background by 5 pCi/g of radium-226 (the benchmark dose), then Criterion 6(6) requires that such contamination be remediated. The present rulemaking does not change Criterion 6(6). The NRC thus does not agree with the commenter's concern regarding TENORM and unprocessed ore.

Because the 10 CFR 20.1501 survey and monitoring requirements are part of 10 CFR part 20 Subpart F rather than Subpart E, they do not fall within the 10 CFR 20.1401(a) exclusion discussed above. For UR facilities, these survey and monitoring requirements must be read in conjunction with the 10 CFR part 40 Appendix A Criterion 7 and 7A requirements. Together, these 10 CFR part 20 and part 40 requirements help ensure that issues of soil and groundwater contamination—both at operating UR facilities and those undergoing decommissioning—are properly addressed. For example, the operational monitoring and survey requirements in 10 CFR 20.1501 help ensure that the worker and public dose limits set forth in Subparts C and D of 10 CFR part 20 are met, and UR facilities have been subject to these dose limits since 1991, when Subparts C, D, and F were first established. In that 1991 rulemaking, in response to a comment on then-proposed 10 CFR 20.1501 on the lack of specific monitoring requirements, the NRC explained that because 10 CFR part 20 contains the general radiation protection requirements that apply to all classes of NRC licensees, the wording of many of its provisions is necessarily general. (56 FR 23360; May 21, 1991). With the limited exception discussed above regarding 10 CFR part 20 Subpart E requirements, 10 CFR part 20 is still the set of general radiation protection requirements that is applicable to all classes of NRC licensees, including UR facilities. Accordingly, UR facilities are and will remain subject to the 10 CFR 20.1501 survey and monitoring requirements.

However, the revisions to § 20.1501 in the final rule do not establish any new remediation criteria for UR facilities. Standards for decommissioning UR facilities, and the various related requirements for conducting soil and ground-water monitoring at UR facilities, are found in 10 CFR part 40, Appendix A. The final rulemaking does not change any of these requirements. A UR licensee's program that complies with the 10 CFR part 40, Appendix A site remediation criteria would thus not be impacted by § 20.1501(a)'s revised survey requirements, and such programs would not become more complex or expensive as a result of this rulemaking. The 10 CFR part 20 worker and public dose requirements are combined with the remediation criteria for UR facilities in 10 CFR part 40, Appendix A, as has

been the case previous to this rulemaking.

The change in terminology from ''radioactive material'' to ''residual radioactivity'' in 10 CFR 20.1501(a) will not result in any new operational restrictions at UR facilities. Residual radioactivity, as defined in 10 CFR 20.1003, is not ''residual radioactive material'' as defined in 10 CFR 40.4. The latter term is used only with respect to materials at sites subject to remediation under Title I of the Uranium Mill Tailings Radiation Control Act of 1978, as amended. The challenge to determine background levels of radiation at specific UR sites has not changed as a result of this final rule. Surveys that are reasonable under the circumstances must be performed if there is a potential radiological hazard at a site. Commenters expressing concern about the unlicensed sources that are included in residual radioactivity, such as TENORM and unprocessed ores at a UR facility, have read more into the rule change in § 20.1501 than is intended. For example, UR facilities must currently manage ore, because Criterion 5H requires that licensees protect underlying soils and groundwater from ore stockpile contamination. Furthermore, ore remaining at a UR site during decommissioning is considered 11e.(2) byproduct material and may be placed into the tailings impoundment, so long as it is not removed from the site for processing at another facility. As previously stated, radioactive soil contamination at UR sites undergoing decommissioning is addressed by Criterion 6(6). None of this is changed by the final rule.

Comment G.15: Applicability to byproduct manufacturing licensees.

One commenter argued that radionuclide and radiopharmaceutical manufacturing licensees are within the scope of currently operating sites that the NRC would not expect to become ''legacy sites.'' The regulations should therefore categorically exempt them from the additional residual radioactivity monitoring requirements.

Response: Radionuclide and radiopharmaceutical manufacturing licensees are byproduct material licensees regulated under the requirements of 10 CFR part 30. If such a facility has no credible release scenario that could contribute to significant subsurface residual radioactivity at the site, then it is likely that the licensee will not be affected by the final rule changes to 10 CFR part 20.

Comment G.16: Applicability to research and test reactors.

Several commenters argued that research and test reactor licensees should be exempt from the final rule changes to new 10 CFR 20.1406(c) and amended 10 CFR 20.1501.

Response: Research and test reactors are licensed under the requirements of 10 CFR part 50. If a research and test reactor has no credible release scenario that could contribute to significant subsurface residual radioactivity at the site, then it is likely that the licensee of such a reactor will not be affected by the final rule changes to 10 CFR part 20.

Comment G.17: Applicability to water treatment facilities.

One commenter asked the NRC to address the potential applicability to licensed water treatment facilities and to make it clear that such survey and monitoring requirements likely will not be necessary at such facilities because: (1) Their licensed operations involve the production of uranium-laden ion exchange (IX) resins that are substantially similar, if not identical, to those generated at *in situ* uranium recovery (ISR) facilities; (2) all equipment that generates such resins is, by license condition, contained within structures/buildings that provide primary and secondary containment to minimize, if not eliminate, potential releases of licensed material; (3) the resins do not present credible release scenarios where potential subsurface contamination would be implicated; and (4) the licenses contain strict monitoring and survey requirements.

Response: Licensees who possess uranium-laden resins at water treatment plants are source material licensees regulated under 10 CFR part 40. Licensees possessing uranium-laden resins at water treatment plants are not subject to the 10 CFR part 40 Appendix A criteria, and are thus subject to the new 10 CFR part 20 requirements. However, if a water treatment facility has no credible release scenario that could contribute to significant subsurface residual radioactivity at the site, then it is likely that the facility will not be affected by the final rule changes to 10 CFR part 20.

Comment G.18: Residual radioactivity at publicly owned sewage treatment works.

A commenter noted that the NRC's conclusion that municipal waste treatment facilities were unlikely to have significant concentrations of long-lived radionuclides fails to account for the potential impacts to such facilities if (1) the new uranium and radium Maximum Contaminant Levels (MCLs) are enforced effectively by EPA and their delegated States, and (2) uranium and/or radium water treatment residuals are released in an uncontrolled manner into sanitary sewers or other discharge points from which such residuals could migrate.

Response: Regardless of whether the drinking water treatment plant is: (1) Not removing radium from the drinking water (such as prior to the new EPA drinking water standards for radionuclides) or (2) removing radium from drinking water and discharging the radium-laden residuals to the sanitary sewage system, the amount of radium (or other radionuclide found in the source water) that reaches the publicly owned sewage treatment works (POTW) is unchanged. The NRC assumes, for purposes of this rulemaking, that EPA drinking water standards will be enforced effectively at municipal water treatment plants, and that any release of uranium and/or radium residuals will be done in a controlled manner consistent with license conditions and regulations. Recommendations are available from the ISCORS regarding actions that a POTW operator may take to determine if there is radioactive contamination at its facility and how to interpret the detection results. The recommendations are contained in ISCORS Technical Report 2004–04 (ML103400184).

Comment G.19: Definition of residual radioactivity.

One commenter, supported by several others, argued that licensees should not be required to control unlicensed material in a manner that is substantively different from that required by a non-licensee. This same commenter stated that the definition of ''residual radioactivity'' in 10 CFR 20.1003 is inconsistent with a risk-informed approach to regulation and with the recently-issued RIS 2008–03 ''Return/Re-Use of Previously Discharged Radioactive Effluents'' (ML072120368). In further support of this argument, the commenter cited the proposed rule's preamble (73 FR 3815; January 22, 2008) as excluding from the rule's scope off-site contamination attributable to previously released effluents, thus demonstrating the inconsistency of requiring the licensee to control onsite unlicensed material. This commenter accordingly requested that the NRC revise the definition of ''residual radioactivity'' by deleting its reference to unlicensed sources, and its reference to routine releases of radioactive material.

Response: ''Residual radioactivity'' is a term already defined in 10 CFR 20.1003. Because no changes to this term were proposed when this rulemaking action was published for public comment, the request to now

change the definition is outside the scope of this rulemaking. In considering the comment, the NRC re-examined the cited section of the proposed rule's preamble (73 FR 3815). As stated there, the scope of this rulemaking ''does not include offsite contamination discovered during decommissioning.'' The final rule deletes the following text which conditioned the above statement: ''unless such contamination is an extension of onsite contamination (*e.g.,* a contaminated groundwater plume originating from the licensee's facility).'' What the NRC may later choose to do regarding offsite contamination discovered during decommissioning is unknown at this point, and making the above deletion avoids any limitation on future actions the NRC may take on this issue.

When RIS 2008–03 was issued, the term ''radioactive material'' was used in 10 CFR 20.1501(a), which created the need to differentiate licensed from unlicensed material. The RIS 2008–03 provides a distinction between onsite and offsite unlicensed material. Offsite unlicensed material results primarily from authorized effluent discharges to unrestricted areas that have been evaluated in accordance with regulatory requirements. Radioactive effluent discharge controls, environmental dispersion modeling, and dose assessments ensure that any public dose is within public radiation protection standards. The licensed radioactive material that was properly discharged in accordance with 10 CFR part 20 to the unrestricted area is no longer the responsibility of the licensee. However, onsite unlicensed material is sometimes co-mingled with licensed radioactive material (for example from leaks or spills) and generally cannot be distinguished from or separated from licensed radioactive material. Both licensed and unlicensed radioactivity (*e.g.,* from returned or re-used effluents) at the site are the responsibility of the licensee, during operations and during decommissioning. Unlicensed radioactivity from the return or recycle of previously discharged radioactive effluents can be discharged in liquid or gaseous effluents to the environment in accordance with RIS 2008–03. The control of residual radioactivity at the site during operations increases the assurance that the 10 CFR 20.1402 criteria will be met at the time of decommissioning. The reasons that the NRC is using the term ''residual radioactivity'' in new § 20.1406(c) and amended § 20.1501 were set forth in the proposed rule's preamble (73 FR 3814). The NRC does not agree that the definition of ''residual radioactivity'' in 10 CFR 20.1003 is inconsistent with RIS 2008–03.

Comment G.20: Clarify what is meant by ''significant'' residual radioactivity.

A commenter stated that the term ''significant'' is not defined and may be open to wide interpretation by licensees and others. Similarly, several other commenters stated that the NRC should define ''significant'' contamination, and should specify: (1) Methods required to conduct surveys and their frequency, to ensure consistency in the groundwater monitoring and sampling program; and (2) the constituents to be sampled, the timing and frequency of the sampling, sampling techniques, and how to analyze samples.

Response: The intended meaning of the phrase ''significant residual radioactivity''—which is not a defined regulatory term—is discussed in the proposed rule's preamble (73 FR 3815 and 3835). As stated there, ''significant'' residual radioactivity is a quantity of radioactive material that would later require remediation during decommissioning to meet the unrestricted use criteria of 10 CFR 20.1402. The DG–4014 proposes guidance to licensees on acceptable methods to conduct soil and groundwater sampling to meet the new survey requirements.

Comment G.21: Subsurface and significant contamination.

One commenter disagreed with the statement in the proposed rule's preamble (73 FR 3819) that subsurface contamination occurs in an area at least 15 centimeters (6 inches) below the surface, arguing that instead it should be defined to, and inclusive of, the groundwater table. The same commenter noted that ''Significant contamination'' is not defined, contrary to a recommendation made at Page 22 of the 2006 Final Report of the NRC Liquid Radioactive Release Lessons Learned Task Force (ML062650312).

Response: The NRC's use of the term ''subsurface'' in the proposed rule preamble is consistent with the definition of ''subsurface'' used in NUREG–1575, ''Multi-Agency Radiation Survey and Assessment of Materials and Equipment Manual (MARSAME)'' (ML070110228). As stated on Page 3–14 of that manual, the surface layer is represented as the top 15 centimeters (6 in.) and may include gravel fill, waste piles, concrete, or asphalt paving. Subsurface soil and media are defined on that same page of the manual as any solid materials not considered surface soil.

In this rulemaking, the NRC decided not to make ''significant contamination'' a defined term in the regulations. Instead, the NRC found that ''residual radioactivity''—which is already a defined regulatory term—covers the type of subsurface contamination that prompted the creation of the Liquid Radioactive Release Lessons Learned Task Force. Additionally, as stated in the response to Comment G.20, the proposed rule's preamble provides guidance on the level of residual radioactivity that is considered to be ''significant.''

Comment G.22: Additional site characterization and monitoring not warranted.

Several commenters stated that the proposed NRC regulations could have the unintended consequence of triggering performance of extensive characterization and remediation efforts, without regard to the degree of actual health and safety impact. The proposed regulations would require the evaluation of subsurface contamination based on future decommissioning exposure scenarios, even though no foreseeable operating exposure limits would be exceeded. Furthermore, due to access constraints, it is unlikely that subsurface characterization efforts at an operating reactor would provide any better DCE input data (*i.e.,* volumes and locations of subsurface media exceeding decommissioning criteria) than that produced by experienced decommissioning experts making engineering judgments using information currently available as 10 CFR 50.75(g) file data.

Response: As stated in the proposed rule's preamble (73 FR 3813), the NRC identified the need for licensees during facility operations to timely report the existence of subsurface contamination that has the potential to complicate future decommissioning efforts. But as indicated in responses to other comments, these commenters incorrectly state that the proposed regulations require the immediate evaluation of subsurface contamination even in cases where no foreseeable operating exposure limits would be exceeded by the contamination. As stated in DG–4014, a licensee may decide to perform extensive characterization following its initial scoping surveys and preliminary characterization to determine if an area at the site contains significant residual radioactivity. There may be a need for additional monitoring and modeling, following evaluation of the initial scoping surveys, based on the significance of a spill or leak. But if there is no significant residual radioactivity at a site, then it is likely that the licensee's current monitoring

plan is sufficient and no additional surveys or monitoring are necessary. When there is significant residual radioactivity at a site, survey results will serve as a technical basis to support the licensee's estimates of volumes and locations of subsurface contamination. Such estimates will, in turn, aid the licensee in arriving at a more accurate DCE.

Comment G.23: Frequency of surveys.

One commenter said that the phrase in 10 CFR 20.1501(b), which requires licensees to keep records from surveys ''describing the location and amount of subsurface residual radioactivity identified at the site,'' does not clarify whether the surveys are to be simply one-time snapshots of residual radioactivity at one time, or are to be conducted periodically. The commenter urged the NRC to specify that surveys are mandatory and to be conducted periodically, and that the results submitted to the NRC will be made public.

Response: The frequency of surveys is dependent on site-specific conditions and is a topic discussed in guidance. The survey results that are included in records important for decommissioning are a licensee recordkeeping requirement for NRC review. As noted in the response to Comment D.4, the NRC understands that power reactor licensees will be submitting the onsite groundwater sampling results as part of their annual effluent and environmental reports. The NRC understands that this information is planned to be publicly available in ADAMS, similar to the annual effluent and environmental reports that are currently publicly available.

Comment G.24: Assessed background radioactivity prior to operation.

One commenter questioned the NRC statement that materials licensees already must assess their background radiation prior to operation. Another commenter argued that materials licensees are not now required by 10 CFR 20.1301(a)(1) to make comprehensive measurements of radioactivity in soil or groundwater before operation to distinguish levels of residual radioactive material from that due to natural background or the operations of others.

Response: The following statement in the proposed rule's preamble is not correct: ''All licensees with operating facilities must have performed an assessment of background radiation prior to operating their facility, to be compliant with the requirements in 10 CFR 20.1301(a)(1)'' (73 FR 3819). The NRC regrets the error. Measuring background before plant operation is not a regulatory requirement in 10 CFR parts 20, 50 or 52. Instead, as stated in Regulatory Guide 4.1, ''Programs for Monitoring Radioactivity in the Environs of Nuclear Power Plants,'' a licensee or license applicant for a nuclear power plant should initiate preoperational monitoring 2 years before operations to provide a sufficient data base for comparison with operational data. This would include surveys of background radioactivity.

Comment G.25: The proposed rule effectively eliminates the option to use restricted release for license termination.

A commenter stated that the intent of the proposed rule is to address significant amounts of residual radioactivity at a site in order to achieve effective decommissioning planning. The proposed rule assumes that for operating facilities, these events would result in a quantity of residual radioactivity that would later require remediation during decommissioning in order to meet the unrestricted use criteria of 10 CFR 20.1402. The established approach for determining the cost under ALARA is not factored into the proposed remediation decision. Further, as currently worded, the proposed rule and draft regulatory guidance have the apparently unintended consequence of eliminating the ability to use the restricted release criteria at license termination, because a spill has to be remediated to the Derived Concentration Guideline Levels (DCGLs) for unrestricted release of the site. If the licensee does not remediate to the screening DCGLs, it must put money into its decommissioning fund to remediate such that the license can be terminated for unrestricted use of the site.

Response: The NRC does not agree that it is effectively eliminating licensees' use of the restricted release option for license termination. On the contrary, the changes being made to 10 CFR 30.35(e)(1)(i)(B), 40.36(d)(1)(i)(B), 70.25(e)(1)(i)(B), and 72.30(b)(2)(iii) allow licensees during facility operations to base their DFP on the 10 CFR 20.1403 restricted release criteria, if the licensee can demonstrate its ability to meet the provisions of § 20.1403. The NRC will accept a reasonable methodology used by a licensee to (1) evaluate remediation costs that support a licensee's decision regarding its response to a spill or leak and (2) demonstrate that the licensee is achieving doses at the site that are ALARA. The DCGL screening criteria in NUREG 1757, Volume 1, Rev. 1, ''Consolidated NMSS Decommissioning Guidance,'' apply when the site is a relatively simple site with residual radioactivity in topsoil, typically in the top 15 centimeters of surface soils. For more complex sites with deeper subsurface residual radioactivity, the criteria for significant residual radioactivity may require an evaluation using a more complex modeling code, such as RESRAD or its equivalent, to determine whether the subsurface residual radioactivity is significant with respect to decommissioning criteria of 25 mrem per year TEDE. The DG–4014 proposes more guidance to licensees on this topic.

Comment G.26: Reporting and recordkeeping requirements.

Numerous commenters addressed the reporting and recordkeeping requirements. Most were critical, although for widely differing reasons. Several commenters criticized the requirements as unnecessary or too broad. One agreed that documentation of subsurface contamination should be placed in decommissioning records. However, the commenter stated that a small leak or spill inside a building that is promptly cleaned up is not a decommissioning issue. Thus, the commenter objected to references to ''any'' leakage or spills. Another commenter stated that licensees are currently required to report significant environmental impacts to both NRC–Agreement State agencies and the EPA. A commenter from a power reactor stated that reporting rules under Part 20 were unnecessary because of the requirements already in place in 10 CFR 50.75(g). One commenter also pointed to potential double counting, noting that 10 CFR part 20 prohibits gaseous effluent releases to the atmosphere above regulatory limits. In accordance with 10 CFR part 50, Appendix I, releases within regulatory limits must account for the dose to the public. Thus, low levels of radioactivity could be deposited onto the site due to rainout, washout and other means, which could then leach into the subsoil. The proposed rule does not consider that these gaseous effluents are accounted for at the time of their release, causing them to be counted again. Finally, one commenter stated that if the proposed rule is finalized, more than 60 days will be needed to implement it. At least a year should be provided to prepare the required reports.

Response: Licensees are responsible for completing decommissioning activities and thus must, for decommissioning planning purposes, determine which leaks and spills must be documented. The NRC has removed its reference to ''any'' leakage or spills in DG–4014. The NRC agrees that

gaseous effluents that are properly discharged in accordance with 10 CFR part 20 to an unrestricted area are no longer the responsibility of the licensee. However, because onsite unlicensed material is sometimes co-mingled with licensed radioactive material (for example from leaks or spills) and generally cannot be distinguished from or separated from licensed radioactive material, both licensed and unlicensed radioactivity (*e.g.,* from returned or reused effluents) at the site are the responsibility of the licensee, during operations and during decommissioning. The control of residual radioactivity at the site during operations ensures that the 10 CFR part 20 Subpart E criteria for unrestricted release will be met at the time of decommissioning. The NRC agrees with the commenter on the effective date of the final rule and has established an implementation period of eighteen months following publication of the final rule in the **Federal Register**.

Comment G.27: Public documentation of spills and leaks.

Several commenters argued that the proposed rule was inadequate because, although licensees are required to keep records of spills and leaks on site, they are not required to notify NRC regional office or headquarters that such spills and leaks have occurred. Thus, information about spills and leaks will not be added to the ''public side'' of the Commission's ADAMS document management system, nor will the Commission ever ''possess'' a document for purposes of the Federal Freedom of Information Act. The proposed rule will not enable the public to see the company's memo documenting the leak, spill, or plume. These commenters argued that the final rule must require that all licensees submit their documentation of spills and leaks to the NRC and that the NRC promptly make such documentation available to the public. One stated that operating facilities must be required to inform state and local officials of the following, with follow-up notification to the NRC: (1) Onsite leaks and spills into groundwater and (2) onsite or offsite water sample results that exceed established criteria in the radiological monitoring program. Another said that all surveys and reports of leaks and spills prepared pursuant to § 20.1406, § 20.1501 and § 50.75(g) must be submitted to the NRC and disclosed to the general public through publication on the NRC'S ADAMS Database.

Response: The proposed rule did not contain new reporting requirements regarding spills and leaks, and the issues raised in this comment are not within the scope of this rulemaking.

H. Financial Assurance Mechanisms and Reporting

Comment H.1: Need for regulations.

Several commenters argued that the current decommissioning rules in 10 CFR parts 20, 30, 50, 70, and 72 already provide reasonable assurance of adequate protection of public health, safety, and the environment related to decommissioning, and that therefore new and additional financial assurance requirements are unnecessary. One commenter, whose comments were endorsed by several other commenters, cited that statement in SECY–03–0069 that ''no licensee providing a parent company or self-guarantee has entered bankruptcy or has failed to proceed with decommissioning projects in an adequate manner.'' This commenter further quoted the SECY statement that the NRC ''staff has not observed an example of an NRC licensee whose decommissioning funding fell short because of inadequate disclosure of the licensee's financial position.'' One commenter stated that the proposed rules contained some modest improvements in financial assurance for materials facilities and interim spent fuel storage installations but argued that it did nothing to require licensees of operating power reactors to set aside sufficient funds for decommissioning.

Response: The proposed rule did not identify any changes to financial assurance requirements specifically applicable to licensees of operating power reactors. Thus, comments arguing for such changes are outside the scope of this rulemaking and will not be considered here.

The NRC agrees with the other commenters that an extensive revision to the financial assurance requirements applicable to operating reactors is not necessary, because in general the current requirements have worked effectively since they were promulgated in 1988. However, since then, the financial industry, accounting standards, bankruptcy law, and commercial law and practices have evolved, and the NRC periodically amends its financial assurance rules to address these changes. The NRC disagrees with the commenters that the current rules are fully adequate and require no changes to update or improve them. The agency's goal is to address potential risks to the financial assurance system as they are identified, rather than waiting until the risks manifest themselves as delays in decommissioning or the addition of more legacy sites.

Comment H.2: Financial tests.

One commenter stated that the current financial tests in Appendix A (Parent Company Guarantee) and Appendix C (Self-Guarantee) of Part 30 have proved to be an economical way for materials licensees to demonstrate financial assurance sufficient to fund decommissioning efforts. The NRC has not demonstrated a need, and in fact it is unnecessary, to impose greater restrictions in those tests to provide reasonable assurance of decommissioning funding. Another commenter expressed support for the clarification in the proposed rule that adjustments of ''+'' or ''−'' to bond ratings are included. However, another commenter questioned the proposed requirement that bond ratings be for the most recent ''uninsured, uncollateralized, and unencumbered'' bond issuance. The commenter stated that the NRC had not presented any evidence concerning the need for this change, particularly because ratings for senior secured debt are a relevant indicator of good financial health. The same commenter argued that although annual reevaluation of the financial test was already the practice, such reevaluations should not be required to be certified by an independent Certified Public Accountant (CPA).

Response: Although the NRC agrees that the current parent company guarantee and self-guarantee mechanisms have been effective means of demonstrating financial assurance, it believes that the revisions to the financial tests that determine eligibility to use the guarantees will strengthen the tests and thereby increase the assurance provided by the guarantees. Other changes will codify established NRC practice. The NRC currently allows the use of ''+'' and ''−'' bond ratings. The requirement for ''uninsured, uncollateralized, and unencumbered'' bonds is currently part of some, but not all, financial tests used by the NRC, and the agency is making all the tests consistent with respect to this criterion. The NRC is convinced that this requirement is desirable and increases assurance. An uninsured, uncollateralized, and unencumbered bond rating is an opinion as to the issuer's ability to meet its repayment obligations in a timely manner. Rating agencies typically go through an extensive financial evaluation process and credit analysis before they assign ratings to the debt of an organization, including meeting with management, examination of financial statements, research into industry and market conditions, and review of non-publicly available information obtained from the

organization. However, bonds that are insured, collateralized, or encumbered are not rated in the same manner. Instead, the rating of insured bonds is based on the rating assigned to the insurance company and can change significantly if that rating changes. The NRC notes recent public discussions of sudden declines in the rating of insured debt instruments based on declines in the rating of the insurers. Similarly, the rating of collateralized bonds depends on an evaluation of the quality of the collateral, rather than an evaluation of the underlying financial condition of the bond issuer and can change quickly and significantly if the quality of the collateral declines. Bonds issued for certain purposes (usually by public entities) may be tied (encumbered) to property that is affected by activities paid for by the revenues from the bonds, and the property may, in turn, serve as collateral for the bonds. The ratings for such bonds may be affected by all of these factors. Therefore, the NRC requires that when bonds are used as part of a demonstration that the firm can pass a financial test, the bonds are uninsured, uncollateralized, and unencumbered. With respect to CPA certifications, this requirement is currently part of the financial tests, and the NRC did not propose to revise it. The agency, therefore, is going forward with the changes as proposed.

Comment H.3: Insurance.

One commenter addressed the NRC's decision not to require materials licensees to obtain environmental cleanup insurance/onsite property damage insurance. The commenter agreed with the NRC's assessment that the cost of such insurance would be prohibitive for a very rare event.

Response: In the absence of any comments supporting the inclusion of an insurance requirement, the agency plans to continue tracking the issue but is not adopting such a requirement at this time.

Comment H.4: License transfer application.

The three commenters who addressed this topic supported the proposed requirement to supply financial assurance information as part of a license transfer application. Two comments supported the § 30.34 proposed requirements.

Another commenter supported the proposed addition to 10 CFR 72.50. This commenter pointed to the possibility of a licensee's spinning off a merchant nuclear plant into a new holding company with limited financial assets. The commenter stated that under the current regulations, it remains unclear what financial assurance applicants must provide to the NRC in order to address this issue.

Response: The NRC agrees with the commenters that it is important, before approving a license transfer, to determine whether the proposed license transferee will be able to provide the required financial assurance for decommissioning. Therefore, the NRC is adopting this proposed requirement.

Comment H.5: Tangible net worth requirement increase to $21 Million.

One commenter agreed with the proposal to increase the tangible net worth requirement in the existing financial tests to address inflation since the financial tests were adopted, but argued that the amount of $19 million was based on a calculation performed in 2005. This commenter stated that the NRC should recalculate the proposed $19 million for tangible net worth on the basis of 2007 or 2008 to ensure that it is fully current. The commenter estimated that approximately $21 million would be the more appropriate amount.

Another commenter noted that the proposed rule would also modify Part 30, Appendix C to add a new criterion to the financial test for an entity that would provide a self-guarantee. The proposal would add a requirement for demonstrating a tangible net worth of at least $19 million. The commenter noted that the only basis given for this change is that it would make Appendix C consistent with the financial tests in Appendix A (parent company guarantees) and Appendix D (companies with no outstanding rated bonds). However, the commenter argued that the proposed change is unnecessary—first, because the proposed test ($19 million) has no correlation to the decommissioning obligation and second, because a focus on tangible net worth as a measure of financial stability and risk of default is unnecessary. The commenter stated that for many companies a $19 million tangible net worth test that excludes intangible assets would serve little purpose. The commenter concluded that the NRC should not adopt this requirement.

Response: The NRC agrees with the comment to increase the tangible net worth requirement to $21 million for the financial tests, as discussed in section II.N.7 of this document and has made this change in the final rule text. The NRC disagrees with the second comment regarding the proposed addition to Appendix C of Part 30 of a requirement for licensees and applicants to have a tangible net worth of at least $21 million. Although the $21 million tangible net worth minimum might in some cases be substantially less than the estimated costs of decommissioning, the purpose of this requirement is not to match estimated costs of decommissioning, but rather, as stated in section II.N.7, to provide greater assurance of financial stability and hence a lower likelihood of bankruptcy. Further, as discussed in section II.N.7, the reasons for adopting the tangible net worth test as one criterion for using a guarantee apply today as much as they did when the parent guarantee was established in 1988. Because a tangible net worth of at least $21 million is considered by the NRC as an effective financial threshold among the other financial tests that may be applied by licensees to use a guarantee mechanism, the NRC amended Appendix C of Part 30 to include the $21 million tangible net worth requirement.

Comment H.6: Inclusion of salvage value.

One commenter argued that the NRC should consider allowing DCEs to consider the resale value of product and other valuable assets, determined on a case-by-case basis. The amount could be limited to less than the contingency factor in the cost estimate.

Response: Since the financial assurance requirements were promulgated in 1988, the NRC has taken the consistent position, expressed in guidance until issuance of this proposed rule, that licensees should not take credit in their DCEs for the value of any materials that may be byproducts of the decommissioning process (*e.g.,* salvage value). Estimates of salvage value are considered extremely speculative and uncertain, and allowing such estimates to be included in DCEs as offsets would raise the possibility that the amount of financial assurance would be inadequate if at the time of decommissioning such salvage value could not be realized. Allowing salvage value to be included up to the amount of the contingency factor would subvert the reason for the contingency factor, because it is required to address unforeseen technical situations that increase the cost of decommissioning.

Comment H.7: Assume 1 percent real rate of return in § 20.1403 trust.

Several commenters addressed the proposal to require licensees to assume only a 1 percent real rate of return on funds set aside to provide long-term care and maintenance of sites decommissioned for restricted use. Commenters' positions ranged from support for the proposal to statements that the 1 percent rate was too high and statements that it was unnecessarily low.

Comment H.7.1: One commenter who supported the proposal noted that a

similar provision is currently contained in 10 CFR part 40, Appendix A, Criterion 10, which provides that if a site-specific evaluation shows that a sum greater than the minimum amount specified in the rule is necessary for long-term surveillance following decontamination and decommissioning of a uranium mill site, then the total amount to cover the cost of long-term surveillance must be that amount that would yield interest in an amount sufficient to cover the annual costs of site surveillance, assuming a 1 percent annual real rate of interest. The commenter noted that once reclamation is complete at Title II uranium mill tailings sites, the licensee is required to transfer the land containing the 11(e)2 byproduct to the Federal Government/ Department of Energy (DOE) or to the State government (if the State agrees to accept it) along with funds (a minimum of $250,000 in 1978 dollars or more if necessary) to fund long-term site monitoring and maintenance, assuming a 1 percent real rate of return on the funds. The commenter believed that extending this type of regulation to other licensees is consistent and fair.

Response: No response is necessary.

Comment H.7.2: One commenter criticized the proposed amendment to 10 CFR 20.1403. This commenter argued that the 30-year period of interest rates examined by the NRC resulting in the 1 percent proposal did not adequately represent the highly variable history of interest rates. The commenter argued that the NRC should incorporate the uncertainty of predicting future interest rates into its analysis of the correct rates for long-term care by adopting a sliding and declining interest rate assumption. The commenter cited an academic expert's suggestion for a sliding scale of interest rates ranging from 4 percent (years 1–5) to 0 percent (years 300 and over). However, the commenter did not explicitly endorse the sliding scale provided in its comments.

Response: For the reasons discussed in the January 22, 2008, proposed rule, the NRC's view remains that an assumed 1 percent annual rate of return is an appropriate criterion to qualify for license termination under restricted conditions. From 1975 to 2005, U.S. Treasury Bills returned an average of 1.58 percent per year, and government bonds returned an average of 4.87 percent per year (73 FR 3824; January 22, 2008). Additionally, the method by which the assumed annual real rate of return would be applied is the same as the method required by 10 CFR part 40, Appendix A, Criterion 10 (rule for determining the adequacy of funds provided by a licensee for long-term surveillance and control of tailings prior to the termination of a uranium or thorium mill license). NUREG–0706 provides details to determine the minimum charge for long-term surveillance and control. Pages 14–12 through 14–16 of NUREG–0706, Volume 1 (ML032751663) provide examples of the method, including Table 14.2 that shows different levels of the total fund amount based on three values of annual monitoring expense and three values for the real rate of return. The method used to derive the values in Table 14.2 is known as an annuity that has no definite end, which would be appropriate for long-term surveillance and control of a site contaminated with uranium or thorium. An annuity that has no definite end is a ''perpetuity,'' or a ''perpetual annuity.'' The present value of a perpetuity is equal to the amount of the annual payment, assumed to be in identical amounts each year, divided by the appropriate rate of return. The perpetuity acceptable to the NRC includes the annual payments for an independent third-party to perform the surveillance and control work, including the 25 percent contingency. For example, if the annual payment were determined to be $200,000 at the time the license was terminated, then a minimum amount of $20 million would be required at an assumed 1 percent real rate of return. This method to derive the value of an adequate amount of decommissioning financial assurance is not the same as a sinking fund method, suggested by the commenter, in which a sliding scale of interest rates could be applied over a specified period of time. The NRC considers an assumed annual 1 percent real rate of return on investment to be appropriate for 10 CFR 20.1403(c)(1), as it is for 10 CFR part 40, Appendix A, Criterion 10, even if historically low rates of return prevail for extended periods of time. The method is well suited for assessment of sites for which restricted use is planned for license termination. Accordingly, the NRC is making no change to the rule text in 10 CFR 20.1403(c)(1) in the final rule compared to the proposed rule.

Comment H.7.3: Some commenters argued that the proposed rate to be used in determining the appropriate amount to be set aside in a trust for long-term surveillance and monitoring was too low. They argued that the trust funds should be managed to the standard of care required by State or Federal law or one or more State or Federal regulatory agencies with jurisdiction over the trust funds, or to the standard of care of that a prudent investor would use in the same circumstances. In light of these new restrictions on the handling and segregation of long-term funds, the adequacy of the trust funds should be assessed based on an assumed annual 2 percent real rate of return on investment. This would bring the treatment of long-term surveillance and monitoring funds into line with the other NRC regulatory provisions, such as 10 CFR 50.75(e)(l)(ii), which permit credit for projected earnings using up to a 2 percent annual real rate of return. One commenter noted that the 2 percent real rate of return assumption is already very conservative and is used over very long periods of time, including safe storage (SAFSTOR) periods for shutdown reactors. The commenter asserted that the NRC should not depart from a real rate of return standard that is already adequately conservative. The commenter stated that it did not find the argument for considering the 1 percent real rate of return compelling.

Response: For the reasons discussed in the response to Comment H.7.2, the NRC believes an assumed 1 percent annual rate of return is an appropriate criterion to qualify for license termination under restricted conditions.

Comment H.8: Standby trust established for all guarantees.

Several commenters opposed the proposed requirement that a standby trust fund be set up at the same time that a licensee proposes using a parent company guarantee for financial assurance. One commenter argued that to qualify for the parent-company guarantee, the licensee's guarantor must pass a rigorous financial test with acceptance criteria that banks, which would engage with licensees to establish the standby trust fund, may not satisfy. There would be no need for such a company, particularly with an AAA rating, to establish a trust fund with a bank with a rating that is at the same level or lower. It makes no sense for the NRC to prefer to accept this potentially greater vulnerability. Another commenter noted that a Part 50 reactor licensee may have established a decommissioning trust and be using a guarantee to provide financial assurance for the balance of the decommissioning assurance required. This commenter argued that a standby trust should not be required to support a parent company guarantee if the licensee has already established a decommissioning trust. The same commenter also argues that, for non-reactor licensees, this requirement imposes an unnecessary burden and significant cost, including the cost to develop the trust arrangements and ongoing trustee fees. These costs are not insignificant in the context of the amount of the guarantees

being provided by many non-reactor licensees. Moreover, the cost is simply not justified, given the already very high thresholds for qualifying to give a guarantee (*e.g.,* an investment grade credit rating). A company that drops to a slightly below-investment-grade rating is not necessarily in financial distress. This itself is a very early warning signal, which can be used as the trigger point for requiring the creation of the trust and setting aside of funds, long before the company's ability to fund the guarantee can seriously be questioned. Thus, the commenter suggests that the requirement to establish a trust be imposed at the time that this advance indicator of a potential financial issue arises, and payment under a guarantee is required under the new rules. For reactor licensees, the requirement for an existing standby trust is not a major issue, because existing trust arrangements should qualify to serve this purpose. If this requirement is retained, a clarifying sentence should be added: ''An existing trust established for purposes of meeting the prepayment or external sinking fund methods pursuant to 10 CFR 50.75(e)(1) is acceptable to serve as the ''standby trust.'' This commenter concluded that there is insufficient justification to require additional standby trust agreements for financially sound companies well in advance of the need.

Response: As stated in the proposed rule's preamble, the standby trust is necessary to ensure that if the entity supplying financial assurance is required to provide funds, the funds do not need to go directly to the NRC, which would then be required to remit them to the U.S. Treasury. For funds placed in a standby trust, the NRC can issue instructions to the trustee to expend the funds on decommissioning without facing the possibility of significant delays in carrying out decommissioning. If the NRC has required the guarantor to fund the standby trust, it will be because the parent or self-guarantor no longer can pass the financial test and has not been able to obtain alternative financial assurance in an approved form. Thus, because the financial strength of the parent or self-guarantor at that point will not be sufficient to pass the financial test, the argument about the financial vulnerability of the guarantor versus the vulnerability of the trustee is not relevant. Furthermore, the licensee should be able to set up a standby trust with *de minimis* funding at relatively little cost. The NRC is not aware of any reason that a nuclear power reactor could not revise and use a tax-qualified or non-tax-qualified trust fund that the reactor already has in place as its standby trust. Having the trust in place from the beginning of the time that the licensee relies on a guarantee for its financial assurance will ensure that if the funds are needed for decommissioning, delays will not occur while the trust is set up.

Comment H.9: Parent company guarantor is subject to Commission orders.

One commenter noted that the proposed rule would require that what is essentially a consent order be entered into by a parent company seeking to provide a guarantee on behalf of its subsidiary.

Response: A parent company providing a parent company guarantee on behalf of its subsidiary must agree to be subject to Commission orders to make payments under the guarantee agreement. The NRC believes that the parent company's agreement to be subject to such Commission orders is tantamount to consent to NRC personal jurisdiction. The parent company would be acknowledging that it is subject to NRC subject matter jurisdiction, but it would not be waiving any hearing rights or defenses.

Comment H.10: Joint and several liability for the full cost of decommissioning.

Comment H.10: Several commenters objected to the proposed addition of a new joint and several liability provision to Part 30 Appendix A. The provision (designated as Section III.E in the proposed rule) pertains to the parent company guarantee option that NRC licensees have for providing financial assurance, and states as follows:

> The guarantor must agree that it is jointly and severally liable with the licensee for the full cost of decommissioning, and that if the costs of decommissioning and termination of the license exceed the amount guaranteed, the guarantor will pay such additional costs that are not paid by the licensee.

The comments objecting to this provision are collectively summarized in the following paragraphs.

Adopting the proposed requirement would effectively eliminate the ability of power reactor licensees to combine use of the parent company guarantee method with an external sinking fund method for providing financial assurance. In 1998, NRC changed its rules to specifically permit the current practice of using a parent guarantee in combination with a trust fund balance, a practice which had been prohibited until 1998. Now, under existing 10 CFR 50.75(e)(1)(iii)(B), a parent guarantee for a reactor licensee is expected to conform to the ''guarantee and test as contained in Appendix A to 10 CFR part 30.'' Thus, changing Appendix A to Part 30 impacts how 10 CFR 50.75(e)(1) is applied with respect to approval of parent company guarantees, in which a guaranty is typically provided in a limited specified amount in combination with a trust fund or external sinking fund. For example, if a licensee's trust balance is $350 million, and the NRC required amount of assurance is $360 million, a parent company guarantee may be provided in the amount of $10 million. The parent company is not guaranteeing the full $360 million. The preamble of the proposed rule published January 22, 2008 (73 FR 3818) states that no changes to 10 CFR 50.75(e) requirements were being proposed. Imposing the above joint and several liability requirement on power reactors may thus be an unintended consequence of this proposed change to Appendix A to 10 CFR part 30.

Further examples were cited in which parent company guarantees have been approved by the NRC for power reactor licensees, including Orders in individual license transfer cases that do not provide for joint and several liability between a parent guarantor and licensee. In one such case, a company had acquired an ownership share in a reactor licensee, and the NRC approved a guaranty (given by the parent company on behalf of the acquiring company) to provide financial assurance for the difference between the amount that was deposited in a decommissioning trust account and the NRC's 10 CFR 50.75(c) formula amount for decommissioning. Imposition of a new requirement for the parent to assume joint and several liability above and beyond the amount of the parent guarantee would be a fundamental change, after the fact, to the terms of this transaction. There has not been any practical experience demonstrating a need to impose such a joint and several liability requirement on parent guarantors. The proposed rule's package provides no specific evidence of any vulnerability in a parent guarantee arrangement, only a brief reference to a ''potential'' vulnerability (73 FR 3815). The NRC has not articulated a factual or legal basis justifying this proposed change to Part 30.

The parent company guarantee is a legal commitment to cover costs only up to the guarantee amount. If the proposed requirement is adopted, financial auditors might consider it necessary to require the guarantors to reflect the entire projected cost among their liabilities on their financial statements. This could have the result of negatively

impacting corporate credit ratings and the guarantor's ability to borrow.

Response: Between publication of the proposed rule and this final rule, the NRC staff has reconsidered the joint and several liability issue. For the reasons discussed below, and in consideration of the comments summarized previously, the proposed joint and several liability provision is not included as part of the final rule.

During the 1990's, the NRC took steps to address the deregulation of electric utilities. As part of this effort, a ''Final Policy Statement on the Restructuring and Economic Deregulation of the Electric Utility Industry'' was published on August 19, 1997 (62 FR 44071). In responding to comments on joint ownership issues raised in the draft policy statement, the NRC stated in the policy preamble as follows:

> The NRC recognizes that co-owners and co-licensees generally divide costs and output from their facilities by using a contractually-defined, pro rata share standard. The NRC has implicitly accepted this practice in the past and believes that it should continue to be the operative practice, but reserves the right, in highly unusual situations where adequate protection of public health and safety would be compromised if such action were not taken, to consider imposing joint and several liability on co-owners of more than de minimis shares when one or more co-owners have defaulted. The NRC is addressing the issue of non-owner operators separately. (62 FR 44074).

A proposed rule, ''Financial Assurance Requirements for Decommissioning Nuclear Power Reactors,'' was published on September 10, 1997 (62 FR 47588) wherein the NRC stated in the preamble that:

> The regulations do not explicitly impose joint liability on co-owners and co-licensees. * * * [The NRC] sees no need to impose an additional regulatory obligation of joint liability on co-owners or co-licensees. (62 FR 47594).

In response to requested input on how to address the issue of future funding shortfalls caused by underestimates of decommissioning costs, the NRC noted in this preamble its authority to require power reactor licensees to submit their current financial assurance mechanisms for review and stated the following:

> The Commission reserves the right to take the following steps in order to assure a licensee's adequate accumulation of decommissioning funds: Review, as needed, the rate of accumulation of decommissioning funds; and either independently or in cooperation with either the FERC and the State PUC's, take additional actions as appropriate on a case-by-case-basis, including modification of a licensee's schedule for accumulation of decommissioning funds. (62 FR 47597).

In the final rule published on September 22, 1998 (63 FR at 50465 et seq.), ''Financial Assurance Requirements for Decommissioning Nuclear Power Reactors,'' the above-quoted language from the preamble was codified as 10 CFR 50.75(e)(2), and this provision remains in place today.

In the 1998 final rulemaking, rather than revising the Part 50 definition of ''electric utility'' as initially proposed, the NRC instead amended 10 CFR 50.75 by replacing its references to electric utilities with references to power reactor licensees. This action had the effect of separating issues of whether applicants for reactor licenses are financially qualified under 10 CFR 50.33(f) (where the definition of ''electric utility'' is still relevant) from financial assurance issues for decommissioning under 10 CFR 50.75 (63 FR 50466; September 22, 1998).

In this latter area, the NRC endorsed the need for flexibility given the ongoing restructuring of the electric power industry. For example, situations could arise in which the plant operator has greater financial resources than the plant owner, and the NRC therefore declined to exempt operator licensees from financial assurance for decommissioning requirements (63 FR 50468). Among the 1998 amendments, 10 CFR 50.75(e)(1)(vi) was added, and 10 CFR 50.75(e)(1) was otherwise structured to provide a variety of approved financial assurance mechanisms (63 FR 50469).

In 1998, the NRC similarly endorsed using combinations of financial assurance methods. The 1998 rulemaking removed the regulatory prohibition which did not allow use of either the self-guarantee or parent company guarantee ''in combination with other mechanisms'' (but to avoid double counting the same assets, the prohibition on using the self-guarantee and parent company guarantee ''in combination with each other'' was retained) (63 FR 50473). The combination of a self-guarantee or parent company guarantee and an external sinking fund ''appears to provide a relatively low-cost means'' to provide financial assurance while the reactor licensee continues to ''gradually fund decommissioning costs over time.'' Accordingly, 10 CFR 50.75(e)(1) was amended as described above, which ''eliminated the prohibition on combining parent company or self-guarantees with external sinking funds'' (63 FR 50473).

The proposed Decommissioning Planning rule was published for comment on January 22, 2008 (73 FR 3812). The statement in the proposed rule that no changes to 10 CFR 50.75(e) were being proposed was accurate. But the staff failed to acknowledge the connection between 10 CFR 50.75(e)(1) and 10 CFR part 30, Appendix A. The existing parent company guarantee provisions of 10 CFR 50.75(e)(1)(iii) reference 10 CFR part 30, Appendix A. Thus, adding a joint and several liability provision to the Parent Company Guarantee requirements under Section III of Appendix A to Part 30 would effectively change the 10 CFR 50.75(e)(1) requirements. No such change in requirements was intended, and this was not part of the Decommissioning Planning rule's technical basis.

The decision not to establish a joint and several liability requirements should not be construed to mean that the NRC will never seek to impose such liability on the parent corporation of an NRC licensee. In unusual cases where the legal doctrine known as ''piercing the corporate veil'' may be applicable, the NRC may pursue such a remedy (as it has in the past), and the NRC's previous policies and practices regarding joint and several liability are not being changed at this time. Thus, in taking this rulemaking action, the NRC intends no change in its position regarding its legal right to seek funds from a licensee's corporate parent in appropriate, case-specific circumstances.

Comment H.11: Issues when guarantor is in financial distress.

One commenter, supported by several additional commenters, argued that the proposed rule is overly harsh in requiring payment of the guarantee if a triggering event occurs. Options short of such payment should include use of a third party letter of credit. The rules should be revised to provide that upon NRC's determination that the guarantee is no longer acceptable, it may be replaced by another acceptable form of financial assurance.

Response: The current decommissioning financial assurance rules allow a licensee that has previously relied upon a parent guarantee or self-guarantee, but which no longer can do so because it or its parent cannot pass the financial test, to obtain a replacement form of financial assurance. However, if a guarantor's ability to pay its debts is compromised, then the NRC may seek immediate payment of the entire DCE, or a lesser amount if the guarantee is combined with another financial assurance mechanism, to the standby trust. Under the existing financial assurance requirements, a licensee must notify the NRC in writing immediately following

the filing of a bankruptcy action. The revisions to the requirements provide a more detailed description of the information to be provided in such a situation, as previously set forth in guidance.

Comment H.12: Elimination of the escrow.

Several commenters supported retention of the escrow as a financial assurance mechanism. One commenter argued that NRC lacked a clear basis for eliminating the escrow, stating that the escrow account is a sound financial instrument that is protected to the same extent as a trust fund during bankruptcy. It stated that NRC's arguments that a dedicated trust fund should be outside the reach of creditors in a bankruptcy also would apply to a dedicated escrow account. The commenter noted that in cases where the amount of decommissioning funding assurance is relatively small (*e.g.,* $100,000), use of an escrow account may be less expensive and more appropriate, because the cost of trust arrangements and annual trustee fees may be prohibitive. While eliminating the escrow option would thus particularly impact small materials licensees, small minority owners of power reactors during decommissioning may also want to use an escrow account. Two other commenters said that NRC should not limit the options (instruments) available for financial assurance, and noted that Agreement State licensees were using escrows.

Response: As stated in the proposed rule's preamble, the NRC does not agree that escrows are as secure as trust funds in the event of bankruptcy (73 FR 3819), and the commenter's general statements to the contrary are not persuasive. While the NRC agrees that a number of financial assurance options should be available, the NRC must balance cost and availability with other factors, including especially the ability of the mechanism to provide funds for decommissioning when needed. The NRC has evaluated the likelihood that an escrow could survive the bankruptcy, insolvency, or financial incapacity of the licensee, and concluded that in comparison to other financial mechanisms like the trust, surety bond, or letter of credit, the escrow is significantly less secure. The EPA decided in 1981 not to add the escrow account as an approved financial assurance mechanism (January 12, 1981; 46 FR 2827). Based on these considerations, the NRC is removing the escrow from the list of approved mechanisms in 10 CFR 30.35(f)(1), 40.36(e)(1), 70.25(f)(1), and 72.30(e)(1). Note that this rulemaking does not eliminate use of escrows as an option for Part 50 licensees. Power reactor licensees are allowed to continue their use of an escrow account, pursuant to 10 CFR 50.75(e), due to an unintentional omission by the NRC to include paragraphs 10 CFR 50.75(e)(1), (h)(1), and (h)(2) in the scope of the proposed rule text. The NRC plans to propose that regulatory change in the future in a separate rulemaking.

Comment H.13: Elimination of the line of credit.

One commenter supported retention of the line of credit, noting that while no NRC licensees were apparently using a line of credit for financial assurance, such is not the case with respect to Agreement State licensees.

Response: The NRC finds that a letter of credit—which will be available for use—has many of the attributes in terms of cost and availability as a line of credit, but provides greater security. A line of credit can be cancelled quickly if certain financial conditions are not met, while a letter of credit represents a more binding obligation of the financial institution. Based on these considerations, and those discussed in the proposed rule's preamble (73 FR 3826), the NRC is removing the line of credit from the list of approved mechanisms in 10 CFR 30.35(f)(1), 40.36(e)(1), 50.75(e)(1)(iii)(A), 70.25(f)(1), and 72.30(e)(1).

Comment H.14: Allowing intangible assets in the determination of total net worth.

Some commenters disagreed with the proposal to allow intangible assets to be used in the determination of total net worth for purposes of meeting the financial test applied to those seeking to use a parent company or self-guarantee financial assurance method. Two commenters, including CRCPD, pointed to recent overvaluing of bundled mortgage assets and said that in light of this experience, the NRC should reconsider allowing intangible assets to be used in conjunction with an investment grade bond rating to meet financial test criteria.

In contrast, several commenters representing both materials licensees and reactor licensees stated that consideration of intangible assets should be allowed. One commenter noted that the NRC had already granted an exemption to one licensee allowing a company with an investment grade bond rating to consider intangible assets to meet the 10 times ratio test. The commenter noted that intangible assets generally include assets such as goodwill, brand value, or patents and that, as recognized in the proposed rule's preamble (73 FR 3812, 3825), financial accounting standards issued after 1988 (when the NRC's original decommissioning rule was adopted) provide objective methods for valuation of such intangible assets. According to the commenter, for a diversified technology and manufacturing company with a history of acquisitions intangible, assets are a significant measure of the financial stability of the company. Another commenter stated that permitting the consideration of intangible assets is an appropriate change in light of the development of objective methods to value intangible assets.

Response: The NRC agrees with this latter set of comments. The NRC has examined a sample of firm financial reports to ensure that confirmatory information about intangible assets could be obtained from publicly available quarterly and annual reports of publicly traded firms. The NRC finds that bundled mortgage assets are sufficiently dissimilar to intangible assets that the recent problems associated with bundled mortgages do not provide a basis for withdrawing this provision from the final rule. On the basis of these considerations and those discussed in section II.N.6 of this document, the NRC will allow the use of intangible assets.

Comment H.15: CPA evaluation of off-balance sheet transactions.

A commenter opposed the requirement that the CPA provide information about off-balance sheet transactions, stating that it was already difficult to meet the timetable for annual submittal of the financial assurance report, which already must be reviewed by a CPA. The commenter consulted with an independent accountant, who said that meeting the additional requirements would take considerable more evaluation time at a greater cost. According to the commenter, if the proposed provision is adopted, the date for submission of financial assurance reports will need to be extended by at least one month to allow reasonable performance of the additional evaluation. Another commenter argued that CPA certification was an unnecessary burden and cost, because company officials are already required to submit information that is complete and accurate in all material respects, and this should provide adequate assurance that the financial information is being evaluated by qualified company personnel.

Response: Firms may, as a means of reducing risk or achieving tax minimization opportunities, account for certain kinds of transactions off the company's balance sheet. Recent

experience has shown, however, that such off-balance sheet transactions may constitute a source of risk to the firm. Information should be readily available concerning such transactions, particularly for publicly traded firms. Section 401(a) of the Sarbanes-Oxley Act of 2002 requires disclosure of off-balance sheet transactions that may be material. In 2003, the Securities and Exchange Commission issued regulations to implement Section 401(a). The AICPA has prepared materials for company audit committees and accountants on the identification and evaluation of such transactions. The NRC therefore finds that the proposed requirement will be neither difficult nor unduly expensive for licensees to meet. The NRC is therefore retaining the proposed requirement in the final rule.

Comment H.16: CPA verification of bond ratings.

One commenter opposed the proposed new requirement for certification by an independent CPA of a parent company's or a licensee's bond ratings as part of showing that the criteria for using a parent company guarantee or self guarantee are met (as set forth in 10 CFR part 30 Appendices A and C, respectively). The commenter stated that this new requirement would impose an additional unnecessary burden and cost. Company officials now are required to submit information that is complete and accurate in all material respects (*e.g.,* 10 CFR 30.10, 40.10, 50.5, 70.10, and 72.12). This should provide adequate assurance that the specific bond rating is being evaluated by qualified company personnel, and if the importance of such information needs to be emphasized the rule could simply require a company to certify its accuracy.

Response: In the past, those addressing the 10 CFR part 30 Appendices A and C financial test criteria have frequently failed to correctly apply the requirement to use the current rating of the most recent bond issuance. As stated in the proposed rule's preamble (73 FR 3826), the NRC finds that requiring an audit of the bond rating will minimize the potential of future such errors being made. An independent CPA is already required to audit the financial test data for a parent company and a self guarantee, and adding the verification of a bond rating to this existing audit is not a significant burden.

Comment H.17: Requirement to base DFP on unrestricted release.

Two commenters supported the proposal to require licensees to base their DFPs and DCEs on unrestricted release, unless they can show the ability to meet the restricted release criteria. Making early funding arrangements to cover the increased costs of unrestricted release will increase the likelihood that the funds will be available when needed.

Response: The NRC agrees with these comments. Based on these considerations, and those discussed in the proposed rule's preamble (73 FR 3818), the NRC is retaining the proposed requirement in the final rule.

Comment H.18: Basis for the cost estimate in the DFP.

One commenter argued that the DFP should include an estimate of the funds necessary to pay licensing fees. The public should not have to pay the costs of inspections, document reviews, license amendments, and other NRC regulatory activities when a license is taken over by an independent third party. Nor should a licensee be exempted for annual fees that ordinarily would have been assessed. Recovery of these fees should be part of any financial assurance.

Response: Applicable guidance (section A.3.17 of NUREG–1757, Volume 3, Appendix A, ML032471471) specifies that one of the miscellaneous costs that should be included in the DCE is licensing fees. But making this a regulatory requirement was not proposed in the draft rules published for public comment. The NRC thus views this comment as raising issues that are outside the scope of this rulemaking.

Comment H.19: Basis for certification.

Two commenters argued that DCEs should be based on a licensee's actual radionuclide inventory, rather than on license limits. Both stated that, for example, broad scope licensees may be licensed to possess multi-Ci quantities of a broad range of radionuclides, but may actually possess only limited quantities of radionuclides in a narrow range. The DCEs should be based on the historic use as indicated in licensee inventory records.

Response: This concern is addressed in part by existing regulations in 10 CFR parts 30, 40, and 70, allowing licensees holding limited amounts of licensed material to certify and to provide specified amounts of financial assurance. Such licensees need not submit a DCE and DFP to the NRC for approval. The NRC recently updated the certification amounts in another rulemaking, and in the current rulemaking is updating NUREG–1757, Volume 3, Appendix A, Attachment 1 to reflect those changes to certification amounts. However, the agency did not propose in this rulemaking to revise the certification amounts or the basis upon which a licensee determines the certification amount it must provide. Therefore, the request to base the certification amounts on actual radionuclide inventory is not within the scope of this rulemaking.

Comment H.20: Use of third-party costs.

One commenter opposed the proposed requirement in § 30.35(e)(1)(i)(A) that each DFP must be based on the cost of an independent contractor to perform all decommissioning activities. It stated that its industry had extensive experience using licensee staff to perform decommissioning, and made use of custom-designed equipment that only licensee staff was experienced in using safely. Use of licensee staff, according to the commenter, provided the optimum cost effective schedule.

Response: The rule is not intended to preclude the use of licensee staff to carry out decommissioning activities. However, the financial assurance requirements are designed to provide the funds necessary to carry out decommissioning activities even when the licensee is no longer present or financially able to do so and, as a consequence, licensee staff are not available to perform decommissioning. Thus, the NRC has recommended in guidance since 1988 that DFPs be based on the use of third party contractors, which as the commenter notes are likely to be more expensive than licensee staff, to ensure that if third party contractors must be relied upon the necessary funds are available. The proposed rule codifies the previously mentioned guidance.

Comment H.21: Timing of preparation of DFP and DCE.

One commenter stated that the proposed requirement in § 30.35(e)(2) to submit a DFP at the time of license renewal, in addition to submitting one at intervals not to exceed 3 years, would cause an excessive frequency of submissions, because the license renewal interval is typically 5 years. The commenter suggested that submission of an updated DFP be required only at the time of license renewal, or when a substantive change is necessary, or as specified as a license condition. Of these alternatives, the commenter recommended specifying the renewal period as a license condition, possibly on the order of 5 to 6 years. The commenter argued that improvements in operations tended to cancel out inflation in the costs of decommissioning and waste disposal.

Response: Frequent revisions are desirable to ensure that the DCE remains accurate and reflects current prices for labor and materials, even in periods of rapid inflation. On balance, the NRC

finds that the benefits of frequent revisions to the DCE outweigh the costs, and that revisions should be submitted as part of a license renewal request in addition to being submitted every 3 years.

Comment H.22: Status of DFPs for operating power reactors.

One commenter criticized the proposed rule on the basis that it would require all types of licensees, except licensees of operating power reactors, to submit a DFP to the NRC if during the site survey the licensee detects radioactive contamination that would have to be removed during decommissioning. Under the proposed rule, the licensee would have a year after detection of the contamination to submit the funding plan or update to the NRC. The commenter supports this concept, and notes that it may in some instances serve as an incentive to minimize contamination so that the licensee does not have to go to the trouble and expense of preparing or updating a DFP and setting aside additional decommissioning funds. But, the commenter claims, the flaw in the NRC's proposed changes to 10 CFR 30.35, 40.36, 70.25, and 72.30 is the apparent exemption being granted to power reactor licensees. According to the commenter, a survey of a power reactor site may detect an amount of contamination that materially increases the cost of decommissioning, yet the NRC proposes to give such a licensee the option of doing nothing more than recording the information in the plant's decommissioning planning records. This is not acceptable and is not protective of long-term public safety.

Another commenter objected to the proposed rule's failure to require full public reporting of the factors used to estimate decommissioning costs and the NRC's failure to set a specific and responsible deadline for licensee submission of DFPs incorporating costs stemming from known subsurface contamination. The commenter urged the NRC to require power reactor, dry cask storage, and materials licensees to thoroughly survey their facilities for contamination within six months of the final rule's effective date and submit a survey report and a DFP within a year of that date. The commenter said that the NRC also should require reactor licensees to submit an updated DFP to the NRC within a year of discovery of site contamination.

Response: Existing 10 CFR part 50 regulations (*e.g.* § 50.75 and § 50.82) contain a comprehensive set of decommissioning requirements that are unique to power reactors. The NRC does not agree that these requirements fail to adequately protect public health and safety. Moreover, in the proposed rule's preamble, the NRC stated that it was making no changes with respect to the obligated amount for power reactor decommissioning financial assurance (73 FR 3818). Because the proposed rule did not address the manner or amount of financial assurance required for nuclear power reactors, comments seeking such actions are outside the scope of this rulemaking.

Comment H.23: Potential redundancy in DFP requirements.

Two commenters stated that in proposed § 72.30(b), paragraphs (b)(1) and (b)(4) are partially redundant and should be merged. The commenter also noted that the comment also related to the proposed rules in 10 CFR parts 30, 40, and 70.

Response: The NRC disagrees that paragraphs (b)(1) and (b)(4) should be merged. Section 72.30(b) previously read as follows:

> ''(b) The proposed decommissioning plan must also include a decommissioning funding plan containing information on how reasonable assurance will be provided that funds will be available to decommission the ISFSI or MRS. This information must include a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from paragraph (c) of this section, including means of adjusting cost estimates and associated funding levels periodically over the life of the ISFSI or MRS.''

In the proposed rule, 10 CFR 72.30(b)'s first sentence has become paragraph (b)(1), which states the overall general obligation regarding the DFP. The proposed requirement in paragraph (b)(4) largely repeats the text in the last sentence of the preceding paragraph, describing in detail the method of assuring funds. Both paragraphs (b)(1) and (b)(4) have independent utility—just as the two sentences in the former 10 CFR 72.30(b) had—so no change in the final rule will be made in response to this comment.

Comment H.24: Implementation schedule for submission of revised DFPs.

Several commenters addressed the implementation of the revised DCE and DFP requirements. One commenter urged the NRC to allow at least 1 year for licensees to prepare and submit their first updated DFPs and to state this submittal time in the final rule. Another suggested that the NRC should consider a time frame of 5 years for implementation, because existing sites would face significant costs retrofitting or upgrading their facilities.

Response: The NRC has established the final rule effective date to be eighteen months following publication of the final rule in the **Federal Register.** This provides sufficient time to respond to the revised DFP requirements. The NRC concluded that adoption of a period as long as 5 or 6 years between revisions of the DFP could cause the DCEs to fall substantially out of date.

Comment H.25: Special requirements for 10 CFR part 72 licensees.

Comment H.25.1: One commenter, supported by several additional commenters, noted that proposed rule section 10 CFR 72.13 states that only § 72.30(e) and (f) apply to ISFSI general licensees (holders of a Part 50 License). The commenter believes that the basis for excluding ISFSI general licensees from compliance with the new requirements in proposed rule § 72.30(b), (c), and (g), was that these licensees have a Part 50 license and, therefore, have accumulated or have access to adequate funds for decommissioning. However, the commenter argued that as written the proposed rule § 72.30(b)(2)(i) would require holders of a Part 50 license, who are also Part 72 specific licensees, to submit a separate DCE for their ISFSI. This effectively prohibits the Part 50 licensee from continuing to include in the Part 50 DCE, the ISFSI decommissioning costs and related assumptions. The commenter urged the NRC to revise the proposed rule to allow a Part 72 specific licensee, who also holds a Part 50 license, to continue to include in the Part 50 DCE the ISFSI decommissioning costs and related assumptions. The same commenter also noted that, as written, the proposed rule § 72.30(c) would require holders of a Part 50 license, who are also Part 72 specific licensees, to report their adjusted ISFSI DCE information to the NRC at intervals not to exceed 3 years. Part 72 specific licensees that have a Part 50 license normally have included costs for decommissioning of the ISFSI in their Part 50 DCE. The proposed rule should be revised to allow a Part 72 specific licensee with a Part 50 license to continue to report their ISFSI DCE information to the NRC in their Part 50 DCE submittal using the Part 50 reporting interval.

Response: This rulemaking revises § 72.30(b), and adds new paragraphs (c), (d), and (g). Existing paragraph (c) is redesignated as paragraph (e), and existing paragraph (d) is redesignated as paragraph (f). Section 72.13(b) references the Part 72 provisions applicable to those holding Part 72 specific licenses, and 10 CFR 72.13(c) references the Part 72 provisions applicable to those holding Part 72 general licenses. Thus, any amendments

to 10 CFR 72.30 need to be reflected in 10 CFR 72.13.

In considering this comment, the NRC realized that the proposed changes to 10 CFR 72.30—as published in the January 22, 2008, proposed rule—are not fully reflected in the discussion there of the proposed amendments to 10 CFR 72.13. While the NRC correctly stated in its January 2008 proposed rule that 10 CFR 72.13(c) was being amended to reference 10 CFR 72.30(e) and (f)—reflecting the fact that existing 10 CFR 72.13(c) references 10 CFR 72.30(c) and (d)—the proposed revisions to paragraph (b), and the addition of new paragraphs (c), (d), and (g) to 10 CFR 72.30 are not referenced in the discussion of 10 CFR 72.13. As discussed further in this document, the NRC is correcting the inadvertent omissions in the final rule, and finds that Part 72 general licensees were fairly on notice that they were subject to revisions in DFP requirements due to the provisions of existing § 72.30(d)(4).

As stated previously, existing 10 CFR 72.13(c) references 10 CFR 72.30(d). Thus, those holding Part 72 general licenses are subject to the 10 CFR 72.30(d) requirements, including the DFP provisions referenced in 10 CFR 72.30(d)(4). The new provisions in 10 CFR 72.30(b) provide further details of what initial DFPs must include. New paragraph (c) of 10 CFR 72.30 provides a set of timing provisions describing when updated DFPs must be submitted for NRC approval. New paragraph (d) of 10 CFR 72.30 is a special 1-year DFP update provision based on 10 CFR 20.1501 survey results. Together, these new DFP requirements, for purposes of applicability, should be treated the same as the existing 10 CFR 72.30(d)(4) DFP provisions, as it would make no sense to have some but not all DFP requirements be applicable to Part 72 general licensees.

Existing 10 CFR part 72 subpart K requirements already impose similar requirements on Part 72 general licensees. Existing 10 CFR 72.218(a) references 10 CFR 50.54(bb), which is the functional equivalent of a DFP provision in requiring a one-time report setting forth the licensee's program to provide funding for management of spent fuel during the time between when the reactor shuts down and when DOE accepts title to and takes possession of the spent fuel. Existing 10 CFR 72.218(a) further requires that a plan be identified for removing spent fuel from the reactor site in connection with decommissioning activities. Part 72 general licensees are thus already subject to spent fuel funding requirements. Similarly, 10 CFR 72.218(b) references 10 CFR 50.82, stating that such applications must describe how spent fuel will eventually be removed from the reactor site.

A further reason that the new 10 CFR 72.30 provisions referenced previously are applicable to Part 72 general licensees is the connection that some of the provisions have (10 CFR 72.30(b)(2)(iii) and (b)(5), and 72.30(d)) with 10 CFR part 20 requirements. Such requirements are applicable to the Part 72 general licensees, because Part 20 is applicable to all Part 50 licensees.

Accordingly, the final rule amends 10 CFR 72.13(c) so that it correctly references 10 CFR 72.30(b), (c), (d), (e), and (f) as being applicable to holders of Part 72 general licenses.

The requirements of new 10 CFR 72.30(g)—under which licensees must replenish fund levels if decommissioning funds fall below specified levels—are unlike the previously referenced DFP and related requirements in that no similar provisions now exist in either Part 72 or Part 50. Additionally, the January 2008 proposed rule gave no notice that any such provisions would be added to Part 50, and a Part 72 general licensee can only be subject to requirements that a Part 50 licensee is subject to. Accordingly, new 10 CFR 72.30(g) will be applicable only to holders of Part 72 specific licenses. There is no need to amend 10 CFR 72.13(b) in this regard, because it already specifies that 10 CFR 72.30 requirements apply to holders of Part 72 specific licenses.

Comment H.25.2: Another commenter argued that the NRC had approved partial exemptions from 10 CFR 72.30(c)(5) for Part 72 specific licensees to continue to rely on 10 CFR 50.75(e)(1)(ii)(A) as their exclusive mechanism for providing financial assurance for ISFSI decommissioning, even after the reactor's Part 50 license was terminated. This commenter also encouraged the NRC to allow Part 72 specific licensees that no longer have a power reactor license under Part 50 to continue to use the methods of 10 CFR 50.75(b), (e), and (h) without the need for an exemption. The commenter provided recommended wording changes to 10 CFR 72.30(e)(5) to achieve this result.

Response: The NRC agrees with these comments and has made the suggested changes to the final rule text in § 72.30(e)(5), as discussed further in Section IV of this document.

Comment H.25.3: A commenter stated that to meet the requirements of this rule change, a Part 72 specific licensee will need a considerable amount of time and resources to prepare this DFP and its detailed DCE for submittal to the NRC. It is recommended that the NRC provide at least one year following the effective date of the rule change for Part 72 specific licensees to prepare and submit their first updated DFP. This submittal time should be stated in § 72.30(c) of the final rule.

Response: NRC agrees with this comment, except that there is no need to specify a submittal time in § 72.30(c). As explained in Section II.S of this document, an eighteen-month implementation period is provided for all of the final rule requirements (except for the reporting provisions in 10 CFR 50.82(a)(8)(v) and (vii), which are due by March 31, 2013).

Comment H.25.4: Several commenters cited the proposed provision in § 72.30(c) which states: ''If the amount of financial assurance will be adjusted, this cannot be done until the updated decommissioning funding plan is approved.'' The commenters asked why increases could not occur before approval of the DFP. One commenter noted that § 72.54(e) currently states that, ''the amount of financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning * * *'' and recommended that the wording in the last sentence to proposed § 72.30(c) be changed to read as follows: ''If the amount of financial assurance will be decreased, this cannot be done until the updated decommissioning funding plan is approved.''

Response: The NRC agrees with the commenters that it needs to approve only reductions in the amount of financial assurance in the DFP. In conformance with this comment, the NRC has made changes to the final rule text in § 30.35(e)(2), § 40.36(d)(2), § 70.25(e)(2), and § 72.30(c).

Comment H.25.5: A commenter noted that Part 72 does not have provisions for an ISFSI licensee to certify to a prescribed amount of financial assurance like Parts 30, 40, and 70 material licensees do. Therefore, the § 72.30(f)(4) wording, related to certifying to a prescribed amount of financial assurance, should be deleted and § 72.30(f)(4) reworded as: ''(4) Records of the cost estimate performed for the decommissioning funding plan and records of the funding method used for assuring funds are available for decommissioning.'' The same commenter recommended changes in cross references in Part 72 to address proposed rule changes.

Response: The commenter has identified a technical error in the existing regulations which was not identified in the proposed rule. Because

the suggested action to remove ''amount certified for decommissioning'' constitutes a technical correction, the NRC is making the correction in Part 72, even though it was not previously proposed. The NRC is also correcting cross references in the final rule.

Comment H.26: Monitor decommissioning fund investment balance.

Comment H.26.1: Several commenters disagreed with the proposed regulations in 10 CFR 30.35(e)(1)(iv), 40.36(d)(1)(iv), 70.25(e)(1)(iv), and 72.30(b)(6) requiring that if there are changes to the DCE, the amount of financial assurance must be revised to match the cost estimate. One commenter agreed that licensees might consider increasing decommissioning assurance when remediation costs exceed the initial DCE but said the increase should not be a requirement. The actual remediation costs could exceed DCEs due to a licensee deciding for business purposes to choose an expensive method to remediate. This might be to minimize a business interruption or to organize the remediation around ongoing operations. Another commenter stated that the new rules require that additional financial assurance must be provided each year, if there is any shortfall in existing assurance levels. An annual assessment of financial assurance is already required by 10 CFR 50.75(b)(2), but the new rules would impose a firm requirement, which would be less flexible than the NRC's current case-by-case evaluation of the funding plans for shutdown reactors. To assure that the new rule is not interpreted as a departure from current practice, the commenter recommended that the NRC revise the language to provide that either additional assurance be provided or that the licensee submit an acceptable plan for obtaining additional assurance.

Response: Decommissioning financial assurance is required in the amount of the DCE. Just as a licensee that has not used its financial assurance proceeds wisely to remediate a site is still required to provide financial assurance to complete the remediation work, a licensee that decides to use a more expensive remediation method is required to provide financial assurance to cover the entire cost estimate. A plan for obtaining additional assurance is not considered financial assurance, and allowing a licensee to rely on a mere plan may result in significant delays and insufficient funds being available for decommissioning.

Comment H.26.2: Another commenter stated that the new § 72.30(g) of the proposed rule contains excessive requirements for monitoring and correcting fund balances. It noted that Part 72 specific licenses are normally 20-year licenses that will need to be renewed or extended until the U.S. Department of Energy takes title to the spent nuclear fuel. Based on continuing delays in the scheduled opening of the Federal repository, a specific and realistic ISFSI facility decommissioning date cannot be determined; however, it may not occur until approximately 2030 or 2040. Based on such a long period of ISFSI licensed operations, the requirements in § 72.30(g) to monitor decommissioning fund balances ''quarterly'' and ''at any time'' and to increase fund balances ''within 5 days'' are very excessive. The commenter recommended several changes to simplify the rule and reduce an unnecessary burden on Part 72 specific licensees, while still providing adequate assurance and information to the NRC. The commenter stated that it was not clear why the requirements in both § 72.30(g)(1) and (g)(2) are needed, because the required action (increase fund balance within five days) and reporting requirement (30 day report to the NRC) are essentially the same. One monitoring requirement that requires timely action and adequate reporting should be sufficient. Based on the long duration of ISFSI operations, an annual (versus quarterly) monitoring requirement and a 30 day (versus 5 days) requirement to increase the fund balance is considered more reasonable and adequate. The commenter provided recommended wording incorporating this recommendation. The commenter also suggested that the NRC could, if it found it necessary to know when a licensee's fund balance falls below 75 percent of the required amount, add a new reporting provision. The commenter recommended language for such a provision. Finally, the commenter recommended parallel changes to § 30.35(h), § 40.36(g), and § 70.25(h).

Response: While ISFSIs may operate for many years, continuous access to adequate financial funds is crucial if the creation of additional legacy sites is to be avoided and funding shortfalls cannot be tolerated. However, the NRC has considered the fact that some ISFSI licensees hold both Part 72 general and specific licenses at a single ISFSI site. With respect to providing financial assurance, Part 72 general licensees are subject to Part 50 requirements and are thus required by 10 CFR 50.75(b)(2) to adjust their financial assurance annually using a rate at least equal to formula adjustment factors in 10 CFR 50.75(c). As discussed previously in comment section H.25 of this document, new 10 CFR 72.30(g) applies only to Part 72 specific licensees. To achieve greater consistency in how Part 72 general and specific licensees are regulated in this regard, the NRC is revising proposed § 72.30(g)(1) in this final rule to require that the fund balance be monitored every calendar year, rather than every calendar quarter.

The NRC considers ISFSI operations to be at a lesser risk of becoming a legacy site compared to other materials licensees, because many of the Part 72 licensees are also electric utilities and thus can more easily gain access to decommissioning financial assurance funding for their ISFSI operations. The proposed quarterly monitoring requirement is being retained in this final rule for Parts 30, 40, and 70 licensees.

In further response to the comment, the NRC had decided to give Parts 30, 40, 70, and 72 licensees 30 days—rather than the proposed 5 days—to increase the fund balances when specified funding shortfalls exist. The process of obtaining access to funds may, in many cases, take longer than 5 days, and such a short period may have generated an excessive number of exemption requests for more time. Accordingly, the proposed 5-day timing provisions are revised to 30 days in 10 CFR 30.35(h), 40.36(g), 70.25(h), and 72.30(g) of this final rule. Thus, if a fund balance drops by more than 25 percent, the licensee must increase the balance within 30 days of the occurrence, and the increase must be sufficient to cover the cost of decommissioning. If a fund balance drops by 25 percent or less, Parts 30, 40, and 70 licensees must increase the balance within 30 days after the end of the calendar quarter, and the increase must be sufficient to cover the cost of decommissioning. In such cases, Part 72 licensees must increase the balance within 30 days after the end of the calendar year, and the increase must be sufficient to cover the cost of decommissioning.

Comment H.26.3: A commenter requested that the following contents of the financial assurance status reports required by 10 CFR 50.82(a)(8)(v) and (vii) be made available to the public: (1) The amount of funds accumulated to cover the current cost of managing spent fuel, (2) The projected costs of spent fuel management until the Department of Energy takes title to the spent fuel, and (3) The plan to obtain additional spent fuel management funds if the accumulated funds do not cover the projected costs. Potential delays in the availability of a long-term repository, issues of repository capacity, and the

consequent likelihood of long-term storage of spent fuel at reactor sites make this information particularly important. This commenter also stated that the power reactor decommissioning fund should never be allowed to pay for onsite spent fuel storage.

Response: The financial assurance status report, due annually from the power reactor licensees under the proposed requirements in 10 CFR 50.82(a)(8)(v) and (vii), will be subject to the public disclosure requirements in 10 CFR 2.390. If a power reactor licensee considers the submitted information to be proprietary, the licensee must meet the requirements in 10 CFR 2.390(b) to support withholding the report from public disclosure. Absent such a showing, the report will be made publicly available in ADAMS. As stated by the commenter, this final rule requires in 10 CFR 72.30(g) that decommissioning financial assurance funds must be used only for decommissioning activities which would not include onsite spent fuel storage operations.

Comment H.27: Replenish funds if an external sinking fund is used.

Comment H.27.1: On the proposed requirements to track the level of decommissioning financial assurance and to replenish the funds if, as a result of market fluctuations or other causes, they fall below certain specified levels, almost all of the comments addressed the implications of the requirement for ISFSI's and related to 10 CFR 72.30(g) in particular. One commenter noted that the new § 72.30(g) requirements, which are consistent with the new requirements being added to § 30.35(h), § 40.36(g), and § 70.25(h) for other material licensees, would apply only to Part 72 specific licensees. These new requirements are focused on the portion of a licensee's decommissioning funds that have been prepaid or collected and are subject to market variations. The licensee's funds associated with the prepayment and external sinking fund methods will be invested and may be subject to market variations. Because the prepayment method is expected to be fully funded at all times, the commenter believed that the proposed wording would work for that mechanism. However, in the case of the external sinking fund method, the fund is not required to be fully funded until the final facility decommissioning is expected to begin. Section 72.30(b) of the proposed rule would require a Part 72 specific licensee to have an NRC-approved DFP for their external sinking fund and to make deposits into the fund at least annually. Parts 30, 40, and 70 material licensees may also use an external sinking fund and could have an NRC-approved DFP. The proposed wording in § 30.35(h), § 40.36(g), § 70.25(h), and § 72.30(g) does not recognize that a licensee's fund balance for their external sinking fund is not required to contain ''the amount necessary to cover the cost of decommissioning'' until the final facility decommissioning begins. As these proposed rule sections are currently worded, on the effective date of the rule change, some licensees would be required to fully fund their external sinking fund to cover the cost of decommissioning within 5 days and make the 30 day report to the NRC. The commenter therefore recommended that wording similar to the following be added to the proposed § 72.30(g)(1) and (g)(2) and the corresponding sections in Parts 30, 40, and 70: ''If * * *, the fund balance is below the amount necessary to cover the cost of decommissioning, or in the case of an external sinking fund the amount required at that point in time by the approved funding plan, the licensee must increase the balance to provide the required amount of funds. * * *''

Response: If funds from a Part 50 external sinking fund are to be used for Part 72 decommissioning, the funds must be reported separately under 10 CFR 72.30 for the ISFSI and held in a separate subaccount and this subaccount must be identified for spent fuel. The certification for an external sinking fund will include a calculation section in which the licensee can take credit for future contributions that are provided by ratepayers and a 2 percent growth rate for the estimated number of years remaining prior to title transfer and possession of the fuel by DOE. For the Part 72 specific licensee, if this calculation yields anything lower than the total cost estimate, than the fund balance must be increased. If the fund balance is underfunded by more than 25 percent, the Part 72 specific licensee must fully fund the balance within 30 days of when such underfunding occurs. If the fund balance is underfunded by 25 percent or less, than the Part 72 specific licensee must fully fund the balance within 30 days after the end of the calendar year.

Comment H.27.2: A commenter stated that the proposed rule was appropriate only for prepaid funds and should not be applied to ISFSI general licensee facilities using external sinking funds. The commenter also argued that the quarterly monitoring requirements and the reporting requirements were very excessive for ISFSI facilities, which may not be decommissioned until 2030 or 2040. The commenter stated that the rule should specify the NRC position/office which should receive reports and whether a written report is required.

Response: The NRC partially agrees with these comments. The reporting requirements in § 72.30(b), (c), and (d) apply to Part 72 specific and general licensees. Likewise, the financial assurance requirements in § 72.30(e), the maintenance of records important for decommissioning, and the § 72.30(f) DCE funding plan requirements, apply to Part 72 specific and general licensees. The final rule language in § 72.30(e)(5), allowing use of the external sinking fund in 10 CFR 50.75(e)(1)(ii) as the exclusive funding method, applies to Part 72 licensees who hold a 10 CFR part 50 power reactor license and to Part 72 specific licensees who meet the Part 50 definition of an ''electric utility.'' Regarding the reporting requirements in § 72.30(g), which apply to Part 72 specific licensees, if the decommissioning fund balance needs to be replenished, the required written report must be submitted to the Director, Office of Federal and State Materials and Environmental Management Programs. The NRC is not adopting the commenter's suggestions regarding the timing of required reports, finding that the quarterly monitoring of funds is a prudent business practice. Also, the NRC considers the annual reporting of a financial status report to be a reasonable burden as part of a licensee's responsibility to maintain an accurate DFP.

Comment H.27.3: Two commenters supported the changes to § 72.30, because they address the concern that—depending on future NRC actions—spent fuel could remain in dry cask storage at reactors for decades, providing the potential for additional adverse environmental impacts whose remediation costs must be assessed and addressed in the decommissioning plan. This commenter noted that the proposed rule appears to require more specific reporting requirements for ISFSI licensees than would be required for power reactor licensees.

Response: The NRC shares the commenter's concern about the length of time spent fuel may need to be managed at the ISFSI facility. The NRC provides oversight of the facility operations and decommissioning to prevent adverse environmental impacts. The commenter is correct that the content of the spent fuel financial status report to be required by 10 CFR 50.82(a)(8)(vii) differs from the content of decommissioning financial assurance reports required of power reactor licensees.

Comment H.28: Support for more detail in the DCE.

Comment H.28.1: Two commenters supported the proposed requirements in 10 CFR 30.35(e)(2), 40.36(d)(2), 70.25(e)(2), and 72.30(c) requiring the licensee to address how routine spills and accidental releases affect the cost of decommissioning. They believed that this requirement would be a useful reinforcement to the requirements in § 40.36(f) and § 20.1101(b), which had been interpreted to require reducing dose to a receptor, but not to be drivers for environmental monitoring or remediation, particularly if the presumed receptor was not drinking water from the site. Historically, according to these commenters, sites were not characterized until shortly before closure, and routine spills were not considered significant. The commenters believed that the identification of source terms during operations would reduce the possibility of underestimation of public dose. In contrast, one commenter argued that although current regulations do not specifically require a licensee to increase its decommissioning financial assurance following a spill if the licensee decides to defer remediation to a later date, this requirement is covered by broader requirements, including ALARA provisions and the cradle-to-grave principle in managing licensed materials. The commenter pointed out that these provisions can be written into the section of the DFP that specifies how the cost estimate and funding assurance are maintained and kept current. Also, the commenter stated that the plan will typically have a 25 percent contingency for unexpected cost increases that would cover all but the most unusual spill.

Response: The NRC agrees that the documentation of spills and accidental releases will improve the basis for the DCE, and the identification of source terms at the site during operations will help to reduce the possibility of underestimation of public dose due as a result of contaminant migration beyond the licensed site. The NRC regulations allow some discretion in the licensee response to a spill or leak that is not an immediate safety concern. If the licensee chooses to defer remediation to a later date in such a situation, then the licensee must document the release in its records important for decommissioning and the added cost, if any, to remediate the spill or leak which must be included in the cost estimate, DFP, and financial instruments used as decommissioning financial assurance.

Comment H.28.2: One commenter stated that the NRC should ensure that there is a direct correlation between decontamination costs and decommissioning funding assurances. To implement this, the NRC should require bi-annual funding reports and a link between the changes proposed to 10 CFR 20.1501 and the DFP required by 10 CFR 50.75(g).

Response: The NRC agrees with the commenter regarding a direct correlation between the DCE and the financial assurance provided by the licensee. New 10 CFR 20.1501(b) provides a link to the existing 10 CFR 50.75(g) provisions in requiring that survey records of subsurface residual radioactivity be kept with records important for decommissioning.

Comment H.29: Reporting requirements for shut down power reactors.

Comment H.29.1: One commenter interpreted the proposed 10 CFR 50.82(a)(8) reporting requirements as also creating a requirement that an operating utility with a shut-down reactor that funds its spent fuel storage costs from its operating budget, would instead now need to set aside large amounts of dedicated funding to pre-fund the costs of spent fuel storage.

Response: The proposed changes in 10 CFR 50.82(a)(8) specify increased reporting requirements for all licensees with a power reactor in decommissioning status. These reporting requirements do not change in any way the existing 10 CFR 50.75 requirements to prepay decommissioning financial assurance or the existing 10 CFR 50.54(bb) requirements to provide funding for the management of irradiated fuel until title and possession of the fuel is transferred to the Secretary of Energy.

Comment H.29.2: A commenter stated that it is not clear what is meant by ''the decommissioning criteria upon which the estimate is based'' in proposed 10 CFR 50.82(a)(8)(v)(B).

Response: The proposed 10 CFR 50.82(a)(8)(v)(B) is a required element of the annual financial assurance status report to be submitted by shutdown power reactors, requiring such licensees to update DCEs. Such estimates must reflect whether the site is planned to be released for unrestricted use, or is planned to be released under restricted conditions. Both of these release options are available—based on how the term ''decommission'' is defined in § 50.2—and the option chosen will affect decommissioning costs.

Comment H.29.3: One commenter argued that the proposed 10 CFR 50.82(a)(8)(vii) reporting requirement regarding spent fuel management costs was not necessary for facilities that are owned by operating utilities with a significant electric sales income and who have access to rate relief. According to this commenter, for sites owned by an operating utility, the annual expense for nuclear fuel storage will be a very small percentage of the utility's total operating budget and would be included in rate relief proceedings.

Response: Regardless of company size, all licensees must demonstrate and provide adequate financial assurance for decommissioning. For facilities that are owned by an electric utility, as defined in 10 CFR 50.2, this demonstration (described in NUREG–1757, Volume 3, Revision 1 to be released shortly after the final rule) may include a calculation for an external sinking fund in which the licensee can take credit for future contributions that are provided by ratepayers and a 2 percent growth rate for the estimated number of years remaining prior to DOE taking title and possession of the spent fuel. The NRC agrees that the annual expense and future contributions for nuclear fuel storage will be a small percentage of an electric utility's total operating budget.

Comment H.29.4: A commenter noted some technical obstacles to the proposed reporting under 10 CFR 50.82(a)(8). First, because DOE has provided no reliable basis for determining when it will begin to perform and complete its obligation to remove the nation's used nuclear fuel from individual facilities or take title to the fuel, the total cost of fuel storage cannot be estimated. The total cost is the summation of annual expenses over time, and because there is a lack of any definitive information on the duration of the storage periods, it is unreasonable to require the owners to pay up-front a projected unknown total cost of nuclear fuel storage. Second, under the DOE Standard Contract and legal decisions, DOE is liable to pay for the storage cost for nuclear fuel. Ongoing and possible future litigation will eventually determine the schedule and amounts for which the DOE is responsible. For permanently shutdown plants, it is the DOE, not the utility, which should be required to provide financial assurance for fuel storage.

Response: The extent to which the DOE may be responsible for onsite spent fuel storage costs is an issue that is outside the scope of this rulemaking. Moreover, the NRC disagrees with the claim that total spent fuel storage costs cannot be estimated. Similar cost estimates for decommissioning are required by existing regulations (10 CFR 50.82(a)(8)(iii)), and have duly been submitted by NRC licensees. While

estimates of future costs will always be based on uncertainties to some extent, this does not mean that no estimate at all can be made. This is as true for estimated spent fuel storage costs as for any other estimated cost.

Comment H.29.5: One commenter argued that the NRC is imposing a new annual reporting requirement on shutdown reactors that requires a higher level of detail than the annual decommissioning funding status reports currently required under 10 CFR 50.75(f). It is not clear why the existing reports are not adequate, but at a minimum, there should not be duplicative requirements. If the NRC adopts this provision, it should remove the reporting requirement under 10 CFR 50.75(f). To the extent that the NRC's desire is to ensure that appropriate funds will be available by reviewing the historical expenditures, power reactor licensees are able to provide this information. However, it is unlikely to be useful other than for interest's sake, and further use of this data to predict future decommissioning costs may be suspect. The value of the reporting requirement does not justify burden upon licensees, because only a few plants have decommissioned to unrestricted release and this data does not constitute a representative sample. Licensees will be unduly challenged by rate regulators, financial auditors and other stakeholders having opposing interests as they relate to funding decommissioning. The existing NRC minimum funding formulae provide stability in rate regulation prior to retirement. Estimates of only forward-looking expenses have provided the same stability for retired units. This section should be focused only on forward-looking needs to meet decommissioning liabilities.

Response: The final rule 10 CFR 50.82(a)(8)(v) reporting requirements do not duplicate the existing 10 CFR 50.75(f) reporting requirements. As stated in the proposed rule's preamble (73 FR 3828; January 22, 2008), the reports under 10 CFR 50.75(f) do not require information on the actual amount of funds spent on decommissioning, whereas such information is required by proposed 10 CFR 50.82(a)(8)(v). The new reporting requirements are not intended for comparison between different power reactor decommissioning costs. The purpose of obtaining the information reported under 10 CFR 50.82(a)(8)(v) is to identify actual expenditures at a particular site and projected costs to complete the decommissioning.

I. Draft Regulatory Guidance

Comment I.1: The survey and monitoring guidance goes beyond what is required.

Several commenters criticized the draft guidance on subsurface residual radioactivity. They argued that the guidance went substantially beyond what the rule required with respect to site surveys, the timeframe for remediation, retrofitting facilities to eliminate sources of subsurface residual radioactivity, monitoring, use of MARSSIM, and remediation during operations. One commenter, who provided detailed comments on many parts of the guidance, stated that it described actions that were not necessary to protect public health, safety, and the environment.

Response: All comments were reviewed and considered by the agency in preparing DG–4014 to support this final rule.

Comment I.2: The survey and monitoring guidance requires prompt remediation.

A commenter on the draft guidance on subsurface residual radioactivity argued that, as written, the remediation language in the draft regulatory guidance document could have the unintended consequence of disrupting safe plant operation, without regard to actual health or environmental impacts. Another commenter, supported by several additional commenters, argued that the emphasis on ''prompt'' remediation, found especially in the draft guidance, of a leak or spill is unreasonable and is not always practically achievable. Licensees should be given the flexibility to define the appropriate timeframe for clean-up of a spill or leak, taking into consideration ALARA, realistic exposure pathways, and the site-specific soil and groundwater characteristics. Another commenter said it makes little sense to require remediation during the operation of the site. The commenter noted that the draft guidance encourages licensees to perform cost-effectiveness analyses of prompt versus delayed clean up of residual radioactivity at the site.

Response: The NRC is aware that in some cases subsurface residual radioactivity is located where the only feasible remediation measures that can be taken without disrupting safe plant operation must occur at the time of final plant decommissioning. The NRC does not intend that licensees adopt remediation measures that will disrupt safe plant operation. The topic of cleanup activities during facility operations, especially in the context of soil contamination, is very dependent on site-specific conditions. In response to the commenters, the NRC has applied a performance-based approach in the DG–4014 survey and monitoring guidance released for public comment to support this final rule. Small leaks and spills that have no impact on decommissioning planning are not within the scope of the guidance, but the larger leaks and spills to the subsurface that could affect decommissioning planning are addressed in the guidance. The NRC has placed in DG–4014 a discussion on different approaches that may be used by licensees to determine the cost-effectiveness of prompt compared to deferred cleanup. Licensees should become familiar with this guidance, which can help them to develop reasoned explanations to support deferral of cleanup activities where there has been a significant amount of subsurface contamination.

Comment I.3: The survey and monitoring guidance should clarify cost-effectiveness calculations.

One commenter stated that the cost-effectiveness calculation recommended in the guidance will nearly always show that it is more cost-effective to wait until a site has ceased operations to dispose of contaminated soil or conduct any remediation. The proposed regulations would require an evaluation of subsurface contamination based on future decommissioning exposure scenarios, even though no foreseeable operating exposure limits would be exceeded. The guidance describes methods to conduct such evaluations.

Response: The NRC agrees with this comment that it is likely that licensees will decide to remediate soil contamination during decommissioning rather than during operations, although this is a site-specific and licensee-specific decision. The NRC believes it is beneficial for licensees to remediate certain types of contaminating events on a timely basis. This certainly includes contaminating events that have the potential to reach a groundwater pathway or that are cost-effective to perform earlier rather than later as determined by an analysis performed by the licensee, as recommended in DG–4014.

Comment I.4: The survey and monitoring guidance is contrary to Commission direction.

A commenter stated that that the draft guidance's references to MARSSIM for ''subsurface'' survey requirements, documentation and quality assurance/quality control requirements are contrary to the Commission's SRM in SECY–03–0069 regarding MARSSIM.

Response: This final rule is not requiring any MARSSIM submittals. The optional use of the MARSSIM screening values is discussed in DG–4014, along with several other low cost approaches as a means for the licensee to apply sampling concentration results to dose based results. The dose-based results are the basis by which the facility will be evaluated for license termination.

Comment I.5: The financial assurance guidance needs to clarify acceptable methods for Part 72 licensees.

The comments on the revisions to NUREG–1757, Volume 3, raised questions concerning how 10 CFR part 72 licensees, and in particular specific licensees and general licensees, should implement the proposed rules. The commenters also suggested renumbering of certain sections of the guidance and pointed out possible typographical errors.

Response: All comments were reviewed and considered by the agency in preparing Revision 1 to NUREG–1757, Volume 3 to be released shortly after this final rule. Additional sections have been added to the guidance document for the Part 72 licensees.

J. OMB Supporting Statement

In comments on the OMB Supporting Statement submitted to OMB, NEI argued that the NRC's justification for imposing new information collection requirements was flawed, because the proposed rule, including the information collection requirements, was designed to address problems that no longer existed because of intervening regulatory developments. In addition, the NRC enforcement and oversight could address any problems more efficiently. Secondly, NEI argued that the proposed information collection and recordkeeping requirements are not justified, because current reporting and recordkeeping requirements are adequate, and any necessary clarification can be achieved in a less burdensome manner. NEI therefore concluded that the requirements of the Paperwork Reduction Act were not met, because the required balancing of the burden against the need for the information showed that the burden was excessive. NEI argued that the estimate of the burden did not adequately include costs of new equipment, physical containment barriers, procedures, and training, which it suggested might total as much as $500 thousand to $1 million per nuclear power reactor. NEI did not agree with the NRC's conclusion that the voluntary implementation of the nuclear industry's GPI will make it unnecessary for nuclear power reactors to take any additional significant steps to comply with the reporting and recordkeeping requirements of these rules.

In comments on the January 2008 proposed rule, NEI again addressed only the reporting and recordkeeping requirements associated with 10 CFR 20.1406 and 20.1501. NEI noted that the estimate for the burden for Part 50 implementation of those two provisions was zero. NEI then essentially summarized its previous comments on the OMB Supporting Statement, although it also addressed in the same comment proposed implementing guidance. NEI argued that the burden estimate in the supporting statement for implementation of the Part 20 requirements by nuclear power reactors was ''grossly inaccurate'' because as ''an industry, nuclear power plants have spent thousands of person hours and millions of dollars implementing the Industry Groundwater Protection Initiative. Given that the GPI is a voluntary effort and, to some degree, adopts a more graded approach to reevaluation of a site's hydrogeology, as an example, the amount of time and resources necessary to implement the proposed rule using the draft guidance are significantly greater than zero hours.''

Response: The NRC, after careful consideration of the comments, has concluded that the commenters are correct. The time that certain licensees will need to spend in order to determine whether a particular facility is affected by the final rule's Part 20 regulations should have been included as part of the paperwork burden. Therefore, the burden estimate has been increased significantly for new § 20.1406(c) and amended § 20.1501(a) to account for the time necessary to read the regulations, determine their impact, if any, on the licensee, and prepare a record of this activity. However, the NRC does not agree with the commenter that time and other resources used to implement the preexisting voluntary industry groundwater initiative are properly attributable as reporting or recordkeeping burden for this rule. Although the NRC received no public comments on the reporting and recordkeeping requirements in the proposed rule for 10 CFR parts 30, 40, 70, or 72, it has reviewed all of those provisions and in a few instances increased the burden estimates for particular sections of those rules. Finally, the NRC has added an estimate of the burden for 10 CFR part 50 licensees of changes to the financial test requirements in 10 CFR part 30, which are cross-referenced in 10 CFR 50.75.

K. Agreement State Compatibility

Two comments were received on the Agreement State Compatibility table published with the Decommissioning Planning proposed rule. One of the commenters, an organization representing multiple states, stated that it had no issues with the compatibility designations in the proposed rule. Another commenter stated that the Compatibility Table for the final rule should be expanded to include 10 CFR 20.1401 and 20.1402 and that these sections should be assigned Agreement State Compatibility Category B instead of the existing Category C. The commenter believes this change is needed to eliminate inconsistency in regulatory approach in the Agreement States. The commenter believes that some states, using the Compatibility Category C guideline to adopt the NRC ''essential objectives,'' are regulating site termination and release under schemes that are unreasonable and impractical, resulting in excessive burden on licensees without measurable benefit to the public or the environment.

Response: The commenter is correct that 10 CFR 20.1401 and 20.1402 are both assigned Compatibility Category C. But those two sections were not included in the technical basis supporting the Decommissioning Planning proposed rule, and no changes to these regulations were proposed. The NRC does not have a technical basis to support a Compatibility Category change for these regulations, and the change request is outside the scope of this rulemaking. Accordingly, the NRC is making no change in this final rule to the compatibility designations for 10 CFR 20.1401 and 20.1402.

V. Discussion of Final Amendments by Section

Section 20.1403 Criteria for License Termination Under Restricted Conditions

This rulemaking (1) amends § 20.1403(c)(1) to require financial assurance funds to be placed into a trust segregated from the licensee's assets and outside the licensee's administrative control; and (2) eliminates the licensee's option to use other prepayment financial mechanisms, such as the escrow account, government fund, certificate of deposit, or deposit of government securities. This subsection is further amended to require that the initial amount of the trust fund established for long-term care and maintenance be based on a conservative assumption of a 1 percent annual real rate of return on investment.

The current § 20.1403(c)(2) is deleted to remove the licensee's option to use a surety method, insurance, or other guarantee method to provide financial assurance for a restricted release site. The provisions for government entities to provide financial assurance for long-term control and maintenance contained in existing § 20.1403(c)(3) and (4) is retained but redesignated as § 20.1403(c)(2) and (3).

Section 20.1404 Alternate Criteria for License Termination

This rulemaking adds a new § 20.1404(a)(5) specifying a fifth criterion that the NRC must consider in determining whether to terminate a license under alternate site release criteria. This new fifth criterion pertains to whether the licensee has provided sufficient financial assurance in the form of a trust fund to enable an independent third party, including a government custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

Section 20.1406 Minimization of Contamination

This rulemaking adds a new § 20.1406(c) to require licensees, to the extent practical, to conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface. The term ''residual radioactivity,'' defined in 10 CFR part 20, identifies the type and scope of radioactive material that must be considered by licensees to effectively plan for decommissioning activities during facility operations. The term includes licensed and unlicensed radioactive material.

Section 20.1501 General

This rulemaking amends § 20.1501(a) to specify that licensee survey requirements include consideration of residual radioactivity, conforming to the new § 20.1406(c). The linkage between new § 20.1406(c) and amended § 20.1501(a) requires that surveys be performed if there is reason to believe that significant subsurface contamination is present which constitutes a potential radiological hazard.

This rulemaking adds a new § 20.1501(b) to require licensees to maintain records from surveys describing the location and amount of subsurface residual radioactivity identified at the site with records important for decommissioning, in §§ 30.35(g), 40.36(f), 50.75(g), 70.25(g), or 72.30(d), as applicable . Existing § 20.1501(b) has been redesignated as paragraph (c), and existing § 20.1501(c) has been redesignated as paragraph (d).

Section 30.34 Terms and Conditions of Licenses

Existing § 30.34(b) has been redesignated as paragraph (b)(1) and a new paragraph (b)(2) has been added to require that an application for license transfer must include the proposed transferee's identity, its technical and financial qualifications, and a showing that it will be able to provide adequate financial assurance for decommissioning.

Existing § 40.46 and § 70.36 contain parallel provisions to those in § 30.34(b). Sections 40.46 and 70.36 have been redesignated as § 40.46(a) and § 70.36(a), respectively. New § 40.46(b) and § 70.36(b) parallel the new § 30.34(b)(2) provisions described previously.

Section 30.35 Financial Assurance and Recordkeeping for Decommissioning

A new paragraph (c)(6) has been added to 10 CFR 30.35 (and parallel § 40.36(c)(5) and § 70.25(c)(5)), to reflect the changes being made to the § 20.1501(a) survey requirements. If these surveys detect residual radioactivity at a site at levels that would, if left uncorrected, prevent the site from meeting the § 20.1402 criteria for unrestricted use, the licensee must submit a DFP within one year of when the survey is complete.

Existing § 30.35(e) (and in parallel § 40.36(d)(1) and (d)(2), Part 40 Appendix A, § 70.25(e)(1) and (e)(2), and § 72.30(b) and (c)) have been amended to contain new paragraphs (e)(1) and (e)(2). Section 30.35(e)(1) requires that each DFP submitted for review and approval must contain a DCE based on three cost components. Two of the cost components (a dollar amount adequate to cover the cost of an independent contractor to perform all decommissioning activities, and an adequate contingency factor) are described in existing guidance. The new cost component is an estimate of the volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the decommissioning criteria. Additionally, the DCE must be based on the cost of meeting the § 20.1402 criteria for unrestricted use unless it can be adequately shown that the requirements of § 20.1403 will be met.

A new provision, § 30.35(e)(1)(ii), requires the licensee to identify and justify the basis for all key assumptions underlying the DCE.

Section 30.35(e)(1)(iii) retains the existing § 30.35(e) provision requiring a description of the method of assuring funds for decommissioning. Section 30.35(e)(1)(iv) retains the existing § 30.35(e) provision requiring a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the DCE. Section 30.35(e)(1)(v) retains the existing § 30.35(e) requirement that the DFP include ''a signed original of the financial instrument'' being used to provide financial assurance, if it has not been previously submitted and accepted as the financial instrument to cover the cost estimate for decommissioning.

New § 30.35(e)(2) requires that the DFP be submitted at the time of license renewal and at intervals not exceeding 3 years with adjustments as necessary to account for changes in costs and the extent of contamination. The updated DFP must specifically consider the effect of the following events on the cost of decommissioning:

- Spills of radioactive material producing additional residual radioactivity in onsite subsurface material,
- Waste inventory increasing above the amount previously estimated,
- Waste disposal costs increasing above the amount previously estimated,
- Facility modifications,
- Changes in authorized possession limits,
- Actual remediation costs that exceed the previous cost estimate,
- Onsite disposal, and
- Use of a settling pond.

As discussed further in this section, this rulemaking amends the introductory language in 10 CFR 30.35(f) and amends paragraphs (f)(1) through (f)(3). Parallel changes have been made in § 40.36(e), § 40.36(e)(1), (e)(2) and (e)(3), § 70.25(f), § 70.25(f)(1), (f)(2) and (f)(3), § 72.30(e), § 72.30(e)(1), (e)(2) and (e)(3).

Section 30.35(f) is amended to require that the financial instrument used for decommissioning funding assurance include the licensee's name, license number, and docket number, and the name, address, and other contact information of the issuer, and, if a trust is used, the trustee. If there are any changes to this information, the licensee must submit financial instruments reflecting these changes within 30 days.

Section 30.35(f)(1) is amended to require that the prepayment financial method be in the form of a trust. This language parallels the rule text change in § 20.1403, eliminating the four other prepayment mechanisms (*i.e.*, the escrow account, government fund,

certificate of deposit, and deposit of government securities).

Section 30.35(f)(2) is amended to eliminate the existing line of credit option as a guarantee method for financial assurance.

Section 30.35(f)(3) is amended to require an external sinking fund to be in the form of a trust, eliminating the escrow account, government fund, certificate of deposit, and deposit of government securities because of their relative risk of loss during bankruptcy.

Section 30.35(h) has been added (and in parallel new § 40.36(f) and § 70.25(h)) specifying that each licensee must use its financial assurance funds only for decommissioning activities. The new section also requires monitoring by the licensee of its investment balance in the decommissioning trust account. Conservative investments are expected in the trust account. If the investment balance in the trust account is below the estimated cost of decommissioning, but is not below 75 percent of the cost, then the licensee must, within 30 days after the end of the calendar quarter, deposit funds into the trust account to fully cover the estimated cost. If at any time the loss results in a balance that is below 75 percent of the amount necessary to cover the decommissioning cost, the licensee must, within 30 days of such occurrence, deposit funds into the trust account to fully cover the estimated cost. The licensee must report taking such actions to the NRC within 30 days of the occurrence.

Part 30 Appendices A, C, D, and E

This rulemaking makes a set of parallel amendments to 10 CFR part 30, Appendices A, C, D, and E. The types of guarantors for which the financial tests in these appendices apply are:

- Appendix A, Parent company guarantees;
- Appendix C, Self-guarantees;
- Appendix D, Self-guarantees by companies that have no rated commercial bonds; and
- Appendix E, Self-guarantees by non-profit colleges, universities and hospitals.

In the financial test in Section II.A in Appendices A, C, and D of Part 30, this rulemaking adds language to allow the inclusion of intangible assets in the determination of total net worth. Total net worth is defined to exclude the net book value and goodwill of the nuclear facility and site. Tangible net worth is defined to exclude all intangible assets and the net book value of the nuclear facility and site. In Appendix A of the existing rule, Section II.A.1.(i) provides that a parent company guaranteeing to fund the cost of decommissioning must, among other things, have two of three defined financial ratios. This provision has been revised to clarify that in calculating the ratio of liabilities to net worth, the parent company must calculate its total liabilities against its total net worth, which may now include intangible assets. Section II.A.2.(ii) of Appendix A has also been revised to require the licensee to perform a total net worth calculation instead of a tangible net worth calculation. (The parent company must also have a minimum tangible net worth of $21 million, as required by Section II.A.(2).(iii) of Appendix A and described in the next paragraph.) In Appendix D, which establishes financial test criteria for companies that do not issue bonds, Section II.A.(3) has been revised to clarify that a self-guaranteeing company must have, among other things, a ratio of total liabilities divided by total net worth that is less than 1.5.

In the financial test in Section II.A in Appendices A, C, and D of Part 30, this rulemaking requires that the guarantor's tangible net worth be at least $21 million to pass one of the criteria for that financial test.

Each set of changes to Appendices A, C, D, and E of Part 30 requires the independent CPA (who compares the data used in the financial tests against data in year-end financial statements) to evaluate the guarantor's off-balance sheet transactions regarding the impact these transactions may have on the guarantor's ability to pay decommissioning costs. The CPA also must verify bond ratings if these are used to pass the financial test.

For those licensees or guarantors that issue bonds and use the financial test under Section II.B of Appendices A, C, and E of Part 30, this rulemaking specifies that the current rating of the most recent bond issuance of AAA, AA, or A by Standard and Poor's could include adjustments of + or − (*i.e.*, AAA+, AA+, or A+ and AAA−, AA−, and A− would meet the criterion) and the current rating of Aaa, Aa, or A by Moody's could include adjustments of 1, 2, or 3. In each of these appendices, this rulemaking also requires the bond to be the most recent ''uninsured, uncollateralized, and unencumbered'' bond issuance.

In each Appendix A, C, D, and E of Part 30, this rulemaking makes changes to the 90 day test to show continued eligibility for the licensee and guarantor.

In each Appendix A, C, D, and E to Part 30, this rulemaking amends Section III to clarify that the guarantor is required to set up a standby trust, with new criteria for selecting an acceptable trustee.

In Appendix A to Part 30, this rulemaking amends Section III to require that the parent company guarantor agree to make itself subject to Commission orders (e.g., order to make payments under the guarantee agreement).

In each Appendix A, C, D, and E to Part 30, this rulemaking amends Section III to allow the Commission, in cases of the guarantor company's financial distress, to declare the financial assurance guaranteed by the guarantor to be immediately due and payable to the standby trust. The guarantor companies also are required to notify the NRC, in writing, immediately following the occurrence of events signifying financial distress.

Section 40.36 Financial Assurance and Recordkeeping for Decommissioning

This rulemaking amends § 40.36(c)(5) in changes that are parallel to those described under § 30.35(c)(6); amends § 40.36(d)(1) and (d)(2) in changes that are parallel to those described under § 30.35(e)(1) and (e)(2); amends § 40.36(e) in changes that are parallel to those described under § 30.35(f); and amends § 40.36(f) in changes that are parallel to those described under § 30.35(h).

Section 40.46 Inalienability of Licenses

This rulemaking amends § 40.46. The changes are described under the section for § 30.34.

Part 40 Appendix A

This rulemaking amends Appendix A, Criterion 9, to Part 40. For the most part, the changes are parallel to those described under § 30.35(e)(1) and § 30.35(e)(2). However, two errors contained in the proposed published amendments to Criterion 9 are being corrected. First, in proposed Criterion 9(b)(2)—relating to financial surety arrangements that uranium recovery licensees must establish—the term ''residual radioactive material'' was used in describing one of the items that a Commission-approved cost estimate must contain. This term, as defined in existing 10 CFR 40.4, applies only to uranium mill sites that were inactive (so-called Title I sites) as of 1978 when the Uranium Mill Tailings Radiation Control Act was enacted. To avoid confusion, the proposed use of ''residual radioactive material'' is replaced by the phrase ''radioactive contamination'' in Criterion 9(b)(2). Second, in proposed Criterion 9(f)(4)—relating to required adjustments in surety liability amounts—the term ''residual radioactivity'' was used in conjunction

with the phrase ''license termination criteria.'' Such a juxtaposition is appropriate for 10 CFR part 30 licensees and most others. But pursuant to 10 CFR 20.1401(a), the scope of 10 CFR part 20 Subpart E, ''Radiological Criteria for License Termination,'' does not include facilities subject to Part 40 Appendix A, which contains its own set of provisions governing the long term control and remediation of tailings and associated contaminants. Accordingly, in Criterion 9(f)(4), the term ''residual radioactivity'' is replaced by the word ''contamination''; and the phrase ''license termination criteria'' is replaced by the phrase ''applicable remediation criteria.''

Section 50.75 Reporting and Recordkeeping for Decommissioning Planning

This rulemaking eliminates the line of credit in § 50.75(e)(1)(iii)(A) as a guarantee method for financial assurance. Additionally, in the parallel provisions of § 50.75(f)(1) and (f)(2), in each paragraph between its second and third sentences, the following additional sentence is added: ''If any of the preceding items is not applicable, the licensee should so state in its report.'' This change clarifies that not all listed items in § 50.75(f)(1) and (f)(2) are applicable to all reactor licensees, and resolves an issue raised in a recent NRC audit of decommissioning funding assurance requirements. The NRC is also making minor editorial and clarifying changes in § 50.75(f)(1) and (f)(2) that impose no additional requirements, and are not substantive modifications.

Section 50.82 Termination of License

This rulemaking revises § 50.82(a)(4)(i) to require that additional details be included in the PSDAR. The PSDAR must now include a description of the planned decommissioning activities, a schedule for their accomplishment, and an estimate of expected costs. As revised, this regulation will also require that the PSDAR cost estimates include those for managing irradiated fuel.

This rulemaking also adds paragraphs (v) through (vii) to existing § 50.82(a)(8). New paragraph (a)(8)(v) requires that a power reactor licensee, that has submitted its certification of permanent cessation of operation, must report annually on the status of its radiological decommissioning funding on a calendar-year basis.

New paragraph (a)(8)(vi) requires that if funds reported in the financial assurance status report are below the estimated cost to complete the decommissioning, the licensee must include additional financial assurance to make up the difference.

New paragraph (a)(8)(vii) requires an annual report on the status of funds for managing irradiated fuel. This report includes the accumulated amount, the projected costs until title to the fuel is transferred to the Secretary of Energy, and the plan to obtain the necessary additional funds if the total projected cost is higher than the accumulated amount.

Section 70.25 Financial Assurance and Recordkeeping for Decommissioning

This rulemaking amends § 70.25. The changes are parallel to those described under § 30.35.

Section 70.36 Inalienability of Licenses

This rulemaking amends § 70.36. The changes are parallel to those described under § 30.34.

Section 72.13 Applicability

As stated in the January 22, 2008 proposed rule, references in § 72.13(c) to § 72.30 are being changed to conform with the revisions to § 72.30, whereby § 72.30(c) is being redesignated as § 72.30(e), and § 72.30(d) is being redesignated as § 72.30(f). This reflects the fact that existing 10 CFR 72.13(c) references 10 CFR 72.30(c) and (d).

However, the January 2008 notice's discussion of proposed changes in the cross-referencing provisions of § 72.13 did not capture all of the proposed changes to 10 CFR 72.30 (*i.e.,* the revisions to 10 CFR 72.30(b), and the addition of new sections (c), (d), and (g) to 10 CFR 72.30). Section 72.13(b) references the Part 72 provisions applicable to those holding Part 72 specific licenses, and 10 CFR 72.13(c) references the Part 72 provisions applicable to those holding Part 72 general licenses. Thus, any amendments to 10 CFR 72.30 need to be reflected in 10 CFR 72.13. An expanded discussion of the changes in the cross-referencing provisions of § 72.13 is set forth below (a more detailed discussion of these and related issues appears in the response to comment H.25 above).

As stated above, existing 10 CFR 72.13(c) references 10 CFR 72.30(d). Thus, those holding Part 72 general licenses are already subject to all of the existing 10 CFR 72.30(d) requirements. Such requirements include the DFP provisions referenced in 10 CFR 72.30(d)(4)—which this rulemaking redesignates as 10 CFR 72.30(f)(4). The new provisions in 10 CFR 72.30(b) provide further details of what initial DFPs must include. New section (c) of 10 CFR 72.30 presents a set of timing provisions describing when updated DFPs must be submitted for NRC approval. New section (d) of 10 CFR 72.30 is a special 1-year DFP update provision based on 10 CFR 20.1501 survey results. Together, these new DFP requirements, along with the 10 CFR 72.30(f)(4) DFP provisions, will be referenced in 10 CFR 72.13(c), and will thus be applicable to Part 72 general licensees.

Accordingly, the final rulemaking amends 10 CFR 72.13(c) so that it correctly includes references 10 CFR 72.30(b), (c), (d), (e), and (f) that are applicable to holders of Part 72 general licenses.

The requirements of new 10 CFR 72.30(g)—under which licensees must replenish fund levels if decommissioning funds fall below specified levels—are unlike the above-referenced DFP requirements in that no similar provisions now exist in either Part 72 or Part 50. Aside from requirements listed in 10 CFR 72.13(c), a Part 72 general licensee can only be subject to requirements that a Part 50 licensee is subject to. Thus, the new 10 CFR 72.30(g) requirements will be applicable only to holders of Part 72 specific licenses. No amendment to 10 CFR 72.13(b) is necessary to reflect this, because existing 10 CFR 72.13(b) lists § 72.16 through § 72.34 as being among the Part 72 requirements that are applicable to specific licenses.

Section 72.30 Financial Assurance and Recordkeeping for Decommissioning

This rulemaking amends § 72.30. The changes are similar to those described under § 30.35(e), and two existing paragraphs are redesignated.

Additionally, the NRC is amending the newly redesignated § 72.30(e)(5)—formerly § 72.30(c)(5)—to allow a licensee, who is also an electric utility as defined in 10 CFR part 50, to continue to rely on Part 50 mechanisms for decommissioning financial assurance. In the event that funds remaining to be placed into the licensee's ISFSI decommissioning external sinking fund are no longer approved for recovery in rates by a competent rate making authority, the licensee must make changes to provide financial assurance using the methods in 10 CFR 72.30(e). This change was not noticed in the January 2008 proposed rule. It is being made as a result of a public comment on the proposed rule, regarding acceptable mechanisms in providing decommissioning financial assurance under § 72.30(e). The commenter noted that it and another

licensee, each with Part 72 specific licenses, were granted in 2005 exemptions from 10 CFR 72.30(c)(5)—now 72.30(e)(5)—allowing them to continue to use 10 CFR 50.75(e)(1)(ii)(A) as the exclusive mechanism for ISFSI decommissioning financial assurance. This rulemaking change in § 72.30(e)(5) provides adequate financial assurance for decommissioning an ISFSI, and will improve regulatory efficiency and effectiveness by allowing ISFSI licensees who are also an electric utility to continue their use of the Part 50 sinking fund applied to ISFSI decommissioning after the power reactor has been decommissioned.

The NRC is amending the newly redesignated § 72.30(f)(4) to remove the reference to ''the amount certified for decommissioning'' which occurs in the existing regulation, under § 72.30(d)(4). Part 72 does not have provisions for an ISFSI licensee to certify to a prescribed amount of financial assurance. This rulemaking change is being made as a technical correction.

New § 72.30(g) states that each licensee with a Part 72 specific license must use its financial assurance funds only for decommissioning activities. As discussed previously in response to a comment, the NRC in this final rule is revising the proposed § 72.30(g) to require monitoring by the licensee of its investment balance in the decommissioning trust account, on an annual rather than quarterly basis. If, at the end of a calendar year, the investment balance in the trust account is below the estimated cost of decommissioning, but is not below 75 percent of the cost, then licensees must, within 30 days after the end of the calendar year, deposit funds into the trust account to fully cover the estimated cost. If at any time the loss results in a balance that is below 75 percent of the amount necessary to cover the decommissioning cost, the licensee must, within 30 days of such occurrence, deposit funds into the trust account to fully cover the estimated cost. The licensee must report taking such actions to the NRC within 30 days of the occurrence.

Section 72.50 Transfer of License

This rulemaking amends § 72.50 by adding a new paragraph (b)(3), requiring that the license transfer application describe the financial assurance that will be provided for the decommissioning under § 72.30.

Section 72.80 Other Records and Reports

References in § 72.80(e) and (f) are corrected to conform with the changes to § 72.30, whereby § 72.30(d) would become § 72.30(f).

V. Criminal Penalties

For the purpose of Section 223 of the Atomic Energy Act (AEA), the Commission is amending 10 CFR parts 20, 30, 40, 50, 70, and 72 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement.

VI. Agreement State Compatibility

Under the ''Policy Statement on Adequacy and Compatibility of Agreement State Programs'' approved by the Commission on June 30, 1997, and published in the **Federal Register** on September 3, 1997 (62 FR 46517), this final rule is a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among the Agreement States and the NRC requirements. The NRC staff analyzed the final rule in accordance with the procedure established within Part III, ''Categorization Process for NRC Program Elements,'' of Handbook 5.9 to Management Directive 5.9, ''Adequacy and Compatibility of Agreement State Programs'' (a copy of which may be viewed at *http://www.nrc.gov/reading-rm/doc-collections/management-directives/volumes/vol-5.html.*

The NRC program elements (including regulations) are placed into four compatibility categories (See the Compatibility Table in this section). In addition, the NRC program elements also can be identified as having particular health and safety significance or as being reserved solely to the NRC. Compatibility Category A establishes program elements that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. An Agreement State should adopt Category A program elements in an essentially identical manner to provide uniformity in the regulation of agreement material on a nationwide basis. Compatibility Category B establishes program elements that apply to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. Compatibility Category C establishes program elements that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. An Agreement State should adopt the essential objectives of the Category C program elements. Compatibility Category D establishes program elements that do not meet any of the criteria of Category A, B, or C, above, and, thus, do not need to be adopted by Agreement States for purposes of compatibility.

Health and Safety (H&S) are program elements that are not required for compatibility but are identified as having a particular health and safety role (*i.e.,* adequacy) in the regulation of agreement material within the State. Although not required for compatibility, the State should adopt program elements in this H&S category based on those of the NRC that embody the essential objectives of the NRC program elements, because of particular health and safety considerations. Compatibility Category NRC establishes program elements that address areas of regulation that cannot be relinquished to Agreement States under the Atomic Energy Act, as amended, or provisions of 10 CFR. These program elements are not adopted by Agreement States.

The following table lists the parts and sections that have been added or revised by this final rule and their corresponding categorization under the ''Policy Statement on Adequacy and Compatibility of Agreement State Programs.''

COMPATIBILITY TABLE FOR DECOMMISSIONING PLANNING FINAL RULE

Section	Change	Subject	Compatibility	
			Existing	New *
20.1403(c)(1)	Amend	Trust fund for restricted use	C	C
20.1403(c)(2)	Deleted	Acceptable financial assurance methods	C	C
20.1403(c)(3) & (4)	Redesignated	Government entity financial assurance	C	C
20.1404(a)(5)	Add	Trust fund for alternate criteria		C

COMPATIBILITY TABLE FOR DECOMMISSIONING PLANNING FINAL RULE—Continued

Section	Change	Subject	Compatibility	
			Existing	New *
20.1406(c)	Add	Minimize residual radioactivity		C
20.1501(a)	Amend	Surveys and monitoring	H&S	H&S
20.1501(b)	Add	Records from surveys		H&S
30.34(b)(1)	Redesignated	License transfer requirements	C	C
30.34(b)(2)	Add	License transfer requirements		C
30.35(c)(6)	Add	Assess subsurface contamination		D
30.35(d)	No change	Certification amounts financial assurance	H&S **	D
30.35(e)(1)	Amend	Contents of decommissioning funding plan	D ***	H&S
30.35(e)(2)	Amend	Updates of decommissioning funding plan	D ***	H&S
30.35(f)	Amend	Methods for financial assurance	D	D
30.35(h)	Add	Monitor the balance of funds		D
30 Appendix A	Amend	Parent company guarantee	D	D
30 Appendix C	Amend	Self-guarantee with bonds	D	D
30 Appendix D	Amend	Self-guarantee without bonds	D	D
30 Appendix E	Amend	Self-guarantee nonprofits	D	D
40.36(c)(5)	Add	Assess subsurface contamination		D
40.36(d)(1)	Amend	Contents of decommissioning funding plan	H&S	H&S
40.36(d)(2)	Amend	Updates of decommissioning funding plan	H&S	H&S
40.36(e)	Amend	Methods for financial assurance	D	D
40.36(g)	Add	Monitor the balance of funds		D
40.46(a)	Redesignated	License transfer requirements	C	C
40.46(b)	Add	License transfer information requirements		C
40 Appendix A Criterion 9(b)	Amend	DCEs and financial surety [with 11e.(2)]	C	C
40 Appendix A Criterion 9(b)	Amend	DCEs and financial surety [without 11e.(2)].	NRC	NRC
50.75(e) & (f)	Amend	Surety and reporting of status of funding	NRC	NRC
50.82(a)(4)	Amend	Cost information in the PSDAR	NRC	NRC
50.82(a)(8)(v), (vi) & (vii)	Add	Cost information in the annual financial assurance status report.		NRC
70.25(c)(5)	Add	Assess subsurface contamination		D
70.25(d)	No change	Certification amounts financial assurance	H&S **	D
70.25(e)(1)	Amend	Contents of decommissioning funding plan	D ***	H&S
70.25(e)(2)	Amend	Updates of decommissioning funding plan	D ***	H&S
70.25(f)	Amend	Methods for financial assurance	D	D
70.25(h)	Add	Monitor the balance of funds		D
70.36(b)	Add	License transfer requirements		C
72.13 & 72.30(b)	Amend	Applicability and contents of funding plan	NRC	NRC
72.30(c)	Add	Updates of decommissioning funding plan		NRC
72.30(d)	Add	Assess subsurface contamination		NRC
72.30(e)	Amend	Methods for financial assurance	NRC	NRC
72.30(g)	Add	Monitor the balance of funds		NRC
72.50(b)(3) & 72.80	Add	License transfer and other records		NRC

* Final rule compatibility category.

** The compatibility category for § 30.35(d) and § 70.25(d) were incorrectly specified in the 68 FR 57334, October 3, 2003, Financial Assurance for Materials Licensees final rule. The correct category for both of these sections is D.

*** The compatibility category for § 30.35(e) and § 70.25(e) were incorrectly specified in the 68 FR 57334, October 3, 2003, Financial Assurance for Materials Licensees final rule. The correct category for both of these sections is H&S.

VII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Public Law 104–113, requires that Federal agencies use technical standards developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. There are no consensus standards regarding acceptable methods for radiological surveys across a broad spectrum of licensed facilities, or for preparing DCEs or providing financial assurance for decommissioning that would apply to the requirements imposed by this final rule. Thus, the provisions of the Act do not apply to this rule.

VIII. Environmental Assessment and Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR part 51, that this rule is not a major Federal action significantly affecting the quality of the human environment and therefore an environmental impact statement is not required. The Commission has prepared an environmental assessment for this final rule.

The amendments in this final rule require licensees, to the extent practical, to conduct their operations to minimize the introduction of residual radioactivity into the site, particularly in the subsurface soil and groundwater. There are a variety of monitoring methods to evaluate subsurface characteristics, and these are highly site specific with respect to their effectiveness. One or more licensees may find that compliance with the amendments will mean the installation of groundwater monitoring wells and surface monitoring devices at their sites. The installation of these monitoring devices and wells is generally expected

to result in small environmental impacts due to their very localized nature.

During sampling and testing, the amendments introduce the potential for a small amount of increased occupational exposures. These exposures are expected to remain within 10 CFR part 20 limits and to be ALARA. If subsurface contamination is detected, licensees may choose to remediate when contamination levels are lower and more manageable, which could result in reduced future occupational exposure rates than if the contamination conditions were allowed to remain and become increasingly more hazardous. Licensees may alternatively choose to provide adequate funding in response to their knowledge of the extent of any subsurface contamination, which will better ensure that the area is remediated following decommissioning to a degree that supports public health and safety, and protection of the environment.

If significant onsite residual radioactivity in the subsurface is found due to the monitoring imposed by these amendments, such knowledge will better ensure the protection of public health and safety, and protection of the environment. Identifying and resolving the source of the contamination will better ensure that waste is not allowed to migrate offsite. Early identification also provides more time to plan waste remediation strategies that are both safe and cost effective. The effect of the amendments is anticipated to be beneficial to the environment, and it is expected that the overall environmental impacts will be positive.

Therefore, the determination of the environmental assessment is that there will be no significant impact to the human environment from this action.

This conclusion was published in the environmental assessment that was posted to the NRC rulemaking Web site: *http://www.regulations.gov* for 75 days after publication of the proposed rule. Two comments were received on the content of the environmental assessment. These comments did not change the conclusion of the environmental assessment. These comments are discussed in Section III.D of this document.

IX. Paperwork Reduction Act Statement

This final rule contains new or amended information collection requirements contained in 10 CFR parts 20, 30, 40, 50, 70, and 72, that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*). These requirements were approved by the Office of Management and Budget, approval number 3150–0014, –0017, –0020, –0011, –0009, and –0132.

The burden to the public for these information collections is estimated to average 12 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of these information collections, including suggestions for reducing the burden, to the Information Services Branch (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or by Internet electronic mail to *INFOCOLLECTS.Resource@NRC.GOV;* and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB–10202, (3150–0014, –0017, –0020, –0011, –0009, and –0132), Office of Management and Budget, Washington, DC 20503 or by Internet electronic mail to *Christine.J.Kymn@omb.eop.gov.*

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

X. Regulatory Analysis

As part of this final rulemaking, the Commission has prepared a regulatory analysis examining the costs and benefits of the rulemaking and alternatives considered by the Commission.

The regulatory analysis was performed over a 15-year analysis period using 2007 dollars. The implementation of the final rule by industry, the NRC and Agreement States is estimated to cost about $43 million, over the 15-year analysis period at a 3 percent discount rate. The NRC licensee costs are about $6 million, and the NRC costs are about $3 million. Agreement State licensee costs are about $22 million, and Agreement State costs are about $12 million. Virtually all of the industry costs are due to changes to 10 CFR parts 20 and 30.

The regulatory analysis is available for inspection in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD, and may be downloaded from the NRC rulemaking Web site at *http://www.regulations.gov.* Single copies of the regulatory analysis are available from Kevin O'Sullivan, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–8112, e-mail *Kevin.OSullivan@nrc.gov.*

XI. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule will not have a significant economic impact on a substantial number of small entities. Only about 300 NRC materials licensees are required to have decommissioning financial assurance and the large majority of these organizations do not fall within the scope of the definition of ''small entities'' set forth in the Regulatory Flexibility Act or the Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR part 121. Based on the regulatory analysis, the NRC believes that the amendments in this final rule are the least burdensome, most flexible alternative that would accomplish the NRC's regulatory objective.

XII. Backfit Analysis

As discussed more fully in the regulatory analysis, the NRC has determined that the NRC's backfitting rules at issue here (10 CFR 50.109, 70.76, and 72.62) do not require the preparation of a backfit analysis for this rulemaking. A backfit is the modification of equipment or procedures required to operate a facility resulting from new or amended NRC regulations, or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previously applicable staff position.

The new or amended regulations in this final rule either clarify existing requirements, or require the collection and reporting of information using existing equipment and procedures, or are administrative matters outside the scope of the backfitting rules. The amended survey and monitoring requirements in Part 20 of this rulemaking do not constitute a backfit, because they are information collection requirements to support licensee and NRC decisions on decommissioning planning and related activities. The decommissioning financial assurance requirements being amended in Parts 30, 40, 50, 70, and 72 of this rulemaking do not entail modifying any equipment or procedures required to operate the types of NRC-licensed facilities covered by the backfitting rules. These regulatory changes concern administrative matters and are not backfits. Therefore, as discussed further below, the NRC finds that preparation of

a backfit analysis is not required for this rulemaking.

In part, this rulemaking amends 10 CFR 20.1406 and 20.1501. Section 20.1406, ''Minimization of contamination,'' is amended by adding a new subsection (c) to read as follows:

(c) Licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing radiation protection requirements in Subpart B and radiological criteria for license termination in Subpart E of this part.

This is not a backfit because it clarifies licensee requirements under existing regulations applicable to licensed operations. The current § 20.1101(a) requires each licensee to implement a radiation protection program to ensure compliance with the regulations in 10 CFR part 20. The current § 20.1101(b) requires each licensee to use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA, during operations and during decommissioning. These operating procedures and controls need to include methods to minimize the introduction of residual radioactivity into the site, including the subsurface, during active facility operations to achieve doses that are ALARA. Otherwise, licensees will lack a substantive basis to demonstrate that they have achieved, during the life cycle of the facility (which includes decommissioning), public and occupational exposures that are ALARA. The concept of reducing residual radioactivity to ALARA levels as part of the decommissioning criteria has been a position of the NRC since at least 1994 (NUREG–1501, page iii). Licensees should already have these procedures in place as part of their radiation protection program, and 10 CFR 20.1406(c) clarifies this requirement.

As stated previously, this rulemaking also amends 10 CFR 20.1501, ''General'' (part of Subpart F, ''Surveys and Monitoring''). Section 20.1501 is amended by revising subsection (a), and inserting a new subsection (b), to read as follows:

(a) Each licensee shall make or cause to be made, surveys of areas, including the subsurface, that—

(1) May be necessary for the licensee to comply with the regulations in this part; and

(2) Are reasonable under the circumstances to evaluate—

(i) The magnitude and extent of radiation levels; and

(ii) Concentrations or quantities of residual radioactivity; and

(iii) The potential radiological hazards of the radiation levels and residual radioactivity detected.

(b) Notwithstanding § 20.2103(a) of this part, records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning, and such records must be retained in accordance with §§ 30.35(g), 40.36(f), 50.75(g), 70.25(g), or 72.30(d), as applicable.

The amended 10 CFR 20.1501(a) replaces the undefined term ''radioactive material'' with ''residual radioactivity,'' a term already defined in 10 CFR part 20. As defined in existing 10 CFR 20.1003, residual radioactivity includes subsurface contamination within its scope, and the word ''subsurface'' is being added to 10 CFR 20.1501(a). The current 10 CFR 20.1501(a)(2)(iii) already requires the evaluation of potential radiological hazards. Thus, as amended, 10 CFR 20.1501(a) makes clear that subsurface residual radioactivity is a potential radiological hazard that is within the scope of these survey requirements. This clarification of existing requirements does not represent a new NRC position and therefore does not fall within the definition of backfitting as set forth in the applicable backfitting regulations.

As stated previously, new paragraph (b) to 10 CFR 20.1501 requires that survey records describing the location and amount of subsurface residual radioactivity identified at a licensed site be kept with records important for decommissioning. The NRC licensees are already required to keep records important for decommissioning. See, e.g., 10 CFR 50.75(g), 70.25(g), and 72.30(d). Moreover, the new 10 CFR 20.1501(b) is not intended to require recordkeeping of any and all amounts of subsurface residual radioactivity but only amounts that are significant to achieve effective decommissioning planning and ALARA dose requirements. Regulatory changes imposing information collection and reporting requirements do not constitute regulatory actions to which the backfit rule applies. New subsection 20.1501(b) and amended section 20.1501(a) contain provisions which require the licensee to perform surveys to collect data on the location and amount of subsurface residual radioactivity that may be a radiological hazard and important for decommissioning planning. Neither of these provisions constitutes a backfit, because they are information collection requirements to support licensee and NRC decisions on decommissioning activities.

This rulemaking also revises decommissioning planning and financial assurance requirements in 10 CFR parts 30, 40, 50, 70 and 72. These revisions do not entail modifying any equipment or procedures required to operate the types of NRC-licensed facilities subject to the backfitting rules. Therefore, preparation of a backfit analysis is not required for the proposed revisions to the decommissioning planning and financial assurance requirements.

Accordingly, the NRC has determined that the final rule's provisions do not constitute backfitting and do not require the preparation of a backfit analysis. The regulatory analysis identifies the benefits and costs of the rulemaking, discusses the voluntary Industry Ground Water Protection Initiative (GPI), and evaluates other options for addressing the identified issues. The regulatory analysis constitutes a ''disciplined approach'' for evaluating the merits of the final rule and is consistent with the intent of the backfit rule.

XIII. Congressional Review Act

In accordance with the Congressional Review Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects

10 CFR Part 20

Byproduct material, Criminal penalties, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 30

Byproduct material, Criminal penalties, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 40

Criminal penalties, Government contracts, Hazardous materials transportation, Nuclear materials, Reporting and recordkeeping requirements, Source material, Uranium.

10 CFR Part 50

Antitrust, Classified information, Criminal penalties, Fire protection, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements.

10 CFR Part 70

Criminal penalties, Hazardous materials transportation, Material control and accounting, Nuclear materials, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Special nuclear material.

10 CFR Part 72

Administrative practice and procedure, Criminal penalties, Manpower training programs, Nuclear materials, Occupational safety and health, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Spent fuel, Whistleblowing.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR parts 20, 30, 40, 50, 70, and 72.

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

■ 1. The authority citation for Part 20 continues to read as follows:

Authority: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 953, 955, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236, 2297f), secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note), sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

■ 2. In § 20.1403, paragraph (c)(2) is removed, paragraphs (c)(3) and (c)(4) are redesignated as paragraphs (c)(2) and (c)(3), and paragraph (c)(1) is revised to read as follows:

§ 20.1403 Criteria for license termination under restricted conditions.

* * * * *

(c) * * *

(1) Funds placed into a trust segregated from the licensee's assets and outside the licensee's administrative control, and in which the adequacy of the trust funds is to be assessed based on an assumed annual 1 percent real rate of return on investment;

* * * * *

■ 3. In § 20.1404, paragraph (a)(5) is added to read as follows:

§ 20.1404 Alternate criteria for license termination.

(a) * * *

(5) Has provided sufficient financial assurance in the form of a trust fund to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

* * * * *

■ 4. In § 20.1406, paragraph (c) is added to read as follows:

§ 20.1406 Minimization of contamination.

* * * * *

(c) Licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing radiation protection requirements in Subpart B and radiological criteria for license termination in Subpart E of this part.

■ 5. In § 20.1501, paragraphs (b) and (c) are redesignated as paragraphs (c) and (d), paragraphs (a) introductory text, (a)(2)(ii) and (a)(2)(iii) are revised, and a new paragraph (b) is added to read as follows:

§ 20.1501 General.

(a) Each licensee shall make or cause to be made, surveys of areas, including the subsurface, that —

* * * * *

(2) * * *

(ii) Concentrations or quantities of residual radioactivity; and

(iii) The potential radiological hazards of the radiation levels and residual radioactivity detected.

(b) Notwithstanding § 20.2103(a) of this part, records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning, and such records must be retained in accordance with §§ 30.35(g), 40.36(f), 50.75(g), 70.25(g), or 72.30(d), as applicable.

* * * * *

PART 30—RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BY-PRODUCT MATERIAL

■ 6. The authority citation for part 30 continues to read as follows:

Authority: Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. 109–58, 119 Stat. 549 (2005).

Section 30.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102–486, sec. 2902, 106 Stat. 3123 (42 U.S.C. 5851). Section 30.34(b) also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 30.61 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

■ 7. In § 30.34, paragraph (b) is redesignated as paragraph (b)(1) and a new paragraph (b)(2) is added to read as follows:

§ 30.34 Terms and conditions of licenses.

* * * * *

(b) * * *

(2) An application for transfer of license must include:

(i) The identity, technical and financial qualifications of the proposed transferee; and

(ii) Financial assurance for decommissioning information required by § 30.35.

* * * * *

■ 8. In § 30.35, a new paragraph (c)(6) is added, and paragraphs (e), (f) introductory text, (f)(1), (f)(2) introductory text, and paragraph (f)(3) are revised, and a new paragraph (h) is added to read as follows:

§ 30.35 Financial assurance and recordkeeping for decommissioning.

* * * * *

(c) * * *

(6) If, in surveys made under 10 CFR 20.1501(a), residual radioactivity in the facility and environment, including the subsurface, is detected at levels that would, if left uncorrected, prevent the site from meeting the 10 CFR 20.1402 criteria for unrestricted use, the licensee must submit a decommissioning funding plan within one year of when the survey is completed.

* * * * *

(e)(1) Each decommissioning funding plan must be submitted for review and approval and must contain —

(i) A detailed cost estimate for decommissioning, in an amount reflecting:

(A) The cost of an independent contractor to perform all decommissioning activities;

(B) The cost of meeting the 10 CFR 20.1402 criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of 10 CFR 20.1403, the cost estimate may be based on meeting the 10 CFR 20.1403 criteria;

(C) The volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination; and

(D) An adequate contingency factor.

(ii) Identification of and justification for using the key assumptions contained in the DCE;

(iii) A description of the method of assuring funds for decommissioning from paragraph (f) of this section, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;

(iv) A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and

(v) A signed original of the financial instrument obtained to satisfy the requirements of paragraph (f) of this section (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).

(2) At the time of license renewal and at intervals not to exceed 3 years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this can not be done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs:

(i) Spills of radioactive material producing additional residual radioactivity in onsite subsurface material;

(ii) Waste inventory increasing above the amount previously estimated;

(iii) Waste disposal costs increasing above the amount previously estimated;

(iv) Facility modifications;

(v) Changes in authorized possession limits;

(vi) Actual remediation costs that exceed the previous cost estimate;

(vii) Onsite disposal; and

(viii) Use of a settling pond.

(f) The financial instrument must include the licensee's name, license number, and docket number, and the name, address, and other contact information of the issuer, and, if a trust is used, the trustee. When any of the foregoing information changes, the licensee must, within 30 days, submit financial instruments reflecting such changes. The financial instrument submitted must be a signed original or signed original duplicate, except where a copy of the signed original is specifically permitted. Financial assurance for decommissioning must be provided by one or more of the following methods:

(1) *Prepayment.* Prepayment is the deposit before the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment must be made into a trust account, and the trustee and the trust must be acceptable to the Commission.

(2) *A surety method, insurance, or other guarantee method.* These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, or letter of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix A to this part. For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix C to this part. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in Appendix D to this part. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in Appendix E to this part. Except for an external sinking fund, a parent company guarantee or a guarantee by the applicant or licensee may not be used in combination with any other financial methods used to satisfy the requirements of this section. A guarantee by the applicant or licensee may not be used in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

* * * * *

(3) *An external sinking fund in which deposits are made at least annually, coupled with a surety method, insurance, or other guarantee method, the value of which may decrease by the amount being accumulated in the sinking fund.* An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund must be in the form of a trust. If the other guarantee method is used, no surety or insurance may be combined with the external sinking fund. The surety, insurance, or other guarantee provisions must be as stated in paragraph (f)(2) of this section.

* * * * *

(h) In providing financial assurance under this section, each licensee must use the financial assurance funds only for decommissioning activities and each licensee must monitor the balance of funds held to account for market variations. The licensee must replenish the funds, and report such actions to the NRC, as follows:

(1) If, at the end of a calendar quarter, the fund balance is below the amount necessary to cover the cost of decommissioning, but is not below 75 percent of the cost, the licensee must increase the balance to cover the cost, and must do so within 30 days after the end of the calendar quarter.

(2) If, at any time, the fund balance falls below 75 percent of the amount necessary to cover the cost of decommissioning, the licensee must increase the balance to cover the cost, and must do so within 30 days of the occurrence.

(3) Within 30 days of taking the actions required by paragraph (h)(1) or (h)(2) of this section, the licensee must provide a written report of such actions to the Director, Office of Federal and State Materials and Environmental Management Programs, and state the new balance of the fund.

■ 9. In Appendix A to Part 30, Section II, the introductory text of paragraph A, paragraphs A.1.(i), A.1.(ii), A.1.(iii), A.2.(i), A.2.(ii), A.2.(iii), B, and C.1. are revised, in Section III paragraphs B, C, and D are revised, and new paragraphs E, F, and G are added to read as follows:

Appendix A to Part 30—Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

* * * * *

II. * * *

A. To pass the financial test, the parent company must meet the criteria of either paragraph A.1 or A.2 of this section. For purposes of applying the Appendix A criteria, tangible net worth must be

calculated to exclude all intangible assets and the net book value of the nuclear facility and site, and total net worth, which may include intangible assets, must be calculated to exclude the net book value and goodwill of the nuclear facility and site.

1. * * *

(i) Two of the following three ratios: A ratio of total liabilities to total net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.5; and

(ii) Net working capital and tangible net worth each at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all nuclear facilities or parts thereof (or prescribed amount if a certification is used); and

(iii) Tangible net worth of at least $21 million; and

* * * * *

2. * * *

(i) A current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, A, or BBB (including adjustments of + and −) as issued by Standard and Poor's or Aaa, Aa, A, or Baa (including adjustment of 1, 2, or 3) as issued by Moody's; and

(ii) Total net worth at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all nuclear facilities or parts thereof (or prescribed amount if a certification is used); and

(iii) Tangible net worth of at least $21 million; and

* * * * *

B. The parent company's independent certified public accountant must compare the data used by the parent company in the financial test, which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. The accountant must evaluate the parent company's off-balance sheet transactions and provide an opinion on whether those transactions could materially adversely affect the parent company's ability to pay for decommissioning costs. The accountant must verify that a bond rating, if used to demonstrate passage of the financial test, meets the requirements of paragraph A of this section. In connection with the auditing procedure, the licensee must inform the NRC within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

C.1. After the initial financial test, the parent company must annually pass the test and provide documentation of its continued eligibility to use the parent company guarantee to the Commission within 90 days after the close of each succeeding fiscal year.

* * * * *

III. * * *

* * * * *

B. If the licensee fails to provide alternate financial assurance as specified in the Commission's regulations within 90 days after receipt by the licensee and Commission of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide alternative financial assurance that meets the provisions of the Commission's regulations in the name of the licensee.

C. The parent company guarantee and financial test provisions must remain in effect until the Commission has terminated the license, accepted in writing the parent company's alternate financial assurances, or accepted in writing the licensee's financial assurances.

D. A standby trust to protect public health and safety and the environment must be established for decommissioning costs before the parent company guarantee agreement is submitted. The trustee and trust must be acceptable to the Commission. An acceptable trustee includes an appropriate State or Federal Government agency or an entity which has the authority to act as a trustee, whose trust operations are regulated and examined by a Federal or State agency. The Commission has the right to change the trustee. An acceptable trust will meet the regulatory criteria established in these regulations that govern the issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.

E. The guarantor must agree that it would be subject to Commission orders to make payments under the guarantee agreement.

F. The guarantor must agree that if the guarantor admits in writing its inability to pay its debts generally, or makes a general assignment for the benefit of creditors, or any proceeding is instituted by or against the guarantor seeking to adjudicate it as bankrupt or insolvent, or seeking dissolution, liquidation, winding-up, reorganization, arrangement, adjustment, protection, relief or composition of it or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking the entry of an order for relief or the appointment of a receiver, trustee, custodian, or other similar official for the guarantor or for any substantial part of its property, or the guarantor takes any action to authorize or effect any of the actions stated in this paragraph, then the Commission may:

1. Declare that the financial assurance guaranteed by the parent company guarantee agreement is immediately due and payable to the standby trust set up to protect the public health and safety and the environment, without diligence, presentment, demand, protest or any other notice of any kind, all of which are expressly waived by guarantor; and

2. Exercise any and all of its other rights under applicable law.

G. 1. The guarantor must agree to notify the NRC, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 (Bankruptcy) of the United States Code, or the occurrence of any other event listed in paragraph F of this Appendix, by or against:

(i) The guarantor;

(ii) The licensee;

(iii) An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

(iv) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

2. This notification must include:

(i) A description of the event, including major creditors, the amounts involved, and the actions taken to assure that the amount of funds guaranteed by the parent company guarantee for decommissioning will be transferred to the standby trust as soon as possible;

(ii) If a petition of bankruptcy was filed, the identity of the bankruptcy court in which the petition for bankruptcy was filed; and

(iii) The date of filing of any petitions.

■ 10. In Appendix C to part 30, in Section II, paragraphs A., B.(2) and B.(3) are revised, in Section III, paragraphs E and F are revised, and paragraphs G, H, and I are added to read as follows:

Appendix C to Part 30—Criteria Relating To Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

* * * * *

II. * * *

A. To pass the financial test a company must meet all of the criteria set forth in this section. For purposes of applying the Appendix C criteria, tangible net worth must be calculated to exclude all intangible assets and the net book value of the nuclear facility and site, and total net worth, which may include intangible assets, must be calculated to exclude the net book value and goodwill of the nuclear facility and site. These criteria include:

(1) Tangible net worth of at least $21 million, and total net worth at least 10 times the amount of decommissioning funds being assured by a self-guarantee for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all nuclear facilities or parts thereof (or the current amount required if certification is used).

(2) Assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the amount of decommissioning funds being assured by a self-guarantee, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all nuclear facilities or parts thereof (or the current amount required if certification is used).

(3) A current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A (including adjustments of + and −) as issued by Standard and Poor's, or Aaa, Aa, or A (including adjustments of 1, 2, or 3) as issued by Moody's.

B. * * *

(2) The company's independent certified public accountant must compare the data used by the company in the financial test, which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. The accountant must

evaluate the company's off-balance sheet transactions and provide an opinion on whether those transactions could materially adversely affect the company's ability to pay for decommissioning costs. The accountant must verify that a bond rating, if used to demonstrate passage of the financial test, meets the requirements of Section II, paragraph A of this appendix. In connection with the auditing procedure, the licensee must inform the NRC within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(3) After the initial financial test, the company must annually pass the test and provide documentation of its continued eligibility to use the self-guarantee to the Commission within 90 days after the close of each succeeding fiscal year.

* * * * *

III. * * *

E. (1) If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of ''A−'' and above by Standard and Poor's or in any category of ''A3'' and above by Moody's, the licensee will notify the Commission in writing within 20 days after publication of the change by the rating service.

(2) If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poor's and Moody's, the licensee no longer meets the requirements of Section II.A. of this appendix.

F. The applicant or licensee must provide to the Commission a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Commission, the licensee will fund the standby trust in the amount guaranteed by the self-guarantee agreement.

G. (1) A standby trust to protect public health and safety and the environment must be established for decommissioning costs before the self-guarantee agreement is submitted.

(2) The trustee and trust must be acceptable to the Commission. An acceptable trustee includes an appropriate State or Federal Government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency. The Commission has the right to change the trustee. An acceptable trust will meet the regulatory criteria established in these regulations that govern the issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.

H. The guarantor must agree that if the guarantor admits in writing its inability to pay its debts generally, or makes a general assignment for the benefit of creditors, or any proceeding is instituted by or against the guarantor seeking to adjudicate it as bankrupt or insolvent, or seeking dissolution, liquidation, winding-up, reorganization, arrangement, adjustment, protection, relief or composition of it or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking the entry of an order for relief or the appointment of a receiver, trustee, custodian, or other similar official for the guarantor or for any substantial part of its property, or the guarantor takes any action to authorize or effect any of the actions stated in this paragraph, then the Commission may:

(1) Declare that the financial assurance guaranteed by the self-guarantee agreement is immediately due and payable to the standby trust set up to protect the public health and safety and the environment, without diligence, presentment, demand, protest or any other notice of any kind, all of which are expressly waived by guarantor; and

(2) Exercise any and all of its other rights under applicable law.

I. The guarantor must notify the NRC, in writing, immediately following the occurrence of any event listed in paragraph H of this appendix, and must include a description of the event, including major creditors, the amounts involved, and the actions taken to assure that the amount of funds guaranteed by the self-guarantee agreement for decommissioning will be transferred to the standby trust as soon as possible.

■ 11. In Appendix D to Part 30 in Section II, the introductory text of paragraph A., paragraphs A.(1), A.(3), B.(1), and B.(2) are revised, in Section III paragraph D is revised and paragraphs E, F, and G are added to read as follows:

Appendix D to Part 30—Criteria Relating To Use of Financial Tests and Self-Guarantee for Providing Reasonable Assurance of Funds for Decommissioning by Commercial Companies That Have No Outstanding Rated Bonds

* * * * *

II. * * *

A. To pass the financial test a company must meet all of the criteria set forth in this section. For purposes of applying the Appendix D criteria, tangible net worth must be calculated to exclude all intangible assets and the net book value of the nuclear facility and site, and total net worth, which may include intangible assets, must be calculated to exclude the net book value and goodwill of the nuclear facility and site. These criteria include:

(1) Tangible net worth of at least $21 million, and total net worth of at least 10 times the amount of decommissioning funds being assured by a self-guarantee for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all nuclear facilities or parts thereof (or the current amount required if certification is used).

* * * * *

(3) A ratio of cash flow divided by total liabilities greater than 0.15 and a ratio of total liabilities divided by total net worth less than 1.5.

B. * * *

(1) The company's independent certified public accountant must compare the data used by the company in the financial test, which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. The accountant must evaluate the company's off-balance sheet transactions and provide an opinion on whether those transactions could materially adversely affect the company's ability to pay for decommissioning costs. In connection with the auditing procedure, the licensee must inform the NRC within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(2) After the initial financial test, the company must annually pass the test and provide documentation of its continued eligibility to use the self-guarantee to the Commission within 90 days after the close of each succeeding fiscal year.

* * * * *

III. * * *

D. The applicant or licensee must provide to the Commission a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Commission, the licensee will fund the standby trust in the amount of the current cost estimates for decommissioning.

E. A standby trust to protect public health and safety and the environment must be established for decommissioning costs before the self-guarantee agreement is submitted. The trustee and trust must be acceptable to the Commission. An acceptable trustee includes an appropriate State or Federal Government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency. The Commission will have the right to change the trustee. An acceptable trust will meet the regulatory criteria established in the part of these regulations that governs the issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.

F. The guarantor must agree that if the guarantor admits in writing its inability to pay its debts generally, or makes a general assignment for the benefit of creditors, or any proceeding is instituted by or against the guarantor seeking to adjudicate it as bankrupt or insolvent, or seeking dissolution, liquidation, winding-up, reorganization, arrangement, adjustment, protection, relief or composition of it or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking the entry of an order for relief or the appointment of a receiver, trustee, custodian, or other similar official for the guarantor or for any substantial part of its property, or the guarantor takes any action to authorize or effect any of the actions stated in this paragraph, then the Commission may:

(1) Declare that the financial assurance guaranteed by the self-guarantee agreement is immediately due and payable to the standby

trust set up to protect the public health and safety and the environment, without diligence, presentment, demand, protest or any other notice of any kind, all of which are expressly waived by guarantor; and

(2) Exercise any and all of its other rights under applicable law.

G. The guarantor must notify the NRC, in writing, immediately following the occurrence of any event listed in paragraph F of this appendix, and must include a description of the event, including major creditors, the amounts involved, and the actions taken to assure that the amount of funds guaranteed by the self-guarantee agreement for decommissioning will be transferred to the standby trust as soon as possible.

■ 12. In Appendix E to part 30, in Section II, paragraphs A.(1), B.(1), C.(1), and C.(2) are revised, in Section III, paragraphs D and E are revised and paragraphs F, G, and H are added to read as follows:

Appendix E to Part 30—Criteria Relating To Use of Financial Tests and Self-Guarantee for Providing Reasonable Assurance of Funds for Decommissioning by Nonprofit Colleges, Universities, and Hospitals

* * * * *

II. * * *

A. * * *

(1) For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A (including adjustments of + or −) as issued by Standard and Poor's (S&P) or Aaa, Aa, or A (including adjustments of 1, 2, or 3) as issued by Moody's.

* * * * *

B. * * *

(1) For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A (including adjustments of + or −) as issued by Standard and Poor's or Aaa, Aa, or A (including adjustments of 1, 2, or 3) as issued by Moody's.

* * * * *

C. * * *

(1) The licensee's independent certified public accountant must compare the data used by the licensee in the financial test, which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. The accountant must evaluate the licensee's off-balance sheet transactions and provide an opinion on whether those transactions could materially adversely affect the licensee's ability to pay for decommissioning costs. The accountant must verify that a bond rating, if used to demonstrate passage of the financial test, meets the requirements of Section II of this appendix. In connection with the auditing procedure, the licensee must inform the NRC within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the licensee no longer passes the test.

(2) After the initial financial test, the licensee must repeat passage of the test and provide documentation of its continued eligibility to use the self-guarantee to the Commission within 90 days after the close of each succeeding fiscal year.

* * * * *

III. * * *

D. The applicant or licensee must provide to the Commission a written guarantee (a written commitment by a corporate officer or officer of the institution) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Commission, the licensee will fund the standby trust in the amount of the current cost estimates for decommissioning.

E. (1) If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of ''A'' or above by either Standard and Poor's or Moody's, the licensee shall notify the Commission in writing within 20 days after publication of the change by the rating service.

(2) If the licensee's most recent bond issuance ceases to be rated in any category of ''A−'' and above by Standard and Poor's or in any category of ''A3'' and above by Moody's, the licensee no longer meets the requirements of Section II.A. of this appendix.

F. (1) A standby trust to protect public health and safety and the environment must be established for decommissioning costs before the self-guarantee agreement is submitted.

(2) The trustee and trust must be acceptable to the Commission. An acceptable trustee includes an appropriate State or Federal Government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency. The Commission has the right to change the trustee. An acceptable trust will meet the regulatory criteria established in the part of these regulations that governs the issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.

G. The guarantor must agree that if the guarantor admits in writing its inability to pay its debts generally, or makes a general assignment for the benefit of creditors, or any proceeding is instituted by or against the guarantor seeking to adjudicate it as bankrupt or insolvent, or seeking dissolution, liquidation, winding-up, reorganization, arrangement, adjustment, protection, relief or composition of it or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking the entry of an order for relief or the appointment of a receiver, trustee, custodian, or other similar official for guarantor or for any substantial part of its property, or the guarantor takes any action to authorize or effect any of the actions stated in this paragraph, then the Commission may:

(1) Declare that the financial assurance guaranteed by the self-guarantee agreement is immediately due and payable to the standby trust set up to protect the public health and safety and the environment, without diligence, presentment, demand, protest or any other notice of any kind, all of which are expressly waived by guarantor; and

(2) Exercise any and all of its other rights under applicable law.

H. The guarantor must notify the NRC, in writing, immediately following the occurrence of any event listed in paragraph G of this appendix, and must include a description of the event, including major creditors, the amounts involved, and the actions taken to assure that the amount of funds guaranteed by the self-guarantee agreement for decommissioning will be transferred to the standby trust as soon as possible.

PART 40—DOMESTIC LICENSING OF SOURCE MATERIAL

■ 13. The authority citation for part 40 continues to read as follows:

Authority: Secs. 62, 63, 64, 65, 81, 161, 182, 183, 186, 68 Stat. 932, 933, 935, 948, 953, 954, 955, as amended, secs. 11e(2), 83, 84, Pub. L. 95–604, 92 Stat. 3033, as amended, 3039, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2014(e)(2), 2092, 2093, 2094, 2095, 2111, 2113, 2114, 2201, 2232, 2233, 2236, 2282); sec. 274, Pub. L. 86–373, 73 Stat. 688 (42 U.S.C. 2021); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 275, 92 Stat. 3021, as amended by Pub. L. 97–415, 96 Stat. 2067 (42 U.S.C. 2022); sec. 193, 104 Stat. 2835, as amended by Pub. L. 104–134, 110 Stat. 1321, 1321–349 (42 U.S.C. 2243); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. 109–59, 119 Stat. 594 (2005).

Section 40.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102–486, sec. 2902, 106 Stat. 3123 (42 U.S.C. 5851). Section 40.31(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 40.46 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 40.71 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

■ 14. In § 40.36, a new paragraph (c)(5) is added, paragraph (d), the introductory text in paragraph (e), and paragraphs (e)(1), the introductory text of paragraph (e)(2) and paragraph (e)(3) are revised, and a new paragraph (g) is added to read as follows:

§ 40.36 Financial assurance and recordkeeping for decommissioning.

* * * * *

(c) * * *

(5) If, in surveys made under 10 CFR 20.1501(a), residual radioactivity in the facility and environment, including the subsurface, is detected at levels that would, if left uncorrected, prevent the site from meeting the 10 CFR 20.1402 criteria for unrestricted use, the licensee must submit a decommissioning funding plan within one year of when the survey is completed.

(d)(1) Each decommissioning funding plan must be submitted for review and approval and must contain—

(i) A detailed cost estimate for decommissioning, in an amount reflecting:

(A) The cost of an independent contractor to perform all decommissioning activities;

(B) The cost of meeting the 10 CFR 20.1402 criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of 10 CFR 20.1403, the cost estimate may be based on meeting the 10 CFR 20.1403 criteria;

(C) The volume of onsite subsurface material containing residual radioactivity that will require remediation; and

(D) An adequate contingency factor.

(ii) Identification of and justification for using the key assumptions contained in the DCE;

(iii) A description of the method of assuring funds for decommissioning from paragraph (e) of this section, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;

(iv) A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and

(v) A signed original, or if permitted, a copy, of the financial instrument obtained to satisfy the requirements of paragraph (e) of this section (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).

(2) At the time of license renewal and at intervals not to exceed 3 years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this can not be done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs:

(i) Spills of radioactive material producing additional residual radioactivity in onsite subsurface material;

(ii) Waste inventory increasing above the amount previously estimated;

(iii) Waste disposal costs increasing above the amount previously estimated;

(iv) Facility modifications;

(v) Changes in authorized possession limits;

(vi) Actual remediation costs that exceed the previous cost estimate;

(vii) Onsite disposal; and

(viii) Use of a settling pond.

(e) The financial instrument must include the licensee's name, license number, and docket number; and the name, address, and other contact information of the issuer, and, if a trust is used, the trustee. When any of the foregoing information changes, the licensee must, within 30 days, submit financial instruments reflecting such changes. The financial instrument submitted must be a signed original or signed original duplicate, except where a copy is specifically permitted. Financial assurance for decommissioning must be provided by one or more of the following methods:

(1) *Prepayment.* Prepayment is the deposit before the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment must be made into a trust account, and the trustee and the trust must be acceptable to the Commission.

(2) *A surety method, insurance, or other guarantee method.* These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, or letter of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix A to this part. For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix C to this part. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in Appendix D to this part. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in Appendix E to this part. Except for an external sinking fund, a parent company guarantee or guarantee by the applicant or licensee may not be used in combination with any other financial methods used to satisfy the requirements of this section. A guarantee by the applicant or licensee may not be used in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

* * * * *

(3) *An external sinking fund in which deposits are made at least annually, coupled with a surety method, insurance, or other guarantee method, the value of which may decrease by the amount being accumulated in the sinking fund.* An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund must be in the form of a trust. If the other guarantee method is used, no surety or insurance may be combined with the external sinking fund. The surety, insurance, or other guarantee provisions must be as stated in paragraph (e)(2) of this section.

* * * * *

(g) In providing financial assurance under this section, each licensee must use the financial assurance funds only for decommissioning activities and each licensee must monitor the balance of funds held to account for market variations. The licensee must replenish the funds, and report such actions to the NRC, as follows:

(1) If, at the end of a calendar quarter, the fund balance is below the amount necessary to cover the cost of decommissioning, but is not below 75 percent of the cost, the licensee must increase the balance to cover the cost, and must do so within 30 days after the end of the calendar quarter.

(2) If, at any time, the fund balance falls below 75 percent of the amount necessary to cover the cost of decommissioning, the licensee must increase the balance to cover the cost, and must do so within 30 days of the occurrence.

(3) Within 30 days of taking the actions required by paragraph (g)(1) or (g)(2) of this section, the licensee must provide a written report of such actions to the Director, Office of Federal and State Materials and Environmental Management Programs, and state the new balance of the fund.

■ 15. In § 40.46, the current paragraph is designated as paragraph (a) and a new paragraph (b) is added to read as follows:

§ 40.46 Inalienability of licenses.

* * * * *

(b) An application for transfer of license must include:

(1) The identity, technical and financial qualifications of the proposed transferee; and

(2) Financial assurance for decommissioning information required by § 40.36 or Appendix A to this part, as applicable.

■ 16. In Appendix A to part 40, Section II, Criterion 9 is revised to read as follows:

Appendix A to Part 40—Criteria Relating to the Operation of Uranium Mills and the Disposition of Tailings or Wastes Produced by the Extraction or Concentration of Source Material From Ores Processed Primarily for Their Source Material Content

* * * * *

II. * * *

Criterion 9—(a) Financial surety arrangements must be established by each mill operator before the commencement of operations to assure that sufficient funds will be available to carry out the decontamination and decommissioning of the mill and site and for the reclamation of any tailings or waste disposal areas. The amount of funds to be ensured by such surety arrangements must be based on Commission-approved cost estimates in a Commission-approved plan, or a proposed revision to the plan submitted to the Commission for approval, if the proposed revision contains a higher cost estimate, for:

(1) Decontamination and decommissioning of mill buildings and the milling site to levels which allow unrestricted use of these areas upon decommissioning, and

(2) The reclamation of tailings and/or waste areas in accordance with technical criteria delineated in Section I of this appendix.

(b) Each cost estimate must contain—

(1) A detailed cost estimate for decontamination, decommissioning, and reclamation, in an amount reflecting:

(i) The cost of an independent contractor to perform the decontamination, decommissioning and reclamation activities; and

(ii) An adequate contingency factor;

(2) An estimate of the amount of radioactive contamination in onsite subsurface material;

(3) Identification of and justification for using the key assumptions contained in the DCE; and

(4) A description of the method of assuring funds for decontamination, decommissioning, and reclamation.

(c) The licensee shall submit this plan in conjunction with an environmental report that addresses the expected environmental impacts of the milling operation, decommissioning and tailings reclamation, and evaluates alternatives for mitigating these impacts. The plan must include a signed original of the financial instrument obtained to satisfy the surety arrangement requirements of this criterion (unless a previously submitted and approved financial instrument continues to cover the cost estimate for decommissioning). The surety arrangement must also cover the cost estimate and the payment of the charge for long-term surveillance and control required by Criterion 10 of this section.

(d) To avoid unnecessary duplication and expense, the Commission may accept financial sureties that have been consolidated with financial or surety arrangements established to meet requirements of other Federal or state agencies and/or local governing bodies for decommissioning, decontamination, reclamation, and long-term site surveillance and control, provided such arrangements are considered adequate to satisfy these requirements and that the portion of the surety which covers the decommissioning and reclamation of the mill, mill tailings site and associated areas, and the long-term funding charge is clearly identified and committed for use in accomplishing these activities.

(e) The licensee's surety mechanism will be reviewed annually by the Commission to assure, that sufficient funds would be available for completion of the reclamation plan if the work had to be performed by an independent contractor.

(f) The amount of surety liability should be adjusted to recognize any increases or decreases resulting from:

(1) Inflation;

(2) Changes in engineering plans;

(3) Activities performed;

(4) Spills, leakage or migration of radioactive material producing additional contamination in onsite subsurface material that must be remediated to meet applicable remediation criteria;

(5) Waste inventory increasing above the amount previously estimated;

(6) Waste disposal costs increasing above the amount previously estimated;

(7) Facility modifications;

(8) Changes in authorized possession limits;

(9) Actual remediation costs that exceed the previous cost estimate;

(10) Onsite disposal; and

(11) Any other conditions affecting costs.

(g) Regardless of whether reclamation is phased through the life of the operation or takes place at the end of operations, an appropriate portion of surety liability must be retained until final compliance with the reclamation plan is determined.

(h) The appropriate portion of surety liability retained until final compliance with the reclamation plan is determined will be at least sufficient at all times to cover the costs of decommissioning and reclamation of the areas that are expected to be disturbed before the next license renewal. The term of the surety mechanism must be open ended, unless it can be demonstrated that another arrangement would provide an equivalent level of assurance. This assurance would be provided with a surety instrument which is written for a specified time (e.g., 5 years) and which must be automatically renewed unless the surety notifies the beneficiary (the Commission or the State regulatory agency) and the principal (the licensee) with reasonable time (e.g., 90 days) before the renewal date of their intention not to renew. In such a situation the surety requirement still exists and the licensee would be required to submit an acceptable replacement surety within a brief time to allow at least 60 days for the regulatory agency to collect.

(i) Proof of forfeiture must not be necessary to collect the surety. In the event that the licensee can not provide an acceptable replacement surety within the required time, the surety shall be automatically collected before its expiration. The surety instrument must provide for collection of the full face amount immediately on demand without reduction for any reason, except for trustee fees and expenses provided for in a trust agreement, and that the surety will not refuse to make full payment. The conditions described previously would have to be clearly stated on any surety instrument which is not open-ended, and must be agreed to by all parties. Financial surety arrangements generally acceptable to the Commission are:

(1) Trust funds;

(2) Surety bonds;

(3) Irrevocable letters of credit; and

(4) Combinations of the financial surety arrangements or other types of arrangements as may be approved by the Commission. If a trust is not used, then a standby trust must be set up to receive funds in the event the Commission or State regulatory agency exercises its right to collect the surety. The surety arrangement and the surety or trustee, as applicable, must be acceptable to the Commission. Self insurance, or any arrangement which essentially constitutes self insurance (e.g., a contract with a State or Federal agency), will not satisfy the surety requirement because this provides no additional assurance other than that which already exists through license requirements.

* * * * *

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES.

■ 17. The authority citation for part 50 continues to read as follows:

Authority: Secs. 102, 103, 104, 105, 161, 182, 183, 186, 189, 68 Stat. 936, 937, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. 109–58, 119 Stat. 194 (2005). Section 50.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102–486, Sec. 2902, 106 Stat. 3123 (42 U.S.C. 5841). Section 50.10 also issued under secs. 101, 185, 68 Stat. 955, as amended (42 U.S.C. 2131, 2235); sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.13, 50.54(dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138).

Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a and Appendix

Q also issued under sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under sec. 204, 88 Stat. 1245 (42 U.S.C. 5844). Sections 50.58, 50.91, and 50.92 also issued under Pub. L. 97–415, 96 Stat. 2073 (42 U.S.C. 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80–50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

■ 18. In § 50.75, the introductory text of paragraph (e)(1)(iii)(A), and paragraphs (f)(1) and (f)(2) are revised to read as follows:

§ 50.75 Reporting and recordkeeping for decommissioning planning.

* * * * *

(e) * * *

(1) * * *

(iii) * * *

(A) These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, or letter of credit. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

* * * * *

(f)(1) Each power reactor licensee shall report, on a calendar-year basis, to the NRC by March 31, 1999, and at least once every 2 years thereafter on the status of its decommissioning funding for each reactor or part of a reactor that it owns. However, each holder of a combined license under part 52 of this chapter need not begin reporting until the date that the Commission has made the finding under § 52.103(g) of this chapter. The information in this report must include, at a minimum, the amount of decommissioning funds estimated to be required pursuant to 10 CFR 50.75(b) and (c); the amount of decommissioning funds accumulated to the end of the calendar year preceding the date of the report; a schedule of the annual amounts remaining to be collected; the assumptions used regarding rates of escalation in decommissioning costs, rates of earnings on decommissioning funds, and rates of other factors used in funding projections; any contracts upon which the licensee is relying pursuant to paragraph (e)(1)(v) of this section; any modifications occurring to a licensee's current method of providing financial assurance since the last submitted report; and any material changes to trust agreements. If any of the preceding items is not applicable, the licensee should so state in its report. Any licensee for a plant that is within 5 years of the projected end of its operation, or where conditions have changed such that it will close within 5 years (before the end of its licensed life), or that has already closed (before the end of its licensed life), or that is involved in a merger or an acquisition shall submit this report annually.

(2) Each power reactor licensee shall report, on a calendar-year basis, to the NRC by March 31, 1999, and at least once every 2 years thereafter on the status of its decommissioning funding for each reactor or part of a reactor that it owns. The information in this report must include, at a minimum, the amount of decommissioning funds estimated to be required pursuant to 10 CFR 50.75(b) and (c); the amount of decommissioning funds accumulated to the end of the calendar year preceding the date of the report; a schedule of the annual amounts remaining to be collected; the assumptions used regarding rates of escalation in decommissioning costs, rates of earnings on decommissioning funds, and rates of other factors used in funding projections; any contracts upon which the licensee is relying pursuant to paragraph (e)(1)(v) of this section; any modifications occurring to a licensee's current method of providing financial assurance since the last submitted report; and any material changes to trust agreements. If any of the preceding items is not applicable, the licensee should so state in its report. Any licensee for a plant that is within 5 years of the projected end of its operation, or where conditions have changed such that it will close within 5 years (before the end of its licensed life), or that has already closed (before the end of its licensed life), or that is involved in a merger or an acquisition shall submit this report annually.

* * * * *

■ 19. In § 50.82, paragraph (a)(4)(i) is revised, and paragraphs (a)(8)(v), (a)(8)(vi), and (a)(8)(vii) are added to read as follows:

§ 50.82 Termination of license.

* * * * *

(a) * * *

(4)(i) Within 2 years following permanent cessation of operations, the licensee shall submit a post-shutdown decommissioning activities report (PSDAR) to the NRC, and a copy to the affected State(s). The PSDAR must contain a description of the planned decommissioning activities along with a schedule for their accomplishment, a discussion that provides the reasons for concluding that the environmental impacts associated with site-specific decommissioning activities will be bounded by appropriate previously issued environmental impact statements, and a site-specific DCE, including the projected cost of managing irradiated fuel.

* * * * *

(8) * * *

(v) After submitting its site-specific DCE required by paragraph (a)(4)(i) of this section, and until the licensee has completed its final radiation survey and demonstrated that residual radioactivity has been reduced to a level that permits termination of its license, the licensee must annually submit to the NRC, by March 31, a financial assurance status report. The report must include the following information, current through the end of the previous calendar year:

(A) The amount spent on decommissioning, both cumulative and over the previous calendar year, the remaining balance of any decommissioning funds, and the amount provided by other financial assurance methods being relied upon;

(B) An estimate of the costs to complete decommissioning, reflecting any difference between actual and estimated costs for work performed during the year, and the decommissioning criteria upon which the estimate is based;

(C) Any modifications occurring to a licensee's current method of providing financial assurance since the last submitted report; and

(D) Any material changes to trust agreements or financial assurance contracts.

(vi) If the sum of the balance of any remaining decommissioning funds, plus earnings on such funds calculated at not greater than a 2 percent real rate of return, together with the amount provided by other financial assurance methods being relied upon, does not cover the estimated cost to complete the decommissioning, the financial assurance status report must include additional financial assurance to cover the estimated cost of completion.

(vii) After submitting its site-specific DCE required by paragraph (a)(4)(i) of this section, the licensee must annually submit to the NRC, by March 31, a report on the status of its funding for managing irradiated fuel. The report must include the following information, current through the end of the previous calendar year:

(A) The amount of funds accumulated to cover the cost of managing the irradiated fuel;

(B) The projected cost of managing irradiated fuel until title to the fuel and possession of the fuel is transferred to the Secretary of Energy; and

(C) If the funds accumulated do not cover the projected cost, a plan to obtain additional funds to cover the cost.

* * * * *

PART 70—DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

■ 20. The authority citation for Part 70 continues to read as follows:

Authority: Secs. 51, 53, 161, 182, 183, 68 Stat. 929, 930, 948, 953, 954, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2201, 2232, 2233, 2282, 2297f); secs. 201, as amended, 202, 204, 206, 88 Stat. 1242, as amended, 1244, 1245, 1246 (42 U.S.C. 5841, 5842, 5845, 5846). Sec. 193, 104 Stat. 2835, as amended by Pub. L. 104–134, 110 Stat. 1321, 1321–349 (42 U.S.C. 2243); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Sections 70.1(c) and 70.20a(b) also issued under secs. 135, 141, Pub. L. 97–425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 70.7 is also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102–486, sec. 2902, 106 Stat. 3123 (42 U.S.C. 5851). Section 70.21(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 70.31 also issued under sec. 57d, Pub. L. 93–377, 88 Stat. 475 (42 U.S.C. 2077). Sections 70.36 and 70.44 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 70.81 also issued under secs. 186, 187, 68 Stat. 955 (42 U.S.C. 2236, 2237). Section 70.82 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138).

■ 21. In § 70.25, a new paragraph (c)(5) is added, paragraph (e), the introductory text in paragraph (f), and paragraph (f)(1), the introductory text of paragraph (f)(2) and paragraph (f)(3) are revised, and a new paragraph (h) is added to read as follows:

§ 70.25 Financial assurance and recordkeeping for decommissioning.

* * * * *

(c) * * *

(5) If, in surveys made under 10 CFR 20.1501(a), residual radioactivity in the facility and environment, including the subsurface, is detected at levels that would, if left uncorrected, prevent the site from meeting the 10 CFR 20.1402 criteria for unrestricted use, the licensee must submit a decommissioning funding plan within one year of when the survey is completed.

* * * * *

(e)(1) Each decommissioning funding plan must be submitted for review and approval and must contain—

(i) A detailed cost estimate for decommissioning, in an amount reflecting:

(A) The cost of an independent contractor to perform all decommissioning activities;

(B) The cost of meeting the 10 CFR 20.1402 criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of 10 CFR 20.1403, the cost estimate may be based on meeting the 10 CFR 20.1403 criteria;

(C) The volume of onsite subsurface material containing residual radioactivity that will require remediation; and

(D) An adequate contingency factor.

(ii) Identification of and justification for using the key assumptions contained in the DCE;

(iii) A description of the method of assuring funds for decommissioning from paragraph (f) of this section, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;

(iv) A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and

(v) A signed original, or, if permitted, a copy, of the financial instrument obtained to satisfy the requirements of paragraph (f) of this section (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).

(2) At the time of license renewal and at intervals not to exceed 3 years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this can not be done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs:

(i) Spills of radioactive material producing additional residual radioactivity in onsite subsurface material;

(ii) Waste inventory increasing above the amount previously estimated;

(iii) Waste disposal costs increasing above the amount previously estimated;

(iv) Facility modifications;

(v) Changes in authorized possession limits;

(vi) Actual remediation costs that exceed the previous cost estimate;

(vii) Onsite disposal; and

(viii) Use of a settling pond.

(f) The financial instrument must include the licensee's name, license number, and docket number; and the name, address, and other contact information of the issuer, and, if a trust is used, the trustee. When any of the foregoing information changes, the licensee must, within 30 days, submit financial instruments reflecting such changes. Financial assurance for decommissioning must be provided by one or more of the following methods:

(1) *Prepayment.* Prepayment is the deposit before the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment must be made into a trust account, and the trustee and the trust must be acceptable to the Commission.

(2) *A surety method, insurance, or other guarantee method.* These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, or letter of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix A to this part. For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix C to this part. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in Appendix D to this part. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in Appendix E to this part. Except for an external sinking fund, a parent company guarantee or a guarantee by the applicant or licensee may not be used in combination with any other financial methods used to satisfy the requirements of this section. A guarantee by the applicant or licensee may not be used in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

* * * * *

(3) *An external sinking fund in which deposits are made at least annually, coupled with a surety method, insurance, or other guarantee method, the value of which may decrease by the amount being accumulated in the sinking fund.* An external sinking fund

is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund must be in the form of a trust. If the other guarantee method is used, no surety or insurance may be combined with the external sinking fund. The surety, insurance, or other guarantee provisions must be as stated in paragraph (f)(2) of this section.

* * * * *

(h) In providing financial assurance under this section, each licensee must use the financial assurance funds only for decommissioning activities and each licensee must monitor the balance of funds held to account for market variations. The licensee must replenish the funds, and report such actions to the NRC, as follows:

(1) If, at the end of a calendar quarter, the fund balance is below the amount necessary to cover the cost of decommissioning, but is not below 75 percent of the cost, the licensee must increase the balance to cover the cost, and must do so within 30 days after the end of the calendar quarter.

(2) If, at any time, the fund balance falls below 75 percent of the amount necessary to cover the cost of decommissioning, the licensee must increase the balance to cover the cost, and must do so within 30 days of the occurrence.

(3) Within 30 days of taking the actions required by paragraph (h)(1) or (h)(2) of this section, the licensee must provide a written report of such actions to the Director, Office of Federal and State Materials and Environmental Management Programs, and state the new balance of the fund.

■ 22. In § 70.36, the current paragraph is designated as paragraph (a) and a new paragraph (b) is added to read as follows:

§ 70.36 Inalienability of licenses.

* * * * *

(b) An application for transfer of license must include:

(1) The identity, technical and financial qualifications of the proposed transferee; and

(2) Financial assurance for decommissioning information required by § 70.25.

PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL, HIGH-LEVEL RADIOACTIVE WASTE, AND REACTOR-RELATED GREATER THAN CLASS C WASTE

■ 23. The authority citation for part 72 continues to read as follows:

Authority: Secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended; sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2232, 2233, 2234, 2236, 2237, 2238, 2282); sec. 274, Pub. L. 86–373, 73 Stat. 688, as amended (42 U.S.C. 2021); sec. 201, as amended; 202, 206, 88 Stat. 1242, as amended; 1244, 1246 (42 U.S.C. 5841, 5842, 5846); Pub. L. 95–601, sec. 10, 92 Stat. 2951, as amended by Pub. L. 102–486, sec. 7902, 106 Stat. 3123 (42 U.S.C. 5851); sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332); secs. 131, 132, 133, 135, 137, 141, Pub. L. 97–425, 96 Stat. 2229, 2230, 2232, 2241; sec. 148, Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10151, 10152, 10153, 10155, 10157, 10161, 10168); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. 109–58, 119 Stat. 549 (2005).

Section 72.44(g) also issued under secs. 142(b) and 148(c), (d), Pub. L. 100–203, 101 Stat. 1330–232, 1330–236 (42 U.S.C. 10162(b), 10168(c), (d)). Section 72.46 also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97–425, 96 Stat. 2230 (42 U.S.C. 10154). Section 72.96(d) also issued under sec. 145(g), Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10165(g)). Subpart J also issued under secs. 2(2), 2(15), 2(19), 117(a), 141(h), Pub. L. 97–425, 96 Stat. 2202, 2203, 2204, 2222, 2224 (42 U.S.C. 10101, 10137(a), 10161(h)). Subparts K and L are also issued under sec. 133, 98 Stat. 2230 (42 U.S.C. 10153) and sec. 218(a), 96 Stat. 2252 (42 U.S.C. 10198).

■ 24. In § 72.13, paragraph (c) is revised to read as follows:

§ 72.13 Applicability.

* * * * *

(c) The following sections apply to activities associated with a general license: 72.1; 72.2(a)(1), (b), (c), and (e); 72.3 through 72.6(c)(1); 72.7 through 72.13(a) and (c); 72.30(b), (c), (d), (e) and (f); 72.32(c) and (d); 72.44(b) and (f); 72.48; 72.50(a); 72.52(a), (b), (d), and (e); 72.60; 72.62; 72.72 through 72.80(f); 72.82 through 72.86; 72.104; 72.106; 72.122; 72.124; 72.126; 72.140 through 72.176; 72.190; 72.194; 72.210 through 72.220, and 72.240(a).

* * * * *

■ 25. In § 72.30, paragraph (b) is revised, paragraph (c) is redesignated as paragraph (e) and the introductory text of the newly redesignated paragraph (e), paragraphs (e)(1), the introductory text of paragraph (e)(2) and paragraph (e)(3) are revised, paragraph (e)(5) is revised, paragraph (d) is redesignated as paragraph (f) and the newly redesignated paragraphs (f)(3)(ii) and (f)(4) are revised, and new paragraphs (c), (d), and (g) are added to read as follows:

§ 72.30 Financial assurance and recordkeeping for decommissioning.

* * * * *

(b) Each holder of, or applicant for, a license under this part must submit for NRC review and approval a decommissioning funding plan that must contain:

(1) Information on how reasonable assurance will be provided that funds will be available to decommission the ISFSI or MRS.

(2) A detailed cost estimate for decommissioning, in an amount reflecting:

(i) The cost of an independent contractor to perform all decommissioning activities;

(ii) An adequate contingency factor; and

(iii) The cost of meeting the § 20.1402 of this chapter criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of § 20.1403 of this chapter, the cost estimate may be based on meeting the § 20.1403 criteria.

(3) Identification of and justification for using the key assumptions contained in the DCE.

(4) A description of the method of assuring funds for decommissioning from paragraph (e) of this section, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility.

(5) The volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination.

(6) A certification that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning.

(c) At the time of license renewal and at intervals not to exceed 3 years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this can not be done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan and must specifically consider the effect of the

following events on decommissioning costs:

(1) Spills of radioactive material producing additional residual radioactivity in onsite subsurface material.

(2) Facility modifications.

(3) Changes in authorized possession limits.

(4) Actual remediation costs that exceed the previous cost estimate.

(d) If, in surveys made under 10 CFR 20.1501(a), residual radioactivity in soils or groundwater is detected at levels that would require such radioactivity to be reduced to a level permitting release of the property for unrestricted use under the decommissioning requirements in part 20 of this chapter, the licensee must submit a new or revised decommissioning funding plan within one year of when the survey is completed.

(e) The financial instrument must include the licensee's name, license number, and docket number; and the name, address, and other contact information of the issuer, and, if a trust is used, the trustee. When any of the foregoing information changes, the licensee must, within 30 days, submit financial instruments reflecting such changes. Financial assurance for decommissioning must be provided by one or more of the following methods:

(1) *Prepayment.* Prepayment is the deposit before the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment must be made into a trust account, and the trustee and the trust must be acceptable to the Commission.

(2) *A surety method, insurance, or other guarantee method.* These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, or letter of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix A to part 30 of this chapter. For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix C to part 30 of this chapter. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in Appendix D to part 30 of this chapter. Except for an external sinking fund, a parent company guarantee or a guarantee by the applicant or licensee may not be used in combination with other financial methods to satisfy the requirements of this section. A guarantee by the applicant or licensee may not be used in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

* * * * *

(3) *An external sinking fund in which deposits are made at least annually, coupled with a surety method, insurance, or other guarantee method, the value of which may decrease by the amount being accumulated in the sinking fund.* An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund must be in the form of a trust. If the other guarantee method is used, no surety or insurance may be combined with the external sinking fund. The surety, insurance, or other guarantee provisions must be as stated in paragraph (e)(2) of this section.

* * * * *

(5) In the case of licensees who are issued a power reactor license under part 50 of this chapter or ISFSI licensees who are an electric utility, as defined in part 50 of this chapter, with a specific license issued under this part, the methods of 10 CFR 50.75(b), (e), and (h), as applicable. In the event that funds remaining to be placed into the licensee's ISFSI decommissioning external sinking fund are no longer approved for recovery in rates by a competent rate making authority, the licensee must make changes to provide financial assurance using one or more of the methods stated in paragraphs (1) through (4) of this section.

(f) * * *

(3) * * *

(ii) All areas outside of restricted areas that require documentation under § 72.30(f)(1).

(4) Records of the cost estimate performed for the decommissioning funding plan and records of the funding method used for assuring funds are available for decommissioning.

(g) In providing financial assurance under this section, each licensee must use the financial assurance funds only for decommissioning activities and each licensee must monitor the balance of funds held to account for market variations. The licensee must replenish the funds, and report such actions to the NRC, as follows:

(1) If, at the end of a calendar year, the fund balance is below the amount necessary to cover the cost of decommissioning, but is not below 75 percent of the cost, the licensee must increase the balance to cover the cost, and must do so within 30 days after the end of the calendar year.

(2) If, at any time, the fund balance falls below 75 percent of the amount necessary to cover the cost of decommissioning, the licensee must increase the balance to cover the cost, and must do so within 30 days of the occurrence.

(3) Within 30 days of taking the actions required by paragraph (g)(1) or (g)(2) of this section, the licensee must provide a written report of such actions to the Director, Office of Federal and State Materials and Environmental Management Programs, and state the new balance of the fund.

■ 26. In § 72.50, paragraph (b)(3) is added to read as follows:

§ 72.50 Transfer of license.

* * * * *

(b) * * *

(3) The application shall describe the financial assurance that will be provided for the decommissioning of the facility under § 72.30.

* * * * *

■ 27. In § 72.80, paragraphs (e) and (f) are revised to read as follows:

§ 72.80 Other records and reports.

* * * * *

(e) Before license termination, the licensee shall forward records required by § 20.2103(b)(4), of this chapter, and § 72.30(f) to the appropriate NRC Regional Office.

(f) If licensed activities are transferred or assigned in accordance with § 72.44(b)(1), the licensee shall transfer the records required by § 20.2103(b)(4), of this chapter, and § 72.30(f) to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated.

* * * * *

Dated at Rockville, Maryland, this 2nd day of June 2011.

For the Nuclear Regulatory Commission.

Andrew L. Bates,

Acting Secretary for the Commission.

[FR Doc. 2011–14267 Filed 6–16–11; 8:45 am]

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Part III

Department of Commerce

National Oceanic and Atmospheric Administration

50 CFR Part 648

Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Annual Catch Limits and Accountability Measures; Proposed Rule

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 100902424–1290–02]

RIN 0648–BA23

Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Annual Catch Limits and Accountability Measures

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to implement an Omnibus Amendment to all Mid-Atlantic Fishery Management Council (Council) fishery management plans (FMPs) in order to bring all Council FMPs into compliance with the requirements of the Magnuson-Stevens Act (MSA), as amended by the Magnuson-Stevens Fishery Conservation and Management Reauthorization Act of 2006 (MSRA), which requires establishment of Annual Catch Limits (ACLs) and Accountability Measures (AMs) for stocks not subject to the annual life cycle or other exemptions. There are multiple intended effects of the Omnibus Amendment: To establish a comprehensive framework for all Council FMPs that is compliant with the MSA requirements and consistent with the National Standard 1 guidelines issued by NMFS; to implement a process that more formally utilizes scientific recommendations in the establishment of annual catch levels; to establish a framework to derive ACLs with AM backstops from that scientific advice; and to establish processes for revisiting and modifying the measures that would be established by the respective FMP amendments so that overfishing is prevented, stocks are rebuilt as needed, and Optimum Yield (OY) may be achieved for all managed stocks under the Council's jurisdiction.

DATES: Comments must be received on or before July 18, 2011.

ADDRESSES: You may submit comments, identified by RIN 0648–BA23, by any one of the following methods:

- *Electronic Submissions:* Submit all electronic public comments via the Federal eRulemaking Portal *http://www.regulations.gov.*
- *Fax:* (978) 281–9135.
- *Mail and hand delivery:* Patricia A. Kurkul, Regional Administrator, NMFS, Northeast Regional Office, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope: ''Comments on Mid-Atlantic ACL/AM Omnibus Amendment Proposed Rule.''

Instructions: All comments received are a part of the public record and will generally be posted to *http://www.regulations.gov* without change. All Personal Identifying Information (for example, name, address, *etc.*) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

NMFS will accept anonymous comments (enter N/A in the required fields, if you wish to remain anonymous). You may submit attachments to electronic comments in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

Copies of the draft Omnibus Amendment document, including the Environmental Assessment and Regulatory Impact Review (EA/RIR) and other supporting documents for the Omnibus Amendment are available from Dr. Christopher M. Moore, Executive Director, Mid-Atlantic Fishery Management Council, Suite 201, 800 North State Street, Dover, DE 19901. The draft Omnibus Amendment, as submitted to NMFS by the Council, is also accessible via the Internet at *http://www.nero.noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Michael Ruccio, Fishery Policy Analyst, (978) 281–9104.

SUPPLEMENTARY INFORMATION:

Background

Congress passed the MSRA in 2006, which was signed into law on January 12, 2007. The MSRA amended the MSA to include new requirements for ACLs and AMs (16 U.S.C. 1853 section 303(a)(15)) and the formal incorporation of scientific advice provided to Regional Fishery Management Councils (RFMCs) from their respective Scientific and Statistical Committees (SSCs) in the establishment of catch levels ((16 U.S.C. 1853 section 302(1)(g)(B)). The inclusion of these new components in the MSA was intended to ensure stock rebuilding, as needed, for stocks subject to overfishing and to ensure all other fish stocks would not become overfished.

National Standard 1 (NS1) of the MSA requires that conservation and management measures ''shall prevent overfishing, while achieving, on a continuing basis, the optimum yield (OY) from each fishery * * *''. NS1 guidelines prepared by NMFS provide definitions and descriptive frameworks for how RFMCs should use Acceptable Biological Catch (ABC) recommendations from their SSCs and how to develop and utilize ACL and AM measures now required under the MSA.

To respond to the MSA requirements and NS1 guidelines, the Council decided to amend the Atlantic Mackerel, Squids, and Butterfish; Atlantic Bluefish; Spiny Dogfish; Summer Flounder, Scup, and Black Sea Bass; the Surfclam and Ocean Quahog; and the Tilefish FMPs in a single, comprehensive action. The Omnibus Amendment development process was envisioned from the onset as a multiple year project given amount of work necessary to develop ABC control rules, ACLs, AMs. The Council conducted public scoping and developed the Omnibus Amendment over the course of 2009 and 2010. The development process included several meetings of the full Council, joint meetings with the Council and Atlantic States Marine Fisheries Commission (Commission), meetings of both the Council's SSC and its scientific uncertainty subcommittee, a subgroup of the full SSC which was formed to develop both ABC control rules and approaches for addressing scientific uncertainty, the Omnibus Amendment Fishery Management Action Team, and four formal public hearings. The Council took final action in August 2010 and NMFS has utilized the interim time between the Council's final action to review, comment, and develop the draft implementing regulations contained in this rule.

NMFS proposes regulations to implement the measures in the Council Omnibus Amendment to establish the following: ABC control rules for use by the SSC in recommending ABC to the Council; a risk policy for use in conjunction with the ABC control rules to inform the SSC of the Council's preferred tolerance for the risk of overfishing a stock; ACLs for all Council-managed stocks except *Loligo* and *Illex* squids, which are exempt from the ACL/AM requirements because they are not overfished and have annual life cycles; comprehensive AMs for all established ACLs; descriptions of the process to review ACL and AM performance; and establishment of processes for the future modification of the measures established through the Omnibus Amendment. The Omnibus Amendment would implement the outlined measures through the following specific FMP amendments: Amendment 13 to the Atlantic

Mackerel, Squids, and Butterfish FMP; Amendment 3 to the Atlantic Bluefish FMP; Amendment 2 to the Spiny Dogfish FMP; Amendment 15 to the Summer Flounder, Scup, and Black Sea Bass FMP; Amendment 16 to the Surfclam and Ocean Quahog FMP; and Amendment 3 to the Tilefish FMP.

A notice of availability (NOA) for the Omnibus Amendment was published on May 23, 2010 (76 FR 29717). As part for the Secretarial review process for FMP amendments, NMFS is soliciting specific feedback on the decision to approve, partially approve, or disapprove the Council's Omnibus Amendment through the NOA. Public comments are being solicited on the amendment through the end of the comment period on July 22, 2011. In addition, NMFS is proposing through this rule, specific measures to implement the Omnibus Amendment and soliciting public input on those specific measures designed to implement the Omnibus Amendment, should it be fully approved by NMFS. Public comments on the proposed rule must be received by the end of the comment period on the amendment, as published in the NOA, to be considered in the decision to approve or disapprove the amendment. All comments received by the end of the comment period on the amendment, whether specifically directed to the amendment or this proposed rule, will be considered in the approval/disapproval decision. Comments received after that date will not be considered in the approval/disapproval decision on the amendment, but may be considered in the development of the final rule. To be considered, comments must be received by close of business on the last day of the comment period; that does not mean postmarked or otherwise transmitted by that date.

Proposed Measures

The remainder of this preamble is organized into sections along the same lines as the Council's Omnibus Amendment document: Proposed ABC control rules and risk policy; FMP and species-specific proposed ACLs and AMs; and proposed performance review and future Omnibus Amendment measures.

ABC Control Rules

The Council's proposed ABC control rule framework considers the robustness of the overfishing level (OFL) calculation and associated probability distribution generated by either the stock assessment or the SSC. The Council has proposed four ABC control rule levels to address the varying amount of scientific uncertainty contained within the stock assessment information and approaches utilized to derive OFL. The control rule levels are generally organized in rank order from the lowest level of scientific uncertainty (*i.e.,* most certain) to most uncertain and/or data poor. The proposed ABC control rules are designed to be used in conjunction with the Council's proposed risk policy described in the next section of this preamble.

The proposed Level 1 ABC control rule represents an ideal assessment. In theory, a Level 1 stock assessment would likely be unbiased and fully consider uncertainty in the precision of estimates. Under the proposed Level 1 control rule, ABC would be determined by the SSC solely on the basis of the probability of overfishing, as informed by the Council's risk policy, and the probability distribution of the OFL.

The proposed ABC control rule for Level 2 assessments has a higher degree of uncertainty than does Level 1. Level 2 assessments are distinguished from Level 1 in that some key features of the stock biology, fisheries that exploit it, or data collection methods are missing from the assessment and, thus, introduce some level of uncertainty to the assessment information. The ABC in Level 2 assessments will be determined by the Council's risk policy, and the OFL probability distribution will be based on the specified distribution in the stock assessment.

The proposed ABC control rule approach for Level 3 assessments is the same as Level 2 except that the assessment does not contain estimates of the OFL probability distribution or, in the opinion of the SSC, the assessment-provided distribution does not adequately reflect uncertainty in the OFL estimate. Assessments in this level are judged by the SSC to over- or underestimate the accuracy of the OFL, and the SSC would adjust the OFL distribution to develop an ABC by using the Council's risk policy or applying a default control rule of 75 percent of the fishing mortality rate (F) at maximum sustainable yield (F_{MSY}) as the ABC if an acceptable OFL distribution cannot be developed by the SSC.

The ABC control rule approach for Level 4 assessments, the lowest level of proposed categorization, does not have point estimates of OFL, or else the OFL distributions are not considered reliable by the SSC. Stocks that are highly uncertain or that fail peer review would fall into the Level 4 category. Stocks in Level 4 may only have a reliable estimate of abundance trend and catch, but may have missing or unreliable absolute abundance, estimates of F, and/or biological reference points. Stocks assigned to Level 4 would have ABC derived by the SSC using case-by-case approaches based on biomass, catch history, and the Council's risk policy.

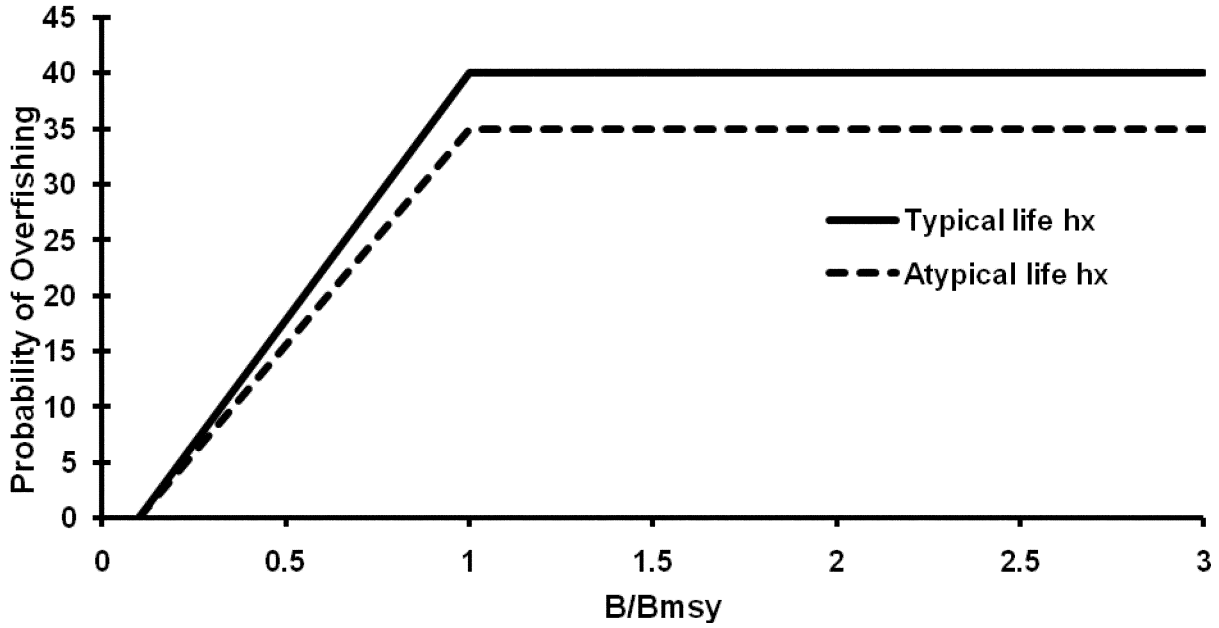
The Council has acknowledged that the SSC may deviate from the control rule framework or level criteria to recommend an ABC to the Council, but must provide adequate justification for so doing, including why the alternative approach applied is consistent with the best available scientific information.

Council Risk Policy

The Council's proposed risk policy is designed to inform the SSC of the Council's tolerance for the risk of overfishing. The Council's preferred risk policy would be used in conjunction with the ABC control rule framework when the SSC makes ABC recommendations. When an OFL distribution is available and considered reliable by the SSC, the applicable tolerance for overfishing risk, as informed by the risk policy, would be selected from the distribution to derive the ABC recommendation.

The Council's recommended risk policy considers whether the life history of the species in question is typical or atypical, as determined by the SSC, and uses the current stock replenishment threshold defined as the ratio of biomass $(B)/B_{MSY}$ to identify the probability of overfishing the stock (see Figure 1). The probability of overfishing would be set at zero when the B/B_{MSY} ratio is less than or equal to 0.10; this was identified by the Council as a preventative measure to ensure that biomass for a given stock does not fall to a very low level from which recovery is more difficult. It should be noted that setting the probability of overfishing at zero does not necessarily equate to a prohibition on catch or even landings. The probability of overfishing increases linearly from zero when the B/B_{MSY} ratio is 0.10 until the ratio of B/B_{MSY} = 1.0. For all B/B_{MSY} ratio values greater than or equal to 1.0, the probability of overfishing the stock becomes constant at 40 percent for species with a typical life history, and 35 percent for species with an atypical life history.

Figure 1. Council's Proposed Overfishing Risk Policy.



For stocks under a rebuilding plan, the risk policy would require that the probability of exceeding the rebuilding target F ($F_{REBUILD}$) would be at least 50 percent, unless modified to a lesser value (*i.e.,* a higher probability that $F_{REBUILD}$ would not be exceeded) through a stock rebuilding plan amendment. The Council has indicated that the SSC will be expected to forward as its ABC recommendation the lower ABC resulting from the two possible calculation methods where applying the risk policy to the rebuilding F probability and OFL probability approaches results in different potential ABCs.

If no OFL is available from a stock assessment and no OFL proxy is provided by the SSC when an ABC recommendation is made, the Council's preferred risk policy would not permit increases in ABC until an acceptable OFL has been identified. This aspect of the risk policy is designed to prevent catch from increasing when there are no available criteria with which to determine whether overfishing will occur for the upcoming fishing year.

Annual Catch Limits and Accountability Measures

General Information. The Council's proposed process would generally rely on the SSC to set ABC at or below OFL, with the reduction from OFL dependent on the amount of scientific uncertainty identified by the SSC. ACLs would be set equal to ABC for all species; however, some species would have sector-level ACLs for commercial and recreational fisheries whose sum would equal the total ABC. These sector ACLs would be based on pre-existing allocations in FMPs. The Council proposes Annual Catch Targets (ACTs) as the primary means of addressing management uncertainty. Council staff or species-specific monitoring committees would review available information and recommend to the Council the amount of reduction from ACL to ACT necessary to address management uncertainty. Where ACLs are divided into sector-specific ACLs, comparable sector ACTs would be utilized that address the associated sector-specific management uncertainties. Estimated discards (*i.e.,* dead discarded catch) would be removed from ACTs to yield either commercial or recreational landing targets, as applicable. In summary, the Council's proposed structure for all FMPs is: OFL ≥ ABC = ACL(s) > ACT(s), with scientific uncertainty addressed at the ABC level by the SSC as an offset from OFL, and management uncertainty addressed by the Council following recommendations from Council staff or species-specific monitoring committees at the ACT level as an offset from the ABC/ACL level.

Many existing proactive AMs in the FMPs will be retained in the Council's proposed approaches. These include adjustments to commercial trip and/or possession limits when landings reach specified levels, and prohibition on retention and landing when commercial quotas are reached. New proactive AMs are being proposed to close recreational fisheries when landings data indicate that target landing levels have been met. The Council has clarified that recreational closures would be based only on ''data in hand,'' and that projection or forecasting of future landings would not be utilized to predict when the recreational target will be met or exceeded. Thus, recreational fishery closures would only occur if landings data indicate that the target level has already been met or exceeded.

The Council has proposed that lb-for-lb repayment of any catch above the established ACLs to be utilized in all fisheries as the primary reactive AM. Because total stock mortality that must be accounted for under ACLs is comprised of both landings and dead discards (*i.e.,* total catch), the Council has, for some species, proposed slightly different AMs dependent on whether discards, landings, or some combination of both has caused an ACL to be exceeded. It is expected that when changes in dead discard mortality estimates cause ACLs to be exceeded, subsequent year measures would both

evoke the lb-for-lb repayment provisions in reactive AMs and will result in modification of the management uncertainty buffer utilized to establish ACTs. The Council may consider numerous corrective actions if ACTs are exceeded but ACLs are not (*e.g.,* changes to landing or possession limits). In addition, for most recreational sector ACLs the comparison of catch would use a 3-year rolling average to evaluate catch performance. Because the final landings and discard data for both commercial and recreational fisheries are not expected to be available in a timely enough manner to implement reactive AM measures in the fishing year immediately following an ACL overage, it is expected that the lb-for-lb repayment would occur 1 year removed from when the ACL was exceeded (*i.e.,* fishing year +1). Adjustments for ACL overages would be handled through the Council's specification processes and would not be evoked during an ongoing fishing season if the information to determine that an ACL has been exceeded becomes available mid-fishing year.

Atlantic Mackerel. The Council took final action on Amendment 11 to the Atlantic Mackerel, Squids, and Butterfish FMP in October 2010, which may, among other things, establish a recreational fishery allocation for mackerel. The Omnibus Amendment was developed with two potential Atlantic mackerel options to respond to the recreational allocation measures being considered under Amendment 11.

Under both Atlantic mackerel scenarios, the Council is proposing that ACL be set equal to ABC. The Atlantic Mackerel Monitoring Committee would recommend any necessary management uncertainty reduction required to offset ACL from either a fishery-level ACT or sector level ACTs, dependent on the status of Amendment 11. Estimated discards would be removed from the ACT or ACTs to yield the Domestic Annual Harvest (DAH) for the commercial fishery and either a formal Recreational Harvest Limit or 15,000-mt recreational allocation dependent on if the measures in Amendment 11 are developed and implemented.

The Council is proposing a proactive AM of general inseason closure authority for the recreational fishery when data in hand indicate that the recreational target has been reached or exceeded. If a recreational allocation is established in Amendment 11, reactive AMs would require lb-for-lb repayment of ACL overages within the respective sector level: At the DAH for commercial landing-induced overages; at the recreational harvest limit, for recreational landing based overages; and at the respective ACT level if the overage was not the result of sector-specific landings (*i.e.,* dead discards, research set-asides).

If a recreational allocation is not established by Amendment 11, or that component of Amendment 11 is disapproved by NMFS, all reactive accountability would occur at the ACL, with lb-for-lb reduction of the ACL in a subsequent fishing year, regardless of the cause (*i.e.,* both landing and dead discard-induced overages would result in ACL reduction).

Butterfish. The Council's proposed structure for the butterfish fishery would set ABC = ACL and use an ACT as an offset to account for management uncertainty. The Council's Butterfish Monitoring Committee would be responsible for recommending the buffer amount for management uncertainty between the ACL and ACT.

Existing proactive AMs would be retained for the butterfish fishery. Specifically, when 80 percent of the DAH is reached, the directed fishery would be closed and an incidental catch limit implemented.

If the ACL is exceeded, lb-for-lb repayment of the overage, regardless if caused by directed landings or estimated dead discards, would occur as soon as is practicable in a subsequent fishing year.

Atlantic Bluefish. The Council's proposed approach for bluefish would establish a fishery-level ACL equal to ABC, with commercial and recreational sector ACTs. Existing provisions in the Bluefish FMP allow a transfer of catch from the recreational allocation to the commercial fishery; thus, the Council has proposed a fishery-level ACL. The Council's Bluefish Monitoring Committee would recommend the level of management uncertainty necessary to offset the sector ACTs from the ACL.

Existing lb-for-lb repayment of individual state commercial quota overages would continue, irrespective of whether the ACL is exceeded. If the ACL is exceeded and no transfer occurred between the recreational and commercial sectors and the recreational fishery is adjudged to have caused the ACL overage, then the recreational sector ACT would repay the overage lb-for-lb as soon as practicable in a future specification setting process. If the ACL is exceeded in a year when a transfer does occur between sectors, the fishery-level ACL would be reduced by the amount of the overage in a subsequent fishing year, and the amount of transfer between the recreational and commercial sectors would also be reduced by the magnitude of the overage. These adjustments would deal with any landings-based overage of the ACL; if estimated dead discards are responsible for the ACL being exceeded, the fishery-level ACL would be reduced (*i.e.,* lb-for-lb repayment) and no modification to the transfer between sectors would be made. Because the ACL for bluefish is at the fishery level, and no sub-ACL is recommended for the recreational fishery, the Council is not proposing a 3-year rolling average for assessing the performance of the bluefish fishery relative to the ACL. Instead, a year-by-year comparison would be used. In addition, because bluefish are jointly managed with the Commission, the Council is proposing an AM that would seek to reconvene the Commission's Bluefish Management Board and the Council if established total catch or landing levels are different for state and Federal waters. This provision would have to be jointly adopted by both the Commission and implemented in the Federal FMP to become effective. The intention of this provision is to ensure that catch and landing levels remain as consistent as practicable for both state and Federal waters.

The Council also proposes that a multi-year specifications process be added to the Bluefish FMP, so that annual catch levels may be established for up to 3 years at a time. This would ensure that all Council FMPs have provisions to permit specifications to be established for up to 3 years at a time.

Spiny Dogfish. The spiny dogfish stock spans both U.S. and Canadian waters, and the FMP requires that consideration be given to the amount of spiny dogfish taken in Canada. To accommodate this provision, the Council is proposing that the SSC recommend a stock-level ABC that considers stock-level scientific uncertainty necessary to reduce from OFL. The estimated Canadian catch would be removed from the ABC, resulting in the Domestic ABC, which would in turn be set equal to the U.S. ACL. The Council's Dogfish Monitoring Committee would recommend any necessary management uncertainty reduction needed to reduce catch from the U.S. ACL to the ACT, thus providing a low probability of exceeding the U.S. ACL. Estimated domestic discard mortality would be removed from the ACT to provide the Total Allowable Landings (TAL) for the commercial fishery.

The Council does not propose changes to the existing proactive AMs that permit Federal trip limits to be established though the specifications process and mechanism to close the

Exclusive Economic Zone (EEZ) when semi-annual commercial landings quotas are reached. The Council is proposing that lb-for-lb repayment of any ACL overage be implemented as the sole reactive AM for the spiny dogfish fishery.

Summer Flounder. The Council proposes that separate commercial and recreational sector ACLs be established for summer flounder, the sum of which would total the ABC. Sector-specific management uncertainty would be identified by the Summer Flounder Monitoring Committee to establish sector-specific ACTs below the sector ACLs. Estimated discard mortality and research set-aside would be removed from the ACTs to yield the recreational harvest limit and commercial quotas, respectively, with the commercial quota further subdivided into state quotas. Both sector and state allocations would remain unchanged from those currently specified in the FMP.

Existing commercial fishery closure and state-by-state overage repayment provisions would remain in the FMP as AM measures. State commercial overage repayment would occur irrespective of whether or not the ACL is exceeded. The Council is proposing general inseason closure authority for the recreational sector, to be implemented if available data indicate that the recreational harvest limit has already been met or exceeded (*i.e.,* data would not be used to project attainment of the recreational harvest limit). In instances where the sector-specific ACL is exceeded, the applicable ACL would be reduced through lb-for-lb overage repayment for a future fishing year through the specifications process. The recreational sector ACL would utilize a 3-year moving average to evaluate performance of the sector. The moving average would be phased in over a period of 3 years: In year one, catch (sum of recreational sector specific landings and dead discards) would be compared to the prior year catch; in year two, an average catch of years one and two would be used; in year three and in all subsequent years, the average catch from the prior three years would be used.

Similar to other jointly-managed species, the Council proposes that language be adopted by the Commission and added to the Federal FMP to ensure that catch levels are consistent in both state and Federal waters to avoid differential effects on Federal permit holders.

Scup. The proposed measures for scup would be essentially the same as those proposed for summer flounder, except that the commercial quota would be allocated into three existing quota periods instead of to individual states. All other provisions would function the same as outlined for summer flounder: Sector-specific ACLs; management uncertainty considerations developed by a scup-specific monitoring committee; and sector-specific ACTs. Commercial quota period overages would continue to have lb-for-lb repayment, consistent with the current FMP provisions, regardless of whether the sector ACL is exceeded. Recreational AMs would be evaluated using the same 3-year average approach described for summer flounder. The joint-management provisions between the Commission and Council also apply for scup.

Black Sea Bass. The proposed measures for black sea bass would be the same as those developed for summer flounder and scup, except that the commercial quota would be administered on a coastwide basis for the fishing year, and lb-for-lb repayment of a commercial landings overage would also occur at the coastwide level, irrespective of whether the commercial-sector ACL is exceeded. All other provisions would function the same as outlined for summer flounder and scup.

Atlantic Surf Clam. The Council's proposed system for surfclams would set ACL = ABC = Total Allowable Catch (TAC). An ACT set below TAC would be recommended by Council staff to address management uncertainty. Existing Individual Transferable Quota (ITQ) accountability requires lb-for-lb repayment of any permit-specific landing overages. This would be retained as the sole AM for the surfclam fishery.

Ocean Quahog. The Council's proposed measures for ocean quahog would set ACL=ABC, with Council staff recommending any necessary management uncertainty reductions to yield separate ACTs for the Maine mahogany quahog fishery and the non-Maine fishery as subdivisions below the ACL. Similar to surf clams, 100 percent of ITQ landing overages that occur within the fishery are required to be repaid lb-for-lb. This would remain in place as the non-Maine fishery AM, regardless of whether the ACL is exceeded. If the ACL is exceeded and harvest in the Maine fishery is the cause, the Maine ACT would be adjusted in a following year through a bushel-for-bushel repayment of the overage.

Tilefish. The Council has proposed that ACL = ABC for tilefish, and that the Tilefish Monitoring Committee would recommend any necessary management uncertainty reduction from ACL to ACT. An estimate of dead discards would be removed from the ACT to produce the Total Allowable Landings (TAL). The existing regulatory structure would continue to allocate 95 percent of the commercially available landings to the Individual Fishing Quota (IFQ) permit holders, and 5 percent would be reserved for incidental catch.

Inseason closure authority already exists for the incidental category to be closed when projected landings total the specified category target. The Council has proposed increasing the incidental trip limit from 300 to 500 lb (136 to 227 kg) based on analyses conducted during development of the Omnibus Amendment. If the incidental category exceeds the 5-percent allocation in any given year, the incidental 500-lb (227-kg) trip limit may be reduced in subsequent fishing years.

The Tilefish FMP already contains lb-for-lb landing overage repayment requirements for IFQ permit holders. This authority would be retained as the primary AM for the commercial fishery. If the incidental category is responsible for an ACL overage, the 5-percent allocation would be reduced lb-for-lb in a subsequent year, and the incidental category trip limit may be adjusted as well. If the ACL is exceeded by any other means (*i.e.,* changes in estimated dead discard amounts), lb-for-lb repayment of the overage from a subsequent fishing year ACL would be enacted prior to any IFQ and incidental permit category allocation calculations.

Future Review and Modification of Omnibus Amendment Implemented Processes

The Council has proposed that ABC control rules be reviewed in detail by the SSC 5 years after the implementation of the Omnibus Amendment measures and at least every 5 years thereafter. Reviews can occur more frequently than 5 years, based on the need to address rebuilding plans, overfished stocks, poor control rule performance resulting in overfishing, or other relevant factors. The Council specified that the process to change any ABC control rules would be consistent with the magnitude of the potential changes: For example, minor changes within the existing four levels based on assessment levels could be developed through the Council's specification or framework adjustment process. Addition of new control rule levels or substantial modification of existing criteria within the four levels may require a full FMP amendment.

The Council has proposed that ACL and AM performance reviews occur at least every 5 years, as well, if ACLs are

not routinely exceeded. Consistent with the NS1 guidelines, if the ACL is exceeded for any species with a frequency greater than 25 percent of the time (*i.e.,* more than 1 in 4 years, or in any 2 consecutive years), the Council has proposed to initiate a review of the ACL, ACT, and AM approaches used.

The Council has included in the Omnibus Amendment a comprehensive listing of items that may be modified through specification or a framework adjustment in an effort to preserve a responsive, adaptive process. The limits to modifications of the ABC control rules, risk policy, ACT control rules, AMs, and actions that may be taken under each FMP are provided. In addition, several items are identified that can only be modified through framework adjustment or FMP amendment.

Classification

Pursuant to section 304(b)(1)(A) of the MSA, the NMFS Assistant Administrator has determined that this proposed rule is consistent with the Atlantic Mackerel, Squids; and Butterfish FMP; Atlantic Bluefish FMP; Spiny Dogfish FMP; Summer Flounder, Scup, and Black Sea Bass FMP; Surfclam and Ocean Quahog FMP; and Tilefish FMP; other provisions of the MSA; and other applicable law, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities.

As outlined in the preamble to this proposed rule, the Omnibus Amendment proposes multiple descriptive processes for Council-managed resources: To implement methods of establishing ABC through control rules; establishment of a Council risk policy for the tolerance of overfishing stocks, a required element of ABC control rules; to establish as framework for specifying ACLs derived from ABC with a comprehensive system of AMs; and to provide a description of the future evaluation and modification processes for the ABC control rules, Council risk policy, ACLs, and AMs. The Council conducted a comprehensive evaluation of the potential socioeconomic impacts of the Omnibus Amendment measures in conjunction with the EA analyses. The formal procedures for addressing both scientific and management uncertainty in the catch limit establishment system proposed by the Omnibus Amendment are administrative, as they are entirely a description of process. While the Omnibus Amendment provides detailed descriptions of the frameworks for how scientific and management uncertainty will be considered, as well as how ACLs and AMs would function, the action contains no actual application of the methods to set ABC, apply the risk policy, or establish specific ACLs or AMs for any of the Council's FMPs. As a result, there are no immediate economic impacts to evaluate. Populating the proposed framework with data, which would result in the establishment of catch levels with measurable impacts, will occur in future actions. As the systems proposed by the Omnibus Amendment are utilized in future actions, the specific impacts resulting from the application of the systems will be evaluated through the Council's specification processes for each FMP.

The Council-conducted analyses identified 3,911 unique fishing entities in the Northeast Region, all but 6 of which were determined to be small entities. However, given the administrative aspects of the proposed measures, there are neither expected direct economic or disproportionate impacts to either small or large regulated entities given the aforementioned description of the administrative processes proposed by the Omnibus Amendment. As a result, an initial regulatory flexibility analysis is not required and none has been prepared. RFA analysis will be conducted, as appropriate, for subsequent actions taken under the Omnibus Amendment established procedures.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: June 3, 2011.

Eric C. Schwaab,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons stated in the preamble, 50 CFR part 648 is proposed to be amended as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

1. The authority citation for part 648 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

2. Section 648.14(u)(2)(vii) is added to read as follows:

§ 648.14 Prohibitions.

* * * * *

(u)* * *

(2)* * *

(vii) Land or possess tilefish in or from the Tilefish Management Unit, on a vessel issued a valid tilefish permit under this part, after the incidental fishery is closed pursuant to § 648.245(b), unless fishing under a valid tilefish IFQ allocation permit as specified in § 648.249(a), or engaged in recreational fishing.

* * * * *

3. Section 648.20 is revised to read as follows:

§ 648.20 Mid-Atlantic Fishery Management Council ABC Control Rules.

General information. The SSC shall review the following criteria, and any additional relevant information, to assign managed stocks to a specific control rule level when developing ABC recommendations. The SSC shall review the ABC control rule level assignment for stocks each time an ABC is recommended. The ABC may be recommended for up to 3 years for all stocks, with the exception of 5 years for spiny dogfish. The SSC may deviate from the control rule methods or level criteria and recommend an ABC that differs from the result of the ABC control rule calculation; however, any such deviation must include the following: A description of why the deviation is warranted, description of the methods used to derive the alternative ABC, and an explanation of how the deviation is consistent with National Standard 2.

(a) *Level 1 criteria.* (1) Assignment of a stock to Level 1 requires the SSC to determine the following:

(i) All important sources of scientific uncertainty are captured in the stock assessment model;

(ii) The probability distribution of the OFL is calculated within the stock assessment and provides an adequate description of the OFL uncertainty;

(iii) The stock assessment model structure and treatment of the data prior to use in the model includes relevant details of the biology of the stock, fisheries that exploit the stock, and data collection methods;

(iv) The stock assessment provides the following estimates: Fishing mortality rate (F) at MSY or an alternate maximum fishing mortality threshold (MFMT) to define OFL, biomass, biological reference points, stock status, OFL, and the respective uncertainties associated with each value; and

(v) No substantial retrospective patterns exist in the stock assessment

estimates of fishing mortality, biomass, and recruitment.

(2) *Level 1 ABC determination.* Stocks assigned to level 1 by the SSC will have the ABC derived by applying acceptable probability of overfishing from the MAFMC's risk policy found in § 648.21(a) through (d) to the probability distribution of the OFL.

(b) *Level 2 criteria.* (1) Assignment of a stock to Level 2 requires the SSC to determine the following:

(i) Key features of the stock biology, the fisheries that exploit it, and/or the data collection methods for stock information are missing from the stock assessment;

(ii) The stock assessment provides reference points (which may be proxies), stock status, and uncertainties associated with each; however, the uncertainty is not fully promulgated through the stock assessment model and/or some important sources of uncertainty may be lacking;

(iii) The stock assessment provides estimates of the precision of biomass, fishing mortality, and reference points; and

(iv) The accuracy of the minimum fishing mortality threshold and projected future biomass is estimated in the stock assessment using ad hoc methods.

(2) *Level 2 ABC determination.* Stocks assigned to level 2 by the SSC will have the ABC derived by applying acceptable probability of overfishing from the MAFMC's risk policy found in § 648.21(a) through (d) to the probability distribution of the OFL.

(c) *Level 3 criteria.* (1) Assignment of a stock to Level 3 requires the SSC to determine that the stock assessment attributes are the same as those for a level 2 assessment listed in § 648.20(d)(1) through (4), except that the stock assessment does not contain an estimated probability distribution of OFL or the stock assessment provided OFL probability distribution is judged by the SSC to not adequately reflect uncertainty in the OFL estimate.

(2) *Level 3 ABC determination.* Stocks assigned to Level 3 will have ABC derived by one of the following two methods:

(i) The SSC will derive the ABC by applying the acceptable probability of overfishing from the MAFMC's risk policy found in § 648.21(a) through (d) to an SSC-adjusted OFL probability distribution. The SSC will use default levels of uncertainty in the adjusted OFL probability distribution based on literature review and evaluation of control rule performance; or,

(ii) If the SSC cannot develop an OFL distribution, a default control rule of 75 percent of the F_{MSY} value will be applied to derive ABC.

(d) *Level 4 criteria.* (1) Assignment of a stock to Level 4 requires the SSC to determine that none of the criteria for Level 1–3 found in § 648.20(a) through (c) were met.

(2) *Level 4 ABC determination.* Stocks assigned to Level 4 will have ABC derived using control rules developed on a case-by-case basis by the SSC based on biomass and catch history and application of the MAFMC's risk policy found in § 648.21(a) through (d).

4. Section 648.21 is revised to read as follows:

§ 648.21 Mid-Atlantic Fishery Management Council Risk Policy.

The risk policy shall be used by the SSC in conjunction with the ABC control rules in § 648.20(a) through (d) to ensure the MAFMC's preferred tolerance for the risk of overfishing is addressed in the ABC development and recommendation process.

(a) *Stocks under a rebuilding plan.* The probability of not exceeding the F necessary to rebuild the stock within the specified time frame (rebuilding F or $F_{REBUILD}$) must be at least 50 percent, unless the default level is modified to a higher probability for not exceeding the rebuilding F through the formal stock rebuilding plan. A higher probability of not exceeding the rebuilding F would be expressed as a value greater than 50 percent (*e.g.,* 75-percent probability of not exceeding rebuilding F, which corresponds to a 25-percent probability of exceeding rebuilding F).

(b) *Stocks not subject to a rebuilding plan.* (1) For stocks determined by the SSC to have an atypical life history, the maximum probability of overfishing as informed by the OFL distribution will be 35 percent for stocks with a ratio of biomass (B) to biomass at MSY (B_{MSY}) of 1.0 or higher (*i.e.,* the stock is at B_{MSY} or higher). The maximum probability of overfishing shall decrease linearly from the maximum value of 35 percent as the B/B_{MSY} ratio becomes less than 1.0 (*i.e.,* the stock biomass less than B_{MSY}) until the probability of overfishing becomes zero at a B/B_{MSY} ratio of 0.10. An atypical life history is generally defined as one that has greater vulnerability to exploitation and whose characteristics have not been fully addressed through the stock assessment and biological reference point development process.

(2) For stocks determined by the SSC to have a typical life history, the maximum probability of overfishing as informed by the OFL distribution will be 40 percent for stocks with a ratio of B to B_{MSY} of 1.0 or higher (*i.e.,* the stock is at B_{MSY} or higher). The maximum probability of overfishing shall decrease linearly from the maximum value of 40 percent as the B/B_{MSY} ratio becomes less than 1.0 (stock biomass less than B_{MSY}) until the probability of overfishing becomes zero at a B/B_{MSY} ratio of 0.10. Stocks with typical life history are those not meeting the criteria in paragraph (b)(1) of this section.

(c) For instances in which the application of the risk policy approaches in either paragraph (b)(1) or (2) of this section using OFL distribution, as applicable given life history determination, results in a more restrictive ABC recommendation than the calculation of ABC derived from the use of $F_{REBUILD}$ at the MAFMC-specified overfishing risk level as outlined in paragraph (a) of this section, the SSC shall recommend to the MAFMC the lower of the ABC values.

(d) If an OFL cannot be determined from the stock assessment, or if a proxy is not provided by the SSC during the ABC recommendation process, ABC levels may not be increased until such time that an OFL has been identified.

5. Section 648.22 is revised to read as follows:

§ 648.22 Specifications.

(a) *Initial recommended annual specifications.* The Atlantic Mackerel, Squid, and Butterfish Monitoring Committee (Monitoring Committee) shall meet annually to develop and recommend the following specifications for consideration by the Squid, Mackerel, and Butterfish Committee of the MAFMC:

(1) Initial OY (IOY), including Research Set-Aside (RSA), DAH, and DAP for *Illex* squid, which, subject to annual review, may be specified for a period of up to 3 years;

(2) ACL; ACT including RSA, DAH, DAP; bycatch level of the TALFF, if any; and butterfish mortality cap for the *Loligo* fishery for butterfish; which, subject to annual review, may be specified for a period of up to 3 years;

(3) ACL; commercial ACT, including RSA, DAH, DAP; JVP if any; TALFF, if any; and recreational ACT, including RSA for mackerel; which, subject to annual review, may be specified for a period of up to 3 years. The Monitoring Committee may also recommend that certain ratios of TALFF, if any, for mackerel to purchases of domestic harvested fish and/or domestic processed fish be established in relation to the initial annual amounts.

(4) IOY, including RSA, DAH, and DAP for *Loligo* squid, which, subject to annual review, may be specified for a period of up to 3 years; and

(5) Inseason adjustment, upward or downward, to the specifications for *Loligo* squid, as specified in paragraph (e) of this section.

(b) *Guidelines.* As the basis for its recommendations under paragraph (a) of this section, the Monitoring Committee shall review the best available data to recommend specifications consistent with the following:

(1) *Loligo and/or Illex squid.* (i) The ABC for any fishing year must be either the maximum OY, or a lower amount, if stock assessments indicate that the potential yield is less than the maximum OY. The OYs specified during a fishing year may not exceed the following amounts:

(A) *Loligo.*—The catch associated with a fishing mortality rate of $F_{Threshold}$.

(B) *Illex.*—Catch associated with a fishing mortality rate of F_{MSY}.

(ii) IOY is a modification of ABC based on social and economic factors. The IOY is composed of RSA and DAH. RSA will be based on requests for research quota as described in paragraph (g) of this section. DAH will be set after deduction for RSA, if applicable.

(2) *Mackerel.*—(i) *ABC.* The MAFMC's SSC shall recommend an ABC to the MAFMC, as described in § 648.20. The mackerel ABC is reduced from the OFL based on an adjustment for scientific uncertainty; the ABC must be less than or equal to the OFL.

(ii) *ACL.* The ACL or Domestic ABC is calculated using the formula ACL = ABC − C, where C is the estimated catch of mackerel in Canadian waters for the upcoming fishing year.

(iii) *OY.* OY may not exceed the ACL, and must take into account the need to prevent overfishing while allowing the fishery to achieve OY on a continuing basis. OY is prescribed on the basis of MSY, as reduced by social, economic, and ecological factors.

(iv) *ACT.* The Monitoring Committee shall identify and review relevant sources of management uncertainty to recommend ACTs for the commercial and recreational fishing sectors as part of the specifications process.

(A) *Commercial sector ACT.* Commercial ACT is composed of RSA, DAH, dead discards, and TALFF. RSA will be based on requests for research quota as described in paragraph (g) of this section. DAH, DAP, and JVP will be set after deduction for RSA, if applicable, and must be projected by reviewing data from sources specified in paragraph (b) of this section and other relevant data, including past domestic landings, projected amounts of mackerel necessary for domestic processing and for joint ventures during the fishing year, projected recreational landings, and other data pertinent for such a projection. The JVP component of DAH is the portion of DAH that domestic processors either cannot or will not use. Economic considerations for the establishment of JVP and TALFF include:

(*1*) Total world export potential of mackerel producing countries.

(*2*) Total world import demand of mackerel consuming countries.

(*3*) U.S. export potential based on expected U.S. harvests, expected U.S. consumption, relative prices, exchange rates, and foreign trade barriers.

(*4*) Increased/decreased revenues to the U.S. from foreign fees.

(*5*) Increased/decreased revenues to U.S. harvesters (with/without joint ventures).

(*6*) Increased/decreased revenues to U.S. processors and exporters.

(*7*) Increases/decreases in U.S. harvesting productivity due to decreases/increases in foreign harvest.

(*8*) Increases/decreases in U.S. processing productivity.

(*9*) Potential impact of increased/decreased TALFF on foreign purchases of U.S. products and services and U.S.-caught fish, changes in trade barriers, technology transfer, and other considerations.

(B) *Recreational sector ACT.* Recreational ACT is composed of RSA, dead discards, and the Recreational Harvest Limit (RHL).

(v) *Performance review.* The Squid, Mackerel, and Butterfish Committee shall conduct a detailed review of fishery performance relative to the mackerel ACL at least every 5 years.

(A) If the ACL is exceeded with a frequency greater than 25 percent (*i.e.,* more than once in 4 years or any two consecutive years), the Squid, Mackerel, and Butterfish Monitoring Committee will review fishery performance information and make recommendations to the MAFMC for changes in measures intended to ensure ACLs are not exceeded as frequently.

(B) The MAFMC may specify more frequent or more specific ACL performance review criteria as part of a stock rebuilding plan following a determination that a stock has become overfished.

(C) Performance reviews shall not substitute for annual reviews that occur to ascertain if prior year ACLs have been exceeded, but may be conducted in conjunction with such reviews.

(3) *Butterfish*—(i) *ABC.* The MAFMC's SSC shall recommend an ABC to the MAFMC, as described in § 648.20. The butterfish ABC is reduced from the OFL based on an adjustment for scientific uncertainty; the ABC must be less than or equal to the OFL.

(ii) *ACL.* The butterfish ACL will be set equal to the butterfish ABC.

(iii) *OY.* OY may not exceed the ACL, and must take into account the need to prevent overfishing while allowing the fishery to achieve OY on a continuing basis. OY is prescribed on the basis of MSY, as reduced by social, economic, and ecological factors.

(iv) *ACT.* The Monitoring Committee shall identify and review relevant sources of management uncertainty to recommend the butterfish ACT as part of the specifications process. The ACT is composed of RSA, DAH, dead discards, and bycatch TALFF that is equal to 0.08 percent of the allocated portion of the mackerel TALFF. RSA will be based on requests for research quota as described in paragraph (g) of this section. DAH and bycatch TALFF will be set after deduction for RSA, if applicable.

(v) The butterfish mortality cap will be allocated to the *Loligo* fishery as follows: Trimester I—65 percent; Trimester II—3.3 percent; and Trimester III—31.7 percent.

(vi) Any underages of the butterfish mortality cap for Trimesters I or II will be applied to Trimester III of the same year, and any overages of the butterfish mortality cap for Trimesters I and II will be applied to Trimester III of the same year.

(vii) *Performance review.* The Squid, Mackerel, and Butterfish Committee shall conduct a detailed review of fishery performance relative to the butterfish ACL in conjunction with review for the mackerel fishery, as outlined in this section.

(c) *Recommended measures.* Based on the review of the data described in paragraph (b) of this section and requests for research quota as described in paragraph (g) of this section, the Monitoring Committee will recommend to the Squid, Mackerel, and Butterfish Committee the measures from the following list that it determines are necessary to ensure that the specifications are not exceeded:

(1) RSA set from a range of 0 to 3 percent of:

(A) The IOY for *Loligo* and/or *Illex.*

(B) The commercial and/or recreational ACT for mackerel.

(C) The ACT for butterfish.

(2) Commercial quotas, set after reductions for research quotas.

(3) The amount of *Loligo, Illex,* and butterfish that may be retained, possessed, and landed by vessels issued the incidental catch permit specified in § 648.4(a)(5)(ii).

(4) Commercial minimum fish sizes.
(5) Commercial trip limits.
(6) Commercial seasonal quotas/closures for *Loligo* and *Illex.*
(7) Minimum mesh sizes.
(8) Commercial gear restrictions.
(9) Recreational harvest limit, set after reductions for research quotas.
(10) Recreational minimum fish size.
(11) Recreational possession limits.
(12) Recreational season.
(13) Changes, as appropriate, to the Northeast Region SBRM, including the coefficient of variation (CV) based performance standard, fishery stratification, and/or reports.
(14) Modification of existing accountability measures (AMs) utilized by the Monitoring Committee.

(d) *Annual fishing measures.* (1) The Squid, Mackerel, and Butterfish Committee will review the recommendations of the Monitoring Committee. Based on these recommendations and any public comment received thereon, the Squid, Mackerel, and Butterfish Committee must recommend to the MAFMC appropriate specifications and any measures necessary to assure that the specifications will not be exceeded. The MAFMC will review these recommendations and, based on the recommendations and any public comment received thereon, must recommend to the Regional Administrator appropriate specifications and any measures necessary to assure that the ACL will not be exceeded. The MAFMC's recommendations must include supporting documentation, as appropriate, concerning the environmental, economic, and social impacts of the recommendations. The Regional Administrator will review the recommendations and will publish a proposed rule in the **Federal Register** proposing specifications and any measures necessary to assure that the specifications will not be exceeded and providing a 30-day public comment period. If the proposed specifications differ from those recommended by the MAFMC, the reasons for any differences must be clearly stated and the revised specifications must satisfy the criteria set forth in this section. The MAFMC's recommendations will be available for inspection at the office of the Regional Administrator during the public comment period. If the annual specifications for squid, mackerel, and butterfish are not published in the **Federal Register** prior to the start of the fishing year, the previous year's annual specifications, excluding specifications of TALFF, will remain in effect. The previous year's specifications will be superseded as of the effective date of the final rule implementing the current year's annual specifications.

(2) The Regional Administrator will make a final determination concerning the specifications for each species and any measures necessary to assure that the specifications will not be exceeded. After the Regional Administrator considers all relevant data and any public comments, notification of the final specifications and any measures necessary to assure that the specifications will not be exceeded and responses to the public comments will be published in the **Federal Register**. If the final specification amounts differ from those recommended by the MAFMC, the reason(s) for the difference(s) must be clearly stated and the revised specifications must be consistent with the criteria set forth in paragraph (b) of this section.

(e) *Inseason adjustments.* The specifications established pursuant to this section may be adjusted by the Regional Administrator, in consultation with the MAFMC, during the fishing year by publishing notification in the **Federal Register**.

(f) *Distribution of annual Loligo squid commercial quota.* (1) A commercial quota for *Loligo* squid will be allocated annually into trimester periods, based on the following percentages: Trimester I (January–April)—43.0 percent; Trimester II (May–August)—17.0 percent; and Trimester III (September–December)—40.0 percent.

(2) Any underages of commercial period quota for Trimester I that are greater than 25 percent of the Trimester I quota will be reallocated to Trimesters II and III of the same year. The reallocation of quota from Trimester I to Trimester II is limited, such that the Trimester II quota may only be increased by 50 percent; the remaining portion of the underage will be reallocated to Trimester III. Any underages of commercial period quota for Trimester I that are less than 25 percent of the Trimester I quota will be applied to Trimester III of the same year. Any overages of commercial quota for Trimesters I and II will be subtracted from Trimester III of the same year.

(g) *Research set-aside (RSA) quota.* Prior to the MAFMC's quota-setting meetings:

(1) NMFS will publish a Request for Proposals (RFP) in the **Federal Register**, consistent with procedures and requirements established by the NOAA Grants Office, to solicit proposals from industry for the upcoming fishing year, based on research priorities identified by the MAFMC.

(2) NMFS will convene a review panel, including the MAFMC's Comprehensive Management Committee and technical experts, to review proposals submitted in response to the RFP.

(i) Each panel member will recommend which research proposals should be authorized to utilize research quota, based on the selection criteria described in the RFP.

(ii) The NEFSC Director and the NOAA Grants Office will consider each panel member's recommendation, and provide final approval of the projects. The Regional Administrator may, when appropriate, exempt selected vessel(s) from regulations specified in each of the respective FMPs through written notification to the project proponent.

(3) The grant awards approved under the RFPs will be for the upcoming fishing year. Proposals to fund research that would start prior to, or that would end after the fishing year, will not be eligible for consideration. All research and/or compensation trips must be completed within the fishing year for which the research grant was awarded.

(4) Research projects will be conducted in accordance with provisions approved and provided in an Exempted Fishing Permit (EFP) issued by the Regional Administrator.

(5) If a proposal is disapproved by the NEFSC Director or the NOAA Grants Office, or if the Regional Administrator determines that the allocated research quota cannot be utilized by a project, the Regional Administrator shall reallocate the unallocated or unused amount of research quota to the respective commercial and recreational fisheries by publication of a notice in the **Federal Register** in compliance with the Administrative Procedure Act, provided:

(i) The reallocation of the unallocated or unused amount of research quota is in accord with National Standard 1, and can be available for harvest before the end of the fishing year for which the research quota is specified; and

(ii) Any reallocation of unallocated or unused research quota shall be consistent with the proportional division of quota between the commercial and recreational fisheries in the relevant FMP and allocated to the remaining quota periods for the fishing year proportionally.

(6) Vessels participating in approved research projects may be exempted from certain management measures by the Regional Administrator, provided that one of the following analyses of the impacts associated with the exemptions is provided:

(i) The analysis of the impacts of the requested exemptions is included as part of the annual quota specification packages submitted by the MAFMC; or

(ii) For proposals that require exemptions that extend beyond the scope of the analysis provided by the MAFMC, applicants may be required to provide additional analysis of impacts of the exemptions before issuance of an EFP will be considered, as specified in the EFP regulations at § 648.12(b).

6. Section 648.23 is revised to read as follows:

§ 648.23 Gear restrictions.

(a) *Mesh restrictions and exemptions.* (1) Vessels subject to the mesh restrictions in this paragraph (a) may not have available for immediate use any net, or any piece of net, with a mesh size smaller than that required.

(2) Owners or operators of otter trawl vessels possessing 1,000 lb (0.45 mt) or more of butterfish harvested in or from the EEZ may only fish with nets having a minimum codend mesh of 3 inches (76 mm) diamond mesh, inside stretch measure, applied throughout the codend for at least 100 continuous meshes forward of the terminus of the net, or for codends with less than 100 meshes, the minimum mesh size codend shall be a minimum of one-third of the net, measured from the terminus of the codend to the headrope.

(3) Owners or operators of otter trawl vessels possessing *Loligo* harvested in or from the EEZ may only fish with nets having a minimum mesh size of 2⅛ inches (54 mm) during Trimesters I (Jan–Apr) and III (Sept–Dec); or 1⅞ inches (48 mm) during Trimester II (May–Aug), diamond mesh, inside stretch measure, applied throughout the codend for at least 150 continuous meshes forward of the terminus of the net, or for codends with less than 150 meshes, the minimum mesh size codend shall be a minimum of one-third of the net measured from the terminus of the codend to the headrope, unless they are fishing consistent with exceptions specified in paragraph (b) of this section.

(i) *Net obstruction or constriction.* Owners or operators of otter trawl vessels fishing for and/or possessing *Loligo* shall not use any device, gear, or material, including, but not limited to, nets, net strengtheners, ropes, lines, or chafing gear, on the top of the regulated portion of a trawl net that results in an effective mesh opening of less than 2⅛ inches (54 mm) during Trimesters I (Jan–Apr) and III (Sept–Dec), or 1⅞ inches (48 mm) during Trimester II (May–Aug), diamond mesh, inside stretch measure. ''Top of the regulated portion of the net'' means the 50 percent of the entire regulated portion of the net that would not be in contact with the ocean bottom if, during a tow, the regulated portion of the net were laid flat on the ocean floor. However, owners or operators of otter trawl vessels fishing for and/or possessing *Loligo* may use net strengtheners (covers), splitting straps, and/or bull ropes or wire around the entire circumference of the codend, provided they do not have a mesh opening of less than 5 inches (12.7 cm) diamond mesh, inside stretch measure. For the purposes of this requirement, head ropes are not to be considered part of the top of the regulated portion of a trawl net.

(ii) *Illex fishery.* Owners or operators of otter trawl vessels possessing *Loligo* harvested in or from the EEZ and fishing during the months of June, July, August, and September for *Illex* seaward of the following coordinates (copies of a map depicting this area are available from the Regional Administrator upon request) are exempt from the *Loligo* gear requirements in paragraph (a)(3) of this section, provided they do not have available for immediate use, as defined in paragraph (b) of this section, any net, or any piece of net, with a mesh size less than 1⅞ inches (48 mm) diamond mesh or any net, or any piece of net, with mesh that is rigged in a manner that is prohibited by paragraph (a)(3) of this section, when the vessel is landward of the specified coordinates.

Point	N. Lat.	W. Long.
M1	43°58.0′	67°22.0′
M2	43°50.0′	68°35.0′
M3	43°30.0′	69°40.0′
M4	43°20.0′	70°00.0′
M5	42°45.0′	70°10.0′
M6	42°13.0′	69°55.0′
M7	41°00.0′	69°00.0′
M8	41°45.0′	68°15.0′
M9	42°10.0′	67°10.0′
M10	41°18.6′	66°24.8′
M11	40°55.5′	66°38.0′
M12	40°45.5′	68°00.0′
M13	40°37.0′	68°00.0′
M14	40°30.0′	69°00.0′
M15	40°22.7′	69°00.0′
M16	40°18.7′	69°40.0′
M17	40°21.0′	71°03.0′
M18	39°41.0′	72°32.0′
M19	38°47.0′	73°11.0′
M20	38°04.0′	74°06.0′
M21	37°08.0′	74°46.0′
M22	36°00.0′	74°52.0′
M23	35°45.0′	74°53.0′
M24	35°28.0′	74°52.0′

(4) *Mackerel, squid, and butterfish bottom trawling restricted areas.* (i) *Oceanographer Canyon.* No permitted mackerel, squid, or butterfish vessel may fish with bottom trawl gear in the Oceanographer Canyon or be in the Oceanographer Canyon unless transiting. Vessels may transit this area provided the bottom trawl gear is stowed in accordance with the provisions of paragraph (b) of this section. Oceanographer Canyon is defined by straight lines connecting the following points in the order stated (copies of a chart depicting this area are available from the Regional Administrator upon request):

OCEANOGRAPHER CANYON

Point	N. Lat.	W. Long.
OC1	40°10.0′	68°12.0′
OC2	40°24.0′	68°09.0′
OC3	40°24.0′	68°08.0′
OC4	40°10.0′	67°59.0′
OC1	40°10.0′	68°12.0′

(ii) *Lydonia Canyon.* No permitted mackerel, squid, or butterfish vessel may fish with bottom trawl gear in the Lydonia Canyon or be in the Lydonia Canyon unless transiting. Vessels may transit this area provided the bottom trawl gear is stowed in accordance with the provisions of paragraph (b) of this section. Lydonia Canyon is defined by straight lines connecting the following points in the order stated (copies of a chart depicting this area are available from the Regional Administrator upon request):

LYDONIA CANYON

Point	N. Lat.	W. Long.
LC1	40°16.0′	67°34.0′
LC2	40°16.0′	67°42.0′
LC3	40°20.0′	67°43.0′
LC4	40°27.0′	67°40.0′
LC5	40°27.0′	67°38.0′
LC1	40°16.0′	67°34.0′

(b) *Definition of ''not available for immediate use.''* Gear that is shown not to have been in recent use and that is stowed in conformance with one of the following methods is considered to be not available for immediate use:

(1) *Nets*—(i) *Below-deck stowage.* (A) The net is stored below the main working deck from which it is deployed and retrieved;

(B) The towing wires, including the leg wires, are detached from the net; and

(C) It is fan-folded (flaked) and bound around its circumference.

(ii) *On-deck stowage.* (A) The net is fan-folded (flaked) and bound around its circumference;

(B) It is securely fastened to the deck or rail of the vessel; and

(C) The towing wires, including the leg wires, are detached from the net.

(iii) *On-reel stowage.* (A) The net is on a reel, its entire surface is covered with canvas or other similar opaque material, and the canvas or other material is securely bound;

(B) The towing wires are detached from the net; and

(C) The codend is removed and stored below deck.

(iv) *On-reel stowage for vessels transiting the Gulf of Maine Rolling Closure Areas, the Georges Bank Seasonal Area Closure, and the Conditional Gulf of Maine Rolling Closure Area.*

(A) The net is on a reel, its entire surface is covered with canvas or other similar opaque material, and the canvas or other material is securely bound;

(B) The towing wires are detached from the doors; and

(C) No containment rope, codend tripping device, or other mechanism to close off the codend is attached to the codend.

(2) *Scallop dredges.* (i) The towing wire is detached from the scallop dredge, the towing wire is completely reeled up onto the winch, the dredge is secured, and the dredge or the winch is covered so that it is rendered unusable for fishing; or

(ii) The towing wire is detached from the dredge and attached to a bright-colored poly ball no less than 24 inches (60.9 cm) in diameter, with the towing wire left in its normal operating position (through the various blocks) and either is wound back to the first block (in the gallows) or is suspended at the end of the lifting block where its retrieval does not present a hazard to the crew and where it is readily visible from above.

(3) *Hook gear (other than pelagic).* All anchors and buoys are secured and all hook gear, including jigging machines, is covered.

(4) *Sink gillnet gear.* All nets are covered with canvas or other similar material and lashed or otherwise securely fastened to the deck or rail, and all buoys larger than 6 inches (15.24 cm) in diameter, high flyers, and anchors are disconnected.

(5) *Other methods of stowage.* Any other method of stowage authorized in writing by the Regional Administrator and subsequently published in the **Federal Register**.

(c) *Mesh obstruction or constriction.* The owner or operator of a fishing vessel shall not use any mesh construction, mesh configuration, or other means that effectively decreases the mesh size below the minimum mesh size, except that a liner may be used to close the opening created by the rings in the aftermost portion of the net, provided the liner extends no more than 10 meshes forward of the aftermost portion of the net. The inside webbing of the codend shall be the same circumference or less than the outside webbing (strengthener). In addition, the inside webbing shall not be more than 2 ft (61 cm) longer than the outside webbing.

7. Section 648.24 is revised to read as follows:

§ 648.24 Fishery closures and accountability measures.

(a) *Fishery closure procedures.*—(1) *Loligo.* NMFS shall close the directed fishery in the EEZ for *Loligo* when the Regional Administrator projects that 90 percent of the *Loligo* quota is harvested in Trimesters I and II, and when 95 percent of the *Loligo* DAH has been harvested in Trimester III. The closure of the directed fishery shall be in effect for the remainder of that fishing period, with incidental catches allowed as specified at § 648.26.

(i) If the Regional Administrator determines that the Trimester I closure threshold has been under-harvested by 25 percent or more, then the amount of the underharvest shall be reallocated to Trimester II and Trimester III, as specified at § 648.22(f)(2), through notice in the **Federal Register**.

(ii) [*Reserved*]

(2) *Illex.* NMFS shall close the directed *Illex* fishery in the EEZ when the Regional Administrator projects that 95 percent of the *Illex* DAH is harvested. The closure of the directed fishery shall be in effect for the remainder of that fishing period, with incidental catches allowed as specified at § 648.26.

(b) *Mackerel AMs.* (1) *Mackerel commercial sector EEZ closure.* NMFS shall close the commercial mackerel fishery in the EEZ when the Regional Administrator projects that 90 percent of the mackerel DAH is harvested, if such a closure is necessary to prevent the DAH from being exceeded. The closure of the commercial fishery shall be in effect for the remainder of that fishing year, with incidental catches allowed as specified in § 648.26. When the Regional Administrator projects that the DAH for mackerel shall be landed, NMFS shall close the commercial mackerel fishery in the EEZ, and the incidental catches specified for mackerel in § 648.26 will be prohibited.

(2) *Mackerel commercial landings overage repayment.* If the mackerel ACL is exceeded, and commercial fishery landings are responsible for the overage, then landings in excess of the DAH will be deducted from the DAH the following year, as a single-year adjustment to the DAH.

(3) *Mackerel recreational sector EEZ closure.* NMFS shall close the recreational mackerel fishery in the EEZ when the Regional Administrator determines that recreational landings have exceeded the RHL. This determination shall be based on observed landings and will not utilize projections of future data.

(4) *Mackerel recreational landings overage repayment.* If the mackerel ACL is exceeded, and the recreational fishery landings are responsible for the overage, then landings in excess of the RHL will be deducted from the RHL for the following year, as a single-year adjustment.

(5) *Non-landing AMs, by sector.* In the event that the ACL is exceeded, and that the overage has not been accommodated through other landing-based AMs, but is attributable to either the commercial or recreational sector (such as research quota overages, dead discards in excess of those otherwise accounted for in management uncertainty, or other non-landing overages), then the exact amount, in pounds, by which the sector ACT was exceeded will be deducted from the following year, as a single-year adjustment.

(6) *Mackerel ACL overage evaluation.* The ACL will be evaluated based on a single-year examination of total catch (landings and discards). Both landings and dead discards will be evaluated in determining if the ACL has been exceeded. NMFS shall make determinations about overages and implement any changes to the ACL, in accordance with the Administrative Procedure Act, through notification in the **Federal Register**, by March 31 of the fishing year in which the deductions will be made.

(c) *Butterfish AMs*—(1) *Butterfish EEZ closure.* NMFS shall close the directed butterfish fishery in the EEZ when the Regional Administrator projects that 80 percent of the butterfish DAH has been harvested. The closure of the directed fishery shall be in effect for the remainder of that fishing year, with incidental catches allowed as specified at § 648.26.

(2) *Butterfish ACL overage repayment.* If the butterfish ACL is exceeded, then catch in excess of the ACL will be deducted from the ACL the following year, as a single-year adjustment.

(3) *Butterfish mortality cap on the Loligo fishery.* NMFS shall close the directed fishery in the EEZ for *Loligo* when the Regional Administrator projects that 80 percent of the butterfish mortality cap has been harvested in Trimester I, and/or when 90 percent of the butterfish mortality cap has been harvested in Trimester III.

(4) *Butterfish ACL overage evaluation.* The ACL will be evaluated based on a single-year examination of total catch (landings and discards). Both landings and dead discards will be evaluated in determining if the ACL has been exceeded. NMFS shall make determinations about overages and implement any changes to the ACL, in accordance with the Administrative Procedure Act, through notification in the **Federal Register**, by March 31 of the fishing year in which the deductions will be made.

(d) *Notification.* Upon determining that a closure is necessary, the Regional Administrator will notify, in advance of the closure, the Executive Directors of the MAFMC, NEFMC, and SAFMC; mail notification of the closure to all holders of mackerel, squid, and butterfish fishery permits at least 72 hours before the effective date of the closure; provide adequate notice of the closure to recreational participants in the fishery; and publish notification of closure in the **Federal Register**.

8. Section 648.25 is revised to read as follows:

§ 648.25 Framework adjustments to management measures.

(a) *Within season management action.* The MAFMC may, at any time, initiate action to add or adjust management measures within the Atlantic Mackerel, Squid, and Butterfish FMP if it finds that action is necessary to meet or be consistent with the goals and objectives of the FMP.

(1) *Adjustment process.* The MAFMC shall develop and analyze appropriate management actions over the span of at least two MAFMC meetings. The MAFMC must provide the public with advance notice of the availability of the recommendation(s), appropriate justification(s) and economic and biological analyses, and the opportunity to comment on the proposed adjustment(s) at the first meeting and prior to and at the second MAFMC meeting. The MAFMC's recommendations on adjustments or additions to management measures must come from one or more of the following categories: Adjustments within existing ABC control rule levels; adjustments to the existing MAFMC risk policy; introduction of new AMs, including sub-ACTs; minimum fish size; maximum fish size; gear restrictions; gear requirements or prohibitions; permitting restrictions, recreational possession limit; recreational seasons; closed areas; commercial seasons; commercial trip limits; commercial quota system, including commercial quota allocation procedure and possible quota set-asides to mitigate bycatch; recreational harvest limit; annual specification quota setting process; FMP Monitoring Committee composition and process; description and identification of EFH (and fishing gear management measures that impact EFH); description and identification of habitat areas of particular concern; overfishing definition and related thresholds and targets; regional gear restrictions; regional season restrictions (including option to split seasons); restrictions on vessel size (LOA and GRT) or shaft horsepower; changes to the Northeast Region SBRM (including the CV-based performance standard, the means by which discard data are collected/obtained, fishery stratification, reports, and/or industry-funded observers or observer set-aside programs); any other management measures currently included in the FMP, set aside quota for scientific research, regional management, and process for inseason adjustment to the annual specification. Measures contained within this list that require significant departures from previously contemplated measures or that are otherwise introducing new concepts may require amendment of the FMP instead of a framework adjustment.

(2) *MAFMC recommendation.* After developing management actions and receiving public testimony, the MAFMC shall make a recommendation to the Regional Administrator. The MAFMC's recommendation must include supporting rationale, if management measures are recommended, an analysis of impacts, and a recommendation to the Regional Administrator on whether to issue the management measures as a final rule. If the MAFMC recommends that the management measures should be issued as a final rule, the MAFMC must consider at least the following factors, and provide support and analysis for each factor considered:

(i) Whether the availability of data on which the recommended management measures are based allows for adequate time to publish a proposed rule, and whether the regulations would have to be in place for an entire harvest/fishing season.

(ii) Whether there has been adequate notice and opportunity for participation by the public and members of the affected industry in the development of the recommended management measures.

(iii) Whether there is an immediate need to protect the resource.

(iv) Whether there will be a continuing evaluation of management measures following their implementation as a final rule.

(3) *NMFS action.* If the MAFMC's recommendation includes adjustments or additions to management measures and, after reviewing the MAFMC's recommendation and supporting information:

(i) If NMFS concurs with the MAFMC's recommended management measures and determines that the recommended management measures should be issued as a final rule based on the factors specified in paragraph (a)(2) of this section, the measures will be issued as a final rule in the **Federal Register**.

(ii) If NMFS concurs with the MAFMC's recommended management measures and determines that the recommended management measures should be published first as a proposed rule, the measures will be published as a proposed rule in the **Federal Register**. After additional public comment, if NMFS concurs with the MAFMC recommendation, the measures will be issued as a final rule in the **Federal Register**.

(iii) If NMFS does not concur, the MAFMC will be notified in writing of the reasons for the non-concurrence.

(4) *Emergency actions.* Nothing in this section is meant to derogate from the authority of the Secretary to take emergency action under section 305(e) of the Magnuson-Stevens Act.

(b) [*Reserved*]

9. Section 648.26 is revised to read as follows:

§ 648.26 Possession restrictions.

(a) *Atlantic mackerel.* During a closure of the commercial Atlantic mackerel fishery that occurs prior to June 1, vessels may not fish for, possess, or land more than 20,000 lb (9.08 mt) of Atlantic mackerel per trip at any time, and may only land Atlantic mackerel once on any calendar day, which is defined as the 24-hr period beginning at 0001 hours and ending at 2400 hours. During a closure of the commercial fishery for mackerel that occurs on or after June 1, vessels may not fish for, possess, or land more than 50,000 lb (22.7 mt) of Atlantic mackerel per trip at any time, and may only land Atlantic mackerel once on any calendar day.

(b) *Loligo.* During a closure of the directed fishery for *Loligo,* vessels may not fish for, possess, or land more than 2,500 lb (1.13 mt) of *Loligo* per trip at any time, and may only land *Loligo* once on any calendar day, which is defined as the 24-hr period beginning at 0001 hours and ending at 2400 hours. If a vessel has been issued a *Loligo* incidental catch permit (as specified at § 648.4(a)(5)(ii)), then it may not fish for, possess, or land more than 2,500 lb

(1.13 mt) of *Loligo* per trip at any time and may only land *Loligo* once on any calendar day.

(c) *Illex.* During a closure of the directed fishery for *Illex,* vessels may not fish for, possess, or land more than 10,000 lb (4.54 mt) of *Illex* per trip at any time, and may only land *Illex* once on any calendar day, which is defined as the 24-hr period beginning at 0001 hours and ending at 2400 hours. If a vessel has been issued an *Illex* incidental catch permit (as specified at § 648.4(a)(5)(ii)), then it may not fish for, possess, or land more than 10,000 lb (4.54 mt) of *Illex* per trip at any time, and may only land *Illex* once on any calendar day.

(d) *Butterfish.* (1) During a closure of the directed fishery for butterfish that occurs prior to October 1, vessels may not fish for, possess, or land more than 250 lb (0.11 mt) of butterfish per trip at any time, and may only land butterfish once on any calendar day, which is defined as the 24-hr period beginning at 0001 hours and ending at 2400 hours. During a closure of the directed fishery for butterfish that occurs on or after October 1, vessels may not fish for, possess, or land more than 600 lb (0.27 mt) of butterfish per trip at any time, and may only land butterfish once on any calendar day. If a vessel has been issued a butterfish incidental catch permit (as specified at § 648.4(a)(5)(ii)), in which case it may not fish for, possess, or land more than 600 lb (0.27 mt) of butterfish per trip at any time, and may only land butterfish once on any calendar day, unless the directed fishery for butterfish closes prior to October 1, then a vessel that has been issued a butterfish incidental catch permit may not fish for, possess, or land more than 250 lb (0.11 mt) of butterfish per trip at any time, and may only land butterfish once on any calendar day.

(2) A vessel issued a butterfish moratorium permit (as specified at § 648.4(a)(5)(i)) may not fish for, possess, or land more than 5,000 lb (2.27 mt) of butterfish per trip at any time, and may only land butterfish once on any calendar day, which is defined as the 24-hr period beginning at 0001 hours and ending at 2400 hours.

10. Section 648.27 is added to read as follows:

§ 648.27 Observer requirements for the Loligo fishery.

(a) A vessel issued a *Loligo* and butterfish moratorium permit, as specified at § 648.4(a)(5)(i), must, for the purposes of observer deployment, have a representative provide notice to NMFS of the vessel name, vessel permit number, contact name for coordination of observer deployment, telephone number or e-mail address for contact; and the date, time, port of departure, and approximate trip duration, at least 72 hr, but no more than 10 days prior to beginning any fishing trip, unless it complies with the possession restrictions in paragraph (c) of this section.

(b) A vessel that has a representative provide notification to NMFS as described in paragraph (a) of this section may only embark on a *Loligo* trip without an observer if a vessel representative has been notified by NMFS that the vessel has received a waiver of the observer requirement for that trip. NMFS shall notify a vessel representative whether the vessel must carry an observer, or if a waiver has been granted, for the specified *Loligo* trip, within 24 hr of the vessel representative's notification of the prospective *Loligo* trip, as specified in paragraph (a) of this section. Any request to carry an observer may be waived by NMFS. A vessel that fishes with an observer waiver confirmation number that does not match the *Loligo* trip plan that was called in to NMFS is prohibited from fishing for, possessing, harvesting, or landing *Loligo* except as specified in paragraph (c) of this section. Confirmation numbers for trip notification calls are only valid for 48 hr from the intended sail date.

(c) A vessel issued a *Loligo* and butterfish moratorium permit, as specified in § 648.4(a)(5)(i), that does not have a representative provide the trip notification required in paragraph (a) of this section is prohibited from fishing for, possessing, harvesting, or landing 2,500 lb (1.13 mt) or more of *Loligo* per trip at any time, and may only land *Loligo* once on any calendar day, which is defined as the 24-hr period beginning at 0001 hours and ending at 2400 hours.

(d) If a vessel issued a *Loligo* and butterfish moratorium permit, as specified in § 648.4(a)(5)(i), intends to possess, harvest, or land 2,500 lb (1.13 mt) or more of *Loligo* per trip or per calendar day, has a representative notify NMFS of an upcoming trip, is selected by NMFS to carry an observer, and then cancels that trip, the representative is required to provide notice to NMFS of the vessel name, vessel permit number, contact name for coordination of observer deployment, and telephone number or e-mail address for contact, and the intended date, time, and port of departure for the cancelled trip prior to the planned departure time. In addition, if a trip selected for observer coverage is canceled, then that vessel is required to carry an observer, provided an observer is available, on its next trip.

11. Section 648.70 is revised to read as follows:

§ 648.70 Annual Catch Limit (ACL).

(a) The MAFMC staff shall recommend to the MAFMC ACLs for the surfclam and ocean quahog fisheries, which shall be less than or equal to the ABCs recommended by the SSC.

(1) *Sectors.* The surfclam and ocean quahog ACLs will be established consistent with the guidelines contained in the Atlantic Surfclam and Ocean Quahog FMP. The ACL for ocean quahog will then be allocated to the Maine and non-Maine components of the fishery according to the allocation guidelines of the Atlantic Surfclam and Ocean Quahog FMP as specified in § 648.78(b).

(2) *Periodicity.* The surfclam and ocean quahog ACLs may be established on an annual basis for up to 3 years at a time, dependent on whether the SSC provides single or multiple year ABC recommendations.

(b) *Performance review.* The MAFMC staff shall conduct a detailed review of the fishery performance relative to the ACLs at least every 5 years.

(1) If the surfclam or the ocean quahog ACL is exceeded with a frequency greater than 25 percent (*i.e.,* more than once in 4 years or any 2 consecutive years), the MAFMC staff will review fishery performance information and make recommendations to the MAFMC for changes in measures intended to ensure the ACL is not exceeded as frequently.

(2) The MAFMC may specify more frequent or more specific ACL performance review criteria as part of a stock rebuilding plan following a determination that a stock has become overfished.

(3) Performance reviews shall not substitute for annual reviews that occur to ascertain if prior year ACLs have been exceeded, but may be conducted in conjunction with such reviews.

12. Section 648.71 is revised to read as follows:

§ 648.71 Annual Catch Targets (ACT).

(a) The MAFMC staff shall identify and review the relevant sources of management uncertainty to recommend ACTs to the MAFMC as part of the surfclam and ocean quahog specification process. The MAFMC staff recommendations shall identify the specific sources of management uncertainty that were considered, technical approaches to mitigating these sources of uncertainty, and any additional relevant information

considered in the ACT recommendation process.

(1) *Sectors.* The surfclam ACT and the sum of the Maine and non-Maine ocean quahog ACTs shall be less than or equal to the ACL for the corresponding stock. The MAFMC staff shall recommend any reduction in catch necessary to address management uncertainty, consistent with paragraph (a) of this section.

(2) *Periodicity.* ACTs may be established on an annual basis for up to 3 years at a time, dependent on whether the SSC provides single or multiple year ABC recommendations.

(b) *Performance review.* The MAFMC staff shall conduct a detailed review of fishery performance relative to ACTs in conjunction with any ACL performance review, as outlined in § 648.70(b)(1) through (3).

13. Section 648.72 is revised to read as follows:

§ 648.72 Specifications.

(a) *Establishing catch quotas.* The amount of surfclams or ocean quahogs that may be caught annually by fishing vessels subject to these regulations will be specified for up to a 3-year period by the Regional Administrator. Specifications of the annual quotas will be accomplished in the final year of the quota period, unless the quotas are modified in the interim pursuant to paragraph (b) of this section. The amount of surfclams available for harvest annually must be specified within the range of 1.85 to 3.4 million bu (98.5 to 181 million L). The amount of ocean quahogs available for harvest annually must be specified within the range of 4 to 6 million bu (213 to 319.4 million L). Quotas for surfclams and ocean quahogs may be specified below these ranges if the ABC recommendation of the SSC limits the ACL to a value less than the minimum of the range indicated.

(1) *Quota reports.* On an annual basis, MAFMC staff will produce and provide to the MAFMC an Atlantic surfclam and ocean quahog annual quota recommendation paper based on the ABC recommendation of the SSC, the latest available stock assessment report prepared by NMFS, data reported by harvesters and processors, and other relevant data, as well as the information contained in paragraphs (a)(1)(i) through (vi) of this section. Based on that report, and at least once prior to August 15 of the year in which a multi-year annual quota specification expires, the MAFMC, following an opportunity for public comment, will recommend to the Regional Administrator annual quotas and estimates of DAH and DAP within the ranges specified for up to a 3-year period. In selecting the annual quotas, the MAFMC shall consider the current stock assessments, catch reports, and other relevant information concerning:

(i) Exploitable and spawning biomass relative to the OY.

(ii) Fishing mortality rates relative to the OY.

(iii) Magnitude of incoming recruitment.

(iv) Projected effort and corresponding catches.

(v) Geographical distribution of the catch relative to the geographical distribution of the resource.

(vi) Status of areas previously closed to surfclam fishing that are to be opened during the year and areas likely to be closed to fishing during the year.

(2) *Public review.* Based on the recommendation of the MAFMC, the Regional Administrator shall publish proposed surfclam and ocean quahog quotas in the **Federal Register.** The Regional Administrator shall consider public comments received, determine the appropriate annual quotas, and publish the annual quotas in the **Federal Register.** The quota shall be set at that amount that is most consistent with the objectives of the Atlantic Surfclam and Ocean Quahog FMP. The Regional Administrator may set quotas at quantities different from the MAFMC's recommendations only if he/she can demonstrate that the MAFMC's recommendations violate the national standards of the Magnuson-Stevens Act or the objectives of the Atlantic Surfclam and Ocean Quahog FMP or other applicable law.

(b) *Interim quota modifications.* Based upon information presented in the quota reports described in paragraph (a)(1) of this section, the MAFMC may recommend to the Regional Administrator a modification to the annual quotas that have been specified for a 3-year period and any estimate of DAH or DAP made in conjunction with such specifications within the ranges specified in paragraph (a)(1) of this section. Based upon the MAFMC's recommendation, the Regional Administrator may propose surfclam and or ocean quahog quotas that differ from the annual quotas specified for the current 3-year period. Such modification shall be in effect for a period of up to 3 years, unless further modified. Any interim modification shall follow the same procedures for establishing the annual quotas that are specified for up to a 3-year period.

(c) *Annual quotas.* The annual quotas for surfclams and ocean quahogs will remain effective unless revised pursuant to this section. At the end of a multiyear quota period, NMFS will issue notification in the **Federal Register** if the previous year's specifications will not be changed.

14. Section 648.73 is revised to read as follows:

§ 648.73 Accountability measures.

(a) *Commercial ITQ fishery.* (1) If the ACL for surfclam or ocean quahog is exceeded, and the overage can be attributed to one or more ITQ allocation holders, the full amount of the overage will be deducted from the appropriate ITQ allocation in the following fishing year.

(2) Any amount of an ACL overage that cannot be otherwise attributed to an ITQ allocation holder will be deducted from the appropriate ACL in the following fishing year.

(b) *Maine mahogany quahog fishery.* If the ocean quahog ACL is exceeded, and the Maine mahogany quahog fishery is responsible for the overage, than the Maine fishery ACT shall be reduced in the following year by an amount equal to the ACL overage.

15. Section 648.74 is revised to read as follows:

§ 648.74 Annual individual allocations.

(a) *General.* (1) Each fishing year, the Regional Administrator shall determine the initial allocation of surfclams and ocean quahogs for the next fishing year for each allocation holder owning an allocation pursuant to paragraph (a)(2) of this section. For each species, the initial allocation for the next fishing year is calculated by multiplying the allocation percentage owned by each allocation owner as of the last day of the previous fishing year in which allocation owners are permitted to permanently transfer allocation percentage pursuant to paragraph (b) of this section (*i.e.,* October 15 of every year), by the quota specified by the Regional Administrator pursuant to § 648.72. The total number of cages of allocation shall be divided by 32 to determine the appropriate number of cage tags to be issued or acquired under § 648.77. Amounts of allocation of 0.5 cages or smaller created by this division shall be rounded downward to the nearest whole number, and amounts of allocation greater than 0.5 cages created by this division shall be rounded upward to the nearest whole number, so that allocations are specified in whole cages. These allocations shall be made in the form of an allocation permit specifying the allocation percentage and the allocation in cages and cage tags for each species. An allocation permit is only valid for the entity for which it is issued. Such permits shall be issued on or before December 15, to allow

allocation owners to purchase cage tags from a vendor specified by the Regional Administrator pursuant to § 648.77(b).

(2) The Regional Administrator may, after publication of a fee notification in the **Federal Register,** charge a permit fee before issuance of the permit to recover administrative expenses. Failure to pay the fee will preclude issuance of the permit.

(b) *Transfers*—(1) *Allocation percentage.* Subject to the approval of the Regional Administrator, part or all of an allocation percentage may be transferred in the year in which the transfer is made, to any person or entity eligible to own a documented vessel under the terms of 46 U.S.C. 12102(a). Approval of a transfer by the Regional Administrator and for a new allocation permit reflecting that transfer may be requested by submitting a written application for approval of the transfer and for issuance of a new allocation permit to the Regional Administrator at least 10 days before the date on which the applicant desires the transfer to be effective, in the form of a completed transfer log supplied by the Regional Administrator. The transfer is not effective until the new holder receives a new or revised annual allocation permit from the Regional Administrator. An application for transfer may not be made between October 15 and December 31 of each year.

(2) *Cage tags.* Cage tags issued pursuant to § 648.77 may be transferred at any time, and in any amount subject to the restrictions and procedure specified in paragraph (b)(1) of this section; provided that application for such cage tag transfers may be made at any time before December 10 of each year. The transfer is effective upon the receipt by the transferee of written authorization from the Regional Administrator.

(3) *Review.* If the Regional Administrator determines that the applicant has been issued a Notice of Permit Sanction for a violation of the Magnuson-Stevens Act that has not been resolved, he/she may decline to approve such transfer pending resolution of the matter.

16. Section 648.75 is revised to read as follows:

§ 648.75 Shucking at sea and minimum surfclam size.

(a) *Shucking at sea*—(1) *Observers.* (i) The Regional Administrator may allow the shucking of surfclams or ocean quahogs at sea if he/she determines that an observer carried aboard the vessel can measure accurately the total amount of surfclams and ocean quahogs harvested in the shell prior to shucking.

(ii) Any vessel owner may apply in writing to the Regional Administrator to shuck surfclams or ocean quahogs at sea. The application shall specify: Name and address of the applicant; permit number of the vessel; method of calculating the amount of surfclams or ocean quahogs harvested in the shell; vessel dimensions and accommodations; and length of fishing trip.

(iii) The Regional Administrator shall provide an observer to any vessel owner whose application is approved. The owner shall pay all reasonable expenses of carrying the observer on board the vessel.

(iv) Any observer shall certify at the end of each trip the amount of surfclams or ocean quahogs harvested in the shell by the vessel. Such certification shall be made by the observer's signature on the daily fishing log required by § 648.7.

(2) *Conversion factor.* (i) Based on the recommendation of the MAFMC, the Regional Administrator may allow shucking at sea of surfclams or ocean quahogs, with or without an observer, if he/she determines a conversion factor for shucked meats to calculate accurately the amount of surfclams or ocean quahogs harvested in the shell.

(ii) The Regional Administrator shall publish notification in the **Federal Register** specifying a conversion factor, together with the data used in its calculation, for a 30-day comment period. After consideration of the public comments and any other relevant data, the Regional Administrator may publish final notification in the **Federal Register** specifying the conversion factor.

(iii) If the Regional Administrator makes the determination specified in paragraph (b)(1) of this section, he/she may authorize the vessel owner to shuck surfclams or ocean quahogs at sea. Such authorization shall be in writing and be carried aboard the vessel.

(b) *Minimum surfclam size.*—(1) *Minimum length.* The minimum length for surfclams is 4.75 inches (12.065 cm).

(2) *Determination of compliance.* No more than 50 surfclams in any cage may be less than 4.75 inches (12.065 cm) in length. If more than 50 surfclams in any inspected cage of surfclams are less than 4.75 inches (12.065 cm) in length, all cages landed by the same vessel from the same trip are deemed to be in violation of the minimum size restriction.

(3) *Suspension.* Upon the recommendation of the MAFMC, the Regional Administrator may suspend annually, by publication in the **Federal Register,** the minimum shell-length standard, unless discard, catch, and survey data indicate that 30 percent of the surfclams are smaller than 4.75 inches (12.065 cm) and the overall reduced shell length is not attributable to beds where the growth of individual surfclams has been reduced because of density dependent factors.

(4) *Measurement.* Length is measured at the longest dimension of the surfclam shell.

17. Section 648.76 is revised to read as follows:

§ 648.76 Closed areas.

(a) *Areas closed because of environmental degradation.* Certain areas are closed to all surfclam and ocean quahog fishing because of adverse environmental conditions. These areas will remain closed until the Regional Administrator determines that the adverse environmental conditions no longer exist. If additional areas are identified by the Regional Administrator as being contaminated by the introduction or presence of hazardous materials or pollutants, they may be closed by the Regional Administrator in accordance with paragraph (c) of this section. The areas closed are:

(1) *Boston Foul Ground.* The waste disposal site known as the ''Boston Foul Ground'' and located at 42°25′36″ N. lat., 70°35′00″ W. long., with a radius of 1 nm (1.61 km) in every direction from that point.

(2) *New York Bight.* The polluted area and waste disposal site known as the ''New York Bight'' and located at 40°25′04″ N. lat., 73°42′38″ W. long., and with a radius of 6 nm (9.66 km) in every direction from that point, extending further northwestward, westward and southwestward between a line from a point on the arc at 40°31′00″ N. lat., 73°43′38″ W. long., directly northward toward Atlantic Beach Light in New York to the limit of the state territorial waters of New York; and a line from the point on the arc at 40°19′48″ N. lat., 73°45′42″ W. long., to a point at the limit of the state territorial waters of New Jersey at 40°14′00″ N. lat., 73°55′42″ W. long.

(3) *106 Dumpsite.* The toxic industrial site known as the ''106 Dumpsite'' and located between 38°40′00″ and 39°00′00″ N. lat., and between 72°00′00″ and 72°30′00″ W. long.

(4) *Georges Bank.* The paralytic shellfish poisoning (PSP) contaminated area, which is located on Georges Bank, and located east of 69° W. long., and south of 42°20′ N. lat.

(b) *Areas closed because of small surfclams.* Areas may be closed because they contain small surfclams.

(1) *Closure.* The Regional Administrator may close an area to surfclams and ocean quahog fishing if

he/she determines, based on logbook entries, processors' reports, survey cruises, or other information, that the area contains surfclams of which:

(i) Sixty percent or more are smaller than 4.5 inches (11.43 cm); and

(ii) Not more than 15 percent are larger than 5.5 inches (13.97 cm) in size.

(2) *Reopening.* The Regional Administrator may reopen areas or parts of areas closed under paragraph (b)(1) of this section if he/she determines, based on survey cruises or other information, that:

(i) The average length of the dominant (in terms of weight) size class in the area to be reopened is equal to or greater than 4.75 inches (12.065 cm); or

(ii) The yield or rate of growth of the dominant shell-length class in the area to be reopened would be significantly enhanced through selective, controlled, or limited harvest of surfclams in the area.

(c) *Procedure.* (1) The Regional Administrator may hold a public hearing on the proposed closure or reopening of any area under paragraph (a) or (b) of this section. The Regional Administrator shall publish notification in the **Federal Register** of any proposed area closure or reopening, including any restrictions on harvest in a reopened area. Comments on the proposed closure or reopening must be submitted to the Regional Administrator within 30 days after publication. The Regional Administrator shall consider all comments and publish the final notification of closure or reopening, and any restrictions on harvest, in the **Federal Register**. Any adjustment to harvest restrictions in a reopened area shall be made by notification in the **Federal Register**. The Regional Administrator shall send notice of any action under this paragraph (c)(1) to each surfclam and ocean quahog processor and to each surfclam and ocean quahog permit holder.

(2) If the Regional Administrator determines, as the result of testing by state, Federal, or private entities, that a closure of an area under paragraph (a) of this section is necessary to prevent any adverse effects fishing may have on the public health, he/she may close the area for 60 days by publication of notification in the **Federal Register**, without prior comment or public hearing. If an extension of the 60-day closure period is necessary to protect the public health, the hearing and notice requirements of paragraph (c)(1) of this section shall be followed.

(d) *Areas closed due to the presence of paralytic shellfish poisoning toxin.*—(1) *Maine mahogany quahog zone.* The Maine mahogany quahog zone is closed to fishing for ocean quahogs except in those areas of the zone that are tested by the State of Maine and deemed to be within the requirements of the National Shellfish Sanitation Program and adopted by the Interstate Shellfish Sanitation Conference as acceptable limits for the toxin responsible for PSP. Harvesting is allowed in such areas during the periods specified by the Maine Department of Marine Resources during which quahogs are safe for human consumption. For information regarding these areas contact the State of Maine Division of Marine Resources.

(2) [Reserved]

18. Section 648.77 is revised to read as follows:

§ 648.77 Cage identification.

Except as provided in § 648.78, the following cage identification requirements apply to all vessels issued a Federal fishing permit for surfclams and ocean quahogs:

(a) *Tagging.* Before offloading, all cages that contain surfclams or ocean quahogs must be tagged with tags acquired annually under provisions of paragraph (b) of this section. A tag must be fixed on or as near as possible to the upper crossbar of the cage. A tag is required for every 60 ft^3 (1,700 L) of cage volume, or portion thereof. A tag or tags must not be removed until the cage is emptied by the processor, at which time the processor must promptly remove and retain the tag(s) for 60 days beyond the end of the calendar year, unless otherwise directed by authorized law enforcement agents.

(b) *Issuance.* The Regional Administrator will issue a supply of tags to each individual allocation owner qualifying for an allocation under § 648.74 prior to the beginning of each fishing year, or he/she may specify, in the **Federal Register**, a vendor from whom the tags shall be purchased. The number of tags will be based on the owner's initial allocation as specified in § 648.74(a). Each tag represents 32 bu (1,700 L) of allocation.

(c) *Expiration.* Tags will expire at the end of the fishing year for which they are issued, or if rendered null and void in accordance with 15 CFR part 904.

(d) *Return.* Tags that have been rendered null and void must be returned to the Regional Administrator, if possible.

(e) *Loss.* Loss or theft of tags must be reported by the owner, numerically identifying the tags to the Regional Administrator by telephone as soon as the loss or theft is discovered and in writing within 24 hours. Thereafter, the reported tags shall no longer be valid for use under this part.

(f) *Replacement.* Lost or stolen tags may be replaced by the Regional Administrator if proper notice of the loss is provided by the person to whom the tags were issued. Replacement tags may be purchased from the Regional Administrator or a vendor with a written authorization from the Regional Administrator.

(g) *Transfer.* See § 648.74(b)(2).

(h) *Presumptions.* Surfclams and ocean quahogs found in cages without a valid state tag are deemed to have been harvested in the EEZ and to be part of an individual's allocation, unless the individual demonstrates that he/she has surrendered his/her Federal vessel permit issued under § 648.4(a)(4) and conducted fishing operations exclusively within waters under the jurisdiction of any state. Surfclams and ocean quahogs in cages with a Federal tag or tags, issued and still valid pursuant to this section, affixed thereto are deemed to have been harvested by the individual allocation holder to whom the tags were issued under the provisions of § 648.77(b) or transferred under the provisions of § 648.74(b).

19. Section 648.78 is added to read as follows:

§ 648.78 Maine mahogany quahog zone.

(a) *Landing requirements.* (1) A vessel issued a valid Maine mahogany quahog permit pursuant to § 648.4(a)(4)(i), and fishing for or possessing ocean quahogs within the Maine mahogany quahog zone, must land its catch in the State of Maine.

(2) A vessel fishing under an individual allocation permit, regardless of whether it has a Maine mahogany quahog permit, fishing for or possessing ocean quahogs within the zone, may land its catch in the State of Maine, or, consistent with applicable state law in any other state that utilizes food safety-based procedures including sampling and analyzing for PSP toxin consistent with those food safety-based procedures used by the State of Maine for such purpose, and must comply with all requirements in §§ 648.74 and 648.77. Documentation required by the state and other laws and regulations applicable to food safety-based procedures must be made available by federally permitted dealers for inspection by NMFS.

(b) *ACT monitoring and closures*—(1) *Catch quota.* (i) The ACT for harvest of mahogany quahogs from within the Maine mahogany quahog zone is 100,000 Maine bu (35,239 hL). The ACL may be revised annually within the range of 17,000 and 100,000 Maine bu (5,991 and 35,239 hL) following the

procedures set forth in §§ 648.72 and 648.73, if applicable.

(ii) All mahogany quahogs landed for sale in Maine by vessels issued a Maine mahogany quahog permit and not fishing for an individual allocation of ocean quahogs under § 648.74 shall be applied against the Maine mahogany quahog ACT, regardless of where the mahogany quahogs are harvested.

(iii) All mahogany quahogs landed by vessels fishing in the Maine mahogany quahog zone for an individual allocation of quahogs under § 648.74 will be counted against the ocean quahog allocation for which the vessel is fishing.

(iv) The Regional Administrator will monitor the ACT based on dealer reports and other available information, and shall determine the date when the ACT will be harvested. NMFS shall publish notification in the **Federal Register** advising the public that, effective upon a specific date, the Maine mahogany quahog quota has been harvested, and notifying vessel and dealer permit holders that no Maine mahogany quahog quota is available for the remainder of the year.

(2) *Maine Mahogany Quahog Advisory Panel.* The MAFMC shall establish a Maine Mahogany Quahog Advisory Panel consisting of representatives of harvesters, dealers, and the Maine Department of Marine Resources. The Advisory Panel shall make recommendations, through the Surfclam and Ocean Quahog Committee of the MAFMC, regarding revisions to the annual quota and other management measures.

20. Section 648.79 is added to read as follows:

§ 648.79 Framework adjustments to management measures.

(a) *Within season management action.* The MAFMC may, at any time, initiate action to add or adjust management measures within the Atlantic Surfclam and Ocean Quahog FMP if it finds that action is necessary to meet or be consistent with the goals and objectives of the plan.

(1) *Adjustment process.* The MAFMC shall develop and analyze appropriate management actions over the span of at least two MAFMC meetings. The MAFMC must provide the public with advance notice of the availability of the recommendation(s), appropriate justification(s) and economic and biological analyses, and the opportunity to comment on the proposed adjustment(s) at the first meeting, and prior to and at the second MAFMC meeting. The MAFMC's recommendations on adjustments or additions to management measures must come from one or more of the following categories: Adjustments within existing ABC control rule levels; adjustments to the existing MAFMC risk policy; introduction of new AMs, including sub-ACTs; description and identification of EFH (and fishing gear management measures that impact EFH); habitat areas of particular concern; set-aside quota for scientific research; VMS; OY range; suspension or adjustment of the surfclam minimum size limit; and changes to the Northeast Region SBRM (including the CV-based performance standard, the means by which discard data are collected/obtained, fishery stratification, reports, and/or industry-funded observers or observer set-aside programs). Issues that require significant departures from previously contemplated measures or that are otherwise introducing new concepts may require amendment of the FMP instead of a framework adjustment.

(2) *MAFMC recommendation.* After developing management actions and receiving public testimony, the MAFMC shall make a recommendation to the Regional Administrator. The MAFMC's recommendation must include supporting rationale, if management measures are recommended, an analysis of impacts, and a recommendation to the Regional Administrator on whether to issue the management measures as a final rule. If the MAFMC recommends that the management measures should be issued as a final rule, it must consider at least the following factors, and provide support and analysis for each factor considered:

(i) Whether the availability of data on which the recommended management measures are based allows for adequate time to publish a proposed rule, and whether the regulations would have to be in place for an entire harvest/fishing season.

(ii) Whether there has been adequate notice and opportunity for participation by the public and members of the affected industry in the development of recommended management measures.

(iii) Whether there is an immediate need to protect the resource.

(iv) Whether there will be a continuing evaluation of management measures adopted following their implementation as a final rule.

(3) *NMFS action.* If the MAFMC's recommendation includes adjustments or additions to management measures and after reviewing the MAFMC's recommendation and supporting information:

(i) If NMFS concurs with the MAFMC's recommended management measures and determines that the recommended management measures should be issued as a final rule based on the factors specified in paragraph (a)(2) of this section, the measures will be issued as a final rule in the **Federal Register**.

(ii) If NMFS concurs with the MAFMC's recommended management measures and determines that the recommended management measures should be published first as a proposed rule, the measures will be published as a proposed rule in the **Federal Register**. After additional public comment, if NMFS concurs with the MAFMC recommendation, the measures will be published as a final rule in the **Federal Register**.

(iii) If NMFS does not concur, the MAFMC will be notified in writing of the reasons for the non-concurrence.

(4) *Emergency actions.* Nothing in this section is meant to derogate from the authority of the Secretary to take emergency action under section 305(e) of the Magnuson-Stevens Act.

(b) [Reserved]

21. Section 648.100 is revised to read as follows:

§ 648.100 ACL.

(a) The Summer Flounder Monitoring Committee shall recommend to the MAFMC separate ACLs for the commercial and recreational summer flounder fisheries, the sum total of which shall be less than or equal to the ABC recommended by the SSC.

(1) *Sector allocations.* The commercial and recreational fishing sector ACLs will be established consistent with the allocation guidelines contained in the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan (FMP).

(2) *Periodicity.* The summer flounder commercial and recreational sector ACLs may be established on an annual basis for up to 3 years at a time, dependent on whether the SSC provides single or multiple year ABC recommendations.

(b) *Performance review.* The Summer Flounder Monitoring Committee shall conduct a detailed review of fishery performance relative to the sector ACLs at least every 5 years.

(1) If one or both of the sector-specific ACLs is exceeded with a frequency greater than 25 percent (*i.e.,* more than once in 4 years or any 2 consecutive years), the Summer Flounder Monitoring Committee will review fishery performance information and make recommendations to the MAFMC for changes in measures intended to ensure ACLs are not exceeded as frequently.

(2) The MAFMC may specify more frequent or more specific ACL performance review criteria as part of a stock rebuilding plan following a determination that the summer flounder stock has become overfished.

(3) Performance reviews shall not substitute for annual reviews that occur to ascertain if prior year ACLs have been exceeded but may be conducted in conjunction with such reviews.

22. Section 648.101 is revised to read as follows:

§ 648.101 ACT.

(a) The Summer Flounder Monitoring Committee shall identify and review the relevant sources of management uncertainty to recommend ACTs for the commercial and recreational fishing sectors as part of the summer flounder specification process. The Summer Flounder Monitoring Committee recommendations shall identify the specific sources of management uncertainty that were considered, technical approaches to mitigating these sources of uncertainty, and any additional relevant information considered in the ACT recommendation process.

(1) *Sectors.* Commercial and recreational specific ACTs shall be less than or equal to the sector-specific ACLs. The Summer Flounder Monitoring Committee shall recommend any reduction in catch necessary to address sector-specific management uncertainty, consistent with paragraph (a) of this section.

(2) *Periodicity.* ACTs may be established on an annual basis for up to 3 years at a time, dependent on whether the SSC provides single or multiple year ABC recommendations.

(b) *Performance review.* The Summer Flounder Monitoring Committee shall conduct a detailed review of fishery performance relative to ACTs in conjunction with any ACL performance review, as outlined in § 648.100(b)(1) through (3).

23. Section 648.102 is revised to read as follows:

§ 648.102 Specifications.

(a) *Commercial quota, recreational landing limits, research set-asides, and other specification measures.* The Summer Flounder Monitoring Committee shall recommend to the MAFMC, through the specifications process, for use in conjunction with each ACL and ACT, a sector-specific research set-aside, estimates of sector-related discards, recreational harvest limit, and commercial quota, along with other measures, as needed, that are projected to ensure the sector-specific ACL for an upcoming fishing year or years will not be exceeded. The measures to be considered by the Summer Flounder Monitoring Committee are:

(1) Research quota set from a range of 0 to 3 percent of the allowable landings level for both the commercial and recreational sectors.

(2) Commercial minimum fish size.

(3) Minimum mesh size.

(4) Restrictions on gear other than otter trawls.

(5) Adjustments to the exempted area boundary and season specified in § 648.108(b)(1) by 30-minute intervals of latitude and longitude and 2-week intervals, respectively, based on data reviewed by Summer Flounder Monitoring Committee during the specification process, to prevent discarding of sublegal sized summer flounder in excess of 10 percent, by weight.

(6) Recreational possession limit set from a range of 0 to 15 summer flounder to achieve the recreational harvest limit, set after reductions for research quota.

(7) Recreational minimum fish size.

(8) Recreational season.

(9) Recreational state conservation equivalent and precautionary default measures utilizing possession limits, minimum fish sizes, and/or seasons set after reductions for research quota.

(10) Changes, as appropriate, to the Northeast Region SBRM, including the CV-based performance standard, fishery stratification, and/or reports.

(11) Modification of existing AM measures and ACT control rules utilized by the Summer Flounder Monitoring Committee.

(b) *Specification fishing measures.* The Demersal Species Committee shall review the recommendations of the Summer Flounder Monitoring Committee. Based on these recommendations and any public comment, the Demersal Species Committee shall recommend to the MAFMC measures necessary that are projected to ensure the sector-specific ACLs for an upcoming fishing year or years will not be exceeded. The MAFMC shall review these recommendations and, based on the recommendations and any public comment, recommend to the Regional Administrator measures that are projected to ensure the sector-specific ACL for an upcoming fishing year or years will not be exceeded. The MAFMC's recommendations must include supporting documentation, as appropriate, concerning the environmental and economic impacts of the recommendations. The Regional Administrator shall review these recommendations and any recommendations of the ASMFC.

(c) After such review, the Regional Administrator will publish a proposed rule in the **Federal Register** to implement a coastwide commercial quota, a recreational harvest limit, research set-aside, adjustments to ACL or ACT resulting from AMs, and additional management measures for the commercial fishery. After considering public comment, NMFS will publish a final rule in the **Federal Register**.

(1) *Distribution of annual commercial quota.* (i) The annual commercial quota will be distributed to the states, based upon the following percentages; state followed by percent share in parenthesis: Maine (0.04756); New Hampshire (0.00046); Massachusetts (6.82046); Rhode Island (15.68298); Connecticut (2.25708); New York (7.64699); New Jersey (16.72499); Delaware (0.01779); Maryland (2.03910); Virginia (21.31676); North Carolina (27.44584).

(ii) [*Reserved*]

(2) *Quota transfers and combinations.* Any state implementing a state commercial quota for summer flounder may request approval from the Regional Administrator to transfer part or its entire annual quota to one or more states. Two or more states implementing a state commercial quota for summer flounder may request approval from the Regional Administrator to combine their quotas, or part of their quotas, into an overall regional quota. Requests for transfer or combination of commercial quotas for summer flounder must be made by individual or joint letter(s) signed by the principal state official with marine fishery management responsibility and expertise, or his/her previously named designee, for each state involved. The letter(s) must certify that all pertinent state requirements have been met and identify the states involved and the amount of quota to be transferred or combined.

(i) Within 10 working days following the receipt of the letter(s) from the states involved, the Regional Administrator shall notify the appropriate state officials of the disposition of the request. In evaluating requests to transfer a quota or combine quotas, the Regional Administrator shall consider whether:

(A) The transfer or combination would preclude the overall annual quota from being fully harvested;

(B) The transfer addresses an unforeseen variation or contingency in the fishery; and

(C) The transfer is consistent with the objectives of the FMP and the Magnuson-Stevens Act.

(ii) The transfer of quota or the combination of quotas will be valid only for the calendar year for which the request was made;

(iii) A state may not submit a request to transfer quota or combine quotas if a request to which it is party is pending before the Regional Administrator. A state may submit a new request when it receives notice that the Regional Administrator has disapproved the previous request or when notice of the approval of the transfer or combination has been filed at the Office of the **Federal Register**.

(iv) If there is a quota overage among states involved in the combination of quotas at the end of the fishing year, the overage will be deducted from the following year's quota for each of the states involved in the combined quota. The deduction will be proportional, based on each state's relative share of the combined quota for the previous year. A transfer of quota or combination of quotas does not alter any state's percentage share of the overall quota specified in paragraph (d)(1)(i) of this section.

(d) *Recreational specification measures.* The Demersal Species Committee shall review the recommendations of the Summer Flounder Monitoring Committee. Based on these recommendations and any public comment, the Demersal Species Committee shall recommend to the MAFMC and ASMFC measures that are projected to ensure the sector-specific ACL for an upcoming fishing year or years will not be exceeded. The MAFMC shall review these recommendations and, based on the recommendations and any public comment, recommend to the Regional Administrator measures that are projected to ensure the sector-specific ACL for an upcoming fishing year or years will not be exceeded. The MAFMC's recommendations must include supporting documentation, as appropriate, concerning the environmental and economic impacts of the recommendations. The MAFMC and the ASMFC will recommend that the Regional Administrator implement either:

(1) *Coastwide measures.* Annual coastwide management measures that constrain the recreational summer flounder fishery to the recreational harvest limit, or

(2) *Conservation equivalent measures.* Individual states, or regions formed voluntarily by adjacent states (*i.e.,* multi-state conservation equivalency regions), may implement different combinations of minimum fish sizes, possession limits, and closed seasons that achieve equivalent conservation as the coastwide measures established under paragraph (e)(1) of this section. Each state or multi-state conservation equivalency region may implement measures by mode or area only if the proportional standard error of recreational landing estimates by mode or area for that state is less than 30 percent.

(i) After review of the recommendations, the Regional Administrator will publish a proposed rule in the **Federal Register** as soon as is practicable to implement the overall percent adjustment in recreational landings required for the fishing year, and the ASMFC's recommendation concerning conservation equivalency, the precautionary default measures, and coastwide measures.

(ii) The ASMFC will review conservation equivalency proposals and determine whether or not they achieve the necessary adjustment to recreational landings. The ASMFC will provide the Regional Administrator with the individual state and/or multi-state region conservation measures for the approved state and/or multi-state region proposals and, in the case of disapproved state and/or multi-state region proposals, the precautionary default measures.

(iii) The ASMFC may allow states assigned the precautionary default measures to resubmit revised management measures. The ASMFC will detail the procedures by which the state can develop alternate measures. The ASMFC will notify the Regional Administrator of any resubmitted state proposals approved subsequent to publication of the final rule and the Regional Administrator will publish a notice in the **Federal Register** to notify the public.

(iv) After considering public comment, the Regional Administrator will publish a final rule in the **Federal Register** to implement either the state specific conservation equivalency measures or coastwide measures to ensure that the applicable specified target is not exceeded.

(e) *Research quota.* See § 648.22(g).

24. Section 648.103 is revised to read as follows:

§ 648.103 Accountability measures.

(a) *Commercial sector EEZ closure.* The Regional Administrator shall close the EEZ to fishing for summer flounder by commercial vessels for the remainder of the calendar year by publishing notification in the **Federal Register** if he/she determines that the inaction of one or more states will cause the commercial sector ACL to be exceeded, or if the commercial fisheries in all states have been closed. The Regional Administrator may reopen the EEZ if earlier inaction by a state has been remedied by that state, or if commercial fisheries in one or more states have been reopened without causing the sector ACL to be exceeded.

(b) *State commercial landing quotas.* The Regional Administrator will monitor state commercial quotas based on dealer reports and other available information and shall determine the date when a state commercial quota will be harvested. The Regional Administrator shall publish notification in the **Federal Register** advising a state that, effective upon a specific date, its commercial quota has been harvested and notifying vessel and dealer permit holders that no commercial quota is available for landing summer flounder in that state.

(1) *Commercial ACL overage evaluation.* The commercial sector ACL will be evaluated based on a single-year examination of total catch (landings and dead discards). Both landings and dead discards will be evaluated in determining if the commercial sector ACL has been exceeded.

(2) *Commercial landings overage repayment.* All summer flounder landed for sale in a state shall be applied against that state's annual commercial quota, regardless of where the summer flounder were harvested. Any landings in excess of the commercial quota in any state, inclusive of any state-to-state transfers, will be deducted from that state's annual quota for the following year in the final rule that establishes the annual state-by-state quotas, irrespective of whether the commercial sector ACL is exceeded. The overage deduction will be based on landings for the current year through October 31 and on landings for the previous calendar year that were not included when the overage deduction was made in the final rule that established the annual quota for the current year. If the Regional Administrator determines during the fishing year that any part of an overage deduction was based on erroneous landings data that were in excess of actual landings for the period concerned, he/she will restore the overage that was deducted in error to the appropriate quota allocation. The Regional Administrator will publish notification in the **Federal Register** announcing such restoration.

(c) *Recreational landings sector closure.* The Regional Administrator will monitor recreational landings based on the best available data and shall determine if the recreational harvest limit has been met or exceeded. The

determination will be based on observed landings and will not utilize projections of future landings. At such time that the available data indicate that the recreational harvest limit has been met or exceeded, the Regional Administrator shall publish notification in the **Federal Register** advising that, effective on a specific date, the summer flounder recreational fishery in the EEZ shall be closed for remainder of the calendar year.

(1) *Recreational ACL overage evaluation.* The recreational sector ACL will be evaluated based on a 3-year moving average comparison of total catch (landings and dead discards). Both landings and dead discards will be evaluated in determining if the 3-year average recreational sector ACL has been exceeded. The 3-year moving average will be phased in over the first 3 years, beginning with 2012: Total recreational catch from 2012 will be compared to the 2012 recreational sector ACL; the average total catch from both 2012 and 2013 will be compared to the average of the 2012 and 2013 recreational sector ACLs; the average total catch from 2012, 2013, and 2014 will be compared to the average of the 2012, 2013, and 2014 recreational sector ACLs; and for all subsequent years, the preceding 3-year average recreational total catch will be compared to the preceding 3-year average recreational sector ACL.

(2) *Recreational landing overage repayment.* If available data indicate that the recreational sector ACL has been exceeded and the landings have exceeded the RHL, the exact poundage of the landings overage will be deducted, as soon as is practicable, from a subsequent single fishing year recreational sector ACT.

(d) *Non-landing accountability measures, by sector.* In the event that a sector ACL has been exceeded and the overage has not been accommodated through landing-based AMs, then the exact amount by which the sector ACL was exceeded, in pounds, will be deducted, as soon as is practicable, from the applicable subsequent single fishing year sector ACL.

(e) *State/Federal disconnect AM.* If the total catch, allowable landing, commercial quotas and/or RHL measures adopted by the ASMFC Summer Flounder Management Board and the MAFMC differ for a given fishing year, administrative action will be taken as soon as is practicable to revisit the respective recommendations of the two groups. The intent of this action shall be to achieve alignment through consistent state and Federal measures so no differential effects occur on Federal permit holders.

25. Section 648.104 is revised to read as follows:

§ 648.104 Minimum fish sizes.

(a) *Moratorium (commercial) permitted vessels.* The minimum size for summer flounder is 14 inches (35.6 cm) TL for all vessels issued a moratorium permit under § 648.4(a)(3), except on board party and charter boats carrying passengers for hire or carrying more than three crew members, if a charter boat, or more than five crew members, if a party boat.

(b) *Party/charter permitted vessels and recreational fishery participants.* Unless otherwise specified pursuant to § 648.107, the minimum size for summer flounder is 19.5 inches (49.53 cm) TL for all vessels that do not qualify for a moratorium permit under § 648.4(a)(3), and charter boats holding a moratorium permit if fishing with more than three crew members, or party boats holding a moratorium permit if fishing with passengers for hire or carrying more than five crew members.

(c) The minimum sizes in this section apply to whole fish or to any part of a fish found in possession, *e.g.,* fillets, except that party and charter vessels possessing valid state permits authorizing filleting at sea may possess fillets smaller that the size specified if all state requirements are met.

26. Section 648.105 is revised to read as follows:

§ 648.105 Recreational fishing season.

Unless otherwise specified pursuant to § 648.107, vessels that are not eligible for a moratorium permit under § 648.4(a)(3), and fishermen subject to the possession limit, may fish for summer flounder from May 1 through September 30. This time period may be adjusted pursuant to the procedures in § 648.102.

27. Section 648.106 is revised to read as follows:

§ 648.106 Possession restrictions.

(a) *Party/charter and recreational possession limits.* Unless otherwise specified pursuant to § 648.107, no person shall possess more than two summer flounder in, or harvested from, the EEZ, unless that person is the owner or operator of a fishing vessel issued a summer flounder moratorium permit, or is issued a summer flounder dealer permit. Persons aboard a commercial vessel that is not eligible for a summer flounder moratorium permit are subject to this possession limit. The owner, operator, and crew of a charter or party boat issued a summer flounder moratorium permit are subject to the possession limit when carrying passengers for hire or when carrying more than five crew members for a party boat, or more than three crew members for a charter boat. This possession limit may be adjusted pursuant to the procedures in § 648.102.

(b) If whole summer flounder are processed into fillets, the number of fillets will be converted to whole summer flounder at the place of landing by dividing the fillet number by two. If summer flounder are filleted into single (butterfly) fillets, each fillet is deemed to be from one whole summer flounder.

(c) Summer flounder harvested by vessels subject to the possession limit with more than one person on board may be pooled in one or more containers. Compliance with the daily possession limit will be determined by dividing the number of summer flounder on board by the number of persons on board, other than the captain and the crew. If there is a violation of the possession limit on board a vessel carrying more than one person, the violation shall be deemed to have been committed by the owner and operator of the vessel.

(d) *Commercially permitted vessel possession limits.* Owners and operators of otter trawl vessels issued a permit under § 648.4(a)(3) that fish with or possess nets or pieces of net on board that do not meet the minimum mesh requirements and that are not stowed in accordance with § 648.108(e), may not retain 100 lb (45.3 kg) or more of summer flounder from May 1 through October 31, or 200 lb (90.6 kg) or more of summer flounder from November 1 through April 30, unless the vessel possesses a valid summer flounder small-mesh exemption LOA and is fishing in the exemption area as specified in § 648.108(b). Summer flounder on board these vessels must be stored so as to be readily available for inspection in standard 100-lb (45.3-kg) totes or fish boxes having a liquid capacity of 18.2 gal (70 L), or a volume of not more than 4,320 in^3 (2.5 ft^3 or 70.79 cm^3).

28. Section 648.107 is revised to read as follows:

§ 648.107 Conservation equivalent measures for the summer flounder party/charter and recreational fishery.

(a) The Regional Administrator has determined that the recreational fishing measures proposed to be implemented by Massachusetts through North Carolina for 2010 are the conservation equivalent of the recreational fishing season, minimum fish size, and possession limit prescribed in

§§ 648.104(b), 648.105, and 648.106(a), respectively. This determination is based on a recommendation from the Summer Flounder Board of the ASMFC.

(1) Federally permitted party and charter vessels subject to the recreational fishing measures of this part, and other recreational fishing vessels harvesting summer flounder in or from the EEZ and subject to the recreational fishing measures of this part, landing summer flounder in a state whose fishery management measures are determined by the Regional Administrator to be conservation equivalent shall not be subject to the more restrictive Federal measures, pursuant to the provisions of § 648.4(b). Those vessels shall be subject to the recreational fishing measures implemented by the state in which they land.

(2) [*Reserved*]

(b) Federally permitted vessels subject to the recreational fishing measures of this part, and other recreational fishing vessels subject to the recreational fishing measures of this part and registered in states whose fishery management measures are not determined by the Regional Administrator to be the conservation equivalent of the season, minimum size, and possession limit prescribed in §§ 648.104(b), 648.105, and 648.106(a), respectively, due to the lack of, or the reversal of, a conservation equivalent recommendation from the Summer Flounder Board of the ASMFC, shall be subject to the following precautionary default measures: Season, May 1–September 30; minimum size, 21.5 inches (54.61 cm); and a possession limit of two fish.

29. Section 648.108 is revised to read as follows:

§ 648.108 Gear restrictions.

(a) *General.* (1) Otter trawlers whose owners are issued a summer flounder permit and that land or possess 100 lb (45.4 kg) or more of summer flounder from May 1 through October 31, or 200 lb (90.8 kg) or more of summer flounder from November 1 through April 30, per trip, must fish with nets that have a minimum mesh size of 5.5-inch (14.0-cm) diamond or 6.0-inch (15.2-cm) square mesh applied throughout the body, extension(s), and codend portion of the net.

(2) Mesh size is measured by using a wedge-shaped gauge having a taper of 2 cm (0.79 inches) in 8 cm (3.15 inches), and a thickness of 2.3 mm (0.09 inches), inserted into the meshes under a pressure or pull of 5 kg (11.02 lb) for mesh size less than 120 mm (4.72 inches) and under a pressure or pull of 8 kg (17.64 lb) for mesh size at, or greater than, 120 mm (4.72 inches). The mesh size is the average of the measurements of any series of 20 consecutive meshes for nets having 75 or more meshes, and 10 consecutive meshes for nets having fewer than 75 meshes. The mesh in the regulated portion of the net is measured at least five meshes away from the lacings, running parallel to the long axis of the net.

(b) *Exemptions.* Unless otherwise restricted by this part, the minimum mesh-size requirements specified in paragraph (a)(1) of this section do not apply to:

(1) Vessels issued a summer flounder moratorium permit, a Summer Flounder Small-Mesh Exemption Area letter of authorization (LOA), required under paragraph (b)(1)(i) of this section, and fishing from November 1 through April 30 in the exemption area, which is east of the line that follows 72°30.0' W. long. until it intersects the outer boundary of the EEZ (copies of a map depicting the area are available upon request from the Regional Administrator). Vessels fishing under the LOA shall not fish west of the line. Vessels issued a permit under § 648.4(a)(3)(iii) may transit the area west or south of the line, if the vessel's fishing gear is stowed in a manner prescribed under § 648.108(e), so that it is not ''available for immediate use'' outside the exempted area. The Regional Administrator may terminate this exemption if he/she determines, after a review of sea sampling data, that vessels fishing under the exemption are discarding more than 10 percent, by weight, of their entire catch of summer flounder per trip. If the Regional Administrator makes such a determination, he/she shall publish notification in the **Federal Register** terminating the exemption for the remainder of the exemption season.

(i) *Requirements.* (A) A vessel fishing in the Summer Flounder Small-Mesh Exemption Area under this exemption must have on board a valid LOA issued by the Regional Administrator.

(B) The vessel must be in enrolled in the exemption program for a minimum of 7 days.

(ii) [*Reserved*]

(2) Vessels fishing with a two-seam otter trawl fly net with the following configuration, provided that no other nets or netting with mesh smaller than 5.5 inches (14.0 cm) are on board:

(i) The net has large mesh in the wings that measures 8 inches (20.3 cm) to 64 inches (162.6 cm).

(ii) The first body section (belly) of the net has 35 or more meshes that are at least 8 inches (20.3 cm).

(iii) The mesh decreases in size throughout the body of the net to 2 inches (5 cm) or smaller towards the terminus of the net.

(3) The Regional Administrator may terminate this exemption if he/she determines, after a review of sea sampling data, that vessels fishing under the exemption, on average, are discarding more than 1 percent of their entire catch of summer flounder per trip. If the Regional Administrator makes such a determination, he/she shall publish notification in the **Federal Register** terminating the exemption for the remainder of the calendar year.

(c) *Net modifications.* No vessel subject to this part shall use any device, gear, or material, including, but not limited to, nets, net strengtheners, ropes, lines, or chafing gear, on the top of the regulated portion of a trawl net; except that, one splitting strap and one bull rope (if present) consisting of line or rope no more than 3 inches (7.2 cm) in diameter may be used if such splitting strap and/or bull rope does not constrict, in any manner, the top of the regulated portion of the net, and one rope no greater than 0.75 inches (1.9 cm) in diameter extending the length of the net from the belly to the terminus of the codend along the top, bottom, and each side of the net. ''Top of the regulated portion of the net'' means the 50 percent of the entire regulated portion of the net that (in a hypothetical situation) will not be in contact with the ocean bottom during a tow if the regulated portion of the net were laid flat on the ocean floor. For the purpose of this paragraph (c), head ropes shall not be considered part of the top of the regulated portion of a trawl net. A vessel shall not use any means or mesh configuration on the top of the regulated portion of the net, as defined paragraph (c) of this section, if it obstructs the meshes of the net or otherwise causes the size of the meshes of the net while in use to diminish to a size smaller than the minimum specified in paragraph (a) of this section.

(d) *Mesh obstruction or constriction.* (1) A fishing vessel may not use any mesh configuration, mesh construction, or other means on or in the top of the net, as defined in paragraph (c) of this section, that obstructs the meshes of the net in any manner.

(2) No person on any vessel may possess or fish with a net capable of catching summer flounder in which the bars entering or exiting the knots twist around each other.

(e) *Stowage of nets.* Otter trawl vessels retaining 100 lb (45.3 kg) or more of summer flounder from May 1 through October 31, or 200 lb (90.6 kg) or more

of summer flounder from November 1 through April 30, and subject to the minimum mesh size requirement of paragraph (a)(1) of this section may not have ''available for immediate use'' any net or any piece of net that does not meet the minimum mesh size requirement, or any net, or any piece of net, with mesh that is rigged in a manner that is inconsistent with the minimum mesh size requirement. A net that is stowed in conformance with one of the methods specified in § 648.23(b) and that can be shown not to have been in recent use is considered to be not ''available for immediate use.''

(f) The minimum net mesh requirement may apply to any portion of the net. The minimum mesh size and the portion of the net regulated by the minimum mesh size may be adjusted pursuant to the procedures in § 648.102.

30. Section 648.109 is added to read as follows:

§ 648.109 Sea turtle conservation.

Sea turtle regulations are found at 50 CFR parts 222 and 223.

31. Section 648.110 is added to read as follows:

§ 648.110 Framework adjustments to management measures.

(a) *Within season management action.* The MAFMC may, at any time, initiate action to add or adjust management measures within the Summer Flounder, Scup, and Black Sea Bass FMP if it finds that action is necessary to meet or be consistent with the goals and objectives of the FMP.

(1) *Adjustment process.* The MAFMC shall develop and analyze appropriate management actions over the span of at least two MAFMC meetings. The MAFMC must provide the public with advance notice of the availability of the recommendation(s), appropriate justification(s) and economic and biological analyses, and the opportunity to comment on the proposed adjustment(s) at the first meeting and prior to and at the second MAFMC meeting. The MAFMC's recommendations on adjustments or additions to management measures must come from one or more of the following categories: Adjustments within existing ABC control rule levels; adjustments to the existing MAFMC risk policy; introduction of new AMs, including sub-ACTs; minimum fish size; maximum fish size; gear restrictions; gear requirements or prohibitions; permitting restrictions; recreational possession limit; recreational seasons; closed areas; commercial seasons; commercial trip limits; commercial quota system including commercial quota allocation procedure and possible quota set asides to mitigate bycatch; recreational harvest limit; specification quota setting process; FMP Monitoring Committee composition and process; description and identification of essential fish habitat (and fishing gear management measures that impact EFH); description and identification of habitat areas of particular concern; regional gear restrictions; regional season restrictions (including option to split seasons); restrictions on vessel size (LOA and GRT) or shaft horsepower; operator permits; changes to the Northeast Region SBRM (including the CV-based performance standard, the means by which discard data are collected/obtained, fishery stratification, reports, and/or industry-funded observers or observer set-aside programs); any other commercial or recreational management measures; any other management measures currently included in the FMP; and set aside quota for scientific research. Issues that require significant departures from previously contemplated measures or that are otherwise introducing new concepts may require amendment of the FMP instead of a framework adjustment.

(2) *MAFMC recommendation.* After developing management actions and receiving public testimony, the MAFMC shall make a recommendation to the Regional Administrator. The MAFMC's recommendation must include supporting rationale, if management measures are recommended, an analysis of impacts, and a recommendation to the Regional Administrator on whether to issue the management measures as a final rule. If the MAFMC recommends that the management measures should be issued as a final rule, it must consider at least the following factors and provide support and analysis for each factor considered:

(i) Whether the availability of data on which the recommended management measures are based allows for adequate time to publish a proposed rule, and whether the regulations would have to be in place for an entire harvest/fishing season;

(ii) Whether there has been adequate notice and opportunity for participation by the public and members of the affected industry in the development of recommended management measures;

(iii) Whether there is an immediate need to protect the resource; and

(iv) Whether there will be a continuing evaluation of management measures adopted following their implementation as a final rule.

(3) *NMFS action.* If the MAFMC's recommendation includes adjustments or additions to management measures and, if after reviewing the MAFMC's recommendation and supporting information:

(i) NMFS concurs with the MAFMC's recommended management measures and determines that the recommended management measures should be issued as a final rule based on the factors in paragraph (a)(2) of this section, the measures will be issued as a final rule in the **Federal Register**.

(ii) If NMFS concurs with the MAFMC's recommended management measures and determines that the recommended management measures should be published first as a proposed rule, the measures will be published as a proposed rule in the **Federal Register**. After additional public comment, if NMFS concurs with the MAFMC recommendation, the measures will be published as a final rule in the **Federal Register**.

(iii) If NMFS does not concur, the MAFMC will be notified in writing of the reasons for the non-concurrence.

(4) *Emergency actions.* Nothing in this section is meant to derogate from the authority of the Secretary to take emergency action under section 305(e) of the Magnuson-Stevens Act.

(b) [*Reserved*]

32. Section 648.120 is revised to read as follows:

§ 648.120 ACL.

(a) The Scup Monitoring Committee shall recommend to the MAFMC separate ACLs for the commercial and recreational scup fisheries, the sum total of which shall be less than or equal to the ABC recommended by the SSC.

(1) *Sector allocations.* The commercial and recreational fishing sector ACLs will be established consistent with the allocation guidelines contained in the Summer Flounder, Scup, and Black Sea Bass FMP.

(2) *Periodicity.* The scup commercial and recreational sector ACLs may be established on an annual basis for up to 3 years at a time, dependent on whether the SSC provides single or multiple year ABC recommendations.

(b) *Performance review.* The Scup Monitoring Committee shall conduct a detailed review of fishery performance relative to the sector ACLs at least every 5 years.

(1) If one or both of the sector-specific ACLs is exceeded with a frequency greater than 25 percent (*i.e.,* more than once in 4 years or any 2 consecutive years), the Scup Monitoring Committee will review fishery performance information and make recommendations to the MAFMC for changes in measures intended to ensure ACLs are not as frequently exceeded.

(2) The MAFMC may specify more frequent or more specific ACL performance review criteria as part of a stock rebuilding plan following a determination that the scup stock has become overfished.

(3) Performance reviews shall not substitute for annual reviews that occur to ascertain if prior year ACLs have been exceeded but may be conducted in conjunction with such reviews.

33. Section 648.121 is revised to read as follows:

§ 648.121 ACT.

(a) The Scup Monitoring Committee shall identify and review the relevant sources of management uncertainty to recommend ACTs for the commercial and recreational fishing sectors as part of the scup specification process. The Scup Monitoring Committee recommendations shall identify the specific sources of management uncertainty that were considered, technical approaches to mitigating these sources of uncertainty, and any additional relevant information considered in the ACT recommendation process.

(1) *Sectors.* Commercial and recreational specific ACTs shall be less than or equal to the sector-specific ACLs. The Scup Monitoring Committee shall recommend any reduction in catch necessary to address sector-specific management uncertainty, consistent with paragraph (a) of this section.

(2) *Periodicity.* ACTs may be established on an annual basis for up to 3 years at a time, dependent on whether the SSC provides single or multiple year ABC recommendations.

(b) *Performance review.* The Scup Monitoring Committee shall conduct a detailed review of fishery performance relative to ACTs in conjunction with any ACL performance review, as outlined in § 648.120(b)(1) through (3).

34. Section 648.122 is revised to read as follows:

§ 648.122 Specifications.

(a) *Commercial quota, recreational landing limits, research set-asides, and other specification measures.* The Scup Monitoring Committee shall recommend to the Demersal Species Committee of the MAFMC and the ASMFC through the specifications process, for use in conjunction with each ACL and ACT, a sector specific research set-aside, estimates of sector-related discards, recreational harvest limit, and commercial quota, along with other measures, as needed, that are projected to ensure the sector-specific ACL for an upcoming fishing year or years will not be exceeded. The measures to be considered by the Scup Monitoring Committee are as follows:

(1) Research quota set from a range of 0 to 3 percent of the maximum allowed to achieve the specified exploitation rate.

(2) The commercial quota for each of the three periods specified in paragraph (c)(1) of this section for research quota.

(3) Possession limits for the Winter I and Winter II periods, including possession limits that result from potential rollover of quota from Winter I to Winter II. The possession limit is the maximum quantity of scup that is allowed to be landed within a 24-hour period (calendar day).

(4) Percent of landings attained at which the landing limit for the Winter I period will be reduced.

(5) All scup landed for sale in any state during a quota period shall be applied against the coastwide commercial quota for that period, regardless of where the scup were harvested, except as provided in paragraph (c)(5) of this section.

(6) Minimum mesh size.

(7) Recreational possession limit set from a range of 0 to 50 scup to achieve the recreational harvest limit, set after the reduction for research quota.

(8) Recreational minimum fish size.

(9) Recreational season.

(10) Restrictions on gear.

(11) Season and area closures in the commercial fishery.

(12) Total allowable landings on an annual basis for a period not to exceed 3 years.

(13) Changes, as appropriate, to the Northeast Region SBRM, including the CV-based performance standard, fishery stratification, and/or reports.

(14) Modification of existing AM measures and ACT control rules utilized by the Scup Monitoring Committee.

(b) *Specification of fishing measures.* The Demersal Species Committee shall review the recommendations of the Scup Monitoring Committee. Based on these recommendations and any public comment, the Demersal Species Committee shall recommend to the MAFMC measures necessary to assure that the specified ACLs will not be exceeded. The MAFMC's recommendation must include supporting documentation, as appropriate, concerning the environmental and economic impacts of the recommendations. The Regional Administrator shall review these recommendations and any recommendations of the ASMFC. After such review, NMFS will publish a proposed rule to implement a commercial quota in the **Federal Register**, specifying the amount of quota allocated to each of the three periods, possession limits for the Winter I and Winter II periods, including possession limits that result from potential rollover of quota from Winter I to Winter II, the percentage of landings attained during the Winter I fishery at which the possession limits will be reduced, a recreational harvest limit, and additional management measures for the commercial fishery. If the Regional Administrator determines that additional recreational measures are necessary to assure that the sector ACL will not be exceeded, he or she will publish a proposed rule in the **Federal Register** to implement additional management measures for the recreational fishery. After considering public comment, the Regional Administrator will publish a final rule in the **Federal Register** to implement annual measures.

(c) *Distribution of commercial quota.* (1) The annual commercial quota will be allocated into three periods, based on the following percentages:

Period	Percent
Winter I—January–April	45.11
Summer—May–October	38.95
Winter II—November–December	15.94

(2) The commercial quotas for each period will each be distributed to the coastal states from Maine through North Carolina on a coastwide basis.

(d) *Winter I and II commercial quota adjustment procedures.* The Regional Administrator will monitor the harvest of commercial quota for the Winter I period based on dealer reports, state data, and other available information and shall determine the total amount of scup landed during the Winter I period. In any year that the Regional Administrator determines that the landings of scup during Winter I are less than the Winter I quota for that year, he/she shall increase, through publication of a notification in the **Federal Register**, provided such rule complies with the requirements of the Administrative Procedure Act, the Winter II quota for that year by the amount of the Winter I under-harvest. The Regional Administrator shall also adjust, through publication of a notification in the **Federal Register**, the Winter II possession limits consistent with the amount of the quota increase, based on the possession limits established through the annual specifications-setting process.

(e) *Research quota.* See § 648.21(g).

35. Section 648.123 is revised to read as follows:

§ 648.123 Accountability measures.

(a) *Commercial sector period closures.* The Regional Administrator will monitor the harvest of commercial quota for each quota period based on dealer reports, state data, and other available information and shall determine the date when the commercial quota for a period will be harvested. NMFS shall close the EEZ to fishing for scup by commercial vessels for the remainder of the indicated period by publishing notification in the **Federal Register** advising that, effective upon a specific date, the commercial quota for that period has been harvested, and notifying vessel and dealer permit holders that no commercial quota is available for landing scup for the remainder of the period.

(1) *Commercial ACL overage evaluation.* The commercial sector ACL will be evaluated based on a single-year examination of total catch (landings and dead discards). Both landings and dead discards will be evaluated in determining if the commercial sector ACL has been exceeded.

(2) *Commercial landings overage repayment by quota period.* (i) All scup landed for sale in any state during a quota period shall be applied against the coastwide commercial quota for that period, regardless of where the scup were harvested, except as provided in paragraph (a)(2)(iv) of this section, and irrespective of whether the commercial sector ACL is exceeded. Any current year landings in excess of the commercial quota in any quota period will be deducted from that quota period's annual quota in the following year as prescribed in paragraphs (a)(2)(ii) through (iii) of this section:

(ii) For the Winter I and Summer quota periods, landings in excess of the allocation will be deducted from the appropriate quota period for the following year in the final rule that establishes the annual quota. The overage deduction will be based on landings for the current year through October 31 and on landings for the previous calendar year that were not included when the overage deduction was made in the final rule that established the period quotas for the current year. If the Regional Administrator determines during the fishing year that any part of an overage deduction was based on erroneous landings data that were in excess of actual landings for the period concerned, he/she will restore the overage that was deducted in error to the appropriate quota allocation. The Regional Administrator will publish notification in the **Federal Register** announcing the restoration.

(iii) For the Winter II quota period, landings in excess of the allocation will be deducted from the Winter II period for the following year through notification in the **Federal Register** during July of the following year. The overage deduction will be based on landings information available for the Winter II period as of June 30 of the following year. If the Regional Administrator determines during the fishing year that any part of an overage deduction was based on erroneous landings data that were in excess of actual landings for the period concerned, he/she will restore the overage that was deducted in error to the appropriate quota allocation. The Regional Administrator will publish notification in the **Federal Register** announcing the restoration.

(iv) During a fishing year in which the Winter I quota period is closed prior to April 15, a state may apply to the Regional Administrator for authorization to count scup landed for sale in that state from April 15 through April 30 by state-only permitted vessels fishing exclusively in waters under the jurisdiction of that state against the Summer period quota. Requests to the Regional Administrator to count scup landings in a state from April 15 through April 30 against the Summer period quota must be made by letter signed by the principal state official with marine fishery management responsibility and expertise, or his/her designee, and must be received by the Regional Administrator no later than April 15. Within 10 working days following receipt of the letter, the Regional Administrator shall notify the appropriate state official of the disposition of the request.

(c) *Recreational landings sector closure.* The Regional Administrator will monitor recreational landings based on the best available data and shall determine if the recreational harvest limit has been met or exceeded. The determination will be based on observed landings and will not utilize projections of future landings. At such time that the available data indicate that the recreational harvest limit has been met or exceeded, the Regional Administrator shall publish notification in the **Federal Register** advising that, effective on a specific date, the scup recreational fishery in the EEZ shall be closed for the remainder of calendar year.

(1) *Recreational ACL overage evaluation.* The recreational sector ACL will be evaluated based on a 3-year moving average comparison of total catch (landings and dead discards). Both landings and dead discards will be evaluated in determining if the 3-year average recreational sector ACL has been exceeded. The 3-year moving average will be phased in over the first 3 years, beginning with 2012: Total recreational total catch from 2012 will be compared to the 2012 recreational sector ACL; the average total catch from both 2012 and 2013 will be compared to the average of the 2012 and 2013 recreational sector ACLs; the average total catch from 2012, 2013, and 2014 will be compared to the average of 2012, 2013, and 2014 recreational sector ACLs; and for all subsequent years, the preceding 3-year average recreational total catch will be compared to the preceding 3-year average recreational sector ACL.

(2) *Recreational landing overage repayment.* If available data indicate that the recreational sector ACL has been exceeded and the landings have exceeded RHL, the exact amount of the landings overage in pounds will be deducted, as soon as is practicable, from a subsequent single fishing year recreational sector ACT.

(d) *Non-landing accountability measures, by sector.* In the event that a sector ACL has been exceeded and the overage has not been accommodated through landing-based AMs, then the exact poundage amount by which the sector ACL was exceeded will be deducted, as soon as practicable, from a subsequent single fishing year applicable sector ACL through the specification process.

(e) *State/Federal disconnect AM.* If the total catch, allowable landing, commercial quotas and/or RHL measures adopted by the ASMFC Scup Management Board and the MAFMC differ for a given fishing year, administrative action will be taken as soon as is practicable to revisit the respective recommendations of the two groups. The intent of this action shall be to achieve alignment through consistent state and Federal measures so no differential effects occur on Federal permit holders.

36. Section 648.124 is revised to read as follows:

§ 648.124 Commercial Season and Commercial fishery area restrictions.

(a) *Southern Gear Restricted Area*—(1) *Restrictions.* From January 1 through March 15, all trawl vessels in the Southern Gear Restricted Area that fish for or possess non-exempt species as specified in paragraph (a)(2) of this section must fish with nets that have a minimum mesh size of 5.0-inch (12.7-cm) diamond mesh, applied throughout the codend for at least 75 continuous meshes forward of the terminus of the net. For trawl nets with codends

(including an extension) of fewer than 75 meshes, the entire trawl net must have a minimum mesh size of 5.0 inches (12.7 cm) throughout the net. The Southern Gear Restricted Area is an area bounded by straight lines connecting the following points in the order stated (copies of a chart depicting the area are available from the Regional Administrator upon request):

SOUTHERN GEAR RESTRICTED AREA

Point	N. lat.	W. long.
SGA1	39°20′	72°53′
SGA2	39°20′	72°28′
SGA3	38°00′	73°58′
SGA4	37°00′	74°43′
SGA5	36°30′	74°43′
SGA6	36°30′	75°03′
SGA7	37°00′	75°03′
SGA8	38°00′	74°23′
SGA1	39°20′	72°53′

(2) *Non-exempt species.* Unless otherwise specified in paragraph (d) of this section, the restrictions specified in paragraph (a)(1) of this section apply only to vessels in the Southern Gear Restricted Area that are fishing for or in possession of the following non-exempt species: *Loligo* squid, black sea bass, and silver hake (whiting).

(b) *Northern Gear Restricted Area 1*—(1) *Restrictions.* From November 1 through December 31, all trawl vessels in the Northern Gear Restricted Area 1 that fish for or possess non-exempt species as specified in paragraph (b)(2) of this section must fish with nets of 5.0-inch (12.7-cm) diamond mesh, applied throughout the codend for at least 75 continuous meshes forward of the terminus of the net. For trawl nets with codends (including an extension) of fewer than 75 meshes, the entire trawl net must have a minimum mesh size of 5.0 inches (12.7 cm) throughout the net. The Northern Gear Restricted Area 1 is an area bounded by straight lines connecting the following points in the order stated (copies of a chart depicting the area are available from the Regional Administrator upon request):

NORTHERN GEAR RESTRICTED AREA 1

Point	N. lat.	W. long.
NGA1	41°00′	71°00′
NGA2	41°00′	71°30′
NGA3	40°00′	72°40′
NGA4	40°00′	72°05′
NGA1	41°00′	71°00′

(2) *Non-exempt species.* Unless otherwise specified in paragraph (d) of this section, the restrictions specified in paragraph (b)(1) of this section apply only to vessels in the Northern Gear Restricted Area 1 that are fishing for, or in possession of, the following non-exempt species: *Loligo* squid, black sea bass, and silver hake (whiting).

(c) *Transiting.* Vessels that are subject to the provisions of the Southern and Northern GRAs, as specified in paragraphs (a) and (b) of this section, respectively, may transit these areas provided that trawl net codends on board of mesh size less than that specified in paragraphs (a) and (b) of this section are not available for immediate use and are stowed in accordance with the provisions of § 648.23(b).

(d) [*Reserved*]

(e) *Addition or deletion of exemptions.* The MAFMC may recommend to the Regional Administrator, through the framework procedure specified in § 648.130(a), additions or deletions to exemptions for fisheries other than scup. A fishery may be restricted or exempted by area, gear, season, or other means determined to be appropriate to reduce bycatch of scup.

(f) *Exempted experimental fishing.* The Regional Administrator may issue an exempted experimental fishing permit (EFP) under the provisions of § 600.745(b), consistent with paragraph (d)(2) of this section, to allow any vessel participating in a scup discard mitigation research project to engage in any of the following activities: Fish in the applicable gear restriction area; use fishing gear that does not conform to the regulations; possess non-exempt species specified in paragraphs (a)(2) and (b)(2) of this section; or engage in any other activity necessary to project operations for which an exemption from regulatory provision is required. Vessels issued an EFP must comply with all conditions and restrictions specified in the EFP.

(1) A vessel participating in an exempted experimental fishery in the Scup Gear Restriction Area(s) must carry an EFP authorizing the activity and any required Federal fishery permit on board.

(2) The Regional Administrator may not issue an EFP unless s/he determines that issuance is consistent with the objectives of the FMP, the provisions of the Magnuson-Stevens Act, and other applicable law and will not:

(i) Have a detrimental effect on the scup resource and fishery;

(ii) Cause the quotas for any species of fish for any quota period to be exceeded;

(iii) Create significant enforcement problems; or

(iv) Have a detrimental effect on the scup discard mitigation research project.

37. Section 648.125 is revised to read as follows:

§ 648.125 Gear restrictions.

(a) *Trawl vessel gear restrictions*—(1) *Minimum mesh size.* No owner or operator of an otter trawl vessel that is issued a scup moratorium permit may possess 500 lb (226.8 kg) or more of scup from November 1 through April 30, or 200 lb (90.7 kg) or more of scup from May 1 through October 31, unless fishing with nets that have a minimum mesh size of 5.0-inch (12.7-cm) diamond mesh, applied throughout the codend for at least 75 continuous meshes forward of the terminus of the net, and all other nets are stowed in accordance with § 648.23(b)(1). For trawl nets with codends (including an extension) of fewer than 75 meshes, the entire trawl net must have a minimum mesh size of 5.0 inches (12.7 cm) throughout the net. Scup on board these vessels must be stowed separately and kept readily available for inspection. Measurement of nets will conform with § 648.80(f).

(2) *Mesh-size measurement.* Mesh sizes will be measured according to the procedure specified in § 648.104(a)(2).

(3) *Net modification.* The owner or operator of a fishing vessel subject to the minimum mesh requirements in § 648.124 and paragraph (a)(1) of this section shall not use any device, gear, or material, including, but not limited to, nets, net strengtheners, ropes, lines, or chafing gear, on the top of the regulated portion of a trawl net. However, one splitting strap and one bull rope (if present), consisting of line or rope no more than 3 inches (7.2 cm) in diameter, may be used if such splitting strap and/or bull rope does not constrict in any manner the top of the regulated portion of the net, and one rope no greater that 0.75 inches (1.9 cm) in diameter extending the length of the net from the belly to the terminus of the codend along the top, bottom, and each side of the net. ''Top of the regulated portion of the net'' means the 50 percent of the entire regulated portion of the net that (in a hypothetical situation) will not be in contact with the ocean bottom during a tow if the regulated portion of the net were laid flat on the ocean floor. For the purpose of this paragraph (a)(3), head ropes are not considered part of the top of the regulated portion of a trawl net.

(4) *Mesh obstruction or constriction.* (i) The owner or operator of a fishing vessel subject to the minimum mesh restrictions in § 648.124 and in paragraph (a)(1) of this section shall not use any mesh construction, mesh configuration, or other means on, in, or attached to the top of the regulated portion of the net, as defined in paragraph (a)(3) of this section, if it

obstructs or constricts the meshes of the net in any manner.

(ii) The owner or operator of a fishing vessel subject to the minimum mesh requirements in § 648.124 and in paragraph (a)(1) of this section may not use a net capable of catching scup if the bars entering or exiting the knots twist around each other.

(5) *Stowage of nets.* The owner or operator of an otter trawl vessel retaining 500 lb (226.8 kg) or more of scup from November 1 through April 30, or 200 lb (90.7 kg) or more of scup from May 1 through October 31, and subject to the minimum mesh requirements in paragraph (a)(1) of this section, and the owner or operator of a midwater trawl or other trawl vessel subject to the minimum size requirement in § 648.126, may not have available for immediate use any net, or any piece of net, not meeting the minimum mesh size requirement, or mesh that is rigged in a manner that is inconsistent with the minimum mesh size. A net that is stowed in conformance with one of the methods specified in § 648.23(b), and that can be shown not to have been in recent use, is considered to be not available for immediate use.

(6) *Roller gear.* The owner or operator of an otter trawl vessel issued a moratorium permit pursuant to § 648.4(a)(6) shall not use roller rig trawl gear equipped with rollers greater than 18 inches (45.7 cm) in diameter.

(7) *Procedures for changes.* The minimum net mesh and the threshold catch level at which it is required set forth in paragraph (a)(1) of this section, and the maximum roller diameter set forth in paragraph (a)(6) of this section, may be changed following the procedures in § 648.122.

(b) *Pot and trap gear restrictions.* Owners or operators of vessels subject to this part must fish with scup pots or traps that comply with the following:

(1) *Degradable hinges.* A scup pot or trap must have degradable hinges and fasteners made of one of the following degradable materials:

(i) Untreated hemp, jute, or cotton string of 3/16 inches (4.8 mm) diameter or smaller;

(ii) Magnesium alloy, timed float releases (pop-up devices) or similar magnesium alloy fasteners; or

(iii) Ungalvanized or uncoated iron wire of 0.094 inches (2.4 mm) diameter or smaller.

(iv) The use of a single non-degradable retention device designed to prevent loss of the ghost panel after the degradable materials have failed is permitted provided the device does not impair the egress design function of the ghost panel by obstructing the opening or by preventing the panel from opening at such time that the degradable fasteners have completely deteriorated.

(2) *Escape vents.* (i) All scup pots or traps that have a circular escape vent with a minimum of 3.1 inches (7.9 cm) in diameter, or a square escape vent with a minimum of 2.25 inches (5.7 cm) for each side, or an equivalent rectangular escape vent.

(ii) The minimum escape vent size set forth in paragraph (b)(2)(i) of this section may be revised following the procedures in § 648.122.

(3) *Pot and trap identification.* Pots or traps used in fishing for scup must be marked with a code of identification that may be the number assigned by the Regional Administrator and/or the identification marking as required by the vessel's home port state.

37. Section 648.126 is revised to read as follows:

§ 648.126 Minimum fish sizes.

(a) *Moratorium (commercially) permitted vessels.* The minimum size for scup is 9 inches (22.9 cm) TL for all vessels issued a moratorium permit under § 648.4(a)(6). If such a vessel is also issued a charter and party boat permit and is carrying passengers for hire, or carrying more than three crew members if a charter boat, or more than five crew members if a party boat, then the minimum size specified in paragraph (b) of this section applies.

(b) *Party/Charter permitted vessels and recreational fishery participants.* The minimum size for scup is 10.5 inches (26.67 cm) TL for all vessels that do not have a moratorium permit, or for party and charter vessels that are issued a moratorium permit but are fishing with passengers for hire, or carrying more than three crew members if a charter boat, or more than five crew members if a party boat.

(c) The minimum size applies to whole fish or any part of a fish found in possession, *e.g.,* fillets. These minimum sizes may be adjusted pursuant to the procedures in § 648.122.

38. Section 648.127 is revised to read as follows:

§ 648.127 Recreational fishing season.

Vessels that are not eligible for a moratorium permit under § 648.4(a)(6), and fishermen subject to the possession limit specified in § 648.128(a), may not possess scup, except from June 6 through September 27. This time period may be adjusted pursuant to the procedures in § 648.122.

39. Section 648.128 is added to read as follows:

§ 648.128 Possession restrictions.

(a) *Party/Charter and recreational possession limits.* No person shall possess more than 10 scup in, or harvested from, the EEZ unless that person is the owner or operator of a fishing vessel issued a scup moratorium permit, or is issued a scup dealer permit. Persons aboard a commercial vessel that is not eligible for a scup moratorium permit are subject to this possession limit. The owner, operator, and crew of a charter or party boat issued a scup moratorium permit are subject to the possession limit when carrying passengers for hire or when carrying more than five crew members for a party boat, or more than three crew members for a charter boat. This possession limit may be adjusted pursuant to the procedures in § 648.122.

(b) If whole scup are processed into fillets, an authorized officer will convert the number of fillets to whole scup at the place of landing by dividing fillet number by 2. If scup are filleted into a single (butterfly) fillet, such fillet shall be deemed to be from one whole scup.

(c) Scup harvested by vessels subject to the possession limit with more than one person aboard may be pooled in one or more containers. Compliance with the daily possession limit will be determined by dividing the number of scup on board by the number of persons aboard other than the captain and crew. If there is a violation of the possession limit on board a vessel carrying more than one person, the violation shall be deemed to have been committed by the owner and operator.

(d) Scup and scup parts harvested by a vessel with a moratorium or charter or party boat scup permit, or in or from the EEZ north of 35°15.3' N. lat., may not be landed with the skin removed.

40. Section 648.129 is added to read as follows:

§ 648.129 Protection of threatened and endangered sea turtles.

This section supplements existing regulations issued to regulate incidental take of sea turtles under authority of the Endangered Species Act under 50 CFR parts 222 and 223. In addition to the measures required under those parts, NMFS will investigate the extent of sea turtle takes in flynet gear and, if deemed appropriate, may develop and certify a Turtle Excluder Device for that gear.

41. Section 648.130 is added to read as follows:

§ 648.130 Framework adjustments to management measures.

(a) *Within season management action.* See § 648.110(a).

(1) *Adjustment process.* The MAFMC shall develop and analyze appropriate

management actions over the span of at least two MAFMC meetings. The MAFMC must provide the public with advance notice of the availability of the recommendation(s), appropriate justification(s) and economic and biological analyses, and the opportunity to comment on the proposed adjustment(s) at the first meeting and prior to and at the second MAFMC meeting. The MAFMC's recommendations on adjustments or additions to management measures must come from one or more of the following categories: Adjustments within existing ABC control rules; adjustments to the existing MAFMC risk policy; introduction of new AMs, including sub-ACTs; minimum fish size; maximum fish size; gear restrictions; gear restricted areas; gear requirements or prohibitions; permitting restrictions; recreational possession limits; recreational seasons; closed areas; commercial seasons; commercial trip limits; commercial quota system including commercial quota allocation procedure and possible quota set asides to mitigate bycatch; recreational harvest limits; annual specification quota setting process; FMP Monitoring Committee composition and process; description and identification of EFH (and fishing gear management measures that impact EFH); description and identification of habitat areas of particular concern; regional gear restrictions; regional season restrictions (including option to split seasons); restrictions on vessel size (LOA and GRT) or shaft horsepower; operator permits; any other commercial or recreational management measures; any other management measures currently included in the FMP; and set aside quota for scientific research.

(2) *MAFMC recommendation.* See § 648.110(a)(2)(i) through (iv).

(3) *NMFS action.* See § 648.110(a)(3)(i) through (iii).

(4) *Emergency actions.* See § 648.110(a)(4).

(b) [*Reserved*]

42. Section 648.140 is revised to read as follows:

§ 648.140 Annual Catch Limit (ACL).

(a) The Black Sea Bass Monitoring Committee shall recommend to the MAFMC separate ACLs for the commercial and recreational scup fisheries, the sum total of which shall be less than or equal to the ABC recommended by the SSC.

(1) *Sector allocations.* The commercial and recreational fishing sector ACLs will be established consistent with the allocation guidelines contained in the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan.

(2) *Periodicity.* The black sea bass commercial and recreational sector ACLs may be established on an annual basis for up to 3 years at a time, dependent on whether the SSC provides single or multiple year ABC recommendations.

(b) *Performance review.* The Black Sea Bass Monitoring Committee shall conduct a detailed review of fishery performance relative to the sector ACLs at least every 5 years.

(1) If one or both of the sector-specific ACLs is exceeded with a frequency greater than 25 percent (*i.e.,* more than once in 4 years or any 2 consecutive years), the Black Sea Bass Monitoring Committee will review fishery performance information and make recommendations to the MAFMC for changes in measures intended to ensure ACLs are not exceeded as frequently.

(2) The MAFMC may specify more frequent or more specific ACL performance review criteria as part of a stock rebuilding plan following a determination that the black sea bass stock has become overfished.

(3) Performance reviews shall not substitute for annual reviews that occur to ascertain if prior year ACLs have been exceeded but may be conducted in conjunction with such reviews.

43. Section 648.141 is revised to read as follows:

§ 648.141 ACT.

(a) The Black Sea Bass Monitoring Committee shall identify and review the relevant sources of management uncertainty to recommend ACTs for the commercial and recreational fishing sectors as part of the black sea bass specification process. The Black Sea Bass Monitoring Committee recommendations shall identify the specific sources of management uncertainty that were considered, technical approaches to mitigating these sources of uncertainty, and any additional relevant information considered in the ACT recommendation process.

(1) *Sectors.* Commercial and recreational specific ACTs shall be less than or equal to the sector-specific ACLs. The Black Sea Bass Monitoring Committee shall recommend any reduction in catch necessary to address sector-specific management uncertainty, consistent with paragraph (a) of this section.

(2) *Periodicity.* ACTs may be established on an annual basis for up to 3 years at a time, dependent on whether the SSC provides single or multiple-year ABC recommendations.

(b) *Performance review.* The Black Sea Bass Monitoring Committee shall conduct a detailed review of fishery performance relative to ACTs in conjunction with any ACL performance review, as outlined in § 648.140(b)(1)–(3).

44. Section 648.142 is revised to read as follows:

§ 648.142 Specifications.

(a) *Commercial quota, recreational landing limit, research set-aside, and other specification measures.* The Black Sea Bass Monitoring Committee will recommend to the Demersal Species Committee of the MAFMC and the ASMFC, through the specification process, for use in conjunction with the ACL and ACT, sector-specific research set-asides, estimates of the sector-related discards, a recreational harvest limit, a commercial quota, along with other measures, as needed, that are projected to ensure the sector-specific ACL for an upcoming year or years will not be exceeded. The following measures are to be consisted the Black Sea Bass Monitoring Committee:

(1) Research quota set from a range of 0 to 3 percent of the maximum allowed.

(2) A commercial quota, allocated annually.

(3) A commercial possession limit for all moratorium vessels, with the provision that these quantities be the maximum allowed to be landed within a 24-hour period (calendar day).

(4) Commercial minimum fish size.

(5) Minimum mesh size in the codend or throughout the net and the catch threshold that will require compliance with the minimum mesh requirement.

(6) Escape vent size.

(7) A recreational possession limit set after the reduction for research quota.

(8) Recreational minimum fish size.

(9) Recreational season.

(10) Restrictions on gear other than otter trawls and pots or traps.

(11) Total allowable landings on an annual basis for a period not to exceed 3 years.

(12) Changes, as appropriate, to the Northeast Region SBRM, including the CV-based performance standard, fishery stratification, and/or reports.

(13) Modification of the existing AM measures and ACT control rules utilized by the Black Sea Bass Monitoring Committee.

(b) *Specification fishing measures.* The Demersal Species Committee shall review the recommendations of the Black Sea Bass Monitoring Committee. Based on these recommendations and any public comment, the Demersal Species Committee shall make its recommendations to the MAFMC with

respect to the measures necessary to assure that the ACLs are not exceeded. The MAFMC shall review these recommendations and, based on the recommendations and public comment, make recommendations to the Regional Administrator with respect to the measures necessary to assure that sector ACLs are not exceeded. Included in the recommendation will be supporting documents, as appropriate, concerning the environmental and economic impacts of the final rule. The Regional Administrator will review these recommendations and any recommendations of the ASMFC. After such review, the Regional Administrator will publish a proposed rule in the **Federal Register** to implement a commercial quota, a recreational harvest limit, and additional management measures for the commercial fishery. If the Regional Administrator determines that additional recreational measures are necessary to assure that the recreational sector ACL is not exceeded, he or she will publish a proposed rule in the **Federal Register** to implement additional management measures for the recreational fishery. After considering public comment, the Regional Administrator will publish a final rule in the **Federal Register** to implement the measures necessary to assure that recreational sector ACL is not exceeded.

(c) *Distribution of annual commercial quota.* The black sea bass commercial quota will be allocated on a coastwide basis.

(d) *Research quota.* See § 648.21(g).

45. Section 648.143 is revised to read as follows:

§ 648.143 Accountability measures.

(a) *Commercial sector fishery closure.* The Regional Administrator will monitor the harvest of commercial quota based on dealer reports, state data, and other available information. All black sea bass landed for sale in the states from North Carolina through Maine by a vessel with a moratorium permit issued under § 648.4(a)(7) shall be applied against the commercial annual coastwide quota, regardless of where the black sea bass were harvested. All black sea bass harvested north of 35°15.3′ N. lat., and landed for sale in the states from North Carolina through Maine by any vessel without a moratorium permit and fishing exclusively in state waters, will be counted against the quota by the state in which it is landed, pursuant to the FMP for the black sea bass fishery adopted by the ASMFC. The Regional Administrator will determine the date on which the annual coastwide quota will have been harvested; beginning on that date and through the end of the calendar year, the EEZ north of 35°15.3′ N. lat. will be closed to the possession of black sea bass. The Regional Administrator will publish notification in the **Federal Register** advising that, upon, and after, that date, no vessel may possess black sea bass in the EEZ north of 35°15.3′ N. lat. during a closure, nor may vessels issued a moratorium permit land black sea bass during the closure. Individual states will have the responsibility to close their ports to landings of black sea bass during a closure, pursuant to the FMP for the black sea bass fishery adopted by the ASMFC.

(1) *Commercial ACL overage evaluation.* The commercial sector ACL will be evaluated based on a single-year examination of total catch (landings and dead discards). Both landings and dead discards will be evaluated in determining if the commercial sector ACL has been exceeded.

(2) *Commercial landings overage repayment.* Landings in excess of the annual coastwide quota will be deducted from the quota allocation for the following year in the final rule that establishes the annual quota. The overage deduction will be based on landings for the current year through September 30, and landings for the previous calendar year were not included when the overage deduction was made in the final rule that established the annual coastwide quota for the current year. If the Regional Administrator determines during the fishing year that any part of an overage deduction was based on erroneous landings data that were in excess of actual landings for the period concerned, he/she will restore the overage that was deducted in error to the appropriate quota allocation. The Regional Administrator will publish notification in the **Federal Register** announcing the restoration.

(b) *Recreational landings sector closure.* The Regional Administrator will monitor recreational landings based on the best available data and shall determine if the recreational harvest limit has been met or exceeded. The determination will be based on observed landings and will not utilize projections of future landings. At such time that the available data indicate that the recreational harvest limit has been met or exceeded, the Regional Administrator shall publish notification in the **Federal Register** advising that, effective on a specific date, the summer flounder recreational fishery in the EEZ shall be closed for remainder of the calendar year.

(1) *Recreational ACL overage evaluation.* The recreational sector ACL will be evaluated based on a 3-year moving average comparison of total catch (landings and dead discards). Both landings and dead discards will be evaluated in determining if the 3-year average recreational sector ACL has been exceeded. The 3-year moving average will be phased in over the first 3 years, beginning with 2012: Total recreational total catch from 2012 will be compared to the 2012 recreational sector ACL; the average total catch from both 2012 and 2013 will be compared to the average of the 2012 and 2013 recreational sector ACLs; the average total catch from 2012, 2013, and 2014 will be compared to the average of the 2012, 2013, and 2014 recreational sector ACLs and, for all subsequent years, the preceding 3-year average recreational total catch will be compared to the preceding 3-year average recreational sector ACL.

(2) *Recreational landing overage repayment.* If available data indicate that the recreational sector ACL has been exceeded and the landings have exceeded the recreational harvest limit, the exact amount of the landings overage (in pounds) will be deducted, as soon as is practicable, from a subsequent single fishing year recreational sector ACT.

(c) *Non-landing accountability measures, by sector.* In the event that a sector ACL has been exceeded and the overage has not been accommodated through landings-based AMs, then the exact amount of the overage in pounds by which the sector ACL was exceeded will be deducted, as soon as is practicable, from a subsequent single fishing year applicable sector ACL.

(d) *State/Federal disconnect AM.* If the total catch, allowable landings, commercial quotas, and/or recreational harvest limit measures adopted by the ASMFC Black Sea Bass Management Board and the MAFMC differ for a given fishing year, administrative action will be taken as soon as is practicable to revisit the respective recommendations of the two groups. The intent of this action shall be to achieve alignment through consistent state and Federal measures so no differential effects occur to Federal permit holders.

46. Section 648.144 is revised to read as follows:

§ 648.144 Gear restrictions.

(a) *Trawl gear restrictions*—(1) *General.* (i) Otter trawlers whose owners are issued a black sea bass moratorium permit and that land or possess 500 lb (226.8 kg) or more of black sea bass from January 1 through March 31, or 100 lb (45.4 kg) or more of black sea bass from April 1 through December 31, must fish

with nets that have a minimum mesh size of 4.5-inch (11.43-cm) diamond mesh applied throughout the codend for at least 75 continuous meshes forward of the terminus of the net, or for codends with less than 75 meshes, the entire net must have a minimum mesh size of 4.5-inch (11.43-cm) diamond mesh throughout.

(ii) Mesh sizes shall be measured pursuant to the procedure specified in § 648.104(a)(2).

(2) *Net modifications.* No vessel subject to this part shall use any device, gear, or material, including, but not limited to, nets, net strengtheners, ropes, lines, or chafing gear, on the top of the regulated portion of a trawl net except that one splitting strap and one bull rope (if present) consisting of line or rope no more than 3 inches (7.6 cm) in diameter may be used if such splitting strap and/or bull rope does not constrict, in any manner, the top of the regulated portion of the net, and one rope no greater than 0.75 inches (1.9 cm) in diameter extending the length of the net from the belly to the terminus of the codend along the top, bottom, and each side of the net. ''Top of the regulated portion of the net'' means the 50 percent of the entire regulated portion of the net that (in a hypothetical situation) will not be in contact with the ocean bottom during a tow if the regulated portion of the net were laid flat on the ocean floor. For the purpose of this paragraph, head ropes shall not be considered part of the top of the regulated portion of a trawl net.

(3) *Mesh obstruction or constriction.* (i) A fishing vessel may not use any mesh configuration, mesh construction, or other means on or in the top of the net, as defined in paragraph (a)(2) of this section, that obstructs the meshes of the net in any manner, or otherwise causes the size of the meshes of the net while in use to diminish to a size smaller than the minimum established pursuant to paragraph (a)(1)(i) of this section.

(ii) No person on any vessel may possess or fish with a net capable of catching black sea bass in which the bars entering or exiting the knots twist around each other.

(4) *Stowage of nets.* Otter trawl vessels subject to the minimum mesh-size requirement of paragraph (a)(1)(i) of this section may not have ''available for immediate use'' any net or any piece of net that does not meet the minimum mesh size requirement, or any net, or any piece of net, with mesh that is rigged in a manner that is inconsistent with the minimum mesh size requirement. A net that is stowed in conformance with one of the methods specified in § 648.23(b) and that can be shown not to have been in recent use, is considered to be not ''available for immediate use.''

(5) *Roller gear.* Rollers used in roller rig or rock hopper trawl gear shall be no larger than 18 inches (45.7 cm) in diameter.

(b) *Pot and trap gear restrictions*—(1) *Gear marking.* The owner of a vessel issued a black sea bass moratorium permit must mark all black sea bass pots or traps with the vessel's USCG documentation number or state registration number.

(2) All black sea bass traps or pots must have two escape vents placed in lower corners of the parlor portion of the pot or trap that each comply with one of the following minimum size requirements: 1.375 inches by 5.75 inches (3.49 cm by 14.61 cm); a circular vent of 2.5 inches (6.4 cm) in diameter; or a square vent with sides of 2 inches (5.1 cm), inside measure; however, black sea bass traps constructed of wooden laths instead may have escape vents constructed by leaving spaces of at least 1.375 inches (3.49 cm) between two sets of laths in the parlor portion of the trap. These dimensions for escape vents and lath spacing may be adjusted pursuant to the procedures in § 648.140.

(3) *Ghost panel.* (i) Black sea bass traps or pots must contain a ghost panel affixed to the trap or pot with degradable fasteners and hinges. The opening to be covered by the ghost panel must measure at least 3.0 inches (7.62 cm) by 6.0 inches (15.24 cm). The ghost panel must be affixed to the pot or trap with hinges and fasteners made of one of the following degradable materials:

(A) Untreated hemp, jute, or cotton string of 3/16 inches (4.8 mm) diameter or smaller; or

(B) Magnesium alloy, timed float releases (pop-up devices) or similar magnesium alloy fasteners; or

(C) Ungalvanized or uncoated iron wire of 0.094 inches (2.4 mm) diameter or smaller.

(ii) The use of a single non-degradable retention device designed to prevent loss of the ghost panel after the degradable materials have failed is permitted, provided the device does not impair the egress design function of the ghost panel by obstructing the opening or by preventing the panel from opening at such time that the degradable fasteners have completely deteriorated.

47. Section 648.145 is revised to read as follows:

§ 648.145 Possession limit.

(a) No person shall possess more than 25 black sea bass in, or harvested from the EEZ unless that person is the owner or operator of a fishing vessel issued a black sea bass moratorium permit, or is issued a black sea bass dealer permit. Persons aboard a commercial vessel that is not eligible for a black sea bass moratorium permit are subject to this possession limit. The owner, operator, and crew of a charter or party boat issued a black sea bass moratorium permit are subject to the possession limit when carrying passengers for hire or when carrying more than five crew members for a party boat, or more than three crew members for a charter boat. This possession limit may be adjusted pursuant to the procedures in § 648.142.

(b) If whole black sea bass are processed into fillets, an authorized officer will convert the number of fillets to whole black sea bass at the place of landing by dividing fillet number by two. If black sea bass are filleted into a single (butterfly) fillet, such fillet shall be deemed to be from one whole black sea bass.

(c) Black sea bass harvested by vessels subject to the possession limit with more than one person aboard may be pooled in one or more containers. Compliance with the daily possession limit will be determined by dividing the number of black sea bass on board by the number of persons aboard, other than the captain and the crew. If there is a violation of the possession limit on board a vessel carrying more than one person, the violation shall be deemed to have been committed by the owner and operator of the vessel.

(d) Owners or operators of otter trawl vessels issued a moratorium permit under § 648.4(a)(7) and fishing with, or possessing on board, nets or pieces of net that do not meet the minimum mesh requirements specified in § 648.144(a) and that are not stowed in accordance with § 648.144(a)(4) may not retain more than 500 lb (226.8 kg) of black sea bass from January 1 through March 31, or more than 100 lb (45.4 kg) of black sea bass from April 1 through December 31. Black sea bass on board these vessels shall be stored so as to be readily available for inspection in a standard 100-lb (45.4-kg) tote.

48. Section 648.146 is revised to read as follows:

§ 648.146 Recreational fishing season.

Vessels that are not eligible for a moratorium permit under § 648.4(a)(7), and fishermen subject to the possession limit specified in § 648.145(a), may possess black sea bass from May 22 through October 11 and November 1 through December 31, unless this time period is adjusted pursuant to the procedures in § 648.142.

49. Section 648.147 is revised to read as follows:

§ 648.147 Minimum sizes.

(a) *Moratorium (commercially) permitted vessels.* The minimum size for black sea bass is 11 inches (27.94 cm) total length for all vessels issued a moratorium permit under § 648.4(a)(7) normal that fish for, possess, land or retain black sea bass in or from U.S. waters of the western Atlantic Ocean from 35°15.3′ N. Lat., the latitude of Cape Hatteras Light, North Carolina, northward to the U.S.-Canadian border. The minimum size may be adjusted for commercial vessels pursuant to the procedures in § 648.142.

(b) *Party/Charter permitted vessels and recreational fishery participants.* The minimum fish size for black sea bass is 12.5 inches (31.75 cm) TL for all vessels that do not qualify for a moratorium permit, and for party boats holding a moratorium permit, if fishing with passengers for hire or carrying more than five crew members, and for charter boats holding a moratorium permit, if fishing with more than three crew members.

(c) The minimum size in this section applies to the whole fish or any part of a fish found in possession (*e.g.,* fillets), except that party or charter vessels possessing valid state permits authorizing filleting at sea may possess fillets smaller than the size specified if skin remains on the fillet and all other state requirements are met.

50. Section 648.148 is added to read as follows:

§ 648.148 Special management zones.

The recipient of a U.S. Army Corps of Engineers permit for an artificial reef, fish attraction device, or other modification of habitat for purposes of fishing may request that an area surrounding and including the site be designated by the MAFMC as a special management zone (SMZ). The MAFMC may prohibit or restrain the use of specific types of fishing gear that are not compatible with the intent of the artificial reef or fish attraction device or other habitat modification within the SMZ. The establishment of an SMZ will be effected by a regulatory amendment, pursuant to the following procedure:

(a) A SMZ monitoring team comprised of members of staff from the MAFMC, NMFS Northeast Region, and NMFS Northeast Fisheries Science Center will evaluate the request in the form of a written report, considering the following criteria:

(1) Fairness and equity;

(2) Promotion of conservation;

(3) Avoidance of excessive shares;

(4) Consistency with the objectives of Amendment 9 to the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan, the Magnuson-Stevens Act, and other applicable law;

(5) The natural bottom in and surrounding potential SMZs; and

(6) Impacts on historical uses.

(b) The MAFMC Chairman may schedule meetings of MAFMC's industry advisors and/or the SSC to review the report and associated documents and to advise the MAFMC. The MAFMC Chairman may also schedule public hearings.

(c) The MAFMC, following review of the SMZ monitoring teams's report, supporting data, public comments, and other relevant information, may recommend to the Regional Administrator that a SMZ be approved. Such a recommendation will be accompanied by all relevant background information.

(d) The Regional Administrator will review the MAFMC's recommendation. If the Regional Administrator concurs in the recommendation, he or she will publish a proposed rule in the **Federal Register** in accordance with the recommendations. If the Regional Administrator rejects the MAFMC's recommendation, he or she shall advise the MAFMC in writing of the basis for the rejection.

(e) The proposed rule to establish a SMZ shall afford a reasonable period for public comment. Following a review of public comments and any information or data not previously available, the Regional Administrator will publish a final rule if he or she determines that the establishment of the SMZ is supported by the substantial weight of evidence in the record and consistent with the Magnuson-Stevens Act and other applicable law.

51. Section 648.149 is added to read as follows:

§ 648.149 Framework adjustments to management measures.

(a) *Within season management action.* See § 648.110(a).

(1) *Adjustment process.* See § 648.110(a)(1).

(2) *MAFMC recommendation.* See § 648.110(a)(2)(i) through (iv).

(3) *Regional Administrator action.* See § 648.110(a)(3)(i) through (iii).

(4) *Emergency actions.* See § 648.110(a)(4).

(b) [*Reserved*]

52. Section 648.160 is revised to read as follows:

§ 648.160 ACL.

(a) The Bluefish Monitoring Committee shall recommend to the MAFMC an ACL for the bluefish fishery, which shall be less than or equal to the ABC recommended by the SSC.

(1) *Periodicity.* The bluefish fishery ACL may be established on an annual basis for up to 3 years at a time, dependent on whether the SSC provides single or multiple-year ABC recommendations.

(2) [*Reserved*]

(b) *Performance review.* The Bluefish Monitoring Committee shall conduct a detailed review of fishery performance relative to ACL at least every 5 years.

(1) If the ACL is exceeded with a frequency greater than 25 percent (*i.e.,* more than once in 4 years or any 2 consecutive years), the Bluefish Monitoring Committee will review fishery performance information and make recommendations to the MAFMC for changes in measures intended to ensure the ACL is not exceeded as frequently.

(2) The MAFMC may specify more frequent or more specific ACL performance review criteria as part of a stock rebuilding plan following the determination that the bluefish stock has become overfished.

(3) Performance reviews shall not substitute for annual reviews that occur to ascertain if prior year ACLs have been exceeded, but may be conducted in conjunction with such reviews.

53. Section 648.161 is revised to read as follows:

§ 648.161 ACTs.

(a) The Bluefish Monitoring Committee shall identify and review the relevant sources of management uncertainty to recommend ACTs for the commercial and recreational fishing sectors as part of the bluefish specification process. The Bluefish Monitoring Committee recommendations shall identify the specific sources of management uncertainty that were considered, technical approaches to mitigating these sources of uncertainty, and any additional relevant information considered in the ACT recommendation process.

(1) *Sectors.* The sum of the commercial and recreational sector-specific ACTs shall be less than or equal to the fishery level ACL. The Bluefish Monitoring Committee shall recommend any reduction in catch necessary to address sector-specific management uncertainty, consistent with paragraph (a) of this section.

(2) *Periodicity.* ACTs may be established on an annual basis for up to 3 years at a time, dependent on whether the SSC provides single or multiple-year ABC recommendations.

(b) *Performance review.* The Bluefish Monitoring Committee shall conduct a detailed review of fishery performance relative to ACTs in conjunction with any ACL performance review, as outlined in § 648.160(b)(1) through (3).

54. Section 648.162 is revised to read as follows:

§ 648.162 Specifications.

(a) *Recommended measures.* Based on the annual review and requests for research quota as described in paragraph (h) of this section, the Bluefish Monitoring Committee shall recommend to the Coastal Migratory Committee of the MAFMC and the ASMFC the following measures to ensure that the ACL specified by the process outlined in § 648.160(a) will not be exceeded:

(1) A fishery-level TAL;

(2) Research quota set from a range of 0 to 3 percent of TAL;

(3) Commercial minimum fish size;

(4) Minimum mesh size;

(5) Recreational possession limit set from a range of 0 to 20 bluefish;

(6) Recreational minimum fish size;

(7) Recreational season;

(8) Restrictions on gear other than otter trawls and gill nets;

(9) Changes, as appropriate, to the Northeast Region SBRM, including the CV-based performance standard, fishery stratification, and/or reports; and

(10) Modification of existing AM measures and ACT control rules utilized by the Bluefish Monitoring Committee.

(b) *Allocation of TAL*—(1) *Recreational harvest limit.* A total of 83 percent of the TAL will be allocated to the recreational fishery as a harvest limit. If research quota is specified as described in paragraph (g) of this section, the recreational harvest limit will be based on the TAL remaining after the deduction of the research quota.

(2) *Commercial quota.* A total of 17 percent of the TAL will be allocated to the commercial fishery as a quota. If 17 percent of the TAL is less than 10.5 million lb (4.8 million kg) and the recreational fishery is not projected to land its harvest limit for the upcoming year, the commercial fishery may be allocated up to 10.5 million lb (4.8 million kg) as its quota, provided that the combination of the projected recreational landings and the commercial quota does not exceed the TAL. If research quota is specified as described in paragraph (g) of this section, the commercial quota will be based on the TAL remaining after the deduction of the research quota.

(c) *Annual fishing measures.* The MAFMC's Coastal Migratory Committee shall review the recommendations of the Bluefish Monitoring Committee. Based on these recommendations and any public comment, the Coastal Migratory Committee shall recommend to the MAFMC measures necessary to ensure that the ACL will not be exceeded. The MAFMC shall review these recommendations and, based on the recommendations and any public comment, recommend to the Regional Administrator by September 1 measures necessary to ensure that the applicable ACL will not be exceeded. The MAFMC's recommendations must include supporting documentation, as appropriate, concerning the environmental, economic, and social impacts of the recommendations. The Regional Administrator shall review these recommendations and any recommendations of the ASMFC. After such review, NMFS will publish a proposed rule in the **Federal Register** as soon as practicable, to implement an ACL, ACTs, research quota, a coastwide commercial quota, individual state commercial quotas, a recreational harvest limit, and additional management measures for the commercial and recreational fisheries to ensure that the ACL will not be exceeded. After considering public comment, NMFS will publish a final rule in the **Federal Register**.

(d) *Distribution of annual commercial quota.*—(1) The annual commercial quota will be distributed to the states, based upon the following percentages, state followed by allocation in parentheses: ME (0.6685); NH (0.4145); MA (6.7167); RI (6.8081); CT (1.2663); NY (10.3851); NJ (14.8162); DE (1.8782); MD (3.0018); VA (11.8795); NC (32.0608); SC (0.0352); GA (0.0095); and FL (10.0597). **NOTE:** The sum of all state allocations does not add to 100 because of rounding.

(2) [*Reserved*]

(e) *Quota transfers and combinations.* Any state implementing a state commercial quota for bluefish may request approval from the Regional Administrator to transfer part or all of its annual quota to one or more states. Two or more states implementing a state commercial quota for bluefish may request approval from the Regional Administrator to combine their quotas, or part of their quotas, into an overall regional quota. Requests for transfer or combination of commercial quotas for bluefish must be made by individual or joint letter(s) signed by the principal state official with marine fishery management responsibility and expertise, or his/her previously named designee, for each state involved. The letter(s) must certify that all pertinent state requirements have been met and identify the states involved and the amount of quota to be transferred or combined.

(1) Within 10 working days following the receipt of the letter(s) from the states involved, the Regional Administrator shall notify the appropriate state officials of the disposition of the request. In evaluating requests to transfer a quota or combine quotas, the Regional Administrator shall consider whether:

(i) The transfer or combination would preclude the overall annual quota from being fully harvested;

(ii) The transfer addresses an unforeseen variation or contingency in the fishery; and

(iii) The transfer is consistent with the objectives of the Bluefish FMP and Magnuson-Stevens Act.

(2) The transfer of quota or the combination of quotas will be valid only for the calendar year for which the request was made.

(3) A state may not submit a request to transfer quota or combine quotas if a request to which it is party is pending before the Regional Administrator. A state may submit a new request when it receives notification that the Regional Administrator has disapproved the previous request or when notification of the approval of the transfer or combination has been published in the **Federal Register**.

(f) Based upon any changes in the landings data available from the states for the base years 1981–89, the ASMFC and the MAFMC may recommend to the Regional Administrator that the states' shares specified in paragraph (d)(1) of this section be revised. The MAFMC's and the ASMFC's recommendation must include supporting documentation, as appropriate, concerning the environmental and economic impacts of the recommendation. The Regional Administrator shall review the recommendation of the ASMFC and the MAFMC. After such review, NMFS will publish a proposed rule in the **Federal Register** to implement a revision in the state shares. After considering public comment, NMFS will publish a final rule in the **Federal Register** to implement the changes in allocation.

(g) *Research quota.* See § 648.21(g).

55. Section 648.163 is revised to read as follows:

§ 648.163 Accountability Measures (AMs).

(a) *ACL overage evaluation.* The ACL will be evaluated based on a single-year examination of total catch (landings and dead discards). Both landings and dead discards will be evaluated in

determining if the ACL has been exceeded.

(b) *Commercial Sector EEZ closure.* NMFS shall close the EEZ to fishing for bluefish by commercial vessels for the remainder of the calendar year by publishing notification in the **Federal Register** if the Regional Administrator determines that the inaction of one or more states will cause the ACL specified in § 648.160(a) to be exceeded, or if the commercial fisheries in all states have been closed. NMFS may reopen the EEZ if earlier inaction by a state has been remedied by that state, or if commercial fisheries in one or more states have been reopened without causing the ACL to be exceeded.

(c) *State commercial landing quotas.* The Regional Administrator will monitor state commercial quotas based on dealer reports and other available information and shall determine the date when a state commercial quota will be harvested. NMFS shall publish notification in the **Federal Register** advising a state that, effective upon a specific date, its commercial quota has been harvested and notifying vessel and dealer permit holders that no commercial quota is available for landing bluefish in that state.

(1) *Commercial landings overage repayment.* All bluefish landed for sale in a state shall be applied against that state's annual commercial quota, regardless of where the bluefish were harvested. Any overages of the commercial quota landed in any state will be deducted from that state's annual quota for the following year, irrespective of whether the fishery-level ACL is exceeded. If a state has increased or reduced quota through the transfer process described in § 648.162, then any overage will be measured against that state's final adjusted quota.

(2) If there is a quota overage at the end of the fishing year among states involved in the combination of quotas, the overage will be deducted from the following year's quota for each of the states involved in the combined quota, irrespective of whether the fishery-level ACL is exceeded. The deduction will be proportional, based on each state's relative share of the combined quota for the previous year. A transfer of quota or combination of quotas does not alter any state's percentage share of the overall quota specified in § 648.162(d)(1).

(d) *Recreational landings AM when the ACL is exceeded and no sector-to-sector transfer of allowable landings has occurred.* If the fishery-level ACL is exceeded, landings from the recreational fishery are determined to have caused the overage, and no transfer between the commercial and recreational sector has occurred for the fishing year, as outlined in § 648.162(b)(2), then the exact amount, in pounds, by which the ACL was exceeded will be deducted, as soon as is practicable, from a subsequent single fishing year recreational ACT.

(e) *AM for when the ACL is exceeded and a sector-to-sector transfer of allowable landings has occurred.* If the fishery-level ACL is exceeded, landings from the recreational fishery are determined to have caused the overage, and a transfer between the commercial and recreational sector has occurred for the fishing year, as outlined in § 648.162(b)(2), the amount transferred between the recreational and commercial sector may be reduced by the ACL overage amount (pound-for-pound repayment) in a subsequent, single fishing year if the Bluefish Monitoring Committee determines that the ACL overage was the result of too liberal a landings transfer between the two sectors.

(f) *Non-landing AMs.* In the event that the ACL has been exceeded and the overage has not been accommodated through the AM measures in paragraphs (a) through (d) of this section, then the exact amount, in pounds, by which the ACL was exceeded shall be deducted, as soon as is practicable, from a subsequent, single fishing year ACL.

(g) *State/Federal disconnect AM.* If the total catch, allowable landings, commercial quotas, and/or recreational harvest limit measures adopted by the ASMFC Bluefish Management Board and the MAFMC differ for a given fishing year, administrative action will be taken as soon as is practicable to revisit the respective recommendations of the two groups. The intent of this action shall be to achieve alignment through consistent state and Federal measures so no differential effects occur to Federal permit holders.

56. Section 648.164 is revised to read as follows:

§ 648.164 Possession restrictions.

(a) No person shall possess more than 15 bluefish in, or harvested from, the EEZ unless that person is the owner or operator of a fishing vessel issued a bluefish commercial permit or is issued a bluefish dealer permit. Persons aboard a vessel that is not issued a bluefish commercial permit are subject to this possession limit. The owner, operator, and crew of a charter or party boat issued a bluefish commercial permit are not subject to the possession limit when not carrying passengers for hire and when the crew size does not exceed five for a party boat and three for a charter boat.

(b) Bluefish harvested by vessels subject to the possession limit with more than one person on board may be pooled in one or more containers. Compliance with the daily possession limit will be determined by dividing the number of bluefish on board by the number of persons on board, other than the captain and the crew. If there is a violation of the possession limit on board a vessel carrying more than one person, the violation shall be deemed to have been committed by the owner and operator of the vessel.

57. Section 648.165 is revised to read as follows:

§ 648.165 Minimum fish sizes.

If the MAFMC determines through its annual review or framework adjustment process that minimum fish sizes are necessary to assure that the fishing mortality rate is not exceeded, or to attain other FMP objectives, such measures will be enacted through the procedure specified in § 648.162(c) or 648.167.

58. Section 648.166 is added to read as follows:

§ 648.166 Gear restrictions.

If the MAFMC determines through its annual review or framework adjustment process that gear restrictions are necessary to assure that the fishing mortality rate is not exceeded, or to attain other FMP objectives, such measures will be enacted through the procedure specified in § 648.162(c) or 648.167.

59. Section 648.167 is added to read as follows:

§ 648.167 Framework adjustment to management measures.

(a) *Within-season management action.* The MAFMC may, at any time, initiate action to add or adjust management measures if it finds that action is necessary to meet or be consistent with the goals and objectives of the Bluefish FMP.

(1) *Adjustment process.* After a management action has been initiated, the MAFMC shall develop and analyze appropriate management actions over the span of at least two MAFMC meetings. The MAFMC shall provide the public with advance notice of the availability of both the proposals and the analysis and the opportunity to comment on them prior to and at the second MAFMC meeting. The MAFMC's recommendation on adjustments or additions to management measures must come from one or more of the following categories: Adjustments within existing ABC control rule levels; adjustments to the existing MAFMC risk

policy; introduction of new AMs, including sub-ACTs; minimum fish size; maximum fish size; gear restrictions; gear requirements or prohibitions; permitting restrictions; recreational possession limit; recreational season; closed areas; commercial season; description and identification of EFH; fishing gear management measures to protect EFH; designation of habitat areas of particular concern within EFH; changes to the Northeast Region SBRM (including the CV-based performance standard, the means by which discard data are collected/obtained, fishery stratification, reports and/or industry-funded observers or observer set-aside programs); and any other management measures currently included in the FMP. Measures that require significant departures from previously contemplated measures or that are otherwise introducing new concepts may require amendment of the FMP instead of a framework adjustment.

(2) *MAFMC recommendation.* After developing management actions and receiving public testimony, the MAFMC shall make a recommendation to the Regional Administrator. The MAFMC's recommendation must include supporting rationale and, if management measures are recommended, an analysis of impacts and a recommendation to the Regional Administrator on whether to issue the management measures as a final rule. If the MAFMC recommends that the management measures should be issued as a final rule, the MAFMC must consider at least the following factors and provide support and analysis for each factor considered:

(i) Whether the availability of data on which the recommended management measures are based allows for adequate time to publish a proposed rule, and whether regulations have to be in place for an entire harvest/fishing season;

(ii) Whether there has been adequate notice and opportunity for participation by the public and members of the affected industry in the development of the MAFMC's recommended management measures;

(iii) Whether there is an immediate need to protect the resource; and

(iv) Whether there will be a continuing evaluation of management measures adopted following their implementation as a final rule.

(3) *Action by NMFS.* If the MAFMC's recommendation includes adjustments or additions to management measures and, after reviewing the MAFMC's recommendation and supporting information:

(i) If NMFS concurs with the MAFMC's recommended management measures and determines that the recommended management measures should be issued as a final rule based on the factors specified in paragraph (a)(2) of this section, the measures will be issued as a final rule in the **Federal Register**.

(ii) If NMFS concurs with the MAFMC's recommendation and determines that the recommended management measures should be published first as a proposed rule, the measures will be published as a proposed rule in the **Federal Register**. After additional public comment, if NMFS concurs with the MAFMC's recommendation, the measures will be issued as a final rule in the **Federal Register**.

(iii) If NMFS does not concur, the MAFMC will be notified in writing of the reasons for the non-concurrence.

(b) *Emergency action.* Nothing in this section is meant to derogate from the authority of the Secretary to take emergency action under section 305(e) of the Magnuson-Stevens Act.

60. Section 648.230 is revised to read as follows:

§ 648.230 ACLs.

(a) The Spiny Dogfish Monitoring Committee shall recommend to the Joint Spiny Dogfish Committee, an ACL for the commercial spiny dogfish fishery, which shall be less than or equal to the domestic ABC (*i.e.,* the ABC minus Canadian catch) recommended by the SSC as specified in § 648.20.

(1) *Periodicity.* The spiny dogfish ACL may be established on an annual basis for up to 5 years at a time, dependent on whether the SSC provides single or multiple-year ABC recommendations.

(b) *Performance review.* The Spiny Dogfish Monitoring Committee shall conduct a detailed review of fishery performance relative to the ACL at least every 5 years.

(1) If an ACL is exceeded with a frequency greater than 25 percent (*i.e.,* more than once in 4 years or any 2 consecutive years), the Spiny Dogfish Monitoring Committee will review fishery performance information and make recommendations to the Councils for changes in measures intended to ensure ACLs are not exceeded as frequently.

(2) The Councils may specify more frequent or more specific ACL performance review criteria as part of a stock rebuilding plan following a determination that the spiny dogfish stock has become overfished.

(3) Performance reviews shall not substitute for annual reviews that occur to ascertain if prior year ACLs have been exceeded, but may be conducted in conjunction with such reviews.

61. Section 648.231 is revised to read as follows:

§ 648.231 ACT and Total Allowable Level of Landings (TAL).

(a) The Spiny Dogfish Monitoring Committee shall identify and review the relevant sources of management uncertainty to recommend an ACT and a TAL for the fishery as part of the spiny dogfish specification process specified in § 648.232. The Spiny Dogfish Monitoring Committee recommendations shall identify the specific sources of management uncertainty that were considered, technical approaches to mitigating these sources of uncertainty, domestic commercial and recreational discards, and any additional relevant information considered in the ACT and TAL recommendation process.

(1) The ACT shall be identified as less than or equal to the ACL.

(2) The Spiny Dogfish Monitoring Committee shall recommend a TAL to the Joint Spiny Dogfish Committee, which accounts for domestic commercial and recreational discards (ACT minus domestic dead discards). The TAL is equivalent to the annual coastwide commercial quota.

(b) *Periodicity.* The TAL may be established on an annual basis for up to 5 years at a time, dependent on whether the SSC provides single or multiple year ABC recommendations.

(c) *Performance review.* The Spiny Dogfish Monitoring Committee shall conduct a detailed review of fishery performance relative to TALs in conjunction with any ACL performance review, as outlined in § 648.230(b).

62. Section 648.232 is revised to read as follows:

§ 648.232 Specifications.

(a) *Commercial quota and other specification measures.* The Spiny Dogfish Monitoring Committee shall recommend to the Joint Spiny Dogfish Committee a TAL (*i.e.,* annual coastwide commercial quota) and any other measures, including those in paragraphs (a)(1) through (7) of this section, that are necessary to ensure that the commercial ACL will not be exceeded in any fishing year (May 1–April 30), for a period of 1–5 fishing years. The measures that may be recommended include, but are not limited to:

(1) Minimum or maximum fish sizes;

(2) Seasons;

(3) Mesh size restrictions;

(4) Trip limits;

(5) Changes to the Northeast Region SBRM, including the CV-based performance standard, fishery stratification, and/or reports;

(6) Other gear restrictions; and

(7) Changes to AMs and ACT control rules.

(b) *Joint Spiny Dogfish Committee recommendation.* The Councils' Joint Spiny Dogfish Committee shall review the recommendations of the Spiny Dogfish Monitoring Committee. Based on these recommendations and any public comments, the Joint Spiny Dogfish Committee shall recommend to the Councils a TAL, and possibly other measures, including those specified in paragraphs (a)(1) through (7) of this section, necessary to ensure that the ACL specified in § 648.230 will not be exceeded in any fishing year (May 1–April 30), for a period of 1–5 fishing years.

(c) *Council recommendations.* (1) The Councils shall review these recommendations and, based on the recommendations and any public comments, recommend to the Regional Administrator a TAL and other measures necessary to ensure that the ACL specified in § 648.230 will not be exceeded in any fishing year, for a period of 1–5 fishing years. The Councils' recommendations must include supporting documentation, as appropriate, concerning the environmental, economic, and other impacts of the recommendations. The Regional Administrator shall initiate a review of these recommendations and may modify the recommended quota and other management measures to ensure that the ACL specified in § 648.230 will not be exceeded in any fishing year, for a period of 1–5 fishing years. The Regional Administrator may modify the Councils' recommendations using any of the measures that were not rejected by both Councils.

(2) After such review, NMFS shall publish a proposed rule in the **Federal Register** specifying a TAL, adjustments to ACL, ACT, and TAL resulting from the accountability measures specified in § 648.233, and other measures necessary to ensure that the ACL will not be exceeded in any fishing year, for a period of 1–5 fishing years. After considering public comments, NMFS shall publish a final rule in the **Federal Register** to implement the TAL and other measures.

(d) [*Reserved*]

(e) *Distribution of annual quota.* (1) The TAL (*i.e.,* annual coastwide commercial quota) specified according to the process outlined section § 648.231 shall be allocated between two semi-annual quota periods as follows: May 1 through October 31 (57.9 percent); and November 1 through April 30 (42.1 percent).

(2) All spiny dogfish landed for a commercial purpose in the states from Maine through Florida shall be applied against the applicable semi-annual commercial quota, regardless of where the spiny dogfish were harvested.

63. Section 648.233 is revised to read as follows:

§ 648.233 AMs.

(a) *Commercial EEZ closure.* The Regional Administrator shall determine the date by which the quota for each semi-annual period described in § 648.232(e)(1) will be harvested and shall close the EEZ to fishing for spiny dogfish on that date for the remainder of that semi-annual period by publishing notification in the **Federal Register**. Upon the closure date, and for the remainder of the semi-annual quota period, no vessel may fish for or possess spiny dogfish in the EEZ, nor may vessels issued a spiny dogfish permit under this part land spiny dogfish, nor may dealers issued a Federal permit purchase spiny dogfish from vessels issued a spiny dogfish permit under this part.

(b) *ACL overage evaluation.* The ACL will be evaluated based on a single-year examination of total catch (including both landings and dead discards) to determine if the ACL has been exceeded.

(c) *Overage repayment.* In the event that the ACL has been exceeded in a given fishing year, the exact amount in pounds by which the ACL was exceeded shall be deducted, as soon as is practicable, through a notice in the **Federal Register**, from a subsequent single fishing year ACL.

64. Section 648.235 is revised to read as follows:

§ 648.235 Possession and landing restrictions.

(a) *Quota Period 1.* From May 1 through October 31, vessels issued a valid Federal spiny dogfish permit specified under § 648.4(a)(11) may:

(1) Possess up to 3,000 lb (1.36 mt) of spiny dogfish per trip; and

(2) Land only one trip of spiny dogfish per calendar day.

(b) *Quota Period 2.* From November 1 through April 30, vessels issued a valid Federal spiny dogfish permit specified under § 648.4(a)(11) may:

(1) Possess up to 3,000 lb (1.36 mt) of spiny dogfish per trip; and

(2) Land only one trip of spiny dogfish per calendar day.

(c) Regulations governing the harvest, possession, landing, purchase, and sale of shark fins are found at part 600, subpart N, of this chapter.

65. Section 648.237 is removed and reserved to read as follows:

§ 648.237 [Reserved]

66. Section 648.238 is removed and reserved to read as follows:

§ 648.238 [Reserved]

67. Section 648.239 is added to read as follows:

§ 648.239 Framework adjustments to management measures.

(a) *Within season management action.* The Councils may, at any time, initiate action to add or adjust management measures if they find that action is necessary to meet or be consistent with the goals and objectives of the Spiny Dogfish FMP.

(1) *Adjustment process.* After the Councils initiate a management action, they shall develop and analyze appropriate management actions over the span of at least two Council meetings. The Councils shall provide the public with advance notice of the availability of both the proposals and the analysis for comment prior to, and at, the second Council meeting. The Councils' recommendation on adjustments or additions to management measures must come from one or more of the following categories: Adjustments within existing ABC control rule levels; adjustments to the existing MAFMC risk policy; introduction of new AMs, including sub-ACTs; minimum fish size; maximum fish size; gear requirements, restrictions, or prohibitions (including, but not limited to, mesh size restrictions and net limits); regional gear restrictions; permitting restrictions, and reporting requirements; recreational fishery measures (including possession and size limits and season and area restrictions); commercial season and area restrictions; commercial trip or possession limits; fin weight to spiny dogfish landing weight restrictions; onboard observer requirements; commercial quota system (including commercial quota allocation procedures and possible quota set-asides to mitigate bycatch, conduct scientific research, or for other purposes); recreational harvest limit; annual quota specification process; FMP Monitoring Committee composition and process; description and identification of essential fish habitat; description and identification of habitat areas of particular concern; overfishing definition and related thresholds and targets; regional season restrictions (including option to split seasons); restrictions on vessel size (length and GRT) or shaft horsepower; target quotas; measures to mitigate marine mammal entanglements and interactions; regional management; changes to the Northeast Region SBRM, including the CV-based performance

standard, the means by which discard data are collected/obtained, fishery stratification, reports, and/or industry-funded observers or observer set-aside program; any other management measures currently included in the Spiny Dogfish FMP; and measures to regulate aquaculture projects. Measures that require significant departures from previously contemplated measures or that are otherwise introducing new concepts may require amendment of the FMP instead of a framework adjustment.

(2) *Councils' recommendation.* After developing management actions and receiving public testimony, the Councils shall make a recommendation approved by a majority of each Council's members, present and voting, to the Regional Administrator. The Councils' recommendation must include supporting rationale, an analysis of impacts and, if management measures are recommended, a recommendation to the Regional Administrator on whether to issue the management measures as a final rule. If the Councils recommend that the management measures should be issued as a final rule, they must consider at least the following factors and provide support and analysis for each factor considered:

(i) Whether the availability of data on which the recommended management measures are based allows for adequate time to publish a proposed rule and whether regulations have to be in place for an entire harvest/fishing season;

(ii) Whether there has been adequate notice and opportunity for participation by the public and members of the affected industry in the development of the Councils' recommended management measures;

(iii) Whether there is an immediate need to protect the resource; and

(iv) Whether there will be a continuing evaluation of management measures adopted following their implementation as a final rule;

(3) *NMFS action.* If the Councils' recommendation includes adjustments or additions to management measures, then:

(i) If NMFS concurs with the Councils' recommended management measures and determines that the recommended management measures should be issued as a final rule based on the factors specified in paragraph (b)(2) of this section, then the measures will be issued as a final rule in the **Federal Register**.

(ii) If NMFS concurs with the Councils' recommendation and determines that the recommended management measures should be published first as a proposed rule, then the measures will be published as a proposed rule in the **Federal Register**. After additional public comment, if NMFS concurs with the Councils' recommendation, then the measures will be issued as a final rule in the **Federal Register**.

(iii) If NMFS does not concur, the Councils will be notified in writing of the reasons for the non-concurrence.

(iv) Framework actions can be taken only in the case where both Councils approve the proposed measure.

(b) *Emergency action.* Nothing in this section is meant to derogate from the authority of the Secretary to take emergency action under section 305(e) of the Magnuson-Stevens Act.

68. Section 648.290 is revised to read as follows:

§ 648.290 ACL.

(a) The Tilefish Monitoring Committee shall recommend to the MAFMC an ACL for the commercial tilefish fishery, which shall be less than or equal to the ABC recommended by the SSC.

(1) [*Reserved*]

(2) *Periodicity.* The tilefish commercial ACL may be established on an annual basis for up to 3 years at a time, dependent on whether the SSC provides single or multiple-year ABC recommendations.

(b) *Performance review.* The Tilefish Monitoring Committee shall conduct a detailed review of fishery performance relative to the sector ACLs at least every 5 years.

(1) If the ACL is exceeded with a frequency greater than 25 percent (*i.e.,* more than once in 4 years or in any 2 consecutive years), the Tilefish Monitoring Committee will review fishery performance information and make recommendations to the MAFMC for changes in measures intended to ensure ACLs are not as frequently exceeded.

(2) The MAFMC may specify more frequent or more specific ACL performance review criteria as part of a stock rebuilding plan following a determination that the tilefish stock has become overfished.

(3) Performance reviews shall not substitute for annual reviews that occur to ascertain if prior year ACLs have been exceeded, but may be conducted in conjunction with such reviews.

69. Section 648.291 is revised to read as follows:

§ 648.291 ACT.

(a) The Tilefish Monitoring Committee shall identify and review the relevant sources of management uncertainty to recommend an ACT as part of the tilefish specification process. The Tilefish Monitoring Committee recommendations shall identify the specific sources of management uncertainty that were considered, technical approaches to mitigating these sources of uncertainty, and any additional relevant information considered in the ACT recommendation process.

(1) *Sectors.* The ACT shall be less than or equal to the ACL. The Tilefish Monitoring Committee shall include the fishing mortality associated with the recreational fishery in its ACT recommendations only if this source of mortality has not already been accounted for in the ABC recommended by the SSC. The Tilefish Monitoring Committee shall recommend any reduction in catch necessary to address sector-specific management uncertainty, consistent with paragraph (a) of this section.

(2) *Periodicity.* ACTs may be established on an annual basis for up to 3 years at a time, dependent on whether the SSC provides single or multiple-year ABC recommendations.

(b) *Performance review.* The Tilefish Monitoring Committee shall conduct a detailed review of fishery performance relative to ACTs in conjunction with any ACL performance review, as outlined in § 648.290(b)(1)–(3).

70. Section 648.292 is added to read as follows:

§ 648.292 Specifications.

The fishing year is the 12-month period beginning with November 1, annually.

(a) *Annual specification process.* The Tilefish Monitoring Committee shall review the ABC recommendation of the SSC, tilefish landings and discards information, and any other relevant available data to determine if the ACL, ACT, or total allowable landings (TAL) requires modification to respond to any changes to the stock's biological reference points or to ensure that the rebuilding schedule is maintained. The Monitoring Committee will consider whether any additional management measures or revisions to existing measures are necessary to ensure that the TAL will not be exceeded. Based on that review, the Monitoring Committee will recommend ACL, ACT, and TAL to the Tilefish Committee of the MAFMC. Based on these recommendations and any public comment received, the Tilefish Committee shall recommend to the MAFMC the appropriate ACL, ACT, TAL, and other management measures for a single fishing year or up to 3 years. The MAFMC shall review these recommendations and any public comments received, and recommend to

the Regional Administrator, at least 120 days prior to the beginning of the next fishing year, the appropriate ACL, ACT, TAL, the percentage of TAL allocated to research quota, and any management measures to assure that the TAL will not be exceeded, for the next fishing year, or up to 3 fishing years. The MAFMC's recommendations must include supporting documentation, as appropriate, concerning the environmental and economic impacts of the recommendations. The Regional Administrator shall review these recommendations, and after such review, NMFS will publish a proposed rule in the **Federal Register** specifying the annual ACL, ACT, TAL and any management measures to assure that the TAL will not be exceeded for the upcoming fishing year or years. After considering public comments, NMFS will publish a final rule in the **Federal Register** to implement the ACL, ACT, TAL and any management measures. The previous year's specifications will remain effective unless revised through the specification process and/or the research quota process described in paragraph (e) of this section. NMFS will issue notification in the **Federal Register** if the previous year's specifications will not be changed.

(b) *TAL.* (1) The TAL for each fishing year will be 1.995 million lb (905,172 kg) unless modified pursuant to paragraph (a) of this section.

(2) The sum of the TAL and estimated discards shall be less than or equal to the ACT.

(c) *TAL allocation.* For each fishing year, up to 3 percent of the TAL may be set aside for the purpose of funding research. Once a research amount, if any, is set aside, the TAL will first be reduced by 5 percent to adjust for the incidental catch. The remaining TAL will be allocated to the individual IFQ permit holder as described in section § 648.294(a).

(d) *Adjustments to the quota.* If the incidental harvest exceeds 5 percent of the TAL for a given fishing year, the incidental trip limit of 500 lb (226.8 kg) may be reduced in the following fishing year. If an adjustment is required, a notification of adjustment of the quota will be published in the **Federal Register**.

(e) *Research quota.* See § 648.21(g).

71. Section 648.293 is revised to read as follows:

§ 648.293 Accountability measures.

(a) If the ACL is exceeded, the amount of the ACL overage that cannot be directly attributed to IFQ allocation holders having exceeded their IFQ allocation will be deducted from the ACL in the following fishing year. All overages directly attributable to IFQ allocation holders will be deducted from the appropriate IFQ allocation(s) in the subsequent fishing year, as required by § 648.294(f).

(b) [*Reserved*]

72. Section 648.294 is revised to read as follows:

§ 648.294 Individual fishing quota (IFQ) program.

(a) *IFQ allocation permits.* After adjustments for incidental catch, research set asides, and overages, as appropriate, pursuant to § 648.292(c), the Regional Administrator shall divide the remaining TAL among the IFQ allocation permit holders who held an IFQ permit as of September 1 of a giving fishing year. Allocations shall be made by applying the allocation percentages that exist on September 1 of a given fishing year to the IFQ TAL pursuant to § 648.292(c), subject to any deductions for overages pursuant to paragraph (f) of this section. Amounts of IFQ of 0.5 lb (0.23 kg) or smaller created by this allocation shall be rounded downward to the nearest whole number, and amounts of IFQ greater than 0.5 lb (0.23 kg) created by this division shall be rounded upward to the nearest whole number, so that IFQ allocations are specified in whole pounds. These allocations shall be issued in the form of an annual IFQ allocation permit.

(b) *Application*—(1) *General.* Applicants for a permit under this section must submit a completed application on an appropriate form obtained from NMFS. The application must be filled out completely and signed by the applicant. Each application must include a declaration of all interests in IFQ allocations, as defined in § 648.2, listed by IFQ allocation permit number, and must list all Federal vessel permit numbers for all vessels that an applicant owns or leases that would be authorized to possess tilefish pursuant to the IFQ allocation permit. The Regional Administrator will notify the applicant of any deficiency in the application.

(i) [*Reserved*]

(ii) *Renewal applications.* Applications to renew an IFQ allocation permit must be received by September 15 to be processed in time for the November 1 start of the fishing year. Renewal applications received after this date may not be approved, and a new permit may not be issued before the start of the next fishing year. An IFQ allocation permit holder must renew his/her IFQ allocation permit on an annual basis by submitting an application for such permit prior to the end of the fishing year for which the permit is required.

(2) *Issuance.* Except as provided in subpart D of 15 CFR part 904, and provided an application for such permit is submitted by September 15, as specified in paragraph (b)(1)(ii) of this section, NMFS shall issue annual IFQ allocation permits on or before October 31 to those who hold permanent allocation as of September 1 of the current fishing year. During the period between September 1 and October 31, transfer of IFQ is not permitted, as described in paragraph (e)(4) of this section. The IFQ allocation permit shall specify the allocation percentage of the IFQ TAL which the IFQ permit holder is authorized to harvest.

(3) *Duration.* An annual IFQ allocation permit is valid until October 31 of each fishing year unless it is suspended, modified, or revoked pursuant to 15 CFR part 904, or revised due to a transfer of all or part of the allocation percentage under paragraph (e) of this section. All Federal vessel permit numbers that are listed on the IFQ allocation permit are authorized to possess tilefish pursuant to the IFQ allocation permit until the end of the fishing year or until NMFS receives written notification from the IFQ allocation permit holder that the vessel is no longer authorized to possess tilefish pursuant to the subject permit. An IFQ allocation permit holder that wishes to authorize an additional vessel(s) to possess tilefish pursuant to the IFQ allocation permit must send written notification to NMFS that includes the vessel permit number, and the dates on which the IFQ allocation permit holder desires the vessel to be authorized to land IFQ tilefish pursuant to the IFQ allocation permit to be effective.

(4) *Alteration.* An annual IFQ allocation permit that is altered, erased, or mutilated is invalid.

(5) *Replacement.* The Regional Administrator may issue a replacement permit upon written application of the annual IFQ Allocation permit holder.

(6) *Transfer.* The annual IFQ Allocation permit is valid only for the person to whom it is issued. All or part of the allocation specified in the IFQ Allocation permit may be transferred in accordance with paragraph (e) of this section.

(7) *Abandonment or voluntary relinquishment.* Any IFQ Allocation permit that is voluntarily relinquished to the Regional Administrator, or deemed to have been voluntarily relinquished for failure to pay a recoverable cost fee, in accordance with the requirements specified in paragraph

(h)(2) of this section, or for failure to renew in accordance with paragraph (b)(1)(ii) of this section, shall not be reissued or renewed in a subsequent year.

(c) [*Reserved*]

(d) [*Reserved*]

(e) *Transferring IFQ allocations*—(1) *Temporary transfers.* Unless otherwise restricted by the provisions in paragraph (e)(3) of this section, the owner of an IFQ allocation may transfer the entire IFQ allocation, or a portion of the IFQ allocation, to any person or entity eligible to own a documented vessel under the terms of 46 U.S.C. 12102(a). Temporary IFQ allocation transfers shall be effective only for the fishing year in which the temporary transfer is requested and processed, unless the applicant specifically requests that the transfer be processed for the subsequent fishing year. The Regional Administrator has final approval authority for all temporary IFQ allocation transfer requests. The approval of a temporary transfer may be rescinded if the Regional Administrator finds that an emergency has rendered the lessee unable to fish for the transferred IFQ allocation, but only if none of the transferred allocation has been landed.

(2) *Permanent transfers.* Unless otherwise restricted by the provisions in paragraph (e)(3) of this section, an owner of an IFQ allocation may permanently transfer the entire IFQ allocation, or a portion of the IFQ allocation, to any person or entity eligible to own a documented vessel under the terms of 46 U.S.C. 12102(a). The Regional Administrator has final approval authority for all permanent IFQ allocation transfer requests.

(3) *IFQ allocation transfer restrictions.* (i) If IFQ allocation is temporarily transferred to any eligible entity, it may not be transferred by the transferee again within the same fishing year, unless the transfer is rescinded due to an emergency, as described in paragraph (e)(1) of this section.

(ii) A transfer of IFQ will not be approved by the Regional Administrator if it would result in an entity owning, or having an interest in, a percentage of IFQ allocation exceeding 49 percent of the total tilefish adjusted TAL.

(iii) If the owner of an IFQ allocation leases additional quota from another IFQ allocation permit holder, any landings associated with this transferred quota will be deducted from the total yearly landings of the lessee, before his/her base allocation, if any exists, for the purpose of calculating the appropriate cost-recovery fee. As described in paragraph (h) of this section, a tilefish IFQ allocation permit holder with a permanent allocation shall incur a cost-recovery fee, based on the value of landings of tilefish authorized under his/her tilefish IFQ allocation permit, including allocation that he/she leases to another IFQ allocation permit holder.

(4) *Application for an IFQ allocation transfer.* Any IFQ allocation permit holder applying for either permanent or temporary transfer of IFQ allocation must submit a completed IFQ Allocation Transfer Form, available from NMFS. The IFQ Allocation Transfer Form must be submitted to the NMFS Northeast Regional Office at least 30 days before the date on which the applicant desires to have the IFQ allocation transfer effective. The Regional Administrator shall notify the applicants of any deficiency in the application pursuant to this section. Applications for IFQ allocation transfers must be received by September 1 to be processed for the current fishing year.

(i) *Application information requirements.* An application to transfer IFQ allocation must include the following information: The type of transfer (either temporary or permanent); the signature of both parties involved; the price paid for the transfer, indicate eligibility to receive IFQ allocation; the amount of allocation to be transferred, and a declaration; by IFQ Allocation permit number; of all the IFQ allocations that the person or entity receiving the IFQ allocation has an interest. The person or entity receiving the IFQ allocation must indicate the permit numbers of all federally permitted vessels that will possess or land their IFQ allocation. Information obtained from the IFQ Allocation Transfer Form is confidential pursuant to 16 U.S.C. 1881a.

(ii) *Approval of IFQ transfer applications.* Unless an application to transfer IFQ is denied according to paragraph (e)(4)(iii) of this section, the Regional Administrator shall issue confirmation of application approval in the form of a new or updated IFQ allocation permit to the parties involved in the transfer within 30 days of receipt of a completed application.

(iii) *Denial of transfer application.* The Regional Administrator may reject an application to transfer IFQ allocation for the following reasons: The application is incomplete; the transferor does not possess a valid tilefish IFQ allocation permit; the transferor's or transferee's vessel or tilefish IFQ allocation permit has been sanctioned, pursuant to an enforcement proceeding under 15 CFR part 904; the transfer will result in the transferee having a tilefish IFQ allocation that exceeds 49 percent of the adjusted TAL allocated to IFQ allocation permit holders; the transfer is to a person or entity that is not eligible to own a documented vessel under the terms of 46 U.S.C. 12102(a); or any other failure to meet the requirements of this subpart. Upon denial of an application to transfer IFQ allocation, the Regional Administrator shall send a letter to the applicant describing the reason(s) for the denial. The decision by the Regional Administrator is the final decision of the Department of Commerce; there is no opportunity for an administrative appeal.

(f) *IFQ allocation overages.* Any IFQ allocation that is exceeded, including amounts of tilefish landed by a lessee in excess of a temporary transfer of IFQ allocation, will be reduced by the amount of the overage in the subsequent fishing year(s). If an IFQ allocation overage is not deducted from the appropriate allocation before the IFQ allocation permit is issued for the subsequent fishing year, a revised IFQ allocation permit reflecting the deduction of the overage shall be issued by NMFS. If the allocation cannot be reduced in the subsequent fishing year because the full allocation has already been landed or transferred, the IFQ allocation permit will indicate a reduced allocation for the amount of the overage in the next fishing year.

(g) *IFQ allocation acquisition restriction.* No person or entity may acquire more than 49 percent of the annual adjusted tilefish TAL, specified pursuant to § 648.294, at any point during a fishing year. For purposes of this paragraph, acquisition includes any permanent or temporary transfer of IFQ. The calculation of IFQ allocation for purposes of the restriction on acquisition includes IFQ allocation interests held by: A company in which the IFQ holder is a shareholder, officer, or partner; an immediate family member; or a company in which the IFQ holder is a part owner or partner.

(h) *IFQ cost recovery.* A fee shall be determined as described in paragraph (h)(1) of this section, and collected to recover the government costs associated with management, data collection and analysis, and enforcement of the IFQ program. A tilefish IFQ allocation permit holder shall be responsible for paying the fee assessed by NMFS. A tilefish IFQ allocation permit holder with a permanent allocation shall incur a cost-recovery fee, based on the value of landings of tilefish authorized under his/her tilefish IFQ allocation permit, including allocation that he/she leases to another IFQ allocation permit holder. A tilefish IFQ allocation permit holder, with a permanent allocation, shall be

responsible for submitting this payment to NMFS once per year, as specified in paragraph (h)(2) of this section. For the purpose of this section, the cost-recovery billing period is defined as the full calendar year, beginning with the start of the first calendar year following the effective date of the final regulations. NMFS will create an annual IFQ allocation bill for each cost-recovery billing period and provide it to each IFQ allocation permit holder. The bill will include annual information regarding the amount and value of IFQ allocation landed during the prior cost-recovery billing period, and the associated cost-recovery fees. NMFS will also create a report that will detail the costs incurred by NMFS, for the management, enforcement, and data collection and analysis associated with the IFQ allocation program during the prior cost-recovery billing period.

(1) *NMFS determination of the total annual recoverable costs of the tilefish IFQ program.* The Regional Administrator shall determine the costs associated with the management, data collection and analysis, and enforcement of the IFQ allocation program. The recoverable costs will be divided by the amount of the total ex-vessel value of all tilefish IFQ landings during the cost-recovery billing period to derive a percentage. IFQ allocation permit holders will be assessed a fee based on this percentage multiplied by the total ex-vessel value of all landings under their permanent IFQ allocation permit, including landings of allocation that is leased. This fee shall not exceed 3 percent of the total value of tilefish landings of the IFQ allocation permit holder. If NMFS determines that the costs associated with the management, data collection and analysis, and enforcement of the IFQ allocation program exceed 3 percent of the total value of tilefish landings, only 3 percent are recoverable.

(i) *Valuation of IFQ allocation.* The 3-percent limitation on cost-recovery fees shall be based on the ex-vessel value of landed allocation. The ex-vessel value for each pound of tilefish landed by an IFQ allocation holder shall be determined from Northeast Federal dealer reports submitted to NMFS, which include the price per pound at the time of dealer purchase.

(ii) [*Reserved*]

(2) *Fee payment procedure.* An IFQ allocation permit holder who has incurred a cost-recovery fee must pay the fee to NMFS within 45 days of the date of the bill. Cost-recovery payments shall be made electronically via the Federal Web portal, *http://www.pay.gov,* or other Internet sites designated by the Regional Administrator. Instructions for electronic payment shall be available on both the payment Web site and the cost-recovery fee bill. Electronic payment options shall include payment via a credit card, as specified in the cost-recovery bill, or via direct automated clearing house (ACH) withdrawal from a designated checking account. Alternatively, payment by check may be authorized by Regional Administrator if he/she determines that electronic payment is not possible.

(3) *Payment compliance.* If the cost-recovery payment, as determined by NMFS, is not made within the time specified in paragraph (h)(2) of this section, the Regional Administrator will deny the renewal of the appropriate IFQ allocation permit until full payment is received. If, upon preliminary review of a fee payment, the Regional Administrator determines that the IFQ allocation permit holder has not paid the full amount due, he/she shall notify the IFQ allocation permit holder in writing of the deficiency. NMFS shall explain the deficiency and provide the IFQ allocation permit holder 30 days from the date of the notice, either to pay the amount assessed or to provide evidence that the amount paid was correct. If the IFQ allocation permit holder submits evidence in support of the appropriateness of his/her payment, the Regional Administrator shall determine whether there is a reasonable basis upon which to conclude that the amount of the tendered payment is correct. This determination shall be set forth in a Final Administrative Determination (FAD) that is signed by the Regional Administrator. A FAD shall be the final decision of the Department of Commerce. If the Regional Administrator determines that the IFQ allocation permit holder has not paid the appropriate fee, he/she shall require payment within 30 days of the date of the FAD. If a FAD is not issued until after the start of the fishing year, the IFQ allocation permit holder may be issued a letter of authorization to fish until the FAD is issued, at which point the permit holder shall have 30 days to comply with the terms of the FAD or the tilefish IFQ allocation permit shall not be issued, and the letter of authorization shall not be valid until such terms are met. Any tilefish landed pursuant to the above authorization will count against the IFQ allocation permit, if issued. If the Regional Administrator determines that the IFQ allocation permit holder owes additional fees for the previous cost-recovery billing period, and the renewed IFQ allocation permit has already been issued, the Regional Administrator shall issue a FAD and will notify the IFQ allocation permit holder in writing. The IFQ allocation permit holder shall have 30 days from the date of the FAD to comply with the terms of the FAD. If the IFQ allocation permit holder does not comply with the terms of the FAD within this period, the Regional Administrator shall rescind the IFQ allocation permit until such terms are met. If an appropriate payment is not received within 30 days of the date of a FAD, the Regional Administrator shall refer the matter to the appropriate authorities within the U.S. Department of the Treasury for purposes of collection. No permanent or temporary IFQ allocation transfers may be made to or from the allocation of an IFQ allocation permit holder who has not complied with any FAD. If the Regional Administrator determines that the terms of a FAD have been met, the IFQ allocation permit holder may renew the tilefish IFQ allocation permit. If NMFS does not receive full payment of a recoverable cost fee prior to the end of the cost-recovery billing period immediately following the one for which the fee was incurred, the subject IFQ allocation permit shall be deemed to have been voluntarily relinquished pursuant to paragraph (b)(7) of this section.

(4) *Periodic review of the IFQ program.* A formal review of the IFQ program must be conducted by the MAFMC within 5 years of the effective date of the final regulations. Thereafter, it shall be incorporated into every scheduled MAFMC review of the FMP (*i.e.,* future amendments or frameworks), but no less frequently than every 7 years.

73. Section 648.295 is revised to read as follows:

§ 648.295 Tilefish incidental trip limits.

(a) *Incidental trip limit for vessels not fishing under an IFQ allocation.* Any vessel of the United States fishing under a tilefish permit, as described at § 648.4(a)(12), is prohibited from possessing more than 500 lb (226.8 kg) of tilefish at any time, unless the vessel is fishing under a tilefish IFQ allocation permit, as specified at § 648.294(a). Any tilefish landed by a vessel fishing under an IFQ allocation permit, on a given fishing trip, count as landings under the IFQ allocation permit.

(b) *In-season closure of the incidental fishery.* The Regional Administrator will monitor the harvest of the tilefish incidental TAL based on dealer reports and other available information, and shall determine the date when the incidental tilefish TAL has been landed. The Regional Administrator shall

publish a notice in the **Federal Register** notifying vessel and dealer permit holders that, effective upon a specific date, the incidental tilefish fishery is closed for the remainder of the fishing year.

74. Section 648.296 is revised to read as follows:

§ 648.296 Recreational possession limit.

Any person fishing from a vessel that is not fishing under a tilefish vessel permit issued pursuant to § 648.4(a)(12), may land up to eight tilefish per trip. Anglers fishing onboard a charter/party vessel shall observe the recreational possession limit.

75. Section 648.297 is added to read as follows:

§ 648.297 Gear restricted areas.

No vessel of the United States may fish with bottom-tending mobile gear within the areas bounded by the following coordinates:

Canyon	N. Lat.			W. Long.		
	Degrees	Min	Seconds	Degrees	Min	Seconds
Oceanographer	40.0	29.0	50.0	68.0	10.0	30.0
	40.0	29.0	30.0	68.0	8.0	34.8
	40.0	25.0	51.6	68.0	6.0	36.0
	40.0	22.0	22.8	68.0	6.0	50.4
	40.0	19.0	40.8	68.0	4.0	48.0
	40.0	19.0	5.0	68.0	2.0	19.0
	40.0	16.0	41.0	68.0	1.0	16.0
	40.0	14.0	28.0	68.0	11.0	28.0
Lydonia	40.0	31.0	55.2	67.0	43.0	1.2
	40.0	28.0	52.0	67.0	38.0	43.0
	40.0	21.0	39.6	67.0	37.0	4.8
	40.0	21.0	4.0	67.0	43.0	1.0
	40.0	26.0	32.0	67.0	40.0	57.0
	40.0	28.0	31.0	67.0	43.0	0.0
Veatch	40.0	0.0	40.0	69.0	37.0	8.0
	40.0	0.0	41.0	69.0	35.0	25.0
	39.0	54.0	43.0	69.0	33.0	54.0
	39.0	54.0	43.0	69.0	40.0	52.0
Norfolk	37.0	5.0	50.0	74.0	45.0	34.0
	37.0	6.0	58.0	74.0	40.0	48.0
	37.0	4.0	31.0	74.0	37.0	46.0
	37.0	4.0	1.0	74.0	33.0	50.0
	36.0	58.0	37.0	74.0	36.0	58.0
	37.0	4.0	26.0	74.0	41.0	2.0

§ 648.298 [Reserved]

76. Section 648.298 is reserved.

77. Section 648.299 is added to read as follows:

§ 648.299 Framework specifications.

(a) *Within-season management action.* The MAFMC may, at any time, initiate action to add or adjust management measures if it finds that action is necessary to meet or be consistent with the goals and objectives of the Tilefish FMP.

(1) *Specific management measures.* The following specific management measures may be adjusted at any time through the framework adjustment process:

(i) Minimum fish size;

(ii) Minimum hook size;

(iii) Closed seasons;

(iv) Closed areas;

(v) Gear restrictions or prohibitions;

(vi) Permitting restrictions;

(vii) Gear limits;

(viii) Trip limits;

(ix) Adjustments within existing ABC control rule levels;

(x) Adjustments to the existing MAFMC risk policy;

(xi) Introduction of new AMs, including sub ACTs;

(xii) Annual specification quota setting process;

(xiii) Tilefish FMP Monitoring Committee composition and process;

(xiv) Description and identification of EFH;

(xv) Fishing gear management measures that impact EFH;

(xvi) Habitat areas of particular concern;

(xvii) Set-aside quotas for scientific research;

(xviii) Changes to the Northeast Region SBRM, including the CV-based performance standard, the means by which discard data are collected/obtained, fishery stratification, reports, and/or industry-funded observers or observer set-aside programs;

(xix) Recreational management measures, including the bag limit, minimum fish size limit, seasons, and gear restrictions or prohibitions; and

(xx) IFQ program review components, including capacity reduction, safety at sea issues, transferability rules, ownership concentration caps, permit and reporting requirements, and fee and cost-recovery issues.

(xxi) Measures that require significant departures from previously contemplated measures or that are otherwise introducing new concepts may require a formal amendment of the FMP instead of a framework adjustment.

(2) *Adjustment process.* If the MAFMC determines that an adjustment to management measures is necessary to meet the goals and objectives of the FMP, it will recommend, develop, and analyze appropriate management actions over the span of at least two MAFMC meetings. The MAFMC will provide the public with advance notice of the availability of the recommendation, appropriate justifications and economic and biological analyses, and opportunity to comment on the proposed adjustments prior to and at the second MAFMC meeting on that framework action.

(3) *MAFMC recommendation.* After developing management actions and receiving public testimony, the MAFMC will make a recommendation to the Regional Administrator. The MAFMC's recommendation must include supporting rationale and, if management measures are recommended, an analysis of impacts and a recommendation to the Regional Administrator on whether to issue the management measures as a final rule. If the MAFMC recommends that the management measures should

be issued as a final rule, it must consider at least the following factors and provide support and analysis for each factor considered:

(i) Whether the availability of data on which the recommended management measures are based allows for adequate time to publish a proposed rule, and whether regulations have to be in place for an entire harvest/fishing season;

(ii) Whether there has been adequate notice and opportunity for participation by the public and members of the affected industry in the development of the MAFMC's recommended management measures;

(iii) Whether there is an immediate need to protect the resource; and

(iv) Whether there will be a continuing evaluation of management measures adopted following their implementation as a final rule.

(4) *Regional Administrator action.* If the MAFMC's recommendation includes adjustments or additions to management measures and, after reviewing the MAFMC's recommendation and supporting information:

(i) If the Regional Administrator concurs with the MAFMC's recommended management measures and determines that the recommended management measures should be issued as a final rule based on the factors specified in paragraphs (a)(2) and (a)(3) of this section, the measures will be issued as a final rule in the **Federal Register**.

(ii) If the Regional Administrator concurs with the MAFMC's recommendation and determines that the recommended management measures should be published first as a proposed rule, the measures will be published as a proposed rule in the **Federal Register**. After additional public comment, if the Regional Administrator concurs with the MAFMC's recommendation, the measures will be issued as a final rule in the **Federal Register**.

(iii) If the Regional Administrator does not concur with the MAFMC's recommendation, the MAFMC will be notified in writing of the reasons for the non-concurrence.

(b) *Emergency action.* Nothing in this section is meant to derogate from the authority of the Secretary to take emergency action under section 305(e) of the Magnuson-Stevens Act.

§§ 648.1, 648.2, 648.4, 648.6, 648.7, 648.8, 648.12, 648.13, 648.14, 648.15, and 648.94 [Amended]

78. In the table below, for each section in the left column, remove the text from whenever it appears throughout the section and add the text indicated in the right column.

Section	Remove	Add	Frequency
§ 648.1(a)	surf clam	surfclam	2
§ 648.2	surf clam	surfclam	9
§ 648.2	§ 648.70	§ 648.74	1
§ 648.2	§ 648.291(e)(1)	§ 648.294(e)(1)	2
§ 648.4(a)	surf clam	surfclam	4
§ 648.4(a)(3)	§ 648.105	§ 648.106	1
§ 648.4(a)(3)(i)(A)	§ 648.105	§ 648.106	1
§ 648.4(a)(3)(i)(*L*)(*ii*)	§ 648.105	§ 648.106	1
§ 648.4(a)(3)(i)(*L*)(*iii*)	§ 648.104(b)(1)	§ 648.108(b)(1)	1
§ 648.4(a)(5)(ii)	§ 648.21	§ 648.22	1
§ 648.4(a)(6)	§ 648.125	§ 648.128	1
§ 648.4(a)(12)	§ 648.291	§ 648.294	1
§ 648.4(a)(12)	§ 648.293	§ 648.295	1
§ 648.4(a)(12)(i)	§ 648.295	§ 648.296	1
§ 648.6(a)(1)	surf clam	surfclam	2
§ 648.6(c)	surf clam	surfclam	1
§ 648.7(b)(1)(ii)	surf clam	surfclam	4
§ 648.7(b)(2)(ii)	§ 648.291(a)	§ 648.294(a)	1
§ 648.8(e)	surf clam	surfclam	1
§ 648.12	surf clam	surfclam	1
§ 648.12(c)	surf clams	surfclams	1
§ 648.13(i)(2)(iii)	§ 648.123(a)(2), (3), and (4)	§ 648.125 (a)(2), (3), and (4)	1
§ 648.14(g)(1)	§ 648.26	§ 648.27	1
§ 648.14(g)(1)(iii)	§ 648.21(g)	§ 648.22(g)	1
§ 648.14(g)(2)	§ 648.21(g)	§ 648.22(g)	1
§ 648.14(g)(2)(i)	§ 648.21	§ 648.22	1
§ 648.14(g)(2)(ii)(C)	§ 648.25	§ 648.26	1
§ 648.14(g)(3)	§ 648.21(g)	§ 648.22(g)	1
§ 648.14(g)(3)(i)	§ 648.21(d)	§ 648.22(d)	1
§ 648.14(h)	§ 648.21(g)	§ 648.22(g)	1
§ 648.14(n)(1)	§ 648.21(g)	§ 648.22(g)	1
§ 648.14(n)(1)(i)	§ 648.105	§ 648.106	1
§ 648.14(n)(1)(i)	§ 648.102	§ 648.105	1
§ 648.14(n)(1)(ii)(B)	§ 648.105	§ 648.106	1
§ 648.14(n)(1)(iii)	§ 648.104	§ 648.108	1
§ 648.14(n)(1)(iii)	§ 648.105(a)	§ 648.106(a)	1
§ 648.14(n)(2)	§ 648.100(f)	§ 648.102(e)	1
§ 648.14(n)(2)(i)(A)	§ 648.104	§ 648.108	1
§ 648.14(n)(2)(i)(B)	§ 648.105(d)	§ 648.106(d)	1
§ 648.14(n)(2)(i)(B)	§ 648.104(a)	§ 648.108(a)	1
§ 648.14(n)(2)(i)(B)	§ 648.104(b)	§ 648.108(b)	1
§ 648.14(n)(2)(iii)(A)	§ 648.104	§ 648.108	1
§ 648.14(n)(2)(iii)(A)	§ 648.104(e)	§ 648.108(e)	1
§ 648.14(n)(2)(iii)(B)	§ 648.104	§ 648.108	1
§ 648.14(n)(2)(iii)(B)	§ 648.104(f)	§ 648.108(f)	1
§ 648.14(n)(2)(iii)(C)	§ 648.104(b)(1)	§ 648.108(b)(1)	1
§ 648.14(n)(2)(iii)(C)	§ 648.104	§ 648.108	1

Section	Remove	Add	Frequency
§ 648.14(n)(2)(iii)(C)(*3*)	§ 648.100(f)	§ 648.102(e)	1
§ 648.14(n)(2)(iii)(C)(*3*)(*ii*)	§ 648.105	§ 648.106	1
§ 648.14(n)(2)(iii)(C)(*3*)(*iii*)	§ 648.102	§ 648.105	1
§ 648.14(o)(1)	§ 648.120(e)	§ 648.122(e)	1
§ 648.14(o)(1)(ii)(A)	§ 648.122(g)	§ § 648.124 and 648.127	1
§ 648.14(o)(1)(ii)(D)	§ 648.123	§ 648.125	2
§ 648.14(o)(1)(ii)(E)	§ 648.120(b)(3), (4), and (7)	§ 648.122(a)	1
§ 648.14(o)(1)(iii)	§ 648.124	§ 648.126	1
§ 648.14(o)(1)(v)	§ 648.123	§ 648.125	1
§ 648.14(o)(1)(vi)	§ 648.122 (a) or (b)	§ 648.124 (a) or (b)	1
§ 648.14(o)(1)(vi)	§§ 648.122 and 648.123(a)	§§ 648.124 and 648.125(a)	1
§ 648.14(o)(1)(vi)	§ 648.123(b)	§ 648.125(a)(5)	1
§ 648.14(o)(2)	§ 648.120(e)	§ 648.122(e)	1
§ 648.14(o)(2)(i)	§ 648.123	§ 648.125	2
§ 648.14(o)(2)(i)(C)	§ 648.122	§ 648.124	1
§ 648.14(o)(2)(ii)(B)(*3*)	§ 648.120(e)	§ 648.122(e)	1
§ 648.14(o)(2)(ii)(B)(*3*)(*ii*)	§ 648.125	§ 648.128	1
§ 648.14(o)(2)(ii)(B)(*3*)(*iii*)	§ 648.122	§ 648.124	1
§ 648.14(o)(2)(ii)(B)(*3*)(*v*)	§ 648.124(b)	§ 648.126(b)	1
§ 648.14(p)(1)	§ 648.140(e)	§ 648.142(d)	1
§ 648.14(p)(1)(i)	§ 648.142	§ 648.146	1
§ 648.14(p)(1)(v)	§ 648.143	§ 648.147	1
§ 648.14(p)(2)	§ 648.140(e)	§ 648.142(d)	1
§ 648.14(p)(2)(ii)(B)	§ 648.140	§ 648.142	1
§ 648.14(p)(2)(ii)(D)(*3*)	§ 648.140(e)	§ 648.142(d)	1
§ 648.14(p)(2)(ii)(D)(*3*)(*iii*)	§ 648.142	§ 648.146	1
§ 648.14(q)	§ 648.160(h)	§ 648.162(g)	1
§ 648.14(q)(2)(i)	§ 648.161(b)	§ 648.163(b)	1
§ 648.14(q)(2)(ii)	§ 648.161(a)	§ 648.163(a)	1
§ 648.14(u)(2)(ii)	§ 648.293	§ 648.295	1
§ 648.14(u)(2)(ii)	§ 648.291(a)	§ 648.294(a)	1
§ 648.14(u)(2)(iii)	§ 648.291(a)	§ 648.294(a)	1
§ 648.14(u)(2)(vi)	§ 648.291(d)(3) or § 648.291	§ 648.294(d)(3) or § 648.295	1
§ 648.15(b)(1)	§ 648.70	§ 648.74	1
§ 648.15(b)(2)	§ 648.76	§ 648.78	1
§ 648.94(c)(3)(vi)	§ 648.104(a)(1)	§ 648.108(a)(1)	1

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Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 201, 310, and 352
Sunscreen Drug Products for Over-the-Counter Human Use; Final Rules and Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 310

[Docket No. FDA–1978–N–0018] (Formerly Docket No. 1978N–0038)

RIN 0910–AF43

Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing this document to address labeling and effectiveness testing for certain over-the counter (OTC) sunscreen products containing specified active ingredients and marketed without approved applications. This document addresses labeling and effectiveness testing issues raised by the nearly 2,900 submissions that we received in response to the sunscreen proposed rule of August 27, 2007 (2007 proposed rule). The document also identifies specific claims that render a product that is subject to this rule misbranded or would not be allowed on any OTC sunscreen product marketed without an approved application. The document does not address issues related to sunscreen active ingredients or certain other issues regarding the GRASE determination for sunscreen products. The document requires OTC sunscreen products to comply with the content and format requirements for OTC drug labeling contained in the 1999 Drug Facts final rule (published in the **Federal Register** of March 17, 1999, by lifting the delay of implementation date for that rule that we published on September 3, 2004).

DATES: *Effective Date:* This final rule is effective June 18, 2012. For additional information concerning this effective date, see section X in the preamble of this document. The incorporation by reference of a certain publication listed in this rule is approved by the Director of the Federal Register as of June 18, 2012.

Compliance Date: The compliance date for all products subject to this final rule with annual sales less than $25,000 is June 17, 2013. The compliance date for all other products subject to this final rule is June 18, 2012.

Implementation date: FDA is lifting the delay of implementation date for § 201.66 as published at 69 FR 53801, September 3, 2004.

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SUPPLEMENTARY INFORMATION:

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I. Overview of Document

A. Rulemaking History

This section of the document does not discuss every regulatory action associated with OTC sunscreen products. It highlights the major regulatory actions that are related to the regulatory actions being taken in this document. For a complete list of all regulatory actions associated with OTC sunscreen products, please refer to our Web site: *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/ucm072134.htm.*

In the **Federal Register** of May 12, 1993 (58 FR 28194), we published a proposed rule for OTC sunscreen products that identified active ingredients we tentatively considered to be generally recognized as safe and effective (GRASE), as well as associated labeling and sun protection factor (SPF) testing to be required for these OTC sunscreen products (the 1993 proposed rule). The SPF test and corresponding labeling reflect the level of protection against sunburn, which is caused primarily by UVB radiation. The 1993 proposed rule also explained the importance of protection against UVA radiation (58 FR 28194 at 28232 and 28233). The proposed rule referenced published UVA test methods but did not propose a specific method (58 FR 28194 at 28248 to 28250). Rather, the proposed rule stated that a sunscreen product could be labeled as ''broad spectrum,'' or labeled with a similar statement, if it protected against UVA radiation as demonstrated by one of the published UVA tests or a similar test.

In April 1994, we reopened the administrative record to allow additional submissions concerning UVA-related issues. We also announced a public meeting to be held in May 1994 to discuss UVA testing procedures (59 FR 16042, April 5, 1994). We held the public meeting to gather more information to help us determine the most appropriate UVA test method and labeling.

In November 1997, Congress enacted the Food and Drug Administration Modernization Act of 1997 (FDAMA), which addressed OTC sunscreen products among other FDA issues. Section 129 of FDAMA stated that ''not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall issue regulations for over-the-counter sunscreen products for the prevention or treatment of sunburn.'' We then determined that the GRASE active ingredients, SPF testing requirements, and related labeling were issues that we could finalize within the timeframe set by FDAMA. Because we had not previously proposed specific UVA testing and labeling requirements, we did not have sufficient time to finalize these UVA requirements within the FDAMA timeframe.

In the **Federal Register** of May 21, 1999, we published a final rule for OTC

sunscreen products (64 FR 27666). The 1999 sunscreen final rule added the sunscreen monograph (regulations) in part 352 (21 CFR part 352) and included an effective date of May 2001. The 1999 sunscreen final rule stated that we would publish a proposed rule outlining UVA testing and labeling requirements at a future date. In 2000, we extended the effective date for the 1999 sunscreen final rule to December 2002 (65 FR 36319, June 8, 2000).

In December 2001, we stayed the December 2002 effective date of the 1999 sunscreen final rule indefinitely. We took this action because we planned to revise part 352 to add UVA testing and labeling requirements so that OTC sunscreen products would be tested and labeled for both UVB and UVA radiation protection. We included these revisions in a proposed rule that published in the **Federal Register** of August 27, 2007 (72 FR 49070). The 2007 proposed rule identified UVA testing and labeling that we proposed should be required for all OTC sunscreen products. The proposed rule also revised SPF testing and corresponding labeling from the 1999 final rule. The proposed rule did not lift the existing stay of the effective date for part 352.

On September 3, 2004 (69 FR 53801), we delayed until further notice the implementation date for the Drug Facts final rule (64 FR 13254, March 17, 1999) (21 CFR 201.66) for OTC sunscreen products. The Drug Facts final rule (21 CFR 201.66) establishes general labeling format and content requirements for all OTC drugs. We explained that we postponed the implementation date for general Drug Facts labeling requirements for sunscreens because we did not expect to issue the sunscreen final rule containing UVA testing and product-specific labeling requirements (*i.e.,* this document) by the Drug Facts implementation date of May 2005. Therefore, we delayed the implementation date until further notice to prevent sunscreen product manufacturers from having to relabel their products at two closely related time intervals, as initially required by the 1999 Drug Facts final rule and the 1999 sunscreen final rule.

B. Scope of This Document

This final rule establishes the labeling and testing requirements for OTC sunscreen products containing specific ingredients or combinations of ingredients and marketed without an approved application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) (the FD&C Act). The requirements in this final rule will help ensure that these currently marketed sunscreen products are appropriately labeled and tested for both UVA and UVB protection. In addition, the requirements in this final rule will help ensure the proper use of these sunscreens and greater consumer protection from the damaging effects of UV radiation. This final rule also identifies claims that render a product that is subject to this rule misbranded or are not allowed on any OTC sunscreen drug product marketed without an approved application.

As described in the previous section of this document, we issued the 2007 proposed rule as a proposed amendment to the sunscreen monograph requirements in 21 CFR part 352 primarily to establish UVA testing and labeling requirements so that all OTC sunscreen products marketed under the sunscreen monograph would be tested and labeled for both UVB and UVA radiation protection. Sunscreen active ingredients, UVB testing, UVB labeling, and other conditions under which sunscreens would be considered GRASE and not misbranded had been addressed in the 1999 (stayed) final rule. In response to the 2007 proposed rule, however, we received submissions from the public concerning all aspects of the sunscreen monograph (*i.e.,* the conditions specified in the 1999 final rule and the 2007 proposed rule). As discussed further in this section, some of the issues regarding the monograph conditions raised in the public submissions will require further evaluation by us. Therefore, we are not issuing a final monograph with GRASE conditions for sunscreens in this document. Instead, we are publishing this final rule establishing labeling and the effectiveness testing upon which it relies, which applies to the same sunscreens that were the subject of the 2007 proposed rule to amend the monograph, because it is in the best interest of public health to publish this final rule while we work on remaining issues that need to be addressed in order to publish a final monograph. This labeling will help ensure that these products are not misbranded by providing specific indications, directions, warnings, and other important information to help consumers select and use them appropriately.

In this final rule, then, we are codifying in 21 CFR part 201 requirements for OTC sunscreen products containing specified active ingredients and marketed without approved applications under section 505 of the FD&C Act (21 U.S.C. 355) (hereafter referred to as ''covered'' products). With respect to these covered products, this new section 21 CFR 201.327 includes requirements for labeling and the effectiveness testing upon which it relies. Because we have not yet resolved all of the issues regarding conditions under which sunscreens are GRASE and not misbranded, the stay of 21 CFR part 352 remains in effect. Although we are not yet codifying these labeling and related effectiveness testing provisions in the monograph regulation, they do embody the agency's current determination on appropriate regulation of these aspects of sunscreens that were previously identified as falling within the monograph in part 352, and supersede the prior approach embodied in the never-effective provisions of 21 CFR part 352 subparts C and D. While this rule does not lift the stay of part 352, we are lifting the delay of implementation date for the Drug Facts labeling requirements of 21 CFR 201.66. In addition, this rule codifies certain specific claims that render a covered product misbranded or are not allowed on any OTC sunscreen drug product marketed in the United States without an approved application.

We note that all provisions of new 21 CFR 201.327 and the amendments to 310.545 included in this rule apply only to the aforementioned covered products, and references in this document to ''covered'' products recognize this limitation. Manufacturers of sunscreen products that are already being marketed pursuant to an approved application can contact FDA's Center for Drug Evaluation and Research to discuss supplemental submissions that would enable them to include labeling on their products like that specified in this final rule.

C. Issues Outside the Scope of This Document

There are a number of issues that were raised in public submissions responding to the 2007 proposed rule that are outside the scope of this document. The issues fall into two categories:

- GRASE determination for sunscreen products and active ingredients
- Issues affecting multiple OTC drug monographs

As explained below, in this document, we are not addressing these issues related to determining the GRASE status of sunscreen products or sunscreen active ingredients and are not addressing the issues described below affecting multiple OTC drug monographs.

1. Issues Regarding GRASE Determination for Sunscreen Products and Active Ingredients

A large number of submissions on the 2007 proposed rule raised issues related to the conditions that define what constitutes a GRASE finished OTC sunscreen product, irrespective of its active ingredients. These included over 1000 submissions requesting that we limit the monograph to sunscreens that offer broad spectrum protection and have SPF values of 15 or higher. Because this final rule is a labeling rule, and not a monograph, we do not address these issues here but plan to address them in future rulemakings regarding the monograph and conditions for general recognition of safety and effectiveness.

This rule also does not address issues related to the GRASE status of sunscreen active ingredients that are included in the 2007 proposed rule (proposed 21 CFR 352.10 and 352.20). We received 20 submissions raising questions about the safety of ingredients in sunscreens (Ref. 1). Ten of the submissions specifically asked that we ensure that none of the ingredients are carcinogenic. Others asked that we ensure that all ingredients in sunscreens are safe without citing a specific concern. We intend to address carcinogenicity and other safety considerations related to sunscreen active ingredients in a future rulemaking.

We also received submissions requesting that we increase the GRASE concentration of avobenzone from 3 percent to 5 percent (Ref. 1). Another submission points out that there are two USP [1] monographs for zinc oxide:

- Zinc oxide (Ref. 2)
- Zinc oxide neutral (Ref. 3)

The submission would like us to clarify that zinc oxide in OTC sunscreen products can meet the specifications of either USP monograph (Ref. 1). We intend to address all of these issues regarding GRASE determination for sunscreen active ingredients in future rulemakings.

In addition, we received two submissions requesting that we classify three new ingredients not previously marketed in the United States as GRASE: bemotrizinol, bisoctrizole, and octyl triazone (Ref. 1). We found these active ingredients eligible for review under the OTC drug monograph system in 2003 (octyl triazone) and 2005 (bemotrizinol and bisoctrizole) (68 FR 41386, July 11, 2003, and 70 FR 72449, December 5, 2005). We are currently reviewing the safety and effectiveness data submitted for these and other sunscreen active ingredients found eligible for potential addition to the monograph. When we complete our review, we will issue proposed rules stating our tentative conclusions on the safety and effectiveness of all of these ingredients.

2. Issues Affecting Multiple OTC Drug Monographs

This final rule also does not address three issues raised in response to the 2007 sunscreen proposed rule that are not specific to sunscreen products. Because these issues apply more generally to multiple categories of OTC drug products, we are not addressing these issues in this final rule, which is limited to OTC sunscreen products.

The first issue concerns the inclusion of expiration dates on sunscreen labels. We received 12 submissions requesting that we require OTC sunscreen products to be labeled with an expiration date (Ref. 1). Currently, regulations in 21 CFR 211.137(h) do not require that an expiration date be included in labeling if an OTC drug product does not have any dosage limitations and is stable for at least 3 years. This regulation applies to many OTC drug products, including sunscreen products. Any modification of the existing regulations would require publication of a proposed rule addressing all OTC drug products affected by the expiration date regulations.

The second issue concerns the term ''final monograph.'' One submission argued that we should not use this term because it is inaccurate (Ref. 1). As the submission states, ''FDA is to continually evaluate products, so nothing is ever finalized.'' This issue applies to monographs representing all categories of OTC drug products. Therefore, we are not addressing the issue in this document.

The third issue concerns the country of origin listing for all ingredients (*i.e.,* both active and inactive ingredients) on a sunscreen drug product. We received a submission requesting that we provide the country of origin for each ingredient. The submission also requested that manufacturers be required to provide specific details about what each ingredient does in the product. This issue applies to all OTC drug products and, therefore, we are not addressing it in this document.

D. Enforcement Policy

As noted, no final monograph is currently in effect for OTC sunscreen drug products, and in its absence, questions may arise regarding FDA's enforcement policy for OTC sunscreen products marketed without approved applications. To clarify expectations for industry, elsewhere in this issue of the **Federal Register**, we are announcing the availability of a draft guidance document, explaining the agency's intended enforcement policy for these products until a final sunscreen monograph becomes effective.

E. Summary of Major Revisions to the Labeling and Effectiveness Testing Included in the 2007 Proposed Rule

In response to the 2007 proposed rule, we received almost 2,900 submissions from the public. Of these submissions, over 2,500 expressed general support for the proposed rule and urged us to finalize and implement the new rule quickly. Three hundred twenty-five of the submissions raised approximately 90 specific issues related to the proposed rule. We have addressed the issues specifically relating to labeling and effectiveness testing in this final rule. Based on the submissions received, and the information and data included in those submissions or otherwise available to us, we have re-evaluated our position on several issues in the 2007 proposed rule and made several changes to our proposed labeling and testing requirements. Tables 1, 2, 4, and 5 in this document summarize the labeling and effectiveness testing requirements included in the 2007 proposed rule as well as the labeling and effectiveness testing required by this final rule:

- Table 1: PDP Labeling (discussed in section III)
- Table 2: Drug Facts Labeling (discussed in section IV)
- Table 4: SPF Test (discussed in section VI)
- Table 5: Broad Spectrum Test (discussed in section VIII)

Rather than summarizing all of the revisions to the labeling and testing included in the 2007 proposed rule, we are highlighting what we consider to be the most important revisions in this section of the document.

We made the following changes to the proposed labeling:

1. The proposed UVA ''star rating'' is not required on the PDP.

2. A combined ''Broad Spectrum SPF'' statement is required on the PDP for sunscreen products that pass the broad spectrum test established in new 21 CFR 201.327(j). To pass the broad spectrum test, the amount of UVA protection must increase as the SPF value increases.

3. For sunscreen products that pass the broad spectrum test established in new 21 CFR 201.327(j) and have SPF

[1] United States Pharmacopeia.

values of 15 or higher in accordance with the SPF test in 21 CFR 201.327(i):

a. The ''Sun Alert'' warning proposed as the first warning in 2007 is not required (Warning proposed located in 21 CFR 352.52(c)(1)).

b. A new indication statement may be included to inform consumers that using the product ''as directed with other sun protection measures (see Directions [in bold italic font]) decreases the risk of skin cancer and early skin aging caused by the sun.''

c. A new direction statement has been added informing consumers that exposure to the sun increases the risk of skin cancer and early skin aging and providing a list of specific sun protection measures that can decrease this risk.

4. For any OTC sunscreen product that does not pass the broad spectrum test in 21 CFR 201.327(j), or that are broad spectrum with an SPF value less than 15, this final rule, like the 2007 proposed rule, requires that the first warning indicate the adverse consequences of spending time in the sun. The wording of this warning has been revised to state, ''Skin Cancer/Skin Aging Alert [in bold font]: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not [in bold font] skin cancer or early skin aging.''

We also made the following changes to the effectiveness testing proposed in 2007:

1. The number of subjects required in the SPF test has been reduced from 20 subjects to 10 subjects.

2. One in vitro test is required to demonstrate broad spectrum protection rather than the two previously proposed tests (an in vitro test and an in vivo test).

3. The broad spectrum test is a pass/fail test based on the critical wavelength value of 370 nm [2].

II. Administrative and Other Issues

Some of the submissions that we received following publication of the 2007 proposed rule made the following requests involving administrative issues (Ref. 1):

- Extend the comment period of the 2007 proposed rule.
- Lift the stay on 21 CFR part 352, imposed in 2001 (66 FR 67485).
- Allow interim marketing of products containing avobenzone with ensulizole and avobenzone with zinc oxide.
- Set an effective date for this final rule other than the 18 months proposed in the 2007 proposed rule.
- Revise the preemption language included in the 2007 proposed rule by deleting any references regarding the rule's potential preemption of State tort law.

Our positions on these issues are discussed in the remainder of this section of the document.

All of the requests to extend the comment period were submitted before the November 28, 2007 **Federal Register** notice in which we extended the comment period of the 2007 proposed rule (72 FR 67264). In that notice, we extended the close of the comment period from November 26, 2007, to December 26, 2007. We have not received any more requests to extend the comment period since December 2007.

With regard to requests to lift the stay of 21 CFR part 352 (the OTC sunscreen monograph), as already discussed, our 2007 proposed rule anticipated amending the testing and labeling provisions of that monograph and subsequently lifting the stay. However, comments received on the 2007 proposed rule not only addressed labeling and effectiveness testing for final sunscreen formulations, but also raised other issues about the monograph conditions for OTC sunscreen products that require further consideration. As a result, we are not finalizing amendments to part 352 at this time nor lifting the stay placed on that section as enacted in 1999 (66 FR 67485). Rather, this final rule establishes in 21 CFR 201.327 labeling requirements and the effectiveness testing upon which it relies for covered OTC sunscreen drug products. We intend to lift the stay on part 352 when we reach our final conclusions on the conditions under which sunscreen products are GRASE and not misbranded, including a determination regarding sunscreen active ingredients, and publish a revised final monograph. In the interim, the labeling and effectiveness testing provisions of this rule apply to covered OTC sunscreen products.

We received a request that we allow interim marketing of avobenzone combinations in proposed § 352.20(a)(2) prior to issuing a final rule for part 352. Subject to our enforcement discretion, we will continue to allow the marketing of avobenzone combinations provided for in the 1999 sunscreen final rule. However, we are not allowing marketing of the additional avobenzone combinations discussed in the 2007 proposed rule until we reach a final conclusion on the GRASE determination for sunscreen active ingredients and combinations of those ingredients.

We are requiring that this final rule become effective in 1 year, even though we considered 18 months in the 2007 proposed rule (72 FR 49070 at 49110). We are allowing products with annual sales less than $25,000 to comply with this rule in 2 years, as stated in the 2007 proposed rule. In response to the proposed rule, we received one submission arguing that we should require this final rule to become effective in 1 year (Ref. 1). The submission stated that a later effective date would have a negative public health impact. We received eight submissions arguing that we should extend the effective date from the proposed 18 months to 3 years (Ref. 1). The submissions listed the following reasons for allowing more than 18 months:

- Repackaging
- Relabeling
- Testing/retesting
- Removing products from market
- Impact on small businesses

The most common argument was that more time would be needed to test/retest OTC sunscreen products for broad spectrum protection in accordance with both the in vitro and in vivo UVA test methods included in the proposed rule.

We agree with the submission which stated that it would be beneficial for consumers to have this rule become effective within 1 year. As explained in section VIII.A of this document, we are not requiring manufacturers to demonstrate broad spectrum protection by conducting in vivo and in vitro tests. This final rule requires that manufacturers conduct only the simpler and less expensive nonclinical in vitro test to demonstrate broad spectrum protection. In vitro tests are substantially shorter than in vivo tests. Therefore, we are setting an effective date for this rule 1 year from the date of publication in the **Federal Register**. However, we are providing two years for all products with annual sales less than $25,000 to comply with this rule. In addition, in order to ensure that limited testing laboratory capacity does not result in sunscreen shortages during the transition to the new rule, we intend to exercise enforcement discretion for a period of time with regard to the SPF test for certain OTC sunscreen products on the market by June 17, 2011 (see our draft guidance entitled ''Guidance for Industry: Enforcement Policy—OTC Sunscreen Drug Products Marketed Without An Approved Application'' announced elsewhere in this issue of the **Federal Register**).

The submissions stating that additional time is necessary for

[2] Nanometers.

repackaging and relabeling did not submit any information or data to support these arguments (Ref. 1). The argument that more than 18 months is needed to remove non-compliant products from the market is not valid. In the 2007 proposed rule, we indicated that sunscreen products which are already distributed by the effective date of the final rule would not be expected to be relabeled or retested in conformity with the final rule conditions unless these products were subsequently relabeled or repackaged after the effective date (72 FR 49070 at 49109). Consistent with this statement, we do not expect non-compliant products introduced or delivered for introduction into interstate commerce prior to the compliance dates specified for this final rule to be removed from the market.

We received a submission that expressed concern about the agency's preemption discussion in the 2007 proposed rule (72 FR 49070 at 49109 and 49110) and requested that we delete any discussion regarding the rule's potential preemption of State tort law (Ref. 1). The submission claimed that we exceeded our authority when we stated that section 751(a) of the FD&C Act displaces both State legislative requirements and State common law duties. The submission argued that Congress intended to preserve State common law claims by including section 51(e), which exempts State product liability claims from express preemption under section 751(a) of the FD&C Act. The commenter appears to have construed our statement in a way that would nullify section 751(e) of the FD&C Act. We did not intend to suggest that section 751(a) of the FD&C Act preempts State product liability claims, whether based on State legislative enactments or common law, because section 751(e) exempts such actions from the express preemption provision in section 751(a). However, it is important to note that section 751(e) of the FD&C Act exempts only those common law claims that are based on State product liability law. Our revised preemption discussion in section XII remains consistent with applicable law.

The submission also requested that we delete any references to implied preemption. In this final rule, we have omitted any statement regarding implied preemption because, although implied preemption may arise, such scenarios are necessarily case-specific. Section XII of this document makes clear that the sole statutory provision giving preemptive effect to the final rule is section 751 of the FD&C Act.

III. Principal Display Panel (PDP) Labeling

In response to the 2007 sunscreen proposed rule, we received 45 submissions requesting that we revise the proposed principal display panel (PDP) labeling (Ref. 1). We are revising the PDP labeling based, in part, on these submissions (see table 1 of this document). We have decided that the PDP labeling included in this document will simplify the purchase decision for consumers by allowing them to more easily find important information included on the PDP.

TABLE 1—SUMMARY OF PDP LABELING IN THE 2007 PROPOSED RULE AND THIS FINAL RULE USING A BROAD SPECTRUM SPF 30 WATER RESISTANT SUNSCREEN PRODUCT AS EXAMPLE A AND AN SPF 6 SUNSCREEN THAT IS NOT BROAD SPECTRUM AND NOT WATER RESISTANT AS EXAMPLE B

Labeled information	2007 Proposed rule	This final rule
Effectiveness Rating [1]	Example A: "UVB SPF 30 High" "UVA ★★★☆ High" Example B: "UVB SPF 6 Low" "No UVA Protection"	Example A: "Broad Spectrum SPF 30" Example B: "SPF 6"
Water Resistance	Example A: "Water Resistant" Example B: No statement on water resistance	Example A: "Water Resistant (40 minutes)" Example B: No statement on water resistance
Educational Statement	Examples A & B: "UV rays from the sun are made of UVB and UVA. It is important to protect against both UVA and UVB rays."	Examples A & B: No educational statement

[1] The UVA rating in the 2007 proposed rule is a four-tier rating (low, medium, high, highest). The UVA testing in this final rule is pass/fail—a product is either allowed or not allowed to include a broad spectrum statement depending on results of the test described in new 21 CFR 201.327(j) (see section VIII of this document).

A. SPF Statement

In the 2007 sunscreen proposed rule, we proposed redefining the acronym ''SPF'' as the ''sunburn protection factor.'' We also proposed that the term ''UVB SPF'' would be required on the PDP of all OTC sunscreen products (proposed 21 CFR 352.50(a)). This term would be followed by the numerical value determined from SPF testing and one of the following descriptors: ''low,'' ''medium,'' ''high,'' or ''highest.'' For example, a sunscreen product could have contained the statement ''UVB SPF 40 High'' on the PDP.

We received 12 submissions regarding the SPF statement in response to the 2007 sunscreen proposed rule (Ref. 1). Collectively, the submissions made the following requests:

1. Do not change the definition of SPF to ''sunburn protection factor''
2. Remove UVB from ''UVB SPF''
3. Redefine the ''highest'' product category descriptor to include SPF 50
4. Require SPF values expressed in multiples of 5
5. Label SPF as the percent of UVB radiation screened

As discussed in the remainder of this section, we agree with the first and second requests, but are not granting the other three requests.

In this final rule, unlike the 2007 proposed rule, we have no express definitional section. However, we identify ''SPF'' as an abbreviation for ''sun protection factor'' in new 21 CFR 201.327(a)(1), and use it consistently in this way throughout the rule. This use of the term SPF is identical to the definition in the 1999 stayed sunscreen final rule (64 FR 27666). For products that are not broad spectrum, the term ''SPF'' will appear on the PDP with the numerical SPF value calculated according to the test method in new 21

CFR 201.327(i). For broad spectrum sunscreen products, the term ''Broad Spectrum SPF'' will appear on the PDP along with the numerical SPF value calculated according to the test method in new 21 CFR 201.327(i).

The term ''UVB'' will not be required as part of the SPF statement. We are also not requiring the descriptor (*e.g.,* ''high'' or ''low''). We included these two requirements in the 2007 proposed rule because we had concluded that the requirements would help consumers understand the side-by-side SPF numerical rating in conjunction with the UVA star rating, which included the term ''UVA'' and the same descriptors (72 FR 49070 at 49084). As discussed in section III.B of this document, the UVA star rating is not being included in this final rule, and as discussed below, we have concluded that neither the term ''UVB'' nor the descriptor is necessary for consumers to understand the effectiveness statement.

Neither the term ''UVB'' nor a descriptor (*e.g.* ''low'' or ''high'') had been included on sunscreen labels prior to our 2007 proposal, and consumers had been able to make purchase and use decisions based on SPF values alone. Under this final rule, the SPF value will be expressed on the PDP by including the term ''SPF,'' followed by the numerical value determined from the SPF test, similar to how it has appeared on the labels of OTC sunscreen products for more than 30 years. As described in section III.B of this document, for products passing the critical wavelength test in new 21 CFR 201.327(j), the SPF value statement will be expressed as ''Broad Spectrum SPF'' followed by the numerical SPF value calculated according to the test method in 21 CFR 201.327(i).

We received five submissions objecting to the definition of SPF as ''sunburn protection factor'' and only one submission supporting the definition (Ref. 1). The submissions objecting to the definition argued that, if the term ''sunburn protection factor'' is used, consumers may mistakenly assume that a higher SPF value means a higher probability of sunburn. Additionally, they argued that sunscreen products protect against various harmful effects of sun exposure, such as early skin aging and skin cancer, in addition to protecting against sunburn. Some submissions suggested that the term ''sunburn protection factor'' will lead consumers with darker skin to assume that they do not need sunscreen products because they do not burn easily (Ref. 1).

We agree with the arguments provided by the submissions suggesting that the term ''sunburn protection factor'' may be misleading. In the 2007 sunscreen proposed rule, we revised the definition of SPF from ''sun protection factor'' to ''sunburn protection factor'' because we thought that the new definition was more descriptive of what an SPF value represents (72 FR 49070 at 49077). The SPF value is determined from a clinical test with sunburn as the endpoint. However, for broad spectrum sunscreen products, the SPF statement also serves as a relative measure of the magnitude of broad spectrum protection (Ref. 4). In this final rule, while we do not codify a separate definitional section, we continue to use the term ''SPF'' to mean ''sun protection factor,'' as we had done in the 1999 final rule (21 CFR 201.327(a)(1)).

In this final rule, we are also revising the effectiveness statement so that the term ''UVB'' is not required before the term ''SPF,'' as proposed in the 2007 proposed rule (proposed 21 CFR 352.50(a)). We received six submissions requesting this revision (Ref. 1). These submissions argued that ''UVB SPF'' is an incorrect representation of the SPF value determined from a test using a solar stimulator that emits both UVA and UVB radiation. The submissions point out that sunburn is not caused solely by UVB radiation. It is well known that UVA radiation contributes up to 20 percent of the skin's sunburn response (Refs. 5 and 6). One submission points out that if a sunscreen product blocked 100 percent of the incident UVB radiation and none of the erythemally effective UVA radiation, the sunscreen product would have SPF values no higher than 11 (if only 9 percent or 1/11 of UV radiation reaches the skin) (Ref. 4).

We agree that UVA radiation contributes to the development of sunburn. Although the contribution of UVA to sunburn is less than UVB, it is still significant (Ref. 5). Further, as stated in the submissions, protection against UVA radiation is necessary to achieve higher SPF values (Ref. 5). We proposed including the term ''UVB'' in the SPF statement in the 2007 proposed rule to help consumers understand that the SPF effectiveness rating is different from the UVA effectiveness (star) rating being proposed (72 FR 49070 at 49084). However, as discussed elsewhere in this final rule we are not requiring a UVA effectiveness rating on the PDP (see section III.B.). Therefore, the term ''UVB'' is not necessary as part of the SPF statement. In this final rule, we are not requiring the term ''UVB'' be placed before the term ''SPF.''

In the 2007 sunscreen proposed rule, we stated that the SPF value should be followed by one of the descriptors ''low,'' ''medium,'' ''high,'' or ''highest'' (proposed 21 CFR 352.50(a)). The proposed descriptors were included to help consumers understand the SPF value because the label would have included identical descriptors for the UVA star rating. As discussed in section III.B. of this document, we are not requiring a UVA effectiveness rating on the PDP. Therefore, descriptors are no longer required to distinguish the SPF value from the UVA rating on a sunscreen label. Because we are not requiring a descriptor after the SPF value on the PDP in this document, the request to include SPF 50 sunscreen products in the ''highest'' category is no longer relevant.

We received two other requests for revision to the SPF statement with which we do not agree. First, a submission stated that SPF values should only be labeled in multiples of five to be consistent with SPF labeling recommendations by the European Commission (Ref. 7). Second, one request from a submission suggested that SPF values should be expressed as the percent of UV absorption. The submission argued that the current SPF values are misleading because consumers believe an SPF 15 sunscreen product is not very protective even though it screens 93 percent of UV radiation.

We do not agree with either submission. Based on SPF test data we have reviewed, we find that SPF values for sunscreen products generally can be determined with a precision that allows the products to be labeled with SPF values in intervals of less than 5 units (Ref. 1). Therefore, there is no mathematical or statistical basis for restricting SPF values to multiples of five. Contrary to the second request, consumers have relied on SPF values for over 30 years and are familiar with this format. Therefore, expressing SPF values as percentages may be confusing. It would imply that the stated percentage of the entire UV spectrum is absorbed by a sunscreen. However, the SPF values only reflect protection against the portion of the UV spectrum that causes sunburn. Additionally, the percentages of UV radiation screened that the submission notes are theoretical. The percentages are determined in a laboratory setting and not under actual use conditions. For example, laboratory tests may show that an SPF 15 sunscreen absorbs 93 percent of UV rays, but, under actual use conditions, the level of protection provided by an SPF 15 sunscreen product may be significantly below 93 percent. There are a number of factors

that lead to this decreased protection, the most important being under-application of the sunscreen product (72 FR 49070 at 49092). Therefore, if SPF values were expressed as percentages, consumers might mistakenly believe that the sunscreen products they are using provide more protection than they really do provide under actual use conditions.

B. Broad Spectrum Statement

In response to the 2007 proposed rule, we received over 50 submissions collectively making the following four requests regarding the UVA effectiveness rating (Ref. 1):

1. Do not require UVA 4-star rating system.

2. Do not require ''no UVA protection'' statement if a product does not protect against UVA radiation.

3. Do not require the UVA statement to be the same size as the SPF statement.

4. Perform label comprehension studies prior to implementing proposed PDP labeling.

The submissions included arguments, but no data, to support these requests.

We agree with the first and second requests. However, we are not granting the third and fourth requests. Our reasons for these decisions are explained below, but we first summarize the related provisions of this final rule. We are not requiring a star rating or descriptors to indicate the level of UVA protection as proposed. Instead, to indicate the level of UVA and UVB protection, we are establishing a pass/fail broad spectrum test and a broad spectrum labeling statement. If a sunscreen product passes the broad spectrum test (see section VIII.B. of this document), under this final rule, the PDP of the product must include the statement ''Broad Spectrum SPF [insert numerical SPF value resulting from testing under paragraph (i) of this section],'' without any ''UVA'' reference (§ 201.327(a)(1)(i)). We are requiring the Broad Spectrum SPF statement to appear as continuous text with no intervening text or graphics. We are also requiring that the entire text be the same font style, size and color on the same background color. (§ 201.327(a)(1)(ii)).

With regard to the submissions received, nearly all of the 50+ submissions argued against requiring the 4-star rating system to display the level of UVA protection on the PDP of OTC sunscreen products (Ref. 1). Many submissions stated that the presence of stars and a number (SPF) on the PDP will lead to consumer confusion. Some submissions argued that consumers may be confused when determining whether a star is filled or empty, thereby not knowing the UVA protection level. Other submissions argued that consumers are familiar with star ratings, but that the star rating for items such as movies and hotels are based on recommendations and not rigorous data. They suggested several options for labeling UVA protection, such as a numerical rating or another symbol other than stars.

Some submissions suggested that the UVA rating should be proportional to the SPF value but requested that there not be two ratings on the PDP. The submissions cited the European Commission's recommendation that UVA protection increase as the SPF value increases (Ref. 7). The European Commission recommends a minimum UVA protection factor equal to at least one-third of the labeled SPF or a critical wavelength of at least 370 nm, but does not recommend that the actual value of the UVA protection factor or critical wavelength be displayed. The European Commission recommends that the main indicator of sun protection be the SPF value. Broad spectrum protection is indicated by a symbol on sunscreen labels—the acronym ''UVA'' enclosed within a circle the diameter of which should not exceed the height of the SPF value.

We agree with the submissions that the UVA star rating would likely be confusing in conjunction with the numerical SPF rating. We also agree with the submissions requesting that UVA protection should be proportional to the SPF value. We are requiring such proportionality in the broad spectrum test described in this document. Because of this proportionality, there is no longer a need for a separate UVA rating. Instead of a rating, we are requiring a ''broad spectrum'' statement on the PDP if a product has a critical wavelength equal to or greater than 370 nm. This pass/fail ''broad spectrum'' statement is consistent with the recommendations in the submissions citing the recommendations of the European Commission.

As noted, several submissions responding to our proposal for a separate UVA rating with stars suggested that consumer comprehension testing should be performed before the proposed labeling is implemented. We agree with the submissions that consumer comprehension data can be very helpful in formulating labeling changes. In fact, in conjunction with our 1993 proposal to allow products to be labeled as ''broad spectrum'' if they contained sunscreen active ingredients that absorbed UVA radiation (58 FR 28194 at 28233), we requested label comprehension study data to allow us to determine consumer understanding of the terms ''broad spectrum,'' ''UVA,'' and ''UVB'' (58 FR 28194 at 28243). Unfortunately, the data we received were not sufficient to allow us to determine the level of consumer understanding of these terms (72 FR 49070 at 49081 through 49085), and we received no further consumer comprehension data in response to the 2007 proposal to require the UVA star rating. While we acknowledge the value of consumer comprehension data, for reasons explained below, we conclude that conducting consumer comprehension testing is not necessary in this case in light of the labeling we have selected for the final rule.

First, submissions suggesting consumer testing were responding to the UVA star rating in the proposed rule, the value of which would have been based on the results of two tests (72 FR 49070 at 49081 through 49085). As noted, we agree with the submissions suggesting that the 2007 UVA labeling proposal was likely to be confusing. Elsewhere in the document, we also discuss our final choice of a pass-fail test for establishing UV protection (section VIII.B). As a result of these changes in the underlying test method and the submissions on the proposed labeling, we have incorporated a much simpler labeling statement in this final rule. This statement designates as ''broad spectrum'' those products that are demonstrated to have a critical wavelength of at least 370 nm, using the test in new 21 CFR 201.327(j).

Second, unlike in 1993 when we first sought consumer data on the term ''broad spectrum'', and unlike the UVA star rating that we proposed in 2007, consumers are now likely to be familiar with the term ''broad spectrum'' as included in this document because some sunscreen manufacturers have labeled sunscreen products as ''broad spectrum'' for over 20 years. For example, the Johnson and Johnson ''Sundown Broad Spectrum'' line of sunscreens was on the market in 1988 (Ref. 8). As already noted, in our 1993 proposed rule, we not only sought consumer data, but in fact proposed that products be permitted to be labeled as ''broad spectrum'' if they contained sunscreen active ingredients that absorbed UVA radiation, although we did not at that time propose to require a specific test to demonstrate UVA protection (58 FR 28194 at 28233). We continued to allow this statement in the 1999 sunscreen final rule (64 FR 27666 at 27666 through 27667).

Many consumers may also be familiar with the term ''broad spectrum'' because

of public health campaigns and news articles about the importance of broad spectrum UV protection over the last two decades. For example, an article appearing in Working Woman magazine in 1990 urged women to ''make sure to look for the term 'broad spectrum' on the label of a sunscreen'' because ''it means you're getting protection from both types of radiation'' (Ref. 9).

For consumers not already familiar with the term ''broad spectrum,'' the additional indication statement allowed in this document for certain broad spectrum sunscreen products should help consumers recognize the benefit of these products. Under ''Uses'' in Drug Facts, broad spectrum sunscreen products with an SPF value of 15 or higher are allowed the following indication statement: ''if used as directed with other sun protection measures (see Directions [in bold italic font]), decreases the risk of skin cancer and early skin aging caused by the sun'' (new 21 CFR 201.327(c)(2)).

In addition, educational campaigns about sun protection will further inform consumers about the benefits of using sunscreens that include the term ''broad spectrum'' on their labels and have an SPF value of 15 or higher. We expect consumers to learn that a sunscreen labeled with the statement ''Broad Spectrum SPF'' 15 or higher, when used as directed with other sun protection measures, offers more comprehensive protection against sun-induced skin damage than that provided by a sunscreen that is not broad spectrum or that are broad spectrum with an SPF value less than 15.

It is important to note that the broad spectrum test required in this document captures both UVB and UVA protection for the effectiveness of a sunscreen product. The broad spectrum test is not limited to UVA wavelengths as was the case with the proposed test (see section VIII.B of this document). By requiring that a broad spectrum sunscreen provide both UVB and UVA protection in a pass/fail test, the amount of UVA protection for a sunscreen product that passes the test must increase as the SPF increases. For example, a Broad Spectrum SPF 40 sunscreen product provides greater protection against both UVB and UVA than a Broad Spectrum SPF 20 sunscreen product. In contrast, an SPF 40 sunscreen product that is not broad spectrum provides more UVB protection than a SPF 20 sunscreen product that is not broad spectrum, but may not provide more UVA protection.

This proportionality between UVB and UVA protection is important because consumers have been accustomed to basing their purchase decision concerning protection level primarily on the SPF value, and only secondarily on indications of whether or not the sunscreen provides broad spectrum protection. For example, a consumer seeking lower protection may have chosen an SPF 15 sunscreen product, whereas a consumer seeking higher protection may have chosen an SPF 40 sunscreen product. By creating a clear and standardized ''yes/no'' indicator regarding broad spectrum protection, these final labeling requirements will enable consumers to make better and more informed purchase decisions by looking to see if a product has a ''Broad Spectrum SPF'' value on the label. Thus, the ultimate purchase decision would be based on the numerical value associated with the Broad Spectrum SPF statement. For products offering broad spectrum protection, the Broad Spectrum SPF value on the PDP will not only indicate the relative level of protection against UVB radiation but will also reflect the level of UVA protection, with increasing SPF values indicating greater protection against both UVA and UVB radiation. For broad spectrum products, linking the amount of UVA protection to the SPF value, is consistent with the approach taken in Europe (Ref. 7).

For broad spectrum products, we are requiring the broad spectrum statement on the PDP to appear in combination with the SPF statement. For example, an SPF 40 sunscreen product which passes the broad spectrum test will be labeled ''Broad Spectrum SPF 40'' in a uniform font style, size, and color and with the same background color. This placement will help consumers recognize that the particular sunscreen product is broad spectrum in conjunction with the SPF value. As previously explained, the broad spectrum statement and SPF value together will provide a relative measure of both UVB and UVA protection. Combining the broad spectrum and SPF statements will help consumers become more aware of the importance of broad spectrum protection.

Under the 2007 proposed rule, if an OTC sunscreen product was not tested for or did not protect against UVA radiation, the statement ''No UVA protection'' would have been required on the PDP (proposed 21 CFR 352.50(b)(1)). Ten submissions argued against requiring this statement (Ref. 1). Some submissions argued that this statement is misleading because all sunscreen products provide some UVA protection. Submissions also stated that a negative statement is inconsistent with the OTC Drug Review because a drug should only describe the indications for which it is effective. Other submissions suggested that we should require all sunscreen products to provide UVA and UVB protection, making this statement unnecessary.

We have concluded that the ''No UVA Protection'' statement is not necessary and could be misleading. Under this final rule, the labeling on the PDP of sunscreens no longer refers the type of UV radiation (UVA or UVB) protection offered; rather, products that pass the critical wavelength test in 201.327(j) are labeled with ''Broad Spectrum SPF'' values. Under this labeling, consumers who see ''UVA'' on the PDP, even if it is part of the statement ''No UVA Protection,'' may mistakenly believe that the product offers UVA protection. To eliminate this potential misunderstanding, we are not including the ''No UVA Protection'' statement on the PDP.

In contrast to four submissions requesting that we make the UVA statement less prominent than the SPF statement, we are requiring the SPF and broad spectrum statements to be equally prominent on the PDP by appearing as a combined statement. The four submissions stated that they believe UVB radiation contributes more to skin cancer and photodamage than UVA radiation and argued that more prominence should be given to the SPF statement. However, none of the submissions included data to support this argument. Some submissions suggested that consumers are familiar with SPF ratings and that providing another rating with similar prominence may mislead and confuse consumers.

It is well known that both UVA and UVB radiation contribute to photodamage and skin cancer (Refs. 6–7 and 10–12). Therefore, in our view, providing consumers with information about the effectiveness of a sunscreen product for UVA and UVB radiation protection is equally important. We are requiring that the broad spectrum statement be displayed in combination with the SPF statement. The two statements must not be interrupted with any graphics or text. In addition, the broad spectrum statement must be the same font style, size, and color as the SPF statement with the same background color. It is important for consumers to evaluate both statements when making a purchase decision. By requiring this information to be presented with identical prominence on the PDP, consumers should be able to quickly and easily identify sunscreen products that provide broad spectrum protection, as well as the SPF of all sunscreen products. While we are not requiring a negative statement on the

PDP of products that do not pass the critical wavelength test in new 301.327(j), we caution that such products may be misbranded if they include statements regarding UVA protection; such statements may misleadingly imply that the product provides benefits that are similar or superior to those of products labeled with Broad Spectrum SPF values.

C. Water Resistance Statement

In the 2007 sunscreen proposed rule (proposed 21 CFR 352.52), we allowed the PDP of OTC sunscreen products to contain the statement ''water resistant'' if a sunscreen product was shown to retain the labeled SPF value after 40 minutes of water immersion, or ''very water resistant'' if a sunscreen product was shown to retain the labeled SPF value after 80 minutes of water immersion, according to the test in proposed 21 CFR 352.76. We simultaneously proposed that the ''Uses'' section of labeling (not the PDP) indicate specifically whether the product had been established to be water resistant for 40 minutes or 80 minutes, and included specific directions addressing times for reapplication of each product, dependent on its level of water resistance (proposed 21 CFR 352.52(b)(1)(vii), (b)(1)(viii), (d)(2), and (d)(3); 72 FR 49070 at 49113). In this document, we are revising the PDP to contain the statement ''water resistant (40 minutes)'' or ''water resistant (80 minutes)'' as determined by the water resistance test in new 21 CFR 201.327(i)(7). We are removing this information from the indications section of Drug Facts (section IV.B of this document). We continue to include directions based on the duration of water resistance established under the new water resistance test (section IV.D of this document).

One submission stated that including information about water resistance in the indications section as well as in the directions section is ''redundant and confusing'' (Ref. 1). The submission recommended that we delete the indications statement. We agree with the submission. To eliminate redundancy and simplify the labeling for consumers, we are relocating the information formerly contained within the indication statement to the PDP.

The content of the labeling as a whole is the same as that included in the 2007 proposed rule. However the proposed statement on the PDP did not clearly and accurately convey to consumers the difference between ''water resistant'' and ''very water resistant'' sunscreen products. For example, knowing that a sunscreen product is ''very water resistant'' does not give any indication of how much time a consumer can safely spend in the water. Under the 2007 proposed rule, a consumer would have had to read either the ''Uses'' or the ''Directions'' section of the Drug Facts label to determine the duration of water resistance for a sunscreen product (proposed 21 CFR 352.52(b)(1)(vii) and (b)(1)(viii) and proposed 21 CFR 352.52(d)(2) and (d)(3), respectively; 72 FR 49070 at 49113).

Providing, on the PDP, specific information about the actual time (40 or 80 minutes) a consumer can expect a sunscreen product to retain its labeled SPF value is likely to be more helpful to consumers because the information is displayed in one place—on the PDP and not on different parts of the labeling. The revised statements ''water resistant (40 minutes)'' or ''water resistant (80 minutes)'' should make it clearer and easier for consumers to understand water resistance as part of their purchase decision. This water resistance information continues to be reinforced by information in the directions regarding reapplication.

D. UVB and UVA Educational Statement

In the 2007 sunscreen proposed rule, we proposed that the following educational statement be included on the PDP of all OTC sunscreen products (proposed 21 CFR 352.50(c)): ''UV rays from the sun are made of UVB and UVA. It is important to protect against both UVB and UVA rays to prevent sunburn and other skin damage.''

We received four submissions regarding the UVB and UVA educational statement in response to the 2007 sunscreen proposed rule (Ref. 1). The submissions made the following requests:

- Do not require the educational statement on the PDP or
- Combine the educational statement with the sun alert statement and include the combined statement in the ''Other Information'' section of the Drug Facts label.

We considered including the proposed educational statement on the PDP. We concluded that this information is not critical for effective use of sunscreen products, particularly since we are no longer requiring other PDP statements to refer separately to UVA and UVB protection. An understanding that the sun produces ultraviolet (UV) rays or that there are two types of UV rays that reach the earth's surface is not necessary to ensure the safe and effective use of sunscreen products. The explanation of these concepts on sunscreen labeling is potentially confusing and could raise additional questions about their meaning. We could not determine a succinct educational statement that would not also be potentially misleading. Therefore, we have concluded that an educational statement should not be required on the PDP.

As noted, submissions also requested that the proposed educational statement be combined with proposed sun alert, included in the proposed rule as a warning. In section IV.C of this document, we address submissions on the sun alert warning, and explain our decision to incorporate the information regarding the role of certain sunscreens in reducing the risk of skin cancer and early skin aging into a new indication and accompanying directions for sunscreens with Broad Spectrum SPF values of 15 or higher. We are retaining a modified warning to be included as the first warning on sunscreen products that are either not broad spectrum or that are broad spectrum with an SPF value less than 15. Because we are not requiring an educational statement on the PDP and are either eliminating or modifying the proposed sun alert warning, the request to combine these two statements is no longer relevant.

IV. Drug Facts Labeling

In September 2004 (69 FR 53801), we delayed the May 16, 2005, implementation date for the Drug Facts final rule (21 CFR 201.66) for OTC sunscreen products until further notice). The Drug Facts final rule (21 CFR 201.66) establishes general labeling format and content requirements for all OTC drugs. With the additional exception of certain OTC drug products in ''convenience size'' packages (see 67 FR 16304 at 16306 (April 5, 2002), other OTC drug products are already required to comply with 201.66. We delayed implementation of 201.66 for sunscreens so as to avoid the potential that sunscreen manufacturers would have to relabel their products twice within a short time period if a final rule specifying labeling for sunscreens published shortly after the original May 2005 implementation date for the general content and format requirements of the Drug Facts final rule. We published the notice of delay for OTC sunscreens' implementation of the Drug Facts final rule so that such products could simultaneously implement both the general labeling provisions of that rule and the specific labeling provisions for sunscreens when we published a sunscreen labeling final rule. We are now lifting the stay on the implementation of the Drug Facts final

rule for OTC sunscreen products. In this document, we are requiring the same implementation date for the regulations set forth in this labeling and testing final rule (21 CFR 201.327) and in the Drug Facts final rule (21 CFR 201.66) as applied to these sunscreen products.

This action will benefit both consumers and manufacturers. Consumers will benefit by having sunscreen labeling presented in the Drug Facts format that they are familiar with. Manufacturers benefit because they will achieve compliance with two rules through one labeling revision (rather than following the more expensive course of making two labeling changes at two different times).

In 2003 (68 FR 33362, June 4, 2003), we also stayed the part of the skin protectant monograph that describes GRASE combinations of skin protectant and sunscreen active ingredients (21 CFR 347.20(d)). Because this document addresses the labeling and testing of sunscreen products and not the GRASE status of individual sunscreen active ingredients, we are not lifting the stay of 21 CFR 347.20(d).

This document requires much of the Drug Facts labeling included in the 2007 proposed rule. However, we have made several revisions to the proposed labeling. These revisions are discussed in detail throughout the remainder of this section. In addition, table 2 of this document summarizes these revisions as follows:

TABLE 2—SUMMARY OF DRUG FACTS LABELING INCLUDED IN THE 2007 PROPOSED RULE AND THIS FINAL RULE

Drug facts section	2007 Proposed rule	This final rule
Active Ingredients/ Purpose.	Name and amount of ingredient(s) followed by ''sunscreen''	Name and amount of ingredient(s) followed by ''sunscreen.''
Uses	• [low, medium, high, or highest] UVB sunburn protection • [low, medium, high, or highest] UVA protection • retains SPF after 80 minutes of activity in the water	• for all sunscreen products: ''helps prevent sunburn.'' • Optional, for sunscreen products with Broad Spectrum SPF values of 15 or higher, ''if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.''
Warnings	*UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using a sunscreen.* *For external use only* *Stop use and ask a doctor if* skin rash occurs *When using this product* keep out of eyes. Rinse with water to remove. *Keep out of reach of children.* If swallowed, get medical help or contact a Poison Control Center right away.	For sunscreen products that are not broad spectrum or for products that are broad spectrum with an SPF value less than 15, Skin Cancer/Skin Aging Alert [in bold font]: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not [in bold font] skin cancer or early skin aging. For all sunscreens: *For external use only* *Do not use* on damaged or broken skin *Stop use and ask a doctor if* rash occurs *When using this product* keep out of eyes. Rinse with water to remove. *Keep out of reach of children.* If swallowed, get medical help or contact a Poison Control Center right away.

Directions	*Non-Water Resistant Product*
	• apply liberally [# minutes] before sun exposure
	• reapply at least every 2 hours and after towel drying, swimming, or sweating
	• apply and reapply as directed to avoid lowering protection
	• children under 6 months: Ask a doctor
	Water Resistant Product
	• apply liberally [# minutes] before sun exposure
	• reapply after 40 [or 80] minutes of swimming or sweating and after towel drying. Otherwise, reapply at least every 2 hours.
	• apply and reapply as directed to avoid lowering protection
	• children under 6 months: Ask a doctor
	Water Resistant and Non-Water Resistant Products
	No statement
		Non-Water Resistant Product
		• apply liberally 15 minutes before sun exposure
		• use a water resistant sunscreen if swimming or sweating
		• reapply at least every 2 hours
		• children under 6 months: Ask a doctor
		Water Resistant Product
		• apply liberally 15 minutes before sun exposure
		• reapply:
		  • after 40 [or 80] minutes of swimming or sweating
		  • immediately after towel drying
		  • at least every 2 hours
		• children under 6 months: Ask a doctor
		Water Resistant and Non-Water Resistant Products
		For sunscreens with Broad Spectrum SPF values of 15 or higher:
		• Sun Protection Measures [in bold font]. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
		  • limit time in the sun, especially from 10 a.m.–2 p.m.
		  • wear long-sleeved shirts, pants, hats, and sunglasses.

Inactive Ingredients	List inactive ingredients in alphabetical order	List inactive ingredients in alphabetical order.
Other Information	No required statements	• protect this product from excessive heat and direct sun.
Questions?	No required statements	No required statements.

A. Active Ingredients/Purpose

We received one submission regarding the listing of active ingredients and one submission requesting that we provide specific details about what each ingredient does in the product (Ref. 1). One of these submission also requested that we require listing of the percentage of each active ingredient next to the ingredient name.

We are not making any changes to the ''Active ingredients/Purpose'' section of the Drug Facts label. The general OTC labeling regulations specify that the ''quantity of each active ingredient per dosage unit'' be listed with the established name of each active ingredient (21 CFR 201.66(c)(2)). Therefore, every sunscreen product is already required to include the active ingredient names followed by the percentage (weight per volume) in the ''Active ingredients/Purpose'' section, as requested by the first submission.

We are not requiring specific details about what each ingredient does in the product. The function of each active ingredient in an OTC drug product is already required to be listed by 21 CFR 201.66(c)(3), which specifies that the ''Active ingredients/Purpose'' section of the label list the ''general pharmacologic categories or principal intended actions of each active ingredient.'' There is not currently a requirement to list the purpose of inactive ingredients on OTC drug labels. This information is not needed to safely and effectively use sunscreen products. Therefore, in this document, we are not requiring the purpose of inactive ingredients to be listed on sunscreen labels.

B. Uses

1. Indications Statements Proposed in the 2007 Proposed Rule

The 2007 proposed rule included three indication statements under ''Uses'' in Drug Facts:

1. Level of UVB sunburn protection (proposed 21 CFR 352.52(b)(1)(i)–(b)(1)(iv))
2. Level of UVA protection (proposed 21 CFR 352.52(b)(1)(v) and (b)(1)(vi))
3. Extent of water resistance (proposed 21 CFR 352.52(b)(1)(vii) and (b)(1)(viii))

The first statement would have appeared on all monograph sunscreen products. The second statement would only have appeared on monograph sunscreen products providing UVA protection. The third statement would only have appeared on monograph sunscreen products that are water resistant for either 40 or 80 minutes. We received numerous submissions from the public concerning these statements following publication of the 2007 proposed rule (Ref. 1).

We are not requiring these indication statements in this final rule. Instead, all sunscreen products covered by this rule will be required to include the indication statement ''helps prevent sunburn,'' as required in the 1999 sunscreen final rule (64 FR 27666; new 21 CFR 201.327(c)(1)). We are requiring this statement instead of the first proposed statement (level of UVB sunburn protection) because we agree with submissions arguing that sunburn is not caused solely by UVB radiation (Ref. 1). We also agree with submissions arguing that the SPF value by itself on the PDP informs consumers of the level of sunburn protection, so a separate description of the level of sunburn protection does not need to be included as an indication.

In addition, sunscreen products covered by this rule that provide broad spectrum protection according to the test in new 21 CFR 201.327(j) and have SPF values of 15 or higher, may include the following indication statement (new 21 CFR 201.327(c)(2)(i)): ''if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.'' This statement replaces the second proposed indication statement. We are allowing this statement for certain sunscreens covered by this rule based on available clinical studies, the fact that UV radiation from the sun is harmful, and the scientific understanding that substantially limiting overall UVB and UVA exposure reduces the risk of skin cancer and early skin aging.

As discussed in the remainder of this section of the document, it is critical that the indication statement regarding skin cancer and early skin aging includes information about using the products as directed and following other sun protection measures (listed under the heading Directions). We have concluded that the reference to other sun protection measures is necessary to ensure that the consumer's overall UV exposure is substantially decreased. A consumer who relies on the use of a sunscreen with Broad Spectrum SPF value of 15 or higher alone may not obtain a meaningful net decrease from the risk of skin cancer or early skin aging if, because he or she is wearing the sunscreen, the consumer spends more time in the sun and/or wears less protective clothing. In fact, reliance on sunscreen use alone, without also employing other sun protection measures, could actually result in an increase in the consumer's overall UV exposure. Therefore, if the indication statement regarding decreasing risk of skin cancer and early skin aging does not include the information about using the product as directed, which includes following other sun protection measures, the statement will be considered misleading (and thus make a sunscreen product misbranded) (new 21 CFR 201.327(c)(3)). Similarly, sunscreen products covered by the rule that provide broad spectrum with SPF values between 2 and 15 or do not provide broad spectrum protection should not state or imply that the use of a sunscreen product alone will reduce the risk of skin cancer or early skin aging. Doing so would cause the product to be misbranded.

We are not including the third proposed indication statement (regarding water resistance) in this document. As already discussed, under this final rule, information about water resistance is included on the PDP, as well as under ''Directions'' in Drug Facts (see sections III.C and IV.D of this document). We conclude that information about the water resistance of a sunscreen product is more effectively and accurately presented on the PDP and as a direction than as an indication statement. The extent of water resistance informs a consumer about how long the SPF value is retained following water exposure and, therefore, how long an interval can elapse before reapplying the sunscreen product (40 or 80 minutes). In addition, the PDP requirements in this document include the time interval as part of the water resistance statement, so that consumers can readily distinguish between products on this basis when making purchasing decisions. Because we include water resistance on the PDP and under ''Directions,'' we are not including a separate indication statement about water resistance in this document.

2. Statement Regarding Skin Cancer and Early Skin Aging

a. Submissions Arguing For a Skin Cancer and Early Skin Aging Indication

As already stated, in this final rule we have adopted, for the first time, an indication for skin cancer and early skin aging for sunscreen products covered by the rule that have Broad Spectrum SPF values of 15 or higher. In our 2007 proposed rule, we had included indication statements that indicated the degree of protection against both UVB and UVA radiation but that linked UVB protection only to sunburn prevention and did not expressly link UVA

protection to any specific health benefit (proposed 21 CFR 352.52(a)). At the same time, however, we had proposed both an educational statement on the PDP stating that UV rays from the sun are made of both UVB and UVA and that it is important to protect against both types of radiation to prevent sunburn and other skin damage (proposed 21 CFR 352.50 (c)). We also proposed a ''sun alert'' statement as the first warning. This first warning read, ''UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using a sunscreen.'' (proposed 21 CFR 352.52(c)(1)).

In response to our proposed rule, we received a total of 12 submissions asking that we include a specific statement regarding reduction in risk of skin cancer and early skin aging as an indication for covered sunscreens (Ref. 1). The submissions asked that we allow an indication statement informing consumers that the regular, consistent, or continued use of a sunscreen product reduces or helps reduce the risk or chance of developing skin damage, early skin aging, and some types of skin cancer (Ref. 1). These submissions also supported our proposed requirement of a ''sun alert'' on the labeling to inform consumers of the need to limit time in the sun and wear protective clothing. The submissions came from sunscreen manufacturers and public health organizations including the American Academy of Dermatology, the American Cancer Society, and the Skin Cancer Foundation. Many of the submissions provided references to studies that they argued support the inclusion of this indication statement. One submission specifically requested that we allow an anti-aging claim (without mention of skin cancer), and one other submission argued that no sunscreen can claim to prevent cancer (Ref. 1). We received no new data to accompany these requests for a separate indication that the regular use of sunscreen decreases the risk of skin cancer and early skin aging. However, on reconsideration of the data reviewed prior to the 2007 proposed rule, we agree with the argument that the data underpinning our proposed education statement and warning are sufficient to support an appropriately qualified skin cancer and premature skin aging indication for one subset of sunscreens covered by this rule—those that have Broad Spectrum SPF values of 15 or higher. As a result, our final rule provides different labeling for these sunscreens than for sunscreens covered by the rule that are not broad spectrum or that provide broad spectrum with SPF values less than 15. In addition, we conclude that such an indication should not be included in the Warnings section of Drug Facts. We have concluded that, as proposed in 2007, the second sentence of the first warning (*i.e.,* the ''Sun Alert'' warning) is an implied indication: ''It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using a sunscreen.'' Because it follows a warning that ''UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other forms of skin damage,'' the second sentence implies that using any sunscreen, regardless of SPF value or broad spectrum protection, and following other sun protection measures will decrease the risks of skin cancer, early skin aging, and other consequences of UV exposure to the sun. We have concluded, based on a reconsideration of data previously reviewed in the 2007 proposed rule, that, if consumers use broad spectrum sunscreens with SPF values of 15 or higher and follow other sun protection measures, they can reduce their risk of skin cancer and early skin aging. For these products, we agree with the public submissions that this information is most appropriately placed as an indication (*i.e.,* under Uses) with a reference to the need to use the product as directed with other sun protection measures. For these products, we include under the heading Directions, specific reference not only to regularly use sunscreens with Broad Spectrum SPF values of 15 or higher (the subset of sunscreens for which the indication is allowed) but also to employ the other listed sun protection measures listed under Directions. For sunscreen products covered by this rule that are not Broad Spectrum or that are broad spectrum with an SPF value less than 15, however, we conclude that existing data are insufficient to support an indication for reducing risk of skin cancer or early skin aging. In the sections that follow, we explain the specific scientific basis for our conclusion, as well as explain our rationale for the specific framing of the labeling, as included in the final rule, for both subsets of the sunscreens covered by the final rule—those that have Broad Spectrum SPF values of 15 or higher and those that do not have Broad Spectrum or that are Broad spectrum with SPF values less than 15.

b. Limiting Overall UV Exposure Reduces Risk of Skin Cancer and Early Skin Aging

For drugs subject to OTC monographs, like sunscreen products, indication statements about the effectiveness of the drug products must be supported with scientific data (21 CFR 330.10(a)(4)(ii)). In order for an OTC drug to be considered generally recognized as effective (GRAE), there must be a reasonable expectation that, in a given proportion of the target population, the drug will provide clinically significant relief of the type claimed (21 CFR 330.14(a)(4)(ii)). Based on the available data concerning the harmful effects of UV radiation and sunscreen UV protection, we have concluded that sunscreens, in conjunction with the critical behavioral steps of limiting time in the sun particularly during the midday hours and wearing protective clothing (long sleeve shirt, pants, hat, and sunglasses), provide ''clinically significant relief'' in reducing the risk of skin cancer and early skin aging. Based on the available data, we have limited this claim to broad spectrum sunscreen products with an SPF value of 15 or higher.

UV radiation from the sun has been associated with nonmelanoma skin cancers since 1927 and with melanomas since 1952 (Ref. 13). It is estimated that as much as 90 percent of melanomas and nonmelanomas are caused by sun exposure (Ref. 5). In 1992, the International Agency for Research on Cancer (IARC), under the auspices of the World Health Organization, identified UV radiation as a human carcinogen [3] (Ref. 14). More recently, broad spectrum UV radiation was listed as a human carcinogen in the National Toxicology Program's 11th Report on Carcinogens issued in 2005 (Ref. 15). It is important to note that this report indicates that UVB and UVA radiation across the spectrum are known human carcinogens, but that either UVB radiation alone or UVA radiation alone is ''reasonably anticipated to be a human carcinogen.'' This classification is due to the fact that the exact wavelengths of UV radiation that cause different harmful effects (*e.g.,* DNA damage or loss of skin elasticity) have not yet been identified. It is clear, though, that broad spectrum UV radiation causes skin cancer. Broad spectrum UV radiation has also been shown to cause other types of skin damage, including early skin aging (Refs. 6 and 16). Therefore, we agree

[3] A carcinogen is anything that is known to cause the development of cancer. UV radiation is known to cause skin cancer.

with the principle that a reduction, of sufficient magnitude, in broad spectrum UV exposure should reduce the risk of harmful effects to the skin, including skin cancer and early skin aging.

Broad spectrum sunscreens, by absorbing UVA and UVB radiation, decrease consumer exposure to both types of UV radiation from the sun that reach the earth's surface. Other critical behavioral steps, such as limiting time in the sun and wearing protective clothing, also decrease consumer exposure to UVA and UVB radiation. After considering the submissions and other available data, we have concluded that a claim for the reduction in risk of skin cancer and early skin aging is appropriate for certain sunscreen products, when the claim also includes the requirement that consumers use the product as directed and the Directions specify other sun protection measures be followed (see section IV.D of this document). We are basing this claim on the scientific understanding of the harm from UVA and UVB radiation and the absorption and/or reflection of that UV radiation by broad spectrum sunscreens, as well as data from studies concerning sunscreen use and the development of skin cancer or precursors of skin cancer (section IV.B.2.c of this document).

For a sunscreen to be effective (*i.e.,* provide ''clinically significant relief'') in reducing the risk of skin cancer and early skin aging, consumers must not increase their overall exposure to UV radiation by overreliance on sunscreen use. Other behavioral factors could account for such an increase, such as the amount of time spent in the sun and the use of protective clothing. If consumers rely on sunscreen use to spend more time in the sun and/or to wear less protective clothing, then consumers could actually increase their overall UV exposure, which would eliminate the effectiveness of sunscreen use in reducing the risk of skin cancer and early skin aging.

To illustrate this point, it is helpful to consider what has been termed the ''compensation hypothesis.'' As we noted in the 2007 proposed rule, the compensation hypothesis states that consumers who wear high SPF sunscreens generally spend more time in the sun and/or wear less protective clothing (72 FR 49070 at 49086). If the hypothesis is true, consumers would not reduce their risk of skin cancer or early skin aging because their overall UV exposure increases, even though a properly applied (and reapplied) sunscreen absorbs UV radiation and helps prevent sunburn. We cited two retrospective studies which support the compensation hypothesis in the 2007 proposed rule (72 FR 49070 at 49086). Reynolds *et al.* published a study in 1996 finding, in a study of 509 sixth-graders, that adolescents who used sunscreen on both Saturday and Sunday of a Labor Day weekend spent significantly more time in the sun than those who used sunscreen only one day or not at all (Ref. 17). In the second study, parents of 503 children, aged less than 2 to 12 years, were surveyed as to parental attitudes about their children's sun exposure (Ref. 18). The authors reported that ''sunscreen use in children was significantly associated with longer duration of sun exposure'' (Ref. 18).

Increased overall UV exposure might, in fact, increase the risk of skin cancer and early skin aging, despite the proper use of sunscreens. Likewise, if consumers limit time in the sun, especially during midday, and wear more protective clothing (such as broad brimmed hats, long pants, and long sleeve shirts) while outside, but do not use sunscreens for areas of the skin exposed to the sun (such as parts of face and neck), then the consumer may not decrease the risk of skin cancer and early skin aging for sun-exposed areas. For these reasons, for products that are entitled to include an indication for reducing the risk of skin cancer and early skin aging, we continue to direct consumers to follow a comprehensive sun protection program that includes use of sunscreens with Broad Spectrum SPF values of 15 or higher, limiting time in the sun, and wearing protective clothing, similar to the sun protection measures discussed in the 2007 proposed rule (72 FR 49070 at 49089). Nearly identical multi-step behavioral sun protection programs are advocated by a number of medical and public health organizations, including the American Academy of Dermatology, the Skin Cancer Foundation, and the American Cancer Society.

We have concluded that a comprehensive sun protection approach is critical to ensure that consumers who are seeking to obtain a reduction in the risk of skin cancer and early skin aging limit their overall sun exposure. Without the reduction in consumers' overall UV exposure, even a sunscreen with Broad Spectrum SPF value of 15 or higher may not be effective in decreasing the risk of skin cancer and early skin aging. As discussed below, the available clinical studies do not control for these behavioral factors and, therefore, do not demonstrate that even this subset of sunscreens alone reduce the risk of skin cancer and early skin aging. However, based on the scientific understanding of the harm from UV exposure and our assessment of the study data, we have concluded that if consumers use sunscreens with Broad Spectrum SPF values of 15 or higher, limit time in the sun especially during the midday hours, and wear protective clothing when exposed to the sun, the resulting reduction in overall UV exposure will reduce the risk of skin cancer and early skin aging. Therefore, there is sufficient evidence of ''clinically significant relief'' to justify the indication and related directions for this subset of products, as set forth in the rule. However, we conclude that the omission of prominent information in the indication regarding the need for other sun protection measures would misbrand the product, as would the omission of the associated direction specifying these measures. Indeed, it would suggest a different indication than that which available evidence supports. Consequently, we have included in this final rule a new provision indicating that ''Any labeling or promotional materials that suggest or imply that the use, alone, of any sunscreen reduces the risk of or prevents skin cancer or early skin aging will cause the product to be misbranded under section 502 of the FD&C Act (21 U.S.C. 352).'' (new 21 CFR 201.327(c)(3)).

c. Available Scientific Data

We are not aware of any data other than what we reviewed in the 2007 proposed rule that evaluate the effectiveness of sunscreens in reducing the risk of skin cancer or early skin aging for healthy subjects. One more recent study, published in 2009, found that regular use of Broad Spectrum SPF 50+ sunscreen ''may prevent'' the development of actinic keratoses and non-melanoma skin cancer in immune-compromised organ transplant recipients (Ref. 19). We have not relied on this study in reaching our conclusions regarding OTC sunscreens, because we do not consider the immune-compromised study population to be representative of the general population.

We have re-evaluated the data originally reviewed in preparing the 2007 proposed rule to determine whether those data support allowing the indication for all sunscreen products or only for certain sunscreen products. Based on our re-evaluation, we have concluded that the data is supportive of an indication for broad spectrum sunscreens having SPF values of at least 15. Further, we have determined that, while the existing evidence does not support a claim for the use of any sunscreen alone, it does support an indication that the combination of using

a sunscreen with Broad Spectrum SPF value of 15 or higher along with other sun protection measures, reduces the risk of skin cancer and early skin aging, consistent with other positions in the 2007 proposed rule (72 FR 49070 at 49087 through 49090).

To date, there are no clinical studies demonstrating that use of any sunscreen alone can prevent skin cancer. There are two prospective [4] studies that directly examine the role of sunscreen products in preventing skin cancer. Although it did not show any difference in primary endpoints, a large 1999 study conducted in Australia demonstrated that people who applied a Broad Spectrum SPF 15 sunscreen product on a daily basis over a 4.5 year period had a lower overall incidence of one type of skin cancer, squamous cell carcinoma, on the head, neck, arms, and forearms than study participants who did not apply sunscreen (28 cases in the broad spectrum sunscreen group vs. 46 cases in the group not using broad spectrum sunscreen) (Ref. 20). In an extension of that study, van der Pols *et al.* evaluated the same population of subjects over an additional 8 years, and found that the sunscreen users continued to have a statistically significant lower incidence of squamous cell carcinoma over the entire 12.5 year period (Ref. 21). Neither study found that daily sunscreen use had any measurable effect on the most common form of skin cancer, basal cell carcinoma. Further, we are not aware of any studies examining the effect of sunscreen use on the development of melanoma, which is the deadliest form of skin cancer.

Although data from clinical studies addressing the specific end points of cancer is limited, some prospective studies have evaluated the effects of regular sunscreen use on the development of surrogate skin lesions that can be precursors to cancer: actinic keratoses and melanocytic nevi. A small percentage of actinic keratoses progress to squamous cell carcinomas (Ref. 22). At least four studies have demonstrated that the number of actinic keratoses is lower for individuals regularly using sunscreens with Broad Spectrum SPF values of 15 or higher (Refs. 23 through 26). We are not aware of any studies examining the potential effects on surrogate skin lesions of sunscreens that either are not broad spectrum or are broad spectrum with SPF values less than 15.

Two prospective studies have shown that regular use of a Broad Spectrum SPF 30 sunscreen reduces the risk of developing melanocytic nevi, which can progress into melanomas (Ref. 22). In a 2000 study, Gallagher *et al.* examined the formation of new melanocytic nevi in 393 Canadian school children. The group of children given Broad Spectrum SPF 30 sunscreen product had fewer new nevi over the course of the three year study than did children not given sunscreen products or advice on sunscreen use (Ref. 27). The difference was small (24 v. 28 nevi, respectively), but statistically significant ($p = 0.048$). In a follow-up study published in 2005, Lee *et al.* evaluated the same group of children for differences in melanocytic nevi by location on the body and demographic factors (Ref. 28). These investigators found that the sunscreen group had significantly fewer new nevi on the trunk than the control group ($p = 0.05$).

With respect to the role of sunscreen products in decreasing the risk of early skin aging, we are aware of only indirect evidence that sunscreen use decreases early skin aging. One recent study demonstrated that a broad spectrum sunscreen product can reduce the extent of solar UV-induced damage to factors associated with early skin aging even when the SPF value is less than 10 (Ref. 29). Although this study was small, evaluating only 12 Caucasian subjects, it shows the importance of broad spectrum protection. These findings have been corroborated in a large number of studies using broad spectrum sunscreens with SPF values ranging from 19 to 50, as reported by Fourtanier *et al.* in two recent reviews (Refs. 10 and 30).

Neither those studies evaluating the long term effect of regular sunscreen use on the development of skin cancer and early skin aging nor those evaluating the long term effect of sunscreen use on surrogate markers for these conditions were adequately controlled. Such studies, which must take place over many years, make adequate controls extremely difficult, if not impossible to implement. For example, one cannot control for time and duration of exposure, application and re-application amounts, or use of supplemental behavioral measures such as wearing protective clothing for a study which takes place over several years.

Despite their limitation, the results of the short-term effectiveness studies are consistent with our understanding that measures which significantly reduce UV exposure decrease the risk of skin cancer and early skin aging. UVA and UVB radiation is the only known external risk factor for skin cancer and early skin aging. Therefore, measures that significantly reduce both UVA and UVB exposure should decrease the risk of skin cancer and early skin aging. Based on this understanding, limiting time in the sun, wearing protective clothing and using a broad spectrum sunscreen with an SPF value of 15 or higher should decrease the risk of skin cancer and early skin aging. Using a broad spectrum sunscreen with an SPF value of 15 or higher ensures adequate breadth and magnitude of UVA and UVB protection. For these products, the broad spectrum test measures breadth and SPF test measures magnitude of UV protection. Consistent with this scientific principle, the short-term effectiveness studies demonstrate a decrease in the development of surrogates for skin cancer and early skin aging. Thus, we have concluded that the available evidence supports our finding that sunscreen products, in conjunction with limiting time in the sun and wearing protective clothing, reduce the risk of developing skin cancer or early skin aging.

d. Indication Limited to Covered Sunscreens With Broad Spectrum SPF Values of 15 or Higher

In light of the submissions requesting that we reframe our labeling information regarding sunscreen use and reduced risk of skin cancer and premature skin aging as an indication, we re-evaluated skin cancer and aging studies discussed in the 2007 proposed rule to determine whether the skin cancer and early skin aging indication should apply to all sunscreen products or be limited to certain sunscreen products. Available data support this indication only for broad spectrum sunscreens with SPF values of 15 or higher. Several reports have indicated that UV-induced skin damage associated with both skin cancer and early skin aging can be reduced by the use of broad spectrum sunscreens (Refs. 10 and 29 through 31). In a direct comparison of a broad spectrum sunscreen and a non-broad spectrum sunscreen with the same SPF, Moyal and Fourtanier found that the broad spectrum sunscreen provided significantly better protection from UV radiation-induced immunosuppression, a factor associated with both skin cancer and early skin aging (Ref. 32). Furthermore, the National Toxicology Program classified broad spectrum UV radiation as a known human carcinogen because it is not clear which UVB and/or UVA wavelengths contribute to the development of cancer (Ref. 15).

[4] A prospective study is designed to study subjects under pre-specified conditions. These studies differ from retrospective studies that try to prove hypotheses by assessing past experiences. Generally, prospective studies are superior to retrospective studies in demonstrating drug effectiveness.

Therefore, available data indicate that a broad spectrum sunscreen is necessary to reduce the risk of skin cancer. Likewise, we do not know which UVB and/or UVA wavelengths contribute to early skin aging. Therefore, it is reasonable to conclude that reducing the risk of early skin aging also requires a broad spectrum sunscreen (in conjunction with limiting time in the sun and wearing protective clothing).

With regard to SPF value, the available study data concerning the use of sunscreens in reducing the risk of skin cancer is based on products with SPF values of 15 or higher. The sunscreen product used in the 1999 Australian study on skin cancer (squamous cell and basal cell carcinomas) had a Broad Spectrum SPF value of 16, and those that were found to reduce actinic keratoses and nevi had SPF values ranging from 16 to 46. The studies on early skin aging make it difficult to know for certain whether Broad Spectrum SPF values of 15 or higher are necessary to reduce the risk of early skin aging. However, we conclude that the data regarding the minimum sunscreen protection necessary to reduce the risk of skin cancer can be extrapolated to early skin aging. In many ways, the biological processes that take place in response to UV radiation are similar for both conditions. For both skin cancer and early skin aging, UV radiation causes damage in the skin that is not completely repaired and leads to cancer, fine lines, wrinkles, etc. Because the supporting data for a skin cancer claim are based on products with SPF values of 15 or higher, we are only allowing the skin cancer and early skin aging claim for covered sunscreen products that are broad spectrum and have SPF values of at least 15. This rule does not preclude approval of a new drug application including an indication for reduction in risk of skin cancer and early skin aging for any sunscreen product. To be approved, such an application must be supported by the submission of adequate data. This rule also does not preclude future amendment of the sunscreen monograph in 21 CFR part 352, if additional data are provided to support a similar indication for other types of sunscreens.

e. Precedent for an Indication Statement That Includes Behavior Modification

There is at least one other OTC drug product with an indication statement that describes not only the drug's intended effect but also one or more behavioral measures to ensure the effect. The indication statement on the weight loss aid orlistat states that the product is to be used ''for weight loss in overweight adults, 18 years and older, when used along with a reduced-calorie and low-fat diet'' (Ref. 33). The behavioral measure of reduced caloric intake is necessary for consumers to experience weight loss. A low-fat diet is necessary for consumers to avoid the undesirable side effect of diarrhea caused by consuming a high-fat diet while taking orlistat.

The need to include reduced caloric intake as part of the indication statement for orlistat is similar to the need for including the use of other sun protection measures as part of the indication statement for sunscreens. Orlistat increases the likelihood of weight loss by preventing fat from being absorbed as food is digested in the stomach and intestines. If consumers take orlistat and decrease their caloric intake, they increase the likelihood of losing weight. However, if consumers increase their caloric intake while taking orlistat, they are less likely to lose weight. Orlistat's effect of preventing fat absorption could be offset by the high number of calories being eaten. Similarly, the reduction in UV exposure afforded by use of broad spectrum sunscreens with SPF values of 15 or higher can be offset if consumers increase their UV exposure by spending more time in the sun and/or wearing less protective clothing. This increased overall exposure could eliminate the effectiveness of sunscreen use in reducing the risk of skin cancer and early skin aging.

The labeling of prescription cholesterol-lowering drug products (*i.e.,* statins) follows a similar principle by emphasizing that reduction of cholesterol levels requires not only use of the drug product but also a healthy diet. The National Institutes of Health (NIH) specifies therapeutic lifestyle changes that can be followed to lower levels of cholesterol in the blood (Ref. 34). These changes include following a diet restricted in saturated fat and cholesterol, exercising regularly, and managing weight. Used in conjunction with cholesterol reducing drugs (currently available only by prescription), these lifestyle changes improve the chance of effectively treating high cholesterol levels.

Prescription cholesterol-lowering drug products include the behavioral step of following a low fat diet in the indication statement (Ref. 35). The body produces cholesterol, which the drug product inhibits to produce the desired drug effect of lowering cholesterol being made by the body. However, the total cholesterol circulating in the blood reflects cholesterol made by the body plus cholesterol absorbed from foods containing fats. Therefore, if consumers use a statin and minimize the amounts of food containing fats in their diet, then they will reduce the total cholesterol level in the blood. However, if consumers do not minimize the amounts of food containing fats in their diet, they may not reduce the total cholesterol in the blood. The decreased cholesterol production in the body caused by the statin may not be significant compared to the high amount of cholesterol derived from food eaten by consumers.

In the same way that regularly taking an OTC weight loss aid or a prescription cholesterol-lowering drug product without also following a healthy diet may not result in the intended health effect, use of a sunscreen with Broad Spectrum SPF value of 15 or higher without also limiting time in the sun and covering sun-exposed areas may not result in a net reduction in the risk of developing skin cancer or early skin aging. For this reason, we are requiring that the indication statement allowed on sunscreens with Broad Spectrum SPF values of 15 or higher include all parts of the sun protection program and not suggest or imply that use of a sunscreen alone reduces the risk of skin cancer or early skin aging.

C. Warnings

We received submissions requesting that we revise warnings included in the 2007 proposed rule and that we add new warnings not included in the 2007 proposed rule (Ref. 1). In section IV.C.1 of this document, we discuss one new and one revised warning included in this final rule. We are adding the new warning ''Do not use on damaged or broken skin'' (new 21 CFR 201.327(d)(1)). We are revising the warning about skin rash (proposed 21 CFR 352.52(c)(3)): ''Stop use and ask a doctor if skin rash occurs'' to read ''Stop use and ask a doctor if rash occurs.''

In section IV.C.2 of this document, we discuss our revision to the proposed ''Sun Alert'' warning. Under this final rule, the warning proposed for all monograph sunscreens is replaced with an optional indication and required direction on covered sunscreens with Broad Spectrum SPF values of 15 or higher, while covered sunscreens that are broad spectrum with SPF values less than 15 or that do not provide broad spectrum protection will bear a revised warning, called the ''Skin Cancer/Skin Aging Alert.'' (new 21 CFR 201.327(d)(2)).

In section IV.C.3 of this document, we discuss three new warnings that were requested in submissions, but are not

being included in this document. Submissions argued that we should add warnings that the regular use of sunscreen products may cause vitamin D deficiency and may reduce the photoprotective effects of tanning. We also considered adding a warning concerning sunscreen products containing alpha hydroxy acids (AHAs). We are not adding any of these warnings because the available data do not support the need for these warnings.

In summary, this document requires the following warnings on all covered OTC sunscreen products (new 21 CFR 201.327(d)):

- ''Do not use on damaged or broken skin''
- ''Stop use and ask a doctor if rash occurs''
- ''When using this product keep out of eyes. Rinse with water to remove.''

For all covered sunscreen products that either are not broad spectrum or are broad spectrum with SPF values less than 15, this final rule also requires a ''Skin Cancer/Skin Aging Alert'' as the first statement under the heading Warnings. In addition to these warnings, all sunscreen products are required to include the ''external use'' and ''keep out of reach of children'' warning statements required on all topical OTC drug products (21 CFR 201.66(c)(5)(i) and (c)(5)(x)).

1. New and Revised Warnings for Damaged or Broken Skin and Rash

The new warning that we are requiring on all covered sunscreen drug products reads, ''do not use on damaged or broken skin.'' We require this warning or a similar warning for other topical OTC drug products:

- Acne treatments (21 CFR 333.350(c)(3))
- Skin protectants (21 CFR 347.50(c)(6))
- Antiperspirants (21 CFR 350.50(c)(1))

The safety data for these ingredients are based on application to intact (*i.e.,* unbroken or undamaged) skin. We do not have data of the safe use of these ingredients if the skin is not intact. For the same reason, the warning appears on sunscreen products marketed under new drug applications (NDAs).[5] Therefore, in this document, we are requiring this warning for all covered OTC sunscreen products, which are marketed without approved applications (new 21 CFR 201.327(d)(1)(i)).

In addition to the new warning, we are revising the warning in proposed 21 CFR 352.52(c)(3): ''Stop use and ask a doctor if skin rash occurs.'' We are deleting the word ''skin'' so that the new warning reads: ''Stop use and ask a doctor if rash occurs'' (new 21 CFR 201.327(d)(1)(iii)). We received two submissions arguing that the word ''skin'' is unnecessary in this warning because every rash is a skin rash (Ref. 1). We agree and are removing the word to make the warning more concise. Consumers will likely understand the warning without the word ''skin.''

2. Revision of the Proposed ''Sun Alert'' Warning

In 2007, we proposed a warning, based on the ''Sun Alert'' statement cited in the 1999 stayed sunscreen final rule (64 FR 27666 at 27679), as the first statement under the heading Warnings for all monograph sunscreen products regardless of SPF value or broad spectrum protection (proposed 21 CFR 352.52(c)(1)). As proposed, this warning would have stated, ''UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using a sunscreen.'' Submissions regarding this proposed warning are discussed in section IV.B.2 of this document. As noted there, we agree that, as proposed, this warning included an implied indication that all sunscreens reduce the risk of skin cancer and skin aging. Under this final rule, we are no longer requiring a ''Sun Alert'' or similar warning on broad spectrum sunscreens with SPF values of 15 or higher covered by the rule. This decision is based on our re-evaluation of the available scientific data. We are now permitting an indication stating that, used as directed with other sun protection measures, these sunscreens reduce the risk of skin cancer and premature skin aging (new 21 CFR 201.327 (c)(2)).

For these products we are also requiring a new direction statement (new 21 CFR 201.327(e)(1)(iv)). The direction states:

> Sun Protection Measures. [in bold font] Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF of 15 or higher and other sun protection measures including: [bullet] limit time in the sun, especially from 10 a.m.–2 p.m. [bullet] wear long-sleeved shirts, pants, hats, and sunglasses

We have concluded that information about decreasing sun exposure and wearing protective clothing is more appropriate in ''Directions'' than in ''Warnings.'' These measures, in addition to use of a sunscreen with Broad Spectrum SPF value of 15 or higher, are necessary for the consumers' sun protection as part of a comprehensive program.

For covered sunscreen products that do not provide broad spectrum protection or those that do provide broad spectrum protection with SPF values less than 15, we conclude that a warning regarding the risks of skin cancer and skin aging remains necessary. In light of comments received on the ''Sun Alert'' warning proposed in 2007, however, we are revising the text to read as follows: ''Skin Cancer/Skin Aging Alert [in bold font]: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not [in bold font] skin cancer or early skin aging.'' (new 21 CFR 201.327(d)(2). The title ''Skin Cancer/Skin Aging Alert'' more accurately and specifically conveys the nature of the warning that follows than the proposed ''Sun Alert'' warning, particularly since the products that will bear this statement are indicated to help prevent sunburn, one consequence of sun exposure. The first sentence of this warning is a factual statement similar in content to the opening statement of the warning proposed in 2007. Like the proposed ''Sun Alert'' warning, this statement alerts consumers to risks they continue to incur from sun exposure, the conditions under which they will make use of the product. The second sentence clarifies for users the limits on the benefits that the product in hand has been established to provide, specifying that these products have been shown to help prevent sunburn but have not been shown to reduce the risk of skin cancer or early skin aging. Inclusion of this warning is critical to help ensure that consumers do not mistakenly conclude that all sunscreens have been demonstrated to provide the same benefits. It will reinforce the distinction between sunscreens indicated only for preventing sunburn (those that have broad spectrum with SPF values below 15 or that are not broad spectrum) and sunscreens that have also been shown to reduce the risk of skin cancer and early skin aging when used as directed with other sun protection measures (those with Broad Spectrum SPF values of 15 or higher). This warning serves a similar purpose to one required on cosmetic suntanning preparations that do not contain a sunscreen ingredient, which likewise is intended to assist consumers in distinguishing among products that they might otherwise confuse. (See 21 CFR 740.19).

[5] NDAs 21–501, 21–502, 21–471, and 22–009.

3. Warnings Requested in Submissions But Not Included in This Final Rule

We considered adding the following three warnings:

- Sunscreens may reduce the photoprotective effects of tanning
- Increased sun sensitivity caused by alpha hydroxy acids (AHAs) in sunscreen products
- Regular use of sunscreen products may cause vitamin D deficiency

However, as discussed in this section of the document, we conclude that these warnings are not needed for the safe and effective use of sunscreen products.

We received a submission arguing that we should require the following warning on all OTC sunscreen products containing UVA-protective active ingredients (Ref. 1): ''The use of this product will prevent the development of photo-protective facultative pigmentation, a.k.a., a tan.'' The submission implies that UVA protection is not only unnecessary but harmful to consumers. No data were included in the submission.

We agree that tanning caused by UVA radiation offers some protection against sunburn. However, tanning, particularly when attributable to prolonged exposure to UVA radiation in tanning beds or booths, may also have harmful effects on the skin (Refs. 36 and 37). In addition, one study suggests that the protective effects of tanning are small, as a tan only appears to provide an SPF value of approximately 4 (Ref. 36). As stated in the 2007 proposed rule (72 FR 49070 at 49083), we do not know which UVA wavelengths cause specific types of damage (*e.g.,* skin cancer or early skin aging). We continue to assert, however, that protection against UVA radiation is important for consumers' health (72 FR 49070 at 49083). We have concluded that the warning suggested in the submission is not in the best interest of public health because the warning discourages consumers from using broad spectrum sunscreen products. Therefore, we are not requiring any warning related to tanning.

We are not adding any additional warnings to sunscreen products containing AHAs. In the 2007 proposed rule, we requested comment on the need for additional warnings or directions on sunscreen products combined with AHAs (72 FR 49070 at 49110). We made this request in response to a 2005 guidance that we issued for cosmetic products containing alpha hydroxy acids (70 FR 1721, January 10, 2005). The guidance recommends the following warning be included on cosmetic products containing alpha hydroxy acids: ''Sunburn Alert: This product contains an alpha hydroxy acid (AHA) that may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Use a sunscreen and limit sun exposure while using this product and for a week afterwards.''

Many cosmetic products containing alpha hydroxy acids also contain sunscreens because the sunscreen helps protect the skin made sensitive to the sun by the alpha hydroxy acids. The guidance does not address products combining alpha hydroxy acids and sunscreens.

Two submissions stated that additional warnings are not necessary on these products (Ref. 1). We agree with these submissions. We considered added a warning or other labeling to inform consumers that AHAs contained in some sunscreen products may make the consumer more likely to sunburn. However, the sunscreen component of such products would, in fact, protect consumers from sunburn. Furthermore, we have concluded that the addition of sunscreen active ingredients to AHA-containing cosmetic products provides valuable UV protection for consumers. Therefore, at this time, we have concluded that a warning about AHA is not necessary on OTC sunscreen products.

The other new warning requested in submissions relates to vitamin D deficiency. We received six submissions arguing that consumers should be warned that frequent sunscreen use may result in vitamin D deficiency (Ref. 1). The submissions cite articles discussing the negative effects of vitamin D deficiency, such as growth retardation, rickets, and osteoporosis (Ref. 38). The submissions include numerous published articles concerning vitamin D, but only four clinical studies that directly examine the effect of sunscreen use on vitamin D levels. In the remainder of this section, we discuss the four studies included in submissions, as well as three additional studies that we located through a literature search. Collectively, the studies do not demonstrate that the use of sunscreen causes vitamin D deficiency.

The term ''vitamin D'' refers to several forms of the vitamin, but the two forms important to humans are vitamin D_2 (ergocalciferol) and vitamin D_3 (cholecalciferol) (Ref. 39). Vitamin D_2 is obtained by eating vitamin D-rich foods such as fish or food fortified with vitamin D. The skin makes vitamin D_3 when it is exposed to sunlight (Ref. 40) and, therefore, vitamin D production may vary depending on the following factors: (1) Skin pigmentation, (2) age, (3) clothing, (4) season, (5) latitude, (6) time of day, (7) weather conditions, and (8) sunscreen application (Refs. 40–43). Vitamin D deficiency has long been associated with Ricketts, but recent research suggests that vitamin D deficiency may also be associated with other diseases (Ref. 38). However, the threshold of vitamin D blood levels that constitutes a deficiency is currently being re-evaluated by scientific experts (Refs. 40, 44, and 45).

To determine whether sunscreen use causes vitamin D deficiency, we reviewed four clinical studies included in the submissions that explored the effect of sunscreen use on vitamin D levels as well as three studies that we identified in a literature search:

- Matsuoka *et al* 1987 (Ref. 46)
- Matsuoka *et al* 1988 (Ref. 47)
- Marks *et al.* 1995 (Ref. 48)
- Farrerons *et al.* 1998 (Ref. 49)
- Kimlin *et al.,* 2007 (Ref. 50)
- Cusack *et al.,* 2008 (ref. 51)
- Hoesl *et al.,* 2010 (Ref. 52).

All but one of these studies assessed 25-hydroxyvitamin D levels because 25-hydroxyvitamin D is typically used as the biological marker for vitamin D (in the D_2 or D_3 form) (Ref. 53). Much of the data available in the literature involves nonclinical studies, which can be difficult to extrapolate to consumer (human) actual use conditions. Studies with clinical data provide more meaningful results because, if adequately designed, they can be more easily extrapolated to consumer actual use conditions. Therefore, we are focusing discussion in this document on the clinical studies.

In the 1987 study by Matsuoka *et al.,* four subjects applied a sunscreen product with an unknown SPF to the entire body, while four control subjects did not apply any topical product (Ref. 46). All of the subjects were exposed to 1 MED[6] of UV radiation (260–330 nm[7]) and then vitamin D_3 levels were monitored for 15 days. The subjects using sunscreen product applied the sunscreen product 1 hour before UV exposure. The level of vitamin D_3 was determined one day before UV exposure to serve as the baseline measure.

The level of vitamin D_3 in the control group (no sunscreen) increased significantly over baseline 1 day after UV exposure (from ~2 ng/ml[8] to 25 ng/ml) and then decreased gradually, returning to baseline 15 days after UV exposure. In contrast, the levels of vitamin D_3 in the sunscreen group did

[6] MED refers to the lowest dose of UV radiation that produces perceptible reddening of the skin.

[7] Nanometers.

[8] Nanograms per milliliter.

not change significantly from the baseline level (5 ng/ml) at each time point.

Based on this preliminary study, Matsuoka *et al.* conducted another study in 1988 (Ref. 47). This study enrolled 40 subjects from Illinois and Pennsylvania with 20 subjects in the control group and 20 subjects in the sunscreen group. Each time they went outdoors for 1 year, the subjects in the sunscreen group, who had a history of skin cancer, applied a sunscreen product with an unknown SPF to all sun-exposed areas of the body.

Serum 25-hydroxyvitamin D levels were measured in each group at the conclusion of the study and were significantly lower in the sunscreen group than the control group: 40.2 and 91.3 nmol/L,[9] respectively. The difference in 25-hydroxyvitamin D levels between the two groups was statistically significant ($p < 0.001$).

Marks *et al.* conducted a randomized, double-blind controlled clinical study over a summer period in Australia (Ref. 48). In this study, 113 subjects over 40 years old who exhibited at least one solar keratosis (a precursor of carcinoma of the skin) were recruited and divided into two groups. The first group of 56 subjects applied an SPF 17 sunscreen cream. Fifty-five subjects in the control group applied a placebo cream. Subjects in both groups were asked to apply their cream on the head, neck, forearm and dorsal side of each hand once a day in the morning and more frequently if sweating, swimming, or involved in activities that might rub off the cream.

The mean levels of 25-hydroxyvitamin D rose significantly by almost the same amount in both groups over the period of the study. The mean level in the placebo group increased by 12.8 mmol/L, whereas the mean level in the sunscreen group increased by 11.8 mmol/L. The difference between these increases from baseline values was not statistically significant.

In 1998, Farrerons *et al.* carried out a study to examine the effects of sunscreen use on vitamin D levels in elderly individuals (Ref. 49). In this 2-year study, 24 subjects (10 men and 14 women with a mean age of 71 years) were enrolled in the sunscreen group. The subjects had actinic keratosis, basal cell carcinoma, or squamous cell carcinoma. None of the subjects had previously used sunscreen products, but were instructed to apply an SPF 15 sunscreen product to sun-exposed areas of the body each morning, avoid mid-day sun, and wear UV-protective clothing during the spring and autumn. The control group of 19 subjects did not use sunscreen product, but had the same skin characteristics. Mean serum levels of 25-hydroxyvitamin D were measured at eight different time points (four in the autumn and four in the spring) over the two-year study period.

The mean serum levels of 25-hydroxyvitamin D were statistically lower in the sunscreen group as compared to the control group at one spring and one autumn time point ($p < 0.05$). However, the mean serum levels of 25-hydroxyvitamin D were not statistically different between the groups at the other 6 spring and autumn time points.

In 2007, Kimlin *et al.* reported that there was ''no association'' between use of sunscreens with SPF values higher than 15 and blood levels of 25-hydroxyvitamin D in a study of 126 Australian adults 18–87 years of age (Ref. 50). However, the authors stated that mean levels of 25-hydroxy vitamin D increased with increasing frequency of sunscreen use. Interestingly, study ''participants who 'usually' or 'almost always' wore a hat when outdoors'' were significantly more likely to have higher serum 25-hydroxy vitamin D levels than those who wore hats less often (Ref. 50). On the other hand, study participants who usually or almost always wore long sleeve shirts or pants while outside were statistically more likely to have lower serum 25-hydroxyvitamin D levels than those who wore these types of protective clothing less often (Ref. 50).

In 2008, Cusack *et al.* reported that decreased levels of 25-hydroxyvitamin D levels were only ''weakly correlated'' with sunscreen usage in 52 Irish patients with cutaneous lupus erythematosus (Ref. 51). This study population was specifically selected because patients with lupus are particularly sensitive to exposure to the sun. While an analysis of the effects of daily sunscreen use on serum levels of 25-hydroxyvitamin D showed the relationship between these two parameters to be significant, a multivariate analysis of the same data was not significant (Ref. 51).

Most recently, in 2010, Hoesl *et al.* reported ''no statistically significant association'' between serum levels of 25-hydroxyvitamin D and use of the sunscreen drometrizole trisiloxane in a cohort of 15 patients with Xeroderma pigmentosum (Ref. 52). Like those with lupus ertythematosus, patients with Xeroderma pigmentosum are extremely sensitive to the sun. The authors reported that reductions in serum levels of 25-hydroxyvitamin D are ''not associated with any type or duration of sun protection applied by these patients'' (Ref. 52).

These seven clinical studies are inconclusive because the results were contradictory. Two studies suggest that sunscreens decrease vitamin D levels and the other five studies suggest that sunscreens do not decrease vitamin D levels. In addition, the studies were relatively small, only enrolling 8 to 126 subjects. The study with the greatest number of participants was inconclusive showing that people who regularly used sunscreens and wore hats had increased levels of vitamin D, whereas people who regularly wore pants outside had decreased levels (Ref. 50).

Because the preponderance of currently available data suggests that sunscreen use does not cause clinically meaningful decreases in vitamin D levels (*i.e.,* decreases that lead to vitamin D deficiency and/or disease caused by low levels of vitamin D), we are not including a warning regarding vitamin D deficiency on OTC sunscreen products. In addition, determining whether decreases in vitamin D levels result in vitamin D deficiency is especially difficult because the threshold of vitamin D blood levels that constitutes a deficiency is currently being re-evaluated by scientific experts (Refs. 38, 44, and 45). We recognize that certain subpopulations may be at increased risk of vitamin D deficiency, as pointed out in one submission. However, there are many factors that determine the amount of sun exposure necessary to ensure adequate vitamin D levels (*e.g.,* geographical location, season, skin pigmentation, dietary vitamin D intake). Because of these many other factors, it is difficult for us to determine a meaningful message in sunscreen product labeling for consumers, especially in the absence of conclusive data. If we become aware of data from adequate and well-controlled studies demonstrating that regular use of sunscreen causes vitamin D deficiency, we will re-evaluate this issue.

D. Directions

We received numerous submissions requesting that we revise directions included in the 2007 proposed rule (Ref. 1). In response to those requests and our reevaluation of OTC sunscreen labeling, we are revising the following directions:

- ''Reapply after [select one of the following: '40 minutes of' or '80 minutes of' '' for products that satisfy either the water resistant or very water resistant test procedures in proposed paragraphs 352.76(a) and (b), respectively] swimming or [select one of the

[9] Nanomoles per liter.

following: 'sweating' or 'perspiring'] and after towel drying. Otherwise, reapply at least every 2 hours'' (proposed 21 CFR 352.52(d)(2)).

- ''Reapply at least every 2 hours after towel drying, swimming, or sweating'' (proposed 21 CFR 352.52(d)(3)).

These two directions are the reapplication instructions for water resistant and non-water resistant products, respectively. We also received five submissions requesting that we revise the direction: ''Apply [select one of the following: 'liberally' or 'generously'] [and, as an option: 'and evenly'] [insert appropriate time interval, if a waiting period is needed] before sun exposure'' (proposed 21 CFR 352.52(d)(1)(i)). As discussed in this section, we are not revising this direction statement.

In addition to the revisions to these provisions (described in more detail in this section of the document), we are no longer requiring the following proposed direction: ''Apply and reapply as directed to avoid lowering protection'' (proposed 21 CFR 352.52(d)(1)(ii)).

As already discussed, for covered sunscreen products with Broad Spectrum SPF values of 15 or higher, we are requiring the following direction:

''Sun Protection Measures. [in bold font] Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF of 15 or higher and other sun protection measures including: [bullet] limit time in the sun, especially from 10 a.m.–2 p.m. [bullet] wear long-sleeved shirts, pants, hats, and sunglasses''

(new 21 CFR 201.327(e)(1)(iv)). For these products, this direction most appropriately conveys the information proposed in the ''Sun Alert'' warning included in the 2007 proposed rule, and provides the necessary directions to complement the new indication permitted for these products.

In addition to the required directions, we will allow the optional direction heading ''for sunscreen use'' (new 21 CFR 201.327(e)(1)(i)).

1. Revised Directions

We are revising the directions for water resistant sunscreen products (new 21 CFR 201.327(e)(2)) to read:

- Reapply:
- After 40 [or 80] minutes of swimming or sweating
- Immediately after towel drying
- At least every 2 hours

We are also revising the directions for non-water resistant sunscreen products (new 21 CFR 201.327(e)(3)) to read: ''[Bullet] reapply at least every 2 hours [bullet] use a water resistant sunscreen if swimming or sweating.'' These revisions should clarify the directions. We are removing reapplication directions concerning swimming and sweating from non-water resistant products because these products should not be used when swimming or sweating. Instead, we are requiring more accurate directions instructing consumers to use a different sunscreen product—a water resistant sunscreen product—if swimming or sweating.

We considered revising the 2-hour reapplication timeframe because some of the submissions objected to this specific timeframe (Ref. 1). The submissions argued that we should require the word ''often'' instead of a 2-hour reapplication timeframe because there are no data supporting this timeframe. The submissions also point out that the American Academy of Dermatology (AAD) no longer supports a 2-hour timeframe, even though we cited AAD as supporting the 2-hour timeframe in the 2007 proposed rule (72 FR 49070 at 49093).

In its submission following the 2007 proposed rule, the AAD does not state its support for the 2-hour timeframe. However, all of the public education materials from AAD instruct consumers to reapply sunscreen at least every 2 hours (Refs. 54 through 58). In addition, other public health organizations such as the Centers for Disease Control and Prevention (CDC) and the U.S. Environmental Protection Agency (EPA) recommend reapplication at least every 2 hours (Refs. 59 and 60).

We disagree with the submissions stating that data do not support this timeframe. In the 2007 proposed rule, we described two studies demonstrating a significantly decreased sunburn risk if sunscreen product were applied at least every 2 hours (72 FR 49070 at 49092 through 49093). Wright *et al.* found that subjects who reapplied sunscreen every 1 to 2 hours and after swimming were not sunburned (Ref. 61). Similarly, Rigel *et al.* reported that people who reapplied sunscreen every two hours or sooner were five times less likely to sunburn compared to those who reapplied sunscreen only after 2.5 hours or longer (Ref. 62).

One of the submissions following the 2007 proposed rule included results from a computer-simulation of sunscreen product reapplication based on a mathematical model (Ref. 1). The results of this simulation suggested that sunscreen products should be reapplied 15 to 30 minutes after sun exposure begins. The results also suggested that further reapplication of sunscreen product is necessary after vigorous activity that could remove sunscreen product, such as swimming, toweling, excessive sweating, or rubbing. No other reapplication time is suggested. The usefulness of this study in determining whether to revise the directions is limited. In particular, we do not know whether this simulation was validated, because it has not been confirmed with clinical studies. Until we receive clinical studies demonstrating that consumers do not experience skin damage when sunscreen is reapplied at longer timeframes, we will continue to require the 2-hour reapplication timeframe. As discussed in the 1999 final rule, manufacturers may seek approval of different reapplication directions by submitting specific and substantive supporting data to us under an NDA deviation (described in 21 CFR 330.11).

2. Proposed Directions Not Being Revised

We are not revising proposed 21 CFR 352.52(d)(1)(i): ''Apply [select one of the following: 'Liberally' or 'generously'] [and, as an option: 'And evenly'] [insert appropriate time interval, if a waiting period is needed] before sun exposure.'' Several submissions requested that we allow ''smoothly'' to be included in this statement (Ref. 1). However, we continue to consider this word to be vague (72 FR 49070 at 49072 and 49092). Some submissions also requested that we include a specific application amount in place of the terms ''generously'' and ''liberally'' (Ref. 1). For example, the submissions suggested that the statement could read ''apply 2 tablespoonsful.'' The submissions argued that more specific directions would lead to consumers applying more sunscreen product, reflecting the 2 milligrams per square centimeter (mg/cm^2) used during the SPF test. However, specifying a certain amount in the directions will not accomplish this goal. The amount of sunscreen product that needs to be applied to reach 2 mg/cm^2 varies for each sunscreen product and depends on the amount of skin surface area being covered. For example, the volume of sunscreen oil applied to the neck and face will differ greatly from the amount needed to apply a sunscreen lotion to every sun-exposed area of the body. Therefore, we are continuing to require the terms ''generously'' and ''liberally.''

3. Proposed Directions Not Being Required

We are not requiring the proposed statement ''apply and reapply as directed to avoid lowering protection'' (proposed 21 CFR 352.52(d)(1)(ii)). We included this statement in the 2007

proposed rule because reapplication time appears to be critical to achieve proper sun protection (72 FR 49070 at 49093). However, we have concluded that this statement is redundant with more specific reapplication directions and may confuse consumers. It is not clear that consumers will understand the intent of this statement to emphasize the need to follow reapplication instructions. Therefore, we are not requiring the statement in this document.

4. New Directions Resulting From Submissions on the Proposed Rule

For covered sunscreens with Broad Spectrum SPF values of 15 or higher, we are requiring a new Directions statement that emphasizes the need not only to regularly use such a sunscreen, but also to follow other sun protection measures. For these sunscreens, the statement will read, ''[bullet] Sun Protection Measures. [in bold font] Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF of 15 or higher and other sun protection measures including: [Bullet] limit time in the sun, especially from 10 a.m.–2 p.m. [bullet] wear long-sleeved shirts, pants, hats, and sunglasses (new 21 CFR 201.327(e)(1)(iv)). This statement is taken from the proposed warning ''UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using a sunscreen.'' (proposed 21 CFR 352.52(c)(1)). As discussed in section IV.C. of this document, this warning is no longer being required for sunscreens with Broad Spectrum SPF values of 15 or higher. Rather, as discussed in section IV.B of this document, submissions suggested that the information proposed as a warning is better understood as an indication, with the supporting conditions for achieving effectiveness. As described in section IV.B, on reexamination of the scientific data, we agree that an appropriately limited indication for reduction in risk of skin cancer and early skin aging is supported for sunscreens with Broad Spectrum SPF values of 15 or higher. For these products, the direction instructs users how to use the product in a manner that supports that indication.

In this final rule, we are being more specific about the need to limit time in the sun especially during the midday hours of 10 a.m. to 2 p.m. when the intensity of solar radiation is greatest because the sun is at its zenith (*i.e.,* directly overhead). In our 1993 proposed rule, we stated that, ''on any day of the year, the intensity of the UV energy of sunlight is greatest between 10 a.m. and 2 p.m.'' (58 FR 28194 at 28199). We have concluded that this information is important to consumers trying to protect themselves from the sun and are including the information in the new direction statement. This change is also responsive to the concerns of two submissions on the portion of the proposed sun alert that referred to ''limiting time in the sun,'' both of which suggested alternatives intended to provide more concrete information for consumers to act on (Ref. 1).

Several submissions argued that we should allow different Drug Facts labeling for cosmetics containing sunscreens so that consumers will apply the product appropriately for its intended cosmetic use (Ref. 1). For example, the submissions argued that reapplication every 2 hours may not be appropriate for cosmetic-sunscreen products. We disagree with these submissions. Cosmetic-sunscreen combinations that are intended for use as drugs require adequate labeling for their drug use. (See 21 CFR 700.35). The Drug Facts label communicates information to the consumer so that the cosmetic-sunscreen product can be used safely and effectively. To help consumers understand that the sunscreen directions apply to the use of the product as a drug, for sun protection, we are allowing the optional statement ''for sunscreen use:'' to appear as the first line under ''Directions.'' Consumers who are using these products primarily for cosmetic use will be more likely to understand that they might not receive the intended sun protection if they do not follow the directions in the Drug Facts label.

E. Constitutionality of Labeling Statements Regarding Skin Cancer and Skin Aging

Two submissions questioned the constitutionality of the labeling provisions in the 2007 sunscreen proposed rule. Specifically, the submissions contended that our proposed restriction on any claims about the prevention of skin cancer, early skin aging, and related skin damage would violate the sunscreen manufacturers' commercial speech rights under the First Amendment to the U.S. Constitution.

In the 2007 proposed rule preamble, we had concluded that our proposed restriction on claims about the prevention of skin cancer, early skin aging, and related skin damage would be permissible under the First Amendment, in part, because, at that time, we tentatively concluded that there were insufficient scientific data to support inclusion of such claims in the sunscreen monograph. As described elsewhere in this document, we received numerous submissions in response to the 2007 proposed rule, some of which contained references to clinical studies we had reviewed in preparing the 2007 proposed rule about the effectiveness of sunscreens in protecting against the harmful effects of UV radiation. As already described in section IV.B.2, based in part on our re-evaluation of the data from these studies, as well as the scientific fact that reducing exposure to both UVB and UVA radiation by a substantial amount (*i.e.,* equivalent to that provided by a broad spectrum sunscreen with an SPF value of 15 or higher) decreases the risk of damaging the skin, we find that the science supports the conclusion that one subset of sunscreens covered by this rule, broad spectrum sunscreen products with an SPF value of 15 or higher, in conjunction with limiting time in the sun and wearing protective clothing, reduce the risk of developing skin cancer and early skin aging. Our conclusion is reflected in the permissible indication described in this final rule for covered products with Broad Spectrum SPF values of 15 or higher. Although we have decided to permit a claim about the prevention of skin cancer and early skin aging for certain covered sunscreens, as requested in the submissions, we have nevertheless conducted a First Amendment analysis of our requirements concerning the skin cancer/early skin aging claim in this final rule (hereinafter ''skin cancer/early aging indication''), as well as the ''Skin Cancer/Skin Aging Alert'' required as a warning for covered products that do not provide broad spectrum protection with an SPF value of 15 or higher. For the following reasons, we have concluded that these requirements do not violate the First Amendment.

This rule establishes effectiveness testing methods and labeling that are appropriate for the safe and effective use of OTC sunscreen products covered by this rule. Any covered sunscreen product that deviates from the requirements set forth in this labeling regulation and any other applicable labeling regulation would be considered misbranded under section 502 of the FD&C Act. In particular, sunscreen products covered by this rule would be misbranded if they are labeled with a skin cancer/early aging indication but

do not provide broad spectrum protection with an SPF value of 15 or higher. Such products would also be misbranded if they do not include the ''Skin Cancer/Skin Aging Alert'' described in this rule (see 21 CFR 201.327(d)(2)). Covered sunscreen products that do provide broad spectrum protection with an SPF value of 15 or higher would be misbranded if they are labeled with the permissible skin cancer/early aging indication but do not include reference to the need to use the product as directed with other sun protection measures (21 CFR 201.327(c)(3)). Manufacturers of covered sunscreen products that comply with the labeling requirements in this document would not be subject to enforcement actions on the basis that the products are misbranded, provided they comply with all other requirements under section 502 of the FD&C Act. Because this rule applies only to products marketed without approved applications, manufacturers who wish to deviate from the testing or labeling requirements in this document may do so by means of a new drug application (NDA) under section 505 of the FD&C Act.

We have concluded that the labeling requirements in this rule satisfy the applicable tests governing commercial speech, as set forth by the Supreme Court. The requirements for the ''Skin Cancer/Skin Aging Alert'' and the information in the skin cancer/early aging indication about using the product as directed with other sun protection measures, are permissible under the First Amendment because they are reasonably related to the Government's interest in protecting public health (see *Zauderer* v. *Office of Disciplinary Counsel,* 471, U.S. 626, 651 (1985)).

We are requiring covered sunscreen products that do not provide broad spectrum protection with an SPF value of 15 or higher to include the ''Skin Cancer/Skin Aging Alert'' under the ''Warnings'' heading on the label to ensure that consumers are aware of the continued risks of skin cancer and early skin aging that occur from sun exposure, the conditions under which they will be using the product, and that they understand that the product has been shown only to help protect against sunburn. Without this warning, consumers could fail to distinguish between these sunscreen products and other sunscreen products that have been proven to help provide protection against skin cancer and early skin aging. Providing this information is important for consumers to be able to make informed choices about the selection and use of sunscreens.

For covered sunscreen products that do provide broad spectrum protection with an SPF value of 15 or higher, we are requiring that the additional information about using the product as directed with other sun protection measures be included in the indication so that consumers are not misled about how to use these sunscreens effectively or about the conditions under which these sunscreens are effective. Use of a sunscreen alone—even a broad spectrum sunscreen with an SPF value of 15 or higher—has not been shown to reduce the risk of skin cancer or early skin aging if a consumer increases overall UV exposure by spending greater time in the sun and/or wearing less protective clothing. The additional information required in the skin cancer/early aging indication about using the product as directed with additional sun protection measures clarifies how the use of sunscreens is part of a comprehensive sun protection program. Displaying this information elsewhere would underemphasize its importance in relation to the use of these sunscreens for protection against skin cancer and early skin aging (see *N.Y. State Rest. Ass'n* v. *N.Y. City Bd. of Health,* 556 F.3d 114 (2d Cir. 2009); see also 21 U.S.C. 352(c)). Thus, these disclosure requirements will promote the proper use of covered sunscreens and are, therefore, reasonably related to the Government's interest in protecting public health.

Our requirements concerning the skin cancer/early aging indication would also be permissible under the First Amendment using the analytical framework provided in *Central Hudson Gas & Electric Corporation* v. *Public Service Commission,* 447 U.S. 557 (1980). Under *Central Hudson,* commercial speech that is false, misleading, or concerns unlawful activity is not entitled to protection under the First Amendment. While commercial speech that concerns lawful activity and is not misleading receives some protection under the First Amendment, it may nonetheless be regulated by the Government if the following conditions are met: (1) The asserted governmental interest is substantial; (2) the regulation directly advances the asserted governmental interest; and (3) the regulation is not more restrictive than necessary to serve that interest (*Id.* at 566). The Supreme Court has explained that the last element of the *Central Hudson* test is not a ''least restrictive means'' requirement but, rather, requires narrow tailoring (*i.e.,* ''a fit that is not necessarily perfect, but reasonable'' between means and ends) (*Board of Trustees of the State Univ. of N.Y.* v. *Fox,* 492 U.S. 469, 480 (1989)). In subsequent decisions, the Court has also clarified that ''misleading'' in the first element of the test refers to speech that is inherently or actually misleading.

Based on the data currently available, we have concluded that the following statements or omissions would be false or inherently misleading: (1) Use of the skin cancer/early aging indication on the labeling of a sunscreen product that does not provide broad spectrum protection with an SPF value of 15 or higher, (2) the omission of the ''Skin Cancer/Skin Aging Alert'' under the ''Warnings'' heading of the labeling for sunscreen products that do not provide broad spectrum protection with an SPF value of 15 or higher, and (3) use of the skin cancer/early aging indication that omits the required information about using the product as directed with other sun protection measures.

Use of the skin cancer/premature aging indication on the labeling of covered sunscreen products that do not provide broad spectrum protection with an SPF value of 15 or higher would be false or inherently misleading for several reasons. As discussed elsewhere in this document, only broad spectrum UV radiation is classified as a known human carcinogen, according to the National Toxicology Program. Therefore, covered sunscreen products that do not provide broad spectrum UV protection may not reduce the risk of skin cancer. Furthermore, since the precise wavelengths of UV radiation that cause skin cancer and early skin aging are unknown, a covered sunscreen product that only provides protection against part of the UV spectrum may not ensure a reduction in the risk of developing skin cancer or early skin aging. In addition, all of the scientific data that support the skin cancer/early aging indication for certain covered sunscreens were derived from studies that used sunscreen products with an SPF value of 15 or higher. Therefore, the skin cancer/early aging indication would be false or inherently misleading on covered sunscreen products that do not provide this level of protection, because there is a lack of any evidence demonstrating that these products would reduce the risk of skin cancer or early skin aging. Similarly, omitting the ''Skin Cancer/Skin Aging Alert'' on these products, which are identified on their labels as ''sunscreens,'' would be inherently misleading because consumers who are using these products for sun protection would not be sufficiently alerted to the fact that these products have been shown only to

protect against sunburn, while sun exposure also increases the risks of skin cancer and early skin aging.

A skin cancer/early aging indication on a covered product with Broad Spectrum SPF value of 15 or higher that omits the required information about using the product as directed with other sun protection measures would also be false or inherently misleading because sunscreen use alone has not been shown to reduce the risk of skin cancer or early skin aging if a consumer increases overall UV exposure by spending greater time in the sun and/or wearing less protective clothing. As discussed above in this section and elsewhere in this document, without the reduction in consumers' overall UV exposure, a covered sunscreen product may not be effective in reducing consumers' risk of skin cancer and early skin aging.

We also conclude that the labeling claims and omissions described above would cause the product to be misbranded and, therefore, relate to an unlawful activity. As described earlier in this section and elsewhere in this document, labeling regulations establish certain requirements that help ensure the safe and effective use of OTC drug products. The false or misleading labeling described above would cause covered products to be misbranded under section 502 of the act. Therefore, such labeling would concern the illegal sale of misbranded drugs. Under the *Central Hudson* test, then, we have not violated the First Amendment with these requirements, which simply prohibit false or inherently misleading labeling.

Although we conclude that the labeling described above would not be entitled to First Amendment protection under the threshold inquiry of the *Central Hudson* test, we conclude that our regulation directly advances a substantial Government interest and is no more extensive than necessary, and therefore would also pass muster under the test's three remaining steps. Under the first remaining step, we have a substantial interest in protecting public health (see *Pearson* v. *Shalala,* 164 F.3d 650, 656 (DC Cir. 1999) (citing *Rubin* v. *Coors Brewing Co.,* 514 U.S. 476, 484–485 (1995)).

Under the second remaining step of the *Central Hudson* test, our labeling requirements discussed in this section directly advance the Government's interests in protecting public health because they help ensure that covered sunscreen products are adequately labeled for safe and effective use by consumers.

As stated previously in this document, scientific evidence only supports the skin cancer/premature aging indication for sunscreen products that provide broad spectrum protection with an SPF value of 15 or higher. Allowing the skin cancer/early aging indication on sunscreen products for which it is not scientifically supported would lead to consumers unjustifiably relying on such products for protection against skin cancer and early skin aging. Furthermore, the ''Skin Cancer/Skin Aging Alert'' allows consumers to be aware that spending time in the sun increases their risk of skin cancer and early skin aging, and that products on which this alert appears have not been shown to provide this type of protection. The requirement for information in the skin cancer/early aging indication about using sunscreens as directed with sun protection measures also directly advances our interest in protecting public health because these elements are essential for consumers to reduce their overall UV exposure and, consequently, their risk of developing skin cancer and early skin aging. Thus, these requirements directly advance the Government's interest in protecting public health through the safe and effective use of sunscreens.

Under the final remaining step of the *Central Hudson* test, our requirements concerning the skin cancer/early aging indication are not more restrictive than necessary, because there are not numerous and obvious alternatives (*Cincinnati* v. *Discovery Network,* 507 U.S. 410, 418 n. 13 (1993)) to achieve the Government's substantial interests. By permitting the skin cancer/early aging indication only for covered sunscreen products with Broad Spectrum SPF values of 15 or higher, and requiring the ''Skin Cancer/Skin Aging Alert'' for products that do not offer this level of protection, we are ensuring that consumers do not mistakenly rely on sunscreen products that have not been demonstrated to be effective for protection against skin cancer and early skin aging. In addition, labeling that omits a statement regarding the use of other sun protection measures as directed from the skin cancer/early aging indication could lead to consumers foregoing other sun protection measures, thereby negating the protective effect of the sunscreen. Including a statement in the skin cancer/early aging indication regarding the need to follow other sun protection measures as well as the related directions ensures that consumers understand how to use sunscreens to reduce their risk of skin cancer and early skin aging.

It is important to note that manufacturers of OTC sunscreens covered by this rule have several alternatives for adding labeling information that is not included in this labeling regulation. For example, such manufacturers can file an NDA under section 505 of the FD&C Act or submit a petition under 21 CFR 10.30 to amend the labeling regulation. In either case, the manufacturer need only submit the requisite evidence to support the indication or other labeling for the product that differs from that addressed by the regulation. Therefore, we are not being more restrictive than necessary when these viable alternatives are available for manufacturers.

Reacting to the fact that our proposed rule did not permit any indication statement for any sunscreen regarding prevention of skin cancer and early skin aging, one submission asserted that we must consider use of a disclaimer as an alternative means of addressing the limits of the product's effectiveness. As noted previously in this document, this final labeling regulation permits an appropriately limited indication for broad spectrum sunscreens with SPF values of 15 or higher—one stating that when used as directed with other sun protection measures, such products decrease the risk of skin cancer and early skin aging caused by the sun. The claim is authorized for this subset of covered sunscreen products because available scientific data discussed elsewhere in this document are sufficient to substantiate the claim for these products. Because we have included a skin cancer/early skin aging claim in these labeling regulations, we no longer view the submission's request as being applicable.

In any event, we note that the use of disclaimers on drug labeling to qualify inadequately supported or unapproved indications is not an effective, less restrictive means of achieving FDA's substantial interests in protecting public health and preserving the integrity of its premarket approval systems. Indeed, disclaimers on drug labeling would severely undermine the Government's interests here. For over 100 years, Congress has charged FDA with enforcing misbranding laws to protect public health. In 1962, Congress amended the FD&C Act to require that all new drugs be approved as both safe and effective prior to marketing. Congress found that a premarket approval system, requiring specific types of supporting evidence (see 21 U.S.C. 355(d)), and misbranding provisions, among other requirements, were necessary to avoid further tragedies involving unsafe and ineffective drugs. Using disclaimers for drugs would completely undermine the

regulatory framework established by Congress for the protection of public health. FDA's labeling regulations help ensure the safety and effectiveness of OTC drugs and establish the conditions under which a drug is not misbranded under the FD&C Act. If a manufacturer of a covered sunscreen would like to label its sunscreen product in a way that does not conform to this labeling regulation, it cannot circumvent the premarket NDA process.

In summary, we conclude that the labeling requirements provided in this document do not violate the First Amendment.

F. Other Information

We received submissions requesting that we add a new statement about storage conditions under ''Other information'' in the Drug Facts label (Ref. 1). The submissions argued that sunscreen products in containers are often exposed to heat when used at the beach, swimming pools, etc. The concern expressed in the submissions was that heat could cause sunscreen formulations inside containers to change, resulting in less sun protection. We agree with the submissions. Sunscreen products within containers should not be exposed to direct sun and can be protected by wrapping them in towels and/or keeping them in shaded environments (*e.g.,* under an umbrella and/or in a purse or bag). Consumers could also store sunscreen product containers in coolers while outside during hot periods. In this final rule we are requiring the following statement in the ''Other information'' section of the Drug Facts label: ''[Bullet] protect the product in this container from excessive heat and direct sun'' (new 21 CFR 201.327(f)).

In addition to the statement about storage conditions, we received numerous submissions requesting that we relocate the proposed ''sun alert'' warning to the ''Other information'' section of the Drug Facts label. The submissions argued that the ''sun alert'' is an educational statement and not a warning: ''UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using a sunscreen.''

As already discussed, in light of our re-evaluation of the evidence supporting the indications for sunscreens, we have made changes to the labeling to more accurately convey appropriate information to consumers about the benefits, directions, and limitations of two different groups of products covered by the rule—those that provide broad spectrum protection with an SPF value of 15 or higher, and those that do not. We do not agree that this information belongs under the heading ''Other information'' but have included it in modified form under the headings Uses and Directions for products with Broad Spectrum SPF values of 15 or higher (new 201.327(c)(2) and (e)(2), and under a revised ''Skin Cancer/Skin Aging Alert'' under the heading Warnings for other sunscreens (new 201.327(d)(2)).

In this document, we are also removing the optional ''Other information'' statements in proposed 21 CFR 352.52(e):

1. ''Low,'' ''medium,'' ''high'' or ''highest'' ''sunburn protection product''

2. ''Higher SPF products give more sun protection, but are not intended to extend the time spent in the sun.''

According to the 2007 proposed rule, these statements could appear in ''Other information'' or anywhere outside Drug Facts. However, in this rule, we have revised the labeling and are no longer requiring the principal display panel to characterize the level the sunburn protection. Rather, for broad spectrum products, the rule requires only the statement ''Broad Spectrum SPF [fill in tested SPF value]'' to appear on the principal display panel. In light of this revised approach to labeling, we are concerned that including the characterizations of the product as providing ''low,'' ''medium,'' ''high'' or ''highest'' ''sunburn protection would be confusing or misleading, and are no longer including it as an option.

We have concluded that the second statement, although truthful, is not necessary. Consumers likely understand the first part of this statement (higher SPF values represent more sun protection) based on the long-standing inclusion on SPF values on OTC sunscreen products. The second part of the statement (higher SPF products are not intended to extend time spent in the sun) is redundant with the information already provided under ''Uses'' and ''Directions,'' particularly concerning the need for limiting time in the sun (see sections IV.B and IV.D). Although we are not requiring inclusion of the second statement under ''Other information,'' the statement may appear outside the Drug Facts label because it is truthful and nonmisleading.

G. Reduced Labeling

Five submissions requested changes to our proposed regulations allowing reduced labeling for sunscreen products sold in small packages (*i.e.,* packages which meet the requirements in 21 CFR 201.66(d)(10)) that are labeled for use only on small areas of the face. One submission stated that all cosmetic products labeled with sunscreen indications should be required to include all sunscreen product labeling.

After reassessing the criteria for reduced labeling, we are not allowing the reduced labeling included in the 2007 proposed rule. OTC drug labeling regulations (21 CFR 201.66(d)(10)) allow reduced labeling for any OTC drug product sold in a small package, including sunscreen products. In the 2007 proposed rule, we proposed additional reductions in labeling for three types of sunscreen products sold in small packages and intended for use on small areas of the face:

- Proposed 21 CFR 352.52(f)(1)(i)–(f)(1)(iv): Sunscreen products sold in small packages and labeled for use specifically on the lips, nose, ears, and/or around the eyes (*i.e.,* small areas of the face)
- Proposed 21 CFR 352.52(f)(1)(v): Sunscreen-lip protectant combination products sold in small packages
- Proposed 21 CFR 352.52(f)(1)(vi): Sunscreen products formulated as lipsticks, lip products that prolong wear of lipstick, lip gloss, and lip balms

Three submissions argued that we should not restrict labeling exemptions only to sunscreen products sold in small packages and labeled for use on small areas of the face. The submissions stated that reduced labeling provisions should apply to all sunscreen products sold in small packages whether or not they are labeled for use on small parts of the face. Two of the submissions argued that such a restriction violates the Administrative Procedures Act (APA). The submissions cite *Bracco Diagnostics, Inc.,* v. *Shalala* 963 F. Supp. 20, 27–28 (D.D.C. 1997) as evidence that the courts oppose regulations requiring ''two sets of similar products to run down two sets of separate [regulatory] tracks * * * for no apparent reason.''

In this document, we continue to allow the reduced labeling specified in 21 CFR 201.66(d)(10). Therefore, if the information listed under Drug Facts requires more than 60 percent of the total available surface area, the Drug Facts labeling can be reduced by making the formatting changes specified in 21 CFR 201.66(d)(10)(i)–(d)(10)(v). However, in contrast to the 2007 proposed rule, we are not allowing additional reductions in labeling for any sunscreen products.

When we proposed the additional reduced labeling, we recognized that many of the sunscreen products sold in

small packages and labeled for use on small areas of the face could not accommodate full Drug Facts labeling. However, in the last several years, manufacturers have introduced new label designs that permit full Drug Facts labeling on very small packages. For example, some stick products, including lip protectant-external analgesic combinations marketed in 0.15 oz. amounts, have been labeled with wrap-around labels that contain full Drug Facts labeling. If these products can be labeled to accommodate full Drug Facts labeling, then all sunscreen products should be able to accommodate full Drug Facts labeling. Requiring full Drug Facts labeling should not discourage manufacturers from including sunscreen ingredients because of limited labeling space, as stated in the 2007 proposed rule (72 FR 49070 at 49075 through 49077). Therefore, in this document, we are eliminating all of the allowances for reduced labeling in proposed 21 CFR 352.52(f). Sunscreen products can only have reduced labeling for formatting if they meet the criteria in 21 CFR 201.66(d)(10).

V. Miscellaneous Labeling Outside Drug Facts

We received several submissions regarding various performance claims, including comments asking us to allow claims for protection immediately upon application (instant protection) and for extended duration between applications (extended wear) and comments asking us not to allow terms such as ''sunblock,'' ''waterproof,'' and ''sweatproof'' (Ref. 1). These kinds of claims were not included in the 2007 proposed rule (Ref. 1).

We are not including labeling in 21 CFR 201.327 permitting these claims on OTC sunscreen products covered by the rule. The current record does not contain support for any of these kinds of claims. To clarify the status of these kinds of claims, we are finalizing two provisions. We include instant protection and extended wear claims, which are claims that we think may be capable of substantiation, in 21 CFR 310.545(a)(29)(ii). While these claims may not be included on products marketed without approved applications, including them in this provision makes it clear that these claims may be substantiated for an individual product by the submission of adequate data in an NDA.

We agree with the submissions that argue that ''sunblock,'' ''waterproof,'' and ''sweatproof'' claims are false or misleading, as we have stated in previous sunscreen rulemakings (58 FR 28194 at 28228; 64 FR 27666 at 27676 through 27680). These terms are essentially exaggerations of performance that FDA does not think can be substantiated. Accordingly, in this final rule, we codify these as terms or phrases that would be false or misleading on covered products, and are therefore prohibited (21 CFR 201.327(g)).

In addition to submissions requesting that we allow certain labeling outside Drug Facts, we also received a submission requesting that we require information about the UV index (UVI). A stated in the 2007 proposed rule, we have determined that the usage information provided on OTC sunscreen products applies regardless of the UVI value (72 FR 49070 at 49073). Therefore, we will allow but do not require information about the UV index to be included on sunscreen products outside the Drug Facts label.

A submission requested that we require that the UV index appear on sunscreen product labels because this information would help consumers understand and use the UV index to determine their risk of sunburn. The UV index was developed in 1995 by the National Weather Service, Environmental Protection Agency, and Centers for Disease Control and Prevention to provide a forecast of the expected risk of overexposure to UV rays. The UV index is calculated using ozone data, atmospheric pressure, temperature, and cloudiness. As stated in the 2007 proposed rule, we are not requiring labeling of UV index information because it is not necessary for consumers to understand this index in order to safely and effectively use OTC sunscreen products (72 FR 49070 at 49073). However, manufacturers may include truthful and nonmisleading information about the UV index in the labeling outside of Drug Facts if they choose.

We also received a submission requesting that we allow a claim of ''instant protection'' and to allow claims for extended periods of protection between applications (*i.e.,* longer than the 2 hours specified in ''Directions'' in the 2007 proposed rule). The submission argued that several marketed products provide sunburn protection immediately upon application, as demonstrated by test results included in the submissions. In this document, SPF testing requires a 15-minute waiting period between sunscreen application and UV exposure of the test site. It appears that the submitted test method included the same 15-minute waiting period. Therefore, the assertion that this product provides ''instant protection'' does not appear to be substantiated. We also did not receive any data regarding claims for extended periods of use, so it is not clear whether these claims are truthful. Claims that a product provides for an extended period of protection between applications or immediately upon application would have to be supported by data. Therefore, these claims could be made only under approved new drug applications (NDAs) with the required data.

In this document, we are specifically identifying these claims as not allowed on any OTC sunscreen product, regardless of SPF value or broad spectrum protection, without an approved application containing sufficient substantiation to support the claim. (new 21 CFR 310.545(a)(29)(ii)):

- Instant protection or protection immediately upon application
- Claims for ''all-day'' protection or extended wear claims citing a specific number of hours of protection that are inconsistent with the directions for application in 21 CFR 201.327.

In addition, we are identifying the terms ''sunblock'' ''waterproof,'' and ''sweatproof'' as false and misleading, as we have stated in previous sunscreen rulemakings:

- Sunblock (64 FR 27666 at 27679 and 27680)
- Sweatproof (58 FR 28194 at 28227 through 28228)
- Waterproof (58 FR 28194 at 28227 through 28228).

We have previously identified these claims as ones that would render a product misbranded but are addressing them again in this document because OTC sunscreen products currently marketed without approved applications continue to contain the claims. In this final rule, we are listing these false and misleading terms in 21 CFR 201.327(g). These terms may not be included on any OTC sunscreen products covered by the rule.

Finally, in the 2007 proposed rule, we proposed to specify other optional statements that could be included outside of Drug Facts in proposed 21 CFR 352.52(e)(3):

- ''Broad spectrum sunscreen''
- ''Provides [select one of the following: 'UVA and UVB' or 'broad spectrum'] protection''
- ''Protects from UVA and UVB [select one of the following: 'rays' or 'radiation']''
- ''[Select one of the following: 'absorbs' or 'protects'] within the UVA spectrum.''

This final rule is not a monograph, and we do not consider it necessary in this rule to codify optional statements for use outside of ''Drug Facts.'' The labeling required in this document

should provide consumers with the information that they need to safely and effectively use the sunscreen products that it addresses. Under this final rule, products marketed without approved applications that provide broad spectrum protection according to the test in new 21 CFR 201.327(j) of this document will be identified on the PDP by use of the term ''Broad

Spectrum SPF.'' In light of this requirement in the rule for use of the term ''broad spectrum'' on these particular products, including a statement anywhere in the labeling of a product that does not pass the broad spectrum test in 21 CFR 201.327(j) that suggests or implies that the product provides broad spectrum protection would misbrand that product. We likewise caution against references to ''UVA'' (or ''UVA/UVB'') protection on products that do not provide broad spectrum protection as demonstrated by the test in 21 CFR 201.327(j). Such labeling would misbrand the products if it misleadingly suggests that the products provide protection that is equivalent or greater to that provided by products labeled with ''Broad Spectrum SPF'' values or is otherwise false or misleading.

VI. SPF Test Parameters

The 2007 proposed rule included the SPF test from the 1999 final rule with revisions to a few test parameters. In response to the 2007 proposed rule, we received numerous submissions requesting that we revise additional test parameters (Ref. 1). In this document, we have rewritten the regulations describing the SPF test in an effort to make it easier to read and understand and to more closely follow the order in which steps of the SPF testing procedure are conducted. We have also made several revisions to the test parameters. However, we did not make all of the revisions requested in the submissions. Table 4 of this document summarizes test parameters that we considered revising. The table identifies the parameters that we are changing in this document as well as those that we are not changing. Detailed discussion of each test parameter appears throughout the remainder of this section.

TABLE 4—SUMMARY OF SPF TEST PARAMETERS INCLUDED IN THE 2007 PROPOSED RULE AND THIS FINAL RULE

2007 Proposed rule	This final rule
21 CFR 352.70(a). Standard sunscreens	*21 CFR 201.327(i)(2). SPF standard*
Two standards: 8% homosalate (SPF 2—≤15) 7% padimate, 3% oxybenzone (SPF >15)	One standard: 7% padimate, 3% oxybenzone (all SPFs)
HPLC reference standard: no limits set for accuracy of oxybenzone & padimate O	HPLC reference standard: limit set to within 5% of theoretical for accuracy of oxybenzone & padimate O
21 CFR 352.70(b). Light source (solar simulator)	*21 CFR 201.327(i)(1). UV source (solar simulator)*
Emission spectrum specifications: (1) COLIPA [1] 1994 (Ref. 63) (2) no specifications for UVA	Emission spectrum specifications: (1) COLIPA [1] 2006 (Ref. 64) (2) specifications for UVA I and UVA II percentages of total UV
Calibration: every 6 months	Calibration: at least annually
Total irradiance: 1500 Watts/square meter (W/m^2)	Total irradiance: 1500 Watts/square meter (W/m^2)
Beam uniformity: within 20 percent	Beam uniformity: within 20 percent
21 CFR 352.70(c)(7). Number of subjects	*21 CFR 201.327(i)(3). Test subjects*
SPF < 30: 20–25 subjects; ≥ 20 valid results SPF ≥ 30: 25–30 subjects; ≥ 25 valid results	All SPFs: • 10–13 subjects; ≥10 valid results
21 CFR 352.70(c)(4). Test site delineation/subsite	*21 CFR 201.327(i)(4)(i) and (ii). Test site/subsite*
test site area: ≥ 50 cm^2 test subsite area: ≥ 1 cm^2 Distance between subsites: ≥ 1 cm	test site area: ≥ 30 cm^2 test subsite area: ≥ 0.5 cm^2 Distance between subsites: ≥0.8 cm
21 CFR 352.70(c)(5). Application of test materials	*21 CFR 201.327(i)(4)(iii). Applying test materials*
Application amount: 2 milligrams per square centimeter (mg/cm^2) Presaturation of finger cot: Required Water-resistant statement requirements: 20 minute water immersion times 20 minute drying times	Application amount: 2 milligrams per square centimeter (mg/cm^2) Presaturation of finger cot: not required Water-resistant statement requirements: 20 minute water immersion times 15 minute drying times
21 CFR 352.70(d)(3). Determination of individual SPF values	*21 CFR 201.327(i)(5). UV exposure*
Definitions of MED: (1) MED(PS) = MED for protected skin (2) MED(US) = MED for unprotected skin	Definitions of MED: (1) ssMEDp = MED for skin protected by sunscreen standard (2) tpMEDp = MED for skin protected by test product (3) initial MEDu = MED for unprotected skin prior to testing test product (4) final MEDu = MED for unprotected skin determined when testing test product
UV doses for MED(US):	UV doses for initial MEDu:

TABLE 4—SUMMARY OF SPF TEST PARAMETERS INCLUDED IN THE 2007 PROPOSED RULE AND THIS FINAL RULE—Continued

2007 Proposed rule	This final rule
five doses	number of doses not specified
21 CFR 352.70(c)(8) Response criteria	*21 CFR 201.327(i)(5). UV exposure*
Maximal UV exposure:	Maximal UV exposure:
"no more than twice the total energy of the minimal exposure"	not specified

[1] Draft test method entitled "International Sun Protection Factor (SPF) Test Method" developed by the European Cosmetic, Toiletry and Perfumery Association (COLIPA).

We are not making some of the requested changes to certain test parameters because we lack adequate data to determine whether these changes would change the accuracy or reproducibility of the SPF test. We are making changes to some test parameters based on the following developments since the 2007 proposed rule published:

- New data (submitted by the public or published in the scientific literature)
- Technical improvement of SPF testing equipment
- Accumulating experience in the performance of SPF testing
- Efforts towards international harmonization of SPF testing procedures

In support of the requested changes, several submissions (Ref. 1) cited differences between the SPF test in the 2007 proposed rule and the COLIPA SPF test (Ref. 64). The COLIPA SPF test is a joint effort by the cosmetic industry trade associations in Europe, Japan, South Africa, and the United States to harmonize SPF test procedures. The International Organization for Standardization (ISO) is currently developing an SPF test method. Because harmonization of testing methods is important, we are actively involved in the ISO working group responsible for developing methods for assessing the efficacy of sun protection products.

We are revising our proposed SPF test method to be as consistent as possible with the COLIPA SPF test. We acknowledge the merits of harmonizing test methods and are an active participant in ongoing harmonization efforts. However, some of the test parameters in this document differ from comparable parameters in the COLIPA SPF test because we have concluded that the data do not support using the COLIPA SPF test parameters. Throughout the remainder of this section, we discuss whether test parameters in this document match or do not match those in the COLIPA SPF methods.

A. Solar Simulator

Several submissions recommended adopting the solar simulator specifications in the COLIPA SPF test (Ref. 1). We are revising solar simulator specifications to:

- Allow the use of smaller beam, multiport simulators
- Adjust the relative cumulative erythemal effectiveness (RCEE) range specifications for each wavelength band
- Specify that UVA II (320–340 nm) and UVA I (340–400 nm) irradiance should equal or exceed 20 percent and 60 percent, respectively, of the total UV (290–400 nm) irradiance
- Change the regular calibration period from every 6 months to at least once a year

These changes are consistent with the COLIPA SPF test. More importantly, these revisions will allow the SPF test to continue to be accurate and reproducible. For example, we received calibration data demonstrating that solar simulators and their UV lamps are stable for periods longer than 1 year. Therefore, the requirement in the 2007 proposed rule to calibrate every 6 months is unnecessary. The test results should be the same whether calibration is done annually or every 6 months.

In contrast, we are not changing the following solar simulator specifications because changes to these specifications could reduce test accuracy and/or reproducibility:

- Total irradiance limit of 1500 W/m^2
- Total irradiance range of 250–1400 nm
- 20 percent beam uniformity requirement.

These test specifications differ from the COLIPA SPF test, which recommends a 1600 W/m^2 limit and a 10 percent beam uniformity requirement.

Two submissions (Ref. 1) objected to limiting total solar simulator irradiance to 1500 W/m^2 for all wavelengths between 250 and 1400 nm (proposed 21 CFR 352.70(b)(1)). We proposed the 1500 W/m^2 limit because we were concerned that solar simulators operating above this limit could cause excessive heat. Excessive heat could harm test subjects and/or cause loss of dose reciprocity, the correlation between UV dose and resulting erythema. One submission argued that no data indicate that exceeding 1500 W/m^2 causes excessive heat or affects SPF test results. The submission argued that higher intensities should be allowed as long as they are thermally tolerated by test subjects, because allowing higher intensities enables faster SPF testing.

We are not changing the 1500 W/m^2 total irradiance limit. We do not have data demonstrating that exceeding 1500 W/m^2 leads to loss of dose reciprocity. However, we conclude that the limit should be retained to protect test subjects. The COLIPA SPF test cites a study showing that total irradiance of 1600 W/m^2 induces heat and pain in a majority of test subsites, and recommends keeping total irradiance below 1600 W/m^2 (Ref. 64). Therefore, we are keeping the 1500 W/m^2 total irradiance limit (new 21 CFR 201.327(i)(1)(i)).

One submission also objected to the 250–1400 nm range over which total irradiation should be monitored (Ref. 1). The submission argued that portable spectroradiometers are typically incapable of measuring wavelengths out to 1400 nm. According to the submission, emissions from longer wavelengths have not been shown to affect SPF testing.

We are not changing the requirement that total irradiation be monitored over a range of 250–1400 nm. We have concluded that monitoring over this range of wavelengths helps protect SPF test subjects from being exposed to undesirable, unnecessary radiation. The requirement should not impose undue hardship, because longer wavelengths can be monitored using a thermopile, pyroelectric, or similar detectors.

We received two submissions addressing the requirement in proposed 21 CFR 352.70(b)(2) that a solar simulator have "good beam uniformity (within 20 percent) in the exposure plane" (Ref. 1). One submission argued that advances in equipment and monitoring allow for a stricter beam uniformity requirement (<20 percent), which would result in less variability in SPF test results. Another submission argued that the beam uniformity

requirement is only important for large diameter beams and has no impact on SPF testing using small beams.

We are not changing the 20 percent beam uniformity requirement because accurate determination of SPF values relies upon good beam uniformity for all beam sizes. In the 2007 proposed rule, we described how small diameter beams can be tested for beam uniformity (see 72 FR 49070 at 49098). The submission requesting stricter requirements did not include data showing that current solar simulators can reasonably be expected to have beam uniformity less than 20 percent. We conclude that a 20 percent beam uniformity requirement is adequate to produce reliable SPF results. Therefore, we are keeping the requirement that solar simulators demonstrate good beam uniformity (within 20 percent) in new 21 CFR 201.327(i)(1) (iii).

B. Sunscreen Standards

The 2007 proposed rule include two sunscreen standards for use in SPF testing. The two proposed sunscreen standards were a 7 percent padimate O/3 percent oxybenzone standard (mean SPF value of 16.3) and an 8 percent homosalate standard (mean SPF value of 4.47). For SPF testing of sunscreen products with SPF values of 2 to 15, either the padimate O/oxybenzone standard or the homosalate standard would have been required to be tested along with the test sunscreen product. Tests for sunscreen products with SPF values over 15 would have required use of the padimate O/oxybenzone standard.

We received two requests to include an additional sunscreen standard with an SPF value of 30 or higher to test sunscreen products with SPF values of 30 or more (Ref. 1). Neither request specified any particular sunscreen standard formulation with an SPF in this range. If a particular sunscreen standard formulation were specified, we would also need validation data to support including the additional sunscreen standard in the monograph. Therefore, we are not including a sunscreen standard with an SPF value of 30 or more in this document.

We also received a request to include the JCIA SPF 15 'P3' sunscreen standard containing 0.5-percent avobenzone, 3-percent octyl methoxycinnamate, and 2.78-percent phenylbenzimidazole sulfonic acid. To support including the ''P3'' standard, the request included a table showing mean, maximum, and minimum SPF values from tests conducted in labs in Europe, Japan, Australia, and South Africa. We recognize that the ''P3'' standard has been widely used and is included in the COLIPA SPF test, but we are not including the ''P3'' standard in this document. In the 2007 proposed rule (72 FR 49070 at 49095 to 49095), we requested further data to show that testing using the ''P3'' standard could be performed with:

- Low level interlaboratory variation
- Sufficient sensitivity to detect experimental error
- A reasonable degree of accuracy

The submitted data (*i.e.* the table of SPF values) fail to show that the ''P3'' standard meets these performance requirements because they do not show:

- Individual lab results
- The number of tests conducted in each lab
- The number of test subjects used in each test
- Calculated standard errors for each test

Without these data, we cannot assess interlaboratory variability, sensitivity to experimental error, or test result accuracy. In addition, the advantage of using the ''P3'' standard instead of the padimate O/oxybenzone standard is unclear, because both these standards have approximately the same SPF value of 16. Therefore, we are not including the ''P3'' standard in this document.

We are also eliminating the proposed homosalate standard with an SPF value of 4.47 because the padimate O/oxybenzone standard with an SPF value of 16.3 is adequate for validating all test methodologies. In the 2007 proposed rule, we stated that the sunscreen standards were ''method controls rather than calibration tools.'' As a method control, the purpose of the sunscreen standard is verifying proper and consistent performance of test equipment and procedures, rather than verifying the accuracy of the SPF value determined for sunscreen test products. Therefore, we conclude that it is not critical for the SPF value of the sunscreen standard to be close to the SPF value of the sunscreen test product. It is more important that the sunscreen standard demonstrate consistency of test performance. Consequently, we have concluded that including multiple sunscreen standards is unnecessary, and that the padimate O/oxybenzone standard is a suitable sunscreen standard for all sunscreen products. We favor including the padimate O/oxybenzone standard over the homosalate standard because the homosalate standard was only proposed for use for SPF testing of sunscreen products with SPF values lower than 15. Because most currently marketed sunscreen products have SPF values of 15 or higher, the padimate O/oxybenzone standard is used much more frequently than the homosalate standard.

We received one submission identifying errors in the ''Composition of the Padimate O/Oxybenzone Standard Sunscreen'' table that appears in the 2007 proposed rule. As suggested by the submission, we are moving the inactive ingredient ''propylparaben'' from ''Part A'' to ''Part B,'' as it appears in the COLIPA SPF test. We are not revising the listing of the inactive ingredient ''glyceryl monostearate'' to read ''glyceryl monostearate (Glyceryl Stearate SE),'' as suggested. The United States Pharmacopeia defines ''glyceryl monostearate'' as an ''emulsifying and/or solubilizing agent,'' which adequately describes the ingredient that is appropriate for use in the formulation.

C. Test Subjects

In the 2007 proposed rule, we proposed requiring the following numbers of test subjects providing valid results:

- 20 to 25 subjects for sunscreen products with SPF less than 30
- 25 to 30 subjects for sunscreen products with SPF value of 30 or more

We explained that a minimum of 20 subjects would be required to provide an acceptably accurate SPF result (*i.e.,* low standard error of the mean). We had concluded that sunscreen products with SPF values of 30 or more required a greater number of test subjects because we suspected higher test result variability for these sunscreen products. However, the data used for determining appropriate test subject numbers were limited and dated. Therefore, we invited submission of additional data demonstrating what subject numbers would be adequate.

Several submissions recommend requiring 10 to 25 test subjects as in the COLIPA SPF test (Ref. 1). These submissions include data demonstrating that SPF testing can be performed with suitable accuracy and precision with as few as 10 test subjects. The submissions further argued that SPF testing using a minimum of 10 test subjects has been practiced globally for many years, even for sunscreen products with high SPF values.

We agree with the submissions and are lowering the number of test subjects required for SPF testing. We are requiring that a test panel produce a minimum of 10 valid test results. A maximum of three subjects may be rejected from the panel. Therefore, if 3 subjects would be rejected, a test panel would have had to include 13 subjects.

We are reducing the number of test subjects in this document because the

data we received demonstrate that SPF testing can be conducted with adequate accuracy and precision using as few as 10 test subjects, even when testing high SPF products. The submissions include SPF test results for several sunscreen formulations using panels of 20 to 25 test subjects. We randomly selected 10 subjects within each of these panels to determine if using fewer subjects significantly decreased test accuracy and precision. For each of these panels, the mean SPF value and standard error calculated from a randomly selected subset of 10 subjects were not significantly different from those calculated from all 20 to 25 subjects in the panel. Therefore, these data indicate that using as few as 10 test subjects will not compromise SPF test accuracy or precision. Consequently, fewer test sites and subsites need to be tested and fewer test results need to be rejected, thereby decreasing the number of test subjects needed. Our revised SPF test subject number requirement is similar to the COLIPA SPF test requirement. The only significant difference related to test subject number is that we are not including a statistical requirement or allowing individual subjects to be added incrementally to a test panel as allowed under the COLIPA SPF test.

D. Test Sites and Subsites

Several submissions requested the following revisions of the minimum size specifications for test sites and subsites proposed in the 2007 proposed rule (Ref. 1):

- Test site: proposed 50 cm^2 revised to 30 cm^2
- Test subsite: proposed 1 cm^2 revised to 0.5 cm^2
- Subsite separation: proposed 1 cm revised to 0.8 cm

According to the submissions, these smaller revised minimum sizes would allow multiport solar simulators to be used, while the larger proposed sizes would not. These revised specifications have also been adopted in the COLIPA SPF test (Ref. 64).

We are revising the test site and subsite size specifications as requested by these submissions. Our previously proposed specifications were based on single port solar simulators. Some new multiport solar simulators cannot meet these proposed specifications. In the 2007 proposed rule, we stated that reducing test site/subsite size specifications would be considered if data were submitted showing that these reductions would not compromise testing accuracy (72 FR 49070 at 49100). New data show that SPF testing can still be accurately performed using the recommended reduced test site/subsite size specifications (Ref. 1). Therefore, we are revising the test site/subsite size specifications to accommodate new equipment and to harmonize our specifications with global SPF test methods.

E. Finger Cot

In the 2007 proposed rule, we proposed that a finger cot, presaturated with sunscreen, be used to apply the sunscreen in the SPF test (proposed 21 CFR 352.70(c)(5)):

> Use a finger cot compatible with the sunscreen to spread the product as evenly as possible. Pretreat the finger cot by saturating with the sunscreen and then wiping off material before application. Preteatment is meant to ensure that sunscreen is applied at the correct density of 2 mg/cm^2.

We received one submission that objected to the use of finger cots because consumers do not typically use finger cots when applying sunscreens (Ref. 1). Other submissions argued that the presaturation requirement for finger cots is unnecessary and introduces variability in applied amounts (Ref. 1). Other submissions requested the optional use of sponge applicators for testing powder formulations, because they argued that sponge applicators distribute powder formulations more evenly than finger cots (Ref. 1). We are not addressing issues regarding the use of sponge applicators for the testing of powders in this rule. Elsewhere in this issue of the **Federal Register**, we publish an advance notice of proposed rulemaking that discusses sunscreen dosage forms, including powders. We may address this issue in a future rulemaking..

While we acknowledge that consumers do not use finger cots to apply sunscreens, we are continuing to require the use of finger cots in the SPF test. The use of finger cots seems to increase reproducibility of test results, which was why we originally proposed requiring use of finger cots (72 FR 49070 at 49100 through 49101). We agree with the submissions that the presaturation requirement is unnecessary and are removing this requirement. We proposed requiring finger cot presaturation to prevent sunscreen product from adhering to the finger cot instead of being transferred to the test subject's skin, resulting in sunscreen product being applied at less than the intended 2 mg/cm^2. We received study results showing that a residual amount of sunscreen product may adhere to non-presaturated finger cots, but the amount was small (approximately 2 percent) (Ref. 1). In this study, each of 100 finger cots (without presaturation) was weighed before and after sunscreen product application at 2 mg/cm^2 (100 mg sunscreen product applied over 50 cm^2). However, the study did not include a comparison to presaturated finger cots. Therefore, it is difficult to determine the effect of presaturation on residual sunscreen amounts.

In addition, we reassessed the basis for presaturation. We are now concerned that performing the presaturation step may lead to overestimation of SPF values, because the residual amount normally left on a finger cot with presaturation may increase the amount of sunscreen applied to the skin This could lead to overestimation of SPF values. Overestimation of SPF may, in turn, lead to increased incidence of sunburn because consumers may anticipate greater protection than a sunscreen product actually provides. This overestimation risk is a sufficient basis to remove the presaturation step from the proposed SPF test method.

We also received data showing that testing without the presaturation step can produce highly reproducible results (Ref. 1). In a test of 20 subjects without the presaturation step, a control sunscreen product yielded a mean SPF value of 4.19 with a standard error of 0.06 (*i.e.*, 1.4 percent error), while a test sunscreen product yielded a mean SPF value of 15.54 with a standard error of 0.22 (*i.e.*, 1.4 percent error). These errors are small, suggesting that the calculated SPF values did not vary significantly between test subjects. If lack of presaturation increased variability, then the errors would be expected to be larger. Therefore, we are removing the presaturation requirement because of the risk of overestimation of SPF values and our conclusion that the removal of the presaturation step will not affect the reproducibility of SPF test results.

F. Application Amount

We are continuing to require that 2 mg/cm^2 sunscreen product be applied for the SPF test (proposed 21 CFR 352.70(c)(5); new 21 CFR 201.327(i)(4)(iii)). Several submissions argued for a lower application amount that better reflects the actual amount used by consumers, which they argued is commonly 1 mg/cm^2 or less (Ref. 1). These submissions argued that the unrealistically high 2 mg/cm^2 application amount results in SPF values that overstate the actual sun protection provided by the amounts consumers typically apply. Other submissions supported the 2 mg/cm^2 application amount (Ref. 1). These submissions argued that SPF values are relative, not absolute, values that allow comparison of sun protection provided

by different sunscreen products. According to the submissions, changing the application amount will affect the ability of consumers to make this comparison.

We are not changing the sunscreen product application amount because we have concluded that the advantages of continuing to require 2 mg/cm^2 exceed the disadvantages of lowering the amount. Requiring the 2 mg/cm^2 sunscreen product application amount is consistent with SPF test methods used in other countries. The 2 mg/cm^2 application amount is being used in Europe, Australia, Canada, Korea, and Japan (Refs. 65–67). If we lower the application amount, sunscreen products available in the United States will have significantly lower SPF values than similar products available in other countries. This discrepancy in SPF values is counterproductive to our global harmonization efforts and would likely mislead consumers traveling to other countries about the SPF protection of foreign sunscreen products.

Another advantage of continuing to require a 2 mg/cm^2 sunscreen product application amount is greater reproducibility of SPF test results. Bimczok *et al.* compared the SPF values determined using sunscreen product application amounts of 0.5, 1, and 2 mg/cm^2 (Ref. 68). The SPF values determined using 2 mg/cm^2 sunscreen product were more reliable and reproducible than SPF values determined using the lower application amounts. A sunscreen product application amount of 2 mg/cm^2 is a large enough amount to allow visualization of the distribution of sunscreen product as it is applied. This allows for more consistent and uniform application of the sunscreen used in testing. Therefore, the 2 mg/cm^2 sunscreen product application amount is more likely to generate reproducible results.

G. Water Resistance

In the 2007 proposed rule, sunscreen products tested with two 20-minute immersion periods (*i.e.*, 40 minutes total) would be allowed to include a ''water resistant'' statement and sunscreen products tested with four 20-minute immersion periods (*i.e.*, 80 minutes total) would be allowed to include a ''very water resistant'' statement. There is a 20-minute drying period between each immersion period. For example, a ''water resistant'' sunscreen product would be tested by having test subjects in the water for 20 minutes, out of the water for 20 minutes, and in the water for 20 minutes.

We received various requests to revise the test (Ref. 1). One submission recommended longer water immersion times equal to those in water resistance tests used in Australia and New Zealand. Another submission included data from an in vitro water resistance test to support removing the in vivo water resistance test. A third submission stated the test should be eliminated because it is not validated and requires too much time. Further, the submission argued that directions for frequent reapplication make the test unnecessary.

We are continuing to include a water resistance test because water resistance is an important property of sunscreen products that can benefit consumers. The water resistance test indicates that a sunscreen product's labeled SPF protection is retained for a certain period of time after immersion in water. This is useful information to consumers. Therefore, we conclude that a water resistance statement based on the test should be allowed (see section III.C of this document).

We are not changing the 20-minute water immersion periods or the number of immersion periods required. We based these time periods on marketing data indicating that individuals at the beach or the pool spend an average of 21 minutes in the water and go into the water an average of 3.6 times (43 FR 38206 at 38263, August 25, 1978). We have not received any other data supporting different time periods. We have concluded that more or longer water immersion periods are not needed.

We are, however, reducing the drying period from 20 minutes to 15 minutes. We are making this change to decrease the time required for testing. Shorter testing time may increase test accuracy and reproducibility, especially for high SPF sunscreens that retain their water resistance for 80 minutes. In addition, 15 minutes is adequate time to allow for drying. It is possible that sunscreens may lose water resistance with repeated wetting and drying. However, we have concluded that a 15-minute drying period mimics consumer behavior and ensures that the water resistant properties of a sunscreen do not change with multiple cycles of water immersion and drying.

VII. SPF Test Issues (Other than Test Parameters)

A. Pass/Fail (Binomial) SPF Test

Several submissions requested the optional use of a pass/fail (binomial) test to determine the SPF value of a sunscreen product (Ref. 1). These submissions promote the pass/fail test because it would expose fewer subjects to UV irradiation, cost less, and save time. The pass/fail test is based on the hypothesis that a sunscreen product of a certain SPF has a 50:50 probability of preventing the MED response when irradiated with a UV dose correlated with that SPF. For example, a sunscreen product with an expected SPF value of 30 or more should prevent the MED response in greater than 50 percent of test subsites irradiated with a UV dose equivalent to 30 times the UV dose that causes the MED response on unprotected skin. If a test sunscreen product prevents the MED response in a significant number of the subsites (*i.e.*, significantly more subsites that ''pass'' versus ''fail''), then the test sunscreen product would be allowed to be labeled with the SPF correlated to the UV dose.

We are not including the optional use of a pass/fail test for SPF testing. We considered a pass/fail SPF test in the 2007 proposed rule (72 FR 49070 at 49094 to 49095). We stated that a pass/fail test could be a reasonable substitute for our proposed SPF test for sunscreen products with SPF values of 30 or more if certain modifications were made and validation data demonstrated that the test could be performed similarly between labs.

In response to our invitation for public comment, one submission included two studies comparing a pass/fail SPF test to the proposed SPF test: (1) A single center study of four sunscreen products with different SPF values and (2) a multicenter (four laboratories) study of two high SPF sunscreen products. After reviewing these data, we have determined that the pass/fail test has the following drawbacks:

- Each test subsite evaluation is biased towards ''pass'' because the evaluator expects that no skin reaction should occur on subsites protected by the test sunscreen product.
- The test fails to reject test sites where all of the subsites show positive responses or all of the subsites show negative responses.
- The validity of treating each subsite as an independent variable is questionable.
- The test endpoint (any observed reaction) differs from the endpoint in the proposed SPF test (clearly defined erythema).
- A passing test result for the sunscreen standard does not demonstrate that the test is being performed correctly.
- Test results do not include data for water resistant sunscreen products.
- Allowing this test as an option would yield products with different UV

protection levels labeled with the same SPF.

- SPF test methods developed by various standards-setting organizations do not include a pass/fail test.
- The study report includes statistical errors that overstate the statistical power of the test to distinguish whether a test sunscreen product provides significant UV protection.

Therefore, we are not including a pass/fail test in the SPF test procedure, because including a pass/fail test would present numerous complications and the available data indicate that a pass/fail test has disadvantages compared to the SPF test included in this document.

B. Photostability

Several submissions expressed concern about the loss of UV protection by sunscreen products due to breakdown of ingredients from exposure to sunlight (Ref. 1). These submissions recommended a test to ensure that sunscreen products exposed to sunlight retain sufficient UV protection. Submitted data show that the composition of sunscreen products can change from exposure to UV radiation. The submissions argue that the published photostability studies are inconclusive because the studies employ artificial test conditions that may not be appropriately extrapolated to actual use of sunscreens:

- Tested sunscreen active ingredients were contained in solutions rather than in typical sunscreen product formulations
- Tested sunscreen products contained active ingredients that are not representative of the active ingredients included in typical sunscreen products
- Products were tested over a limited range of the UV spectrum

The submissions argue that understanding the photostability of sunscreen active ingredients alone is not useful. Rather, the submissions argue that it is critical to understand the photostability of sunscreen active ingredients as part of an overall sunscreen product.

We agree that the available data have limitations. Although the submissions argue that the inconclusive data support including a test for photostability, we have concluded that the data do not justify requiring a photostability test at this time. We are not able to establish specific photostability test procedures or specifications based on the available data. We have not received data validating the performance of a photostability test, nor have we received data demonstrating that the effectiveness of any particular sunscreen product is significantly diminished because of photodegradation. We maintain that the proposed SPF test procedure does account for photostability to some extent, because the SPF test exposes sunscreen products to UV radiation before an SPF value is determined. Consequently, sunscreen products susceptible to photodegradation have correspondingly lower SPF values. One submission argued that the SPF test does not fully account for photostability because the solar simulator emission spectrum is different than natural sunlight. However, this difference is an unavoidable limitation in testing because solar simulators cannot perfectly replicate natural sunlight.

We acknowledge that UV radiation can change the composition of sunscreen products if the products are not photostable, as demonstrated by the submitted data. However, we are not certain that these data are applicable under actual use conditions. The data regarding the effects of UV radiation on the protection provided by sunscreen active ingredients are limited and inconclusive. Therefore, we are not creating a photostability test as part of the SPF test procedure in this document.

C. In Vitro SPF Test

One submission suggested replacing the proposed in vivo SPF test with an in vitro SPF test (Ref. 1). An in vitro SPF test would have advantages of faster performance, lower expense, and no exposure of subjects to UV radiation.

We agree that an in vitro SPF test has these advantages. However, we are not replacing the in vivo SPF test with an in vitro SPF test for the same reasons we stated in the 2007 proposed rule (72 FR 49070 at 49095). One shortcoming of an in vitro test is the lack of data on the performance characteristics of in vitro test substrates, such as quartz or artificial skin. In the 2007 proposed rule, we stated that data failed to show that a substrate adequately mimicked the physiological characteristics of human skin. We stated that we would consider an in vitro test if validating data demonstrated that the performance of the in vitro test was equivalent to the in vivo test. We have not received adequate data to validate an in vitro SPF test. Therefore, we are not including an in vitro test in this document.

D. Anti-Inflammatory Ingredients

One submission recommended requiring a test to verify that sunscreen products do not contain anti-inflammatory ingredients that significantly decrease erythemic response to UV radiation (Ref. 1). The submission did not identify specific anti-inflammatory ingredients. The submission argued that, by decreasing the erythemal response, these ingredients could falsely inflate SPF values determined in SPF testing. In addition, these anti-inflammatory ingredients may increase the likelihood of unwanted harmful effects from sun exposure because sunburn, a cue to avoid sun exposure, would be less evident.

Although the submission raises a serious concern, we are not aware of any data confirming that this problem exists. Therefore, a test to show that anti-inflammatory ingredients may be decreasing erythemic response to UV radiation is not required at this time. It seems unlikely that anti-inflammatory ingredients will affect SPF values because their anti-erythemic effect is relatively short-lived compared to the 16–24 hour interval between UV exposure and erythema observation in the SPF test.

VIII. Broad Spectrum Test

In this document, we are referring to testing involving the UVA part of the spectrum as ''broad spectrum testing.'' The term ''broad spectrum'' more accurately describes the test as covering the full extent of the terrestrial solar UV spectrum (*i.e.,* UVA and UVB radiation). Section VIII.A. of this document provides our rationale for no longer requiring an in vivo test assessing the persistent pigment darkening associated with UVA radiation. Section VIII.B. of this document explains why the in vitro test should be changed from a modified Diffey-Robson ratio to the critical wavelength test. Section VIII.C. defines the testing parameters to be employed in evaluating the critical wavelength of an OTC sunscreen product.

A. In Vivo Test Method: Not Required

We stated in the 2007 proposed rule that an assessment of UVA protection should include determination of both the magnitude and breadth of absorption in the UVA part of the spectrum (72 FR 49070 at 49102 through 49106). We proposed that an in vivo Persistent Pigment Darkening (PPD) test be used to evaluate the magnitude of absorption and an in vitro test be used to evaluate the breadth of absorption. The PPD test, a modification of the PPD test accepted by JCIA [10] since 1996, is almost identical to the SPF test. It is recognized as a standard for the in vivo assessment of UVA protection by the JCIA and the European Commission

[10] Japanese Cosmetic Industry Association.

(Ref. 7). The most significant differences in the PPD test compared to the SPF test are (1) the light source emits only UVA radiation (320–400 nm) and (2) the endpoint is darkening of the skin (tanning) rather than reddening of the skin (erythema).

We have concluded that the PPD test is not necessary to establish that a sunscreen product provides protection against UVA radiation. The magnitude of absorption over the solar terrestrial UV portion of the spectrum (both UVA and UVB) can be effectively assessed based on the SPF test in combination with a pass/fail broad spectrum in vitro test (see Section VIII.B of this document). If sunscreen products pass the in vitro broad spectrum test, then the amount of UVA radiation protection, as well as UVB radiation protection, must increase as the SPF value increases. For example, a Broad Spectrum SPF 40 sunscreen product must provide more UVB and UVA radiation protection than a Broad Spectrum SPF 20 sunscreen product.

For sunscreen products that pass the in vitro broad spectrum test, we have concluded that the SPF and PPD tests are redundant of each other, but we have reasons to prefer the SPF test. The SPF and PPD tests are both clinical and indicative of the magnitude of absorbance of UV radiation. Furthermore, both tests depend on the skin type of the individual. The SPF test measures skin reddening, which is due primarily to UV radiation in the UVB and UVA II regions (290–340 nm). The PPD test measures skin darkening, which is due primarily to UV radiation in the UVA II part of the spectrum (320–340 nm). Therefore, the UV radiation range covered by the PPD test is also covered by the SPF test. In both tests, the endpoint is indicative of how much UV radiation is absorbed. As the magnitude of UV radiation absorbance increases for a sunscreen product, both the SPF and PPD ratings increase.

We have identified several disadvantages of the PPD test as described in the proposed rule (72 FR 49070 at 49103):

- Human subjects are exposed to high doses of UVA radiation with unknown health consequences.
- Exposure to UVA radiation alone (*i.e.,* in the absence of UVB radiation) is never encountered in nature, and the biological effects of such exposure may differ greatly from those due to exposure to natural sunlight.
- Because it is unclear how tanning relates to the harmful effects of sunlight, it is unclear whether persistent pigment darkening represents a clinically meaningful endpoint.

Other disadvantages are pointed out by Nash *et al.* (Ref. 4):

- The physical properties of sunscreen products may differ when sunscreen products are exposed to UVA radiation alone.
- The PPD test is expensive, time consuming, and labor intensive.
- The ability to identify small differences in pigmentation requires a high degree of expertise and interpretation of pigmentation changes will be dependent on the examiner.
- There may be a high degree of variability in test results between subjects in the same test panel as well as between different test panels for the same sunscreen product.
- The test results may not be reproducible between labs.

Because of these disadvantages of conducting the PPD test, and the fact that information obtained from such tests is already provided by SPF testing for sunscreen products that pass the in vitro broad spectrum test, we are eliminating the requirement to conduct a PPD or any other in vivo UVA test in this final rule.

B. In Vitro Test Method: Critical Wavelength

Many submissions objected to our proposal to use a modification of the Boots adaptation of the Diffey/Robson ratio as an in vitro measure of UVA protection (Ref. 1). The Diffey/Robson ratio evaluates UVA protection relative to UVB protection. The ratio is calculated as the area under the absorbance curve in the UVA region (320–400 nm) divided by the area under the absorbance curve in the UVB region (290–320 nm). As the degree of protection against UVA radiation increases, the ratio increases.

We proposed a modification of this ratio to be calculated as the area under the absorbance curve in the UVA I region (340–400 nm) divided by the area under the absorbance curve over total UVB and UVA range (290–400 nm). We indicated that this modification was necessary because we were concerned that a sunscreen product absorbing strongly in the UVA II region (320–340 nm), but not absorbing strongly in the UVA I region, might produce a disproportionately high ratio value (72 FR 49070 at 49105). We would not consider this sunscreen product to be a good broad spectrum sunscreen product even though it has a high ratio value. We noted the importance of ensuring that protection extends well into the UVA I region (340–400 nm), because neither SPF nor PPD measurements provide much information about the longer wavelengths of UVA radiation. Therefore, we modified the ratio to give more emphasis to the UVA I area under the absorbance curve.

Many submissions argued that we should require a determination of critical wavelength rather than the proposed ratio to determine broad spectrum protection (Ref. 1). We agree with the arguments made in the submissions. Therefore, in this document, we are requiring that broad spectrum protection be assessed by determining the critical wavelength of a sunscreen formulation. The submissions noted the following disadvantages with the proposed ratio:

- The proposed ratio places too much emphasis on the UVA I region, which is not generally considered to contribute significantly to the harmful effects of exposure to UV radiation.
- A large ratio could result if one or more ingredients absorb radiation in the shorter wavelength UVA II region but not at all or only minimally in the longer wavelength UVA I region. For example, oxybenzone absorbs radiation at 340–360 nm, and inclusion of this ingredient at higher concentrations might result in a high ratio even though it does not provide true broad spectrum protection.
- The proposed ratio is not a validated measure of UVA protection and is not used anywhere else in the world.
- To achieve high ratios with existing GRASE active ingredients, the concentrations of ingredients that absorb in the UVB and UVA II parts of the spectrum have to be reduced, lowering protection in these parts of the spectrum (*i.e.,* the SPF has to be lowered to increase the ratio).

We agree that our proposed ratio is not the most appropriate in vitro measure of broad spectrum protection. In agreement with many of the submissions, we have concluded that the ratio places too much emphasis on absorption in the UVA I part of the spectrum. Although there is some evidence that UVA I radiation contributes to immune suppression and an increase in p53-positive cells, the effects of UVA I radiation on these processes are 100 to 1000 times less than the effects attributed to UVB and UVA II radiation (Ref. 4). We also acknowledge that there is no experience using the proposed ratio. Further, we received some data in the submissions that demonstrate the need to reduce SPF values in order to achieve high ratio values. We are concerned that, in an effort to gain UVA protection, consumers may be more susceptible to

sunburn because SPF values could be lower in products with higher ratios.

In agreement with many of the submissions, we have concluded that the critical wavelength method provides a better measure of broad spectrum protection. The critical wavelength (λ_c) is derived from the same data as the modified ratio. The critical wavelength is the wavelength at which the area under the absorbance curve represents 90 percent of the total area under the curve in the UV region. This is expressed mathematically as:

$$\int_{290}^{\lambda c} A(\lambda)d\lambda = 0.9 \int_{290}^{400} A(\lambda)d\lambda$$

In this expression, A(λ) is the mean absorbance at each wavelength, and dλ is the wavelength interval between measurements.

Like the proposed ratio, the critical wavelength measures the breadth of the UV absorbance curve. Unlike the proposed ratio, the critical wavelength does not emphasize certain parts of the UV spectrum, but is a measure of absorbance across the entire solar terrestrial UV spectrum (UVB and UVA radiation). Sunscreen products offering primarily UVB protection would have a critical wavelength less than 320 nm, whereas those providing both UVB and UVA protection would have critical wavelengths between 320 and 400 nm.

The critical wavelength method is simple, reproducible, and inexpensive. It has been used by sunscreen manufacturers to evaluate UVA protection for over a decade and is one of the most commonly used UVA tests. This is evidenced by the organizations that recommend its use for determining broad spectrum protection, including the European Commission, the American Academy of Dermatology, the American Society for Dermatologic Surgery, and the Skin Cancer Foundation (Ref. 1).

In this document, we are requiring that sunscreen products have a critical wavelength of at least 370 nm (the mean value must be equal to or greater than 370 nm) to be labeled as providing broad spectrum protection (see section VIII.B.). This differs from the tiered rating (low, medium, high, and highest) that we included in the 2007 proposed rule (proposed 21 CFR 352.50(b)(2)). We have concluded that the threshold critical wavelength for a broad spectrum statement should be 370 nm. This wavelength is sufficiently difficult to achieve and will ensure that sunscreen products meeting this threshold provide a significant amount of broad spectrum protection. On the other hand, it is not so difficult to formulate sunscreen products to achieve this critical wavelength that manufacturers cannot develop broad spectrum sunscreen products. We have concluded that UV radiation in the range of 370—400 nm is not very harmful based on the available action spectra for sunburn and skin cancer. We conclude that most of the harmful effects from the sun are caused by UV radiation in the range of 290—370 nm. Further, we conclude that critical wavelength (breadth of UVB and UVA protection) coupled with the SPF value (magnitude of UVB and UVA protection) provides a complete measure of broad spectrum protection provided by a sunscreen product.

C. Critical Wavelength Test Parameters

Although the proposed ratio and critical wavelength calculations are different, both tests are based on the construction of a transmittance curve over the range of UV wavelengths from 290 to 400 nm. We received several submissions requesting that we change or, in some cases, better define aspects of the methodology used to measure transmittance over these wavelengths (Ref. 1). Although the submissions, in most cases, referred specifically to the proposed ratio test, the points made regarding methodology apply equally to the critical wavelength test.

We are making several revisions to the section we referred to as the ''UVA in vitro testing procedure'' in the 2007 proposed rule (proposed 21 CFR 352.71). To more accurately describe the test as covering both the UVB and UVA regions of the spectrum, we now refer to the test as the ''broad spectrum test.'' The revisions are listed in Table 5 in the order in which they appear in this section of the document.

TABLE 5—SUMMARY OF REVISIONS TO THE PROPOSED IN VITRO BROAD SPECTRUM TEST INCLUDED IN THIS FINAL RULE

Revised test parameter	2007 proposed rule	This final rule
Plate	Quartz plate (21 CFR 352.71(b))	PMMA[1] plate (21 CFR 201.327(j)(1)(i))
Term ''spectroradiometer''	Spectroradiometer (21 CFR 352.71(c) and (d))	Spectrometer (21 CFR 201.327(j)(1)(ii), (iv), and (v))
Light source for transmittance measurements.	Solar simulator (21 CFR 352.71(a))	Produce a continuous spectral distribution of UV radiation from 290 to 400 nanometers (21 CFR 201.327(j)(1)(iii)
Input optics: Bandwidth	5 nanometers (21 CFR 352.71(d))	1 nanometer (21 CFR 201.327(j)(1)(iv))
Dynamic range of the spectrometer.	Not specified	Sufficient to measure transmittance accurately through highly absorbing sunscreen (21 CFR 201.327(j)(1)(v))
Application of sunscreen drug product to plate.	2.0 mg/cm^2 with single-phase spreading (21 CFR 352.71(e))	0.75 mg/cm^2 with 2-phase spreading (21 CFR 201.327(j)(2))
Pre-Irradiation dose	Proportional to SPF value (21 CFR 352.71(f))	Fixed at 800 J/m^2-eff (21 CFR 201.327(j)(3))
Number of transmittance measurements.	12 measurements of mean transmittance on 5 different plates (21 CFR 352.71(g) and (i))	5 measurements of mean transmittance on 3 different plates (21 CFR 201.327(j)(4) and (6))
Calculation of critical wavelength.	Not applicable	21 CFR 201.327(j)(7))

[1] Polymethylmethacrylate

We re-organized the broad spectrum test parameters in this final rule so that they are listed in the order that the test is done. This section of the document begins with a description of the plates to be used and the requirements for UV spectrometry. The next section addresses application of the sunscreen product to the plate, and the following section addresses the pre-irradiation procedure. The last sections included under broad spectrum test parameters address measuring the amount of radiation transmitted through the sunscreen product, converting these measurements to absorbance values, and calculating the critical wavelength of a sunscreen product.

All of the proposed test parameters were re-evaluated in the preparation of this document. Some of the parameters did not require revision. Test parameters not revised include:

- Sample holder
- Input optics (other than slit width)
- Light source for pre-irradiation
- Calculation of mean transmittance values
- Calculation of mean absorbance values

The parameters defined in this section are based on our review of submitted data (Ref. 1) and peer-reviewed literature. Wherever possible and consistent with sound science, we have attempted to harmonize the parameters with existing standards, including those of the European Commission (Ref. 7) and COLIPA (Ref. 69). As stated earlier in this document, we are also actively involved in the ISO working group responsible for developing methodologies for assessing sun protection (both UVB and UVA protection).

1. Plate

Many submissions argued that we should specify that roughened PMMA (polymethylmethacrylate) plates be used as a substrate rather than roughened quartz included in the 2007 proposed rule (Ref. 1). The submissions stated that they prefer PMMA plates because these plates are:

- Less expensive than quartz
- Disposable—no need to clean or re-roughen
- Readily available with roughened surface
- Validated in COLIPA ring tests and in widespread use for more than a decade
- Recommended by the European Commission and COLIPA

We agree with these submissions and are specifying, in this document, that PMMA plates be used as the substrate in this document. We are specifying the use of PMMA plates primarily because the vast majority of validation data we have reviewed was collected using PMMA rather than quartz plates. Further, we agree with the submissions noting that PMMA plates are less expensive than quartz and, therefore, can be disposable. The disposability of the PMMA plates will eliminate the requirements for cleaning and re-roughening the surface characteristic of quartz plates.

Consistent with COLIPA, we are also specifying the degree of roughness and size of the application area on these plates. Plates should be roughened on one side to a three-dimensional surface topography measure (Sa) between 2 and 7 micrometers. These Sa values are supported by validation studies (Ref. 70) and are comparable to those recommended by COLIPA (Ref. 69). The application area must be at least 16 square centimeters with no side shorter than 4 centimeters. We are also replacing the word ''substrate'' with the simpler and more widely used term ''plate.''

These changes are included in 21 CFR 201.327(j)(1)(i) of this document. Specifying standardized roughness and size parameters will result in more accurate and reproducible intra- and inter-laboratory measurements of broad spectrum photoprotection. Because these PMMA plates of specified roughness and size are already being used in many parts of the world and are recommended by COLIPA, we have concluded that they can be employed in broad spectrum testing in this country with minimal expense or training of personnel.

2. ''Spectroradiometer'' vs. ''Spectrometer''

Four submissions asked us to replace the term ''spectroradiometer'' with the more generally used term ''spectrophotometer'' (Ref. 1). We originally chose the term ''spectroradiometer'' because UV radiation is not detectable by the human eye and, therefore, is not gauged by photometry (which measures visible light). However, the term ''spectrophotometer'' is often used interchangeably with the term ''spectroradiometer.'' In this document, we are replacing the term ''spectroradiometer'' with the more inclusive term ''spectrometer.'' Use of the term ''spectrometer'' allows the use of either a spectroradiometer or spectrophotometer and will make the language more consistent with current COLIPA guidelines (Ref. 69).

3. Light Source for Transmittance Measurements

Four submissions (Ref. 1) asserted that it is inappropriate to specify a solar simulator as the light source for measuring transmittance (proposed 21 CFR 352.71(a)). Three of the submissions argued that radiation emitted from a solar simulator is filtered such that there is very low energy output in the UV region below 300 nm (Ref. 1). One submission noted that a light source filtered in this way cannot provide sufficient energy to measure transmittance through highly absorbing sunscreen products. The same submission suggested that there may not be enough transmittance at wavelengths less than 300 nm to exceed the noise level of the system even in the absence of a sunscreen product (when transmittance should be maximal).

We agree with the submissions and, in 21 CFR 201.327(j)(1)(iii) of this document, are specifying that the light source for transmittance measurements provide continuous, full spectrum radiation from 290 to 400 nanometers. The use of such a light source should maximize instrument transmission properties while retaining full sensitivity. We note that this type of light source is recommended by COLIPA (Ref. 69).

4. Wavelength Interval Between Transmittance Measurements

Two submissions argued that we should reduce the wavelength intervals between transmittance measurements from the proposed 5 nm to 1 nm (Ref. 1). The submissions stated that specifying a smaller interval would produce more accurate results and noted that current spectrometers are capable of making measurements at 1 nm intervals. We agree with the submissions. Additionally, we are aware that the COLIPA guideline (Ref. 69) specifies that transmittance measurements are to be taken at 1 nm intervals. Therefore, we are revising the required input slit bandwidth in this document to specify that it be less than or equal to 1 nm (new 21 CFR 201.327(j)(1)(iv)). We are also revising the measurement interval (new 21 CFR 201.327(j)(4)) to state that transmittance values should be measured at 1 nm intervals.

5. Dynamic Range of the Spectrometer

We are adding new 21 CFR 201.327(j)(1)(v) to specify that the dynamic range of the spectrometer be ''sufficient to measure transmittance accurately through a highly absorbing sunscreen product at all UV

wavelengths (between 290 and 400 nm).'' The information in this section had been included in the section entitled ''Calculation of the spectral transmittance at each wavelength interval'' in the proposed rule (proposed 21 CFR 352.71(g)). We considered requiring a minimum dynamic range of 2.2 absorbance units, as specified in the COLIPA guidelines (Ref. 69). However, we have concluded that it is not necessary to include this requirement because nearly all current spectrometers are capable of measuring a dynamic range of 2.2 absorbance units or better.

6. Application of Sunscreen Product to PMMA Plate

Thirteen submissions (Ref. 1) expressed one or more concerns over the method by which we proposed applying sunscreen product to the plate (proposed 21 CFR 352.71(e)). Eleven of the thirteen submissions recommended we reduce the amount applied from 2 milligrams per square centimeter (mg/cm^2) to between 0.75 and 1.2 mg/cm^2. Three submissions suggested we specify that the sunscreen product be applied with a better defined spreading action. Two submissions requested we consider requiring that a saturated fingertip be used to apply the product rather than a gloved finger.

We are reducing the application amount in this document because transmittance of UV radiation through a film of 2 mg/cm^2 thickness is low and, therefore, can result in inaccurate and/or irreproducible measures of UVA protection. UV detectors have a range of UV radiation that they can accurately measure referred to as the dynamic range. If UV radiation is outside the dynamic range (either lower or higher), measurements from the detector become less accurate and often less reproducible. We received validation data demonstrating that application amounts lower than 2 mg/cm^2 are more accurate and reproducible than an application of 2 mg/cm^2 (Ref. 1). The 2007 proposed rule required an application amount of 2 mg/cm^2 because this is the amount specified in the proposed in vivo SPF and PPD tests. We are not including the PPD test in this document and we have concluded that consistency with the SPF test is not warranted given the concerns about inaccurate and/or irreproducible results with an application amount of 2 mg/cm^2 in the in vitro UVA method. A reduced application amount is consistent with the COLIPA guidelines (Ref. 69). Both of these documents specify an application amount of 0.75 mg/cm^2. Data we have reviewed from the Personal Care Product Council demonstrate that application of 0.75 to 1.0 mg/cm^2 results in good transmission within the dynamic range of UV detectors (Ref. 1). Therefore, in this document, we are reducing the application amount to 0.75 mg/cm^2 to ensure the UV radiation transmitted through sunscreens is within the dynamic range of UV detectors (21 CFR 201.327(j)(2)).

We are also specifying the type of spreading action to be employed when applying sunscreen product to a plate. One submission noted that the type of spreading action employed would depend on the type of product being applied. The submission argued that it might take 30 seconds to evenly spread thicker water resistant creams, but only 10 seconds to evenly spread lotions or oils. We recognize that the very light spreading action for 10 seconds we proposed may not be sufficient to evenly distribute all dosage forms on a plate (proposed 21 CFR 352.71(e)). One submission provided data from a ring test involving 7 different laboratories showing that the UVAI/UV absorbance ratio is affected by the amount of pressure applied during application. A second submission referenced a paper by Ferrero *et al.* which shows that light pressure applied to some sunscreen products results in different ratios than application with greater pressure (Ref. 70). Both submissions recommended adopting a two-phase application process like that recommended by COLIPA (Ref. 69).

We agree that a two-phase spreading action is a more effective means of achieving a film of uniform thickness and distribution for a variety of sunscreen dosage forms than is the proposed 10 seconds of light spreading. This type of spreading action is more reflective of actual use than the method we proposed. Therefore, we are harmonizing the standard with the COLIPA guidelines by specifying that a two-phase process be used. Section 201.327(j)(2) in this document specifies that ''spreading should be done with a very light spreading action for approximately 30 seconds followed by spreading with greater pressure for approximately 30 seconds.''

Two submissions argued that we should specify a saturated fingertip be used rather than a gloved finger. We do not agree for the reasons specified in section VI.E of this document.

7. Pre-Irradiation Dose

Several submissions expressed concern that the pre-irradiation dose we proposed to account for differences in photostability is too high, particularly if we reduce the application amount (Ref. 1). We proposed that the pre-irradiation dose be proportional to the SPF value of a sunscreen product (proposed 21 CFR 352.71(f)). This was to account for the possibility that consumers may spend more time in the sun with higher SPF products. Proportional pre-irradiation dosing is also recommended in the testing procedure published by COLIPA (Ref. 69). In these documents, the pre-irradiation dose is determined relative to the UVA protection factor. Pre-irradiation dose increases as the UVA protection factor increases.

Two submissions suggested that we use a fixed or absolute dose rather than a relative dose proportional to the SPF value of a sunscreen product (Ref. 1). The submissions noted that, at the same time and location on the earth's surface, all sunscreen products are exposed to the same intensity of sunlight. Therefore, sunscreen products with higher SPF values or UVA protection factors should not be exposed to higher pre-irradiation doses.

We agree with these two submissions. It is appropriate to evaluate sunscreen product photostability using a fixed exposure intensity. We have data demonstrating that avobenzone-containing sunscreen products undergo almost complete photodegradation when exposed to doses between 2 and 3 MEDs [11] (Ref. 71). At a dose of 4 MEDs, there were no further decreases in UVB and UVA absorption of five different sunscreen products containing 2.5- to 3- percent avobenzone. These data reflect the worst case scenario for photodegradation because avobenzone appears to be the least photostable active ingredient in the sunscreen monograph. Therefore, all sunscreen products marketed under the monograph are likely to be completely degraded after 4 MEDs. Based on this data, we are specifying a fixed pre-irradiation dose equivalent to 4 MEDs. As we noted in the 2007 proposed rule, one MED for a skin type II individual is 200 J/m^2-eff (72 FR 49070 at 49107). Therefore, in this document, we are specifying a pre-irradiation dose of 4 times 200 J/m^2-eff (800 J/m^2-eff).

8. Number of Transmittance Measurements

Two submissions (Ref. 1) stated that requiring 12 transmittance measurements on each plate as proposed is excessive and not statistically warranted (proposed 21 CFR 352.71(g)). One submission provided data showing that there are no significant differences in UVAI/UV ratios calculated based on 3, 5, 8, or 12

[11] Minimal erythema dose—the lowest UV dose that produces skin reddening (erythema).

sub-sites per plate. The submission argued that we should reduce the number of required test sites per sample to 6. The other submission proposed that we require only one transmittance measurement per plate. The submission suggested that, rather than taking multiple measurements from several small areas on the plate, one measurement could be made over a relatively broad area.

One of the submissions also argued that it is not necessary to evaluate transmittance on five different plates (proposed 21 CFR 352.71(j)). The submission provided data showing that the UVAI/UV ratio for an SPF 15 sunscreen product is not significantly different whether it is measured on 1, 2, 3, or 5 plates (with 12 measurements per plate). We note that the COLIPA guidelines (Ref. 69) recommend that 3 separate plates be used.

We agree with the submissions that requiring 12 discrete measurements on each plate is not necessary to obtain an accurate transmittance spectrum. The submitted data demonstrate that there are no significant differences in UVAI/UV ratios based on 3, 5, 8, or 12 test sites. Similarly, we agree with the submissions that requiring measurements for five plates is not necessary to obtain an accurate transmittance spectrum. Determining 12 transmittance measurements on five plates, as proposed, results in a total of 60 transmittance measurements. Based on the submitted data, a total of 15 transmittance measurements should produce an accurate transmittance spectrum. Therefore, we are requiring 5 or more measurements on at least 3 different plates (21 CFR 201.327(j)(6) in this document.

9. Determination of Critical Wavelength

Critical wavelength is to be determined as described in section VIII.B of this document.

IX. Analysis of Impacts

A. Final Regulatory Impact Analysis

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). OMB has determined that this final rule is a significant regulatory action under Executive Order 12866. Consistent with Executive Order 13563, the approach taken here maintains ''flexibility and freedom of choice for the public,'' above all by providing ''information for the public in a form that is clear and intelligible.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we lack information characterizing the number of products by firm-size and because most affected entities are considered small, we conclude that this final rule will have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. We do not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

1. Background

The purpose of this rule is to finalize labeling and testing conditions under which OTC sunscreen drug products marketed without approved applications are not misbranded. This rule addresses labeling and testing requirements for both UVB and UVA radiation protection. The rule modifies the existing SPF test, specifies a test for broad spectrum protection, and requires changes to the product label that affect both the front of the package (the principal display panel or PDP) and the Drug Facts section. In addition, the rule lifts the stay of effective date applied to the 1999 Drug Facts labeling final rule (64 FR 13254) specifically for sunscreen products (66 FR 67485). All manufacturers of sunscreens will incur some labeling costs due to revisions to both the PDP and the Drug Facts section of the product label (see section IX.A.4 of this document). In addition, many manufacturers will incur additional broad spectrum testing costs unless they have already tested their products according to the broad spectrum test required in this rule. Manufacturers of sunscreens will also incur SPF testing costs (see section IX.A.5 of this document). Some manufactures will also have to relabel products that are currently labeled with claims that are not allowed under this final rule (§ 201.327(g) and § 310.545(a)(29)(ii)).

2. Benefits

As discussed in section IV.B of this document, the regular use of a Broad Spectrum SPF 15 or higher sunscreen product, when combined with limiting time in the sun and wearing clothing to protect sun-exposed areas, reduces the risk of skin cancer and early skin aging. The National Cancer Institute estimates that there are more than one million new cases of non-melanoma skin cancer and more than 68,000 new cases of melanoma per year in the United States (Refs. 72 and 73). According to the National Cancer Institute, about 8,700 persons will die of melanoma in 2010. Fatal cases of non-melanoma skin cancer are less common but nonetheless number several hundred per year. The labeling requirements in this rule, in conjunction with implementing the format and content requirements in 21 CFR 201.66, which were stayed for sunscreens but are being lifted in this rule, will provide consumers with clear and concise information about sunscreen use and protection, and about the role of sun exposure in increasing the risk of skin cancer and early skin aging. Consumers will be able to more easily identify products that reduce the risks of skin cancer and early skin aging, when used as directed. The new requirements for product testing will ensure the accuracy of the SPF value and broad spectrum claim on the product label.

Although we are unable to quantify the effects of clear and concise information, the final rule will provide clearer and more consistent information on the benefits of certain sunscreens in regard to skin cancer risk reduction than is available on current labels. By requiring better information on levels of protection, the rule should contribute to reduced exposure to UVB and UVA radiation and thereby reduce the incidence of skin cancer.

The benefits from reduced incidence of skin cancer will equal the value of the illnesses averted. The most appropriate measure of that value is based on the average willingness to pay to reduce the probability of skin cancer. We would then multiply the value per illness averted by the likely number of illnesses averted to determine the benefits of this final rule. Because we lack estimates of the likely numbers of illnesses averted, we present estimates of the value per

illness averted to illustrate the gains per averted case.

We estimated the value per case of preventing skin cancer for fatal and non-fatal cases of melanoma and non-melanoma skin cancer. The estimated average medical cost of treatment, lost productivity, and willingness to pay to avoid some symptoms and other effects represents a plausible lower bound on willingness to pay to avoid a non-fatal case of skin cancer. For melanoma, the estimated total cost is about $2,860 per non-fatal case; for non-melanoma skin cancer, the total cost is about $1,400 per non-fatal case; (Refs. 74 and 75).

The largest potential public health gains from this final rule would likely come from averted deaths. We can calculate the monetary value of averted fatal cases as either the value of statistical lives saved or the value of statistical life-years saved. Although skin cancers occur at all ages, most cases occur at older ages. For that reason, we estimate the benefit from preventing fatal cases using the value of life years saved. According to the National Cancer Institute, the average age of death from melanoma is 68 (Ref. 73); life expectancy for a person between the ages of 68 and 69 is about 16 years (Ref. 76). If we discount the average years of life saved for averted fatal melanoma with rates of 3 and 7 percent, we get discounted statistical life-years saved equal to 12.6 and 9.4 years. The various studies of fatal cases of non-melanoma skin cancer find mean or median ages of death in the 77 to 82 range (Refs. 77–79). The life expectancy for someone between the ages of 79 and 80 is about 9 years (Ref. 76). If we discount the average years of life saved for fatal non-melanoma skin cancers with discount rates of 3 and 7 percent, we get discounted years saved equal to 7.9 and 6.5 years.

In other analyses of life-years saved, we have used values for a statistical life-year in the $107,000 to $322,000 range (74 FR 33030, July 9, 2009; updated to current prices). For this illustrative analysis, we use a medium value of $214,000 per statistical life-year. We multiply the value of a statistical life-year by the discounted life-years saved per fatal case of melanoma, which yields $2.69 million using a 3 percent rate of discount and $2.02 million using a 7 percent rate of discount. If we multiply the value of a statistical life-year by discounted life-years saved per fatal case of non-melanoma skin cancer, we get $1.67 million using a 3 percent rate of discount and $1.39 million using a 7 percent rate of discount.

The development of melanoma and non-melanoma skin cancer from chronic exposure to sunlight, as well as any preventative effects of sunscreen (or any other intervention), occur with a long lag. To estimate the monetary value of an averted case of melanoma or non-melanoma skin cancer through combining other protective measures with increased broad spectrum and at least SPF 15 protection, we adjust for the lag between increased protection and a decrease in the incidence of non-melanoma skin cancer. The only available long-term study finds a minimum lag of 5 years before any significant risk reduction would occur (Refs. 20 and 21). Substantial reductions occur with a much longer lag, probably 15 to 25 years; we use a 20-year lag in this illustrative analysis. With a 20-year lag discounted at 3 percent, the value per averted statistical case of non-fatal melanoma is $1,586; if we discount for at 7 percent, the value per averted case is $740. With a 20-year lag discounted at 3 percent per year, the monetary value per averted statistical case of non-melanoma skin cancer is $773; if we discount at 7 percent, the value per averted case is $361.

For fatal cases, with the 20-year lag discounted at 3 percent per year, the monetary value per averted statistical case of fatal melanoma is $1.49 million; discounted at 7 percent, the value per averted fatal case is $520,000. With a 20-year lag and a 3 percent rate of discount, the discounted value per averted case of non-melanoma skin cancer is $920,000 million; with a 7 percent rate of discount, value per averted fatal case is $360,000.

We have four estimates of the discounted value per averted cases of melanoma and non-melanoma skin cancer, with values corresponded to non-fatal and fatal cases. The annual benefits of this final rule will be the numbers of cases of each type averted multiplied by the value of each type. We do not, however, have estimates of the numbers of actual or statistical cases that will be averted. Although there is wide agreement among experts that the use of more effective sunscreens reduces the risk of sun-related skin cancer, we are unaware of any studies that quantify the reduced risk. Without quantitative estimates of the risk reduction associated with broad spectrum protection, we are unable to quantity the overall effects of this final rule on public health.

3. Number of Products Affected

Estimating the number of products affected by this rule is difficult because we do not have complete data on the number of OTC sunscreen products currently marketed. Our Drug Listing System does not have accurate information on the number of marketed OTC sunscreen products. In the 2007 proposed rule (72 FR 49070 at 49108), we estimated that there were about 3,000 OTC sunscreen drug products, including cosmetic products containing sunscreen, with about 12,000 SKUs.[12]

In response to the 2007 proposed rule, we received a submission arguing that our estimates of the number of products and SKUs were low but the submission did not suggest a corrected value. We contracted with the consulting firm Eastern Research Group (ERG) to profile the sunscreen market and assess the cost to reformulate a sunscreen product. ERG's full report can be found in Docket No. FDA–1978–N–0018 (Ref. 80). ERG did an extensive search using the internet and other sources and found fewer dosage forms and SKUs than we had estimated. ERG estimates that there are about 3,065 to 3,600 SKUs. More recently, the new FDA labeling cost model estimates that about 3,591 sunscreen SKUs are marketed, with up to 2,348 different formulations. Because these data are based on a recent survey of the market, we conclude that they are more representative of the number of products affected than the estimates in the proposed rule. For this analysis, we therefore use 3,591 SKUs to represent the number of affected sunscreen labels and 2,348 for the number of formulations.

To comply with the rule, sunscreen products currently marketed as providing broad spectrum protection that were already tested using the test method in this rule will have to be re-labeled but will not have to be retested for broad spectrum protection. Other products will be tested for broad spectrum protection and, if they pass and, will be relabeled with the broad spectrum protection claim. Manufacturers may also choose to reformulate their products to pass the test or discontinue production of the products.

We have not attributed any reformulation costs to this final rule but realize that some manufacturers may choose to reformulate their product if it does not pass the broad spectrum test.

4. Cost To Relabel Sunscreen Products

The cost to relabel varies greatly depending on the printing method and number of colors used. In the 2007 proposed rule, we stated that the majority of sunscreen products are packaged in plastic bottles or tubes with the label printed directly on the

[12] SKUs refers to ''stock keeping units,'' which are individual products, packages, and sizes.

container or applied as a decal or paper label during the packaging process.

The labeling requirements in this rule will change both the PDP and the Drug Facts section of the package and are considered a major redesign. Frequent label redesigns are typical for OTC sunscreen products, with redesigns generally implemented every 1 to 2 years. If a scheduled redesign coincides with relabeling required by this rule, the incremental labeling cost will be lower than if the labeling change takes place before scheduled changes. To estimate the cost to relabel, we are assuming that all products will be relabeled and none are discontinued.

In the 2007 proposed rule, we used a model developed for us by the consulting firm RTI International to derive an estimate of the cost to relabel sunscreen products (Ref. 81). The model was developed to estimate the cost of food labels, which are similar to the labels on the products affected by this final rule. In response to the 2007 proposed rule, we received a submission disagreeing with our estimates of how sunscreens are packaged and the cost to relabel these products (Ref. 1). The submission argued that many sunscreen products, particularly sunscreen-cosmetic combinations, have a secondary container and, therefore, an additional label. The submission also argued that some sunscreen products would require a fold-out label or new secondary carton to accommodate the labeling required in this rule. Furthermore, the submission argued that relabeling these products would cost $15,000 to $17,000 per SKU. The submission did not include any data or information to support its estimate.

We agree that cosmetic packaging and labeling is generally more costly than OTC drug labeling. We also agree that manufacturers of sunscreen-cosmetic products would use the packaging norm of the cosmetic industry because those are the products they are competing with. The cost estimates we are using now demonstrate a large variation in the price per SKU to account for the differences in packaging. If the standard content and format changes required by the OTC labeling final rule (64 FR 13254) are being implemented for the first time, there could be increases in the size of container and carton labels. Since we are allowing, in this rule, for a compliance period of 1 year for most products but 2 years for products with low sales volume ($25,000 annually), inventory losses for unused packaging and labels are minimized and accounted for in this analysis.

For this final rule, we use the new FDA labeling cost model developed by RTI International, which includes estimates for changing sunscreen labels. The one-time costs for a major labeling change to sunscreen labels are $7,454 to $18,785, depending on the type of labeling and packaging. The medium estimate is $11,572 per major labeling changes. These costs include mostly labor and materials, with some cost for lost inventory.

We estimate that the timing of scheduled relabeling will coincide with the relabeling required by this rule for 50 percent of the 3,591 SKUs . We estimate the total labeling cost for the SKUs with coinciding scheduled redesign would be minimal administrative costs or about $550 ($310 to $790). Therefore, the total one-time cost for relabeling would be about $13.9 million to $35.1 million, with a medium estimate of $21.8 million ($1,796 \times $11,572 + 1,796 \times $550).

5. Cost To Test or Retest Products To Determine SPF Values

Manufacturers will incur SPF testing costs because the rule requires labeling for OTC sunscreen products to include SPF values determined in accordance with the specific test method that it describes. We will publish draft guidance entitled ''Guidance for Industry: Enforcement Policy—OTC Sunscreen Drug Products Marketed Without An Approved Application'' that describes our intended enforcement policy regarding these OTC sunscreen products. In the draft guidance, we propose to exercise enforcement discretion for a period of 2 years after the publication of this final rule with regard to the SPF testing requirements for certain OTC sunscreen products on the market prior to June 17, 2011. We estimate that 65 to 75 percent of sunscreen reformulations, or 1,526 to 1,761 will require SPF retesting. The cost of an SPF test depends on whether the product is also making water resistance claims and the SPF value being tested; the cost of water resistant testing is much higher than static testing (see Table 6). In their analysis of the sunscreen market ERG found that about 5 percent of products claimed water resistance and SPF values less than 30, 3 percent of products claimed water resistance with SPF greater than 30, while the remaining 92 percent could use the static SPF test. We use those percentages to estimate total SPF testing costs of $3.2 to $5.9 million (see Table 6). The midpoint of estimated SPF testing costs is $4.6 million.

TABLE 6—COST OF SPF TESTING

Type of test	Estimated number of formulations		Cost of test		*Total cost*	
	Low	High	Low	High	Low	High
Water resistant, SPF < 30	76	88	$4,500	$4,860	$343,395	$427,923
Water resistant, > 30	46	53	4,500	5,130	260,037	271,018
SPF static test	1,404	1,620	1,900	3,240	2,667,798	5,249,189
Total Cost for SPF testing					3,217,230	5,948,130

6. Cost to Test or Retest Products for Broad Spectrum Protection

In the proposed rule, we estimated that about 75 percent of sunscreen products would need to be tested for broad spectrum protection. We received a submission arguing that our estimate was too low and that at least 90 percent of products would need to be tested (Ref. 1). The argument in the submission was based on the four-tier UVA star rating in the proposed rule. The submission stated that sunscreen products with ''low,'' one-star protection would need to be tested. We have now changed the rating criteria to pass-fail, where a critical wavelength of at least 370 nm is necessary to make the broad spectrum statement. Over the years, there has been a steady increase in the number of products with claims of broad spectrum protection. A recent survey of marketed products found that 65 percent of the products surveyed met the criteria for the broad spectrum statement (Ref. 82). Products that were tested in accordance with the broad

spectrum test in this rule would not need to be re-tested.

Because the broad spectrum test in this rule is different than the proposed test, we assume that all affected products would need to be tested. In the 2007 proposed rule, we estimated a one-time testing cost of approximately $5.4 million for products that have broad spectrum protection claims. This estimate was based on 2,250 sunscreen products (75 percent of marketed products) being tested with a test cost of $2,400. The test costs were estimated as $2,200 for the proposed in vivo test and $200 for the proposed in vitro test. In this rule, we are not requiring the in vivo test.

In response to the proposed rule, we received two submissions arguing that our estimate of $200 for the cost of the in vitro test was too low (Ref. 1). The first submission states that the cost of an in vitro test is $500, and the second states that the cost is $800. The first submission, from a sunscreen manufacturer, states that $500 is the price charged by an independent testing laboratory to test its product. The second submission does not provide any basis for its estimate. Although the in vitro test in this rule is different than the in vitro test in the 2007 proposed rule, the cost to conduct the tests is the same. ERG found that the cost of the test ranges from $300 to $800 (Ref. 80). Assuming all affected marketed product formulations (1,526 to 1,761 formulations) will be tested for broad spectrum protection at a cost ranging from $300 to $800, the total cost to test sunscreen products for broad spectrum protection is estimated to be $457,860 to $1,408,800 [(1,526 × $300) to (1,761 × $800)].

7. Total Incremental Costs

Because we took steps earlier to mitigate the impact of labeling changes on the sunscreen industry by staying the requirements in earlier rules, the labeling costs in this rule incorporate the labeling costs from three final rules:

1. 1999 OTC drug labeling final rule (64 FR 13254)

2. 1999 Sunscreen final rule (64 FR 27666)

3. This rule.

Manufacturers were able to postpone compliance costs when we chose to stay the labeling requirements for the 1999 final rule that standardized the format and content requirements for labeling OTC drug products (21 CFR part 201), which would have become effective for all sunscreens by 2005 (69 FR 53801). We include, as part of labeling costs, the cost of increased container labels and package size to accommodate the Drug Facts format.

The estimated total one-time incremental cost of this rule range $17.6 to 42.5 million [($13.9 million labeling cost + $3.2 million SPF testing cost + $0.5 million broad spectrum testing cost) to ($35.1 million labeling cost + $5.9 million SPF testing cost + $1.4 million broad spectrum testing cost)]. The medium estimated one-time incremental costs are $27.3 million. Annualized over 10 years, the costs are $2.1 to $5 million using a 3 percent rate of discount and $2.5 to $6.1 million using a 7 percent rate of discount. Annualized medium costs are $3.2 million using a 3 percent rate of discount and $3.9 million using a 7 percent rate of discount. If some manufacturers of sunscreen products have already complied with the 1999 final rule and would not otherwise have to relabel products as a result of this final rule, then these estimates may overstate actual total costs.

8. Analysis of Alternatives

The principal alternatives we identified were the inclusion of several provisions from the 2007 proposed rule. In the 2007 proposed rule, we required in vivo and in vitro tests for determining UVA protection. In this rule, we have eliminated the in vivo test requirement, reducing compliance costs by about $5 million. We also proposed labeling on the PDP that would indicate the level of UVA protection. In this rule, we changed the in vitro test to one that measures both UVB and UVA protection (*i.e.,* broad spectrum protection). We also established a pass/fail broad spectrum protection statement on the PDP in place of a UVA rating.

We considered requiring a negative statement on the PDP indicating that a product did not have broad spectrum protection if it failed the in vitro test. Numerous submissions from manufacturers opposed this requirement, and we are concerned that the statement could be misinterpreted by consumers. Moreover, as noted previously, this alternative is beyond the scope of this final rule, which applies only to products that do provide broad spectrum protection.

B. Small Business Impact (Final Regulatory Flexibility Analysis)

We estimate that about 78 percent of the approximately 100 domestic companies that manufacture OTC sunscreen products would be considered small business entities (defined by the Small Business Administration as having fewer than 750 employees). Because most affected entities are considered small, we conclude that this final rule will have a significant economic impact on a substantial number of small entities. Consequently, this analysis, together with other relevant sections of this document, serves as the Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

The average one-time incremental cost per firm will be about $185,000 to $445,000, with a medium of about $285,000. This burden, described in more detail in section IX.A of this document, includes labeling costs, SPF testing costs, and broad spectrum testing costs. The economic impact will vary by firm, depending on the number of products requiring testing and the number of SKUs requiring labeling. Also, firm-specific impact will vary inversely with the product sales; the per firm burden will be lower for firms with products with high sales volumes. Because the relative economic impact of product retesting is greater for products with lower sales volume, which could disproportionately affect smaller firms, we are providing a longer implementation period (2 years) for products with annual sales of less than $25,000. Because the OTC drug industry is highly regulated, all firms are expected to have access to the necessary professional skills on staff or to have contractual arrangements to comply with the testing requirements of this rule.

X. Paperwork Reduction Act of 1995

This final rule contains certain information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Specifically, the final rule establishes requirements for SPF labeling based on specified testing of covered products, (21 CFR 201.327(a)(1) and (i)). This rule also lifts the delay of implementation date for § 201.66 (21 CFR 201.66), the general OTC Drug Facts labeling format regulation, which has applied to all OTC sunscreen products (69 FR 53801). The information collections associated with § 201.66 have been approved in accordance with the PRA under OMB Control Number 0910–0340, but this approval does not currently include application of these provisions to OTC sunscreens. (76 FR 9022, February 16, 2011). The lifting of the stay of effective date of § 201.66 for OTC sunscreens will modify this information collection.

Elsewhere in this issue of the **Federal Register**, in accordance with section 3506(c)(2)(A) of the PRA (44 U.S.C.

3506(c)(2)(A)), we are publishing a 60-day notice soliciting public comment on the collections of information resulting from this final rule and will then submit these information collection provisions to OMB for approval. These requirements will not be effective until we obtain OMB approval. We will publish a notice concerning OMB approval of these requirements in the **Federal Register** prior to the effective date of this final rule.

With the exceptions noted above, we conclude that the other provisions of this rule are not subject to OMB review under the PRA. Section 201.327 contains specific labeling information, including directions and warnings, which are a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)) and, therefore, are not collections of information. The requirements for obtaining certain medical history information and informed consent from test subjects (21 CFR 201.327(i)(3)(ii) and (i)(3)(iv)) are not collections of information because information collected from subjects of clinical testing does not constitute information under 5 CFR 1320.3(h)(5). There are no recordkeeping provisions associated with the SPF and broad spectrum testing (*i.e.,* effectiveness testing) described in this rule. The burdens of SPF testing as relevant to labeling (third party disclosures) are addressed in the notice published elsewhere in this issue of the **Federal Register**.

XI. Environmental Impact

FDA has determined under 21 CFR 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' The sole statutory provision giving preemptive effect to the final rule is section 751 of the FD&C Act (21 U.S.C. 379r). We have complied with all of the applicable requirements under the Executive order and have determined that the preemptive effects of this rule are consistent with Executive Order 13132.

XIII. References

The following references are on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857, under Docket No. FDA–1978–N–0018 (formerly 1978N–0038) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified all Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.

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List of Subjects

21 CFR Part 201

Drugs, Incorporation by reference, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 201 is amended as follows:

PART 201—LABELING

■ 1. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

■ 2. Section 201.327 is added to subpart G to read as follows:

§ 201.327 Over-the-counter sunscreen drug products; required labeling based on effectiveness testing.

The following provisions apply to sunscreen products containing aminobenzoic acid, avobenzone, cinoxate, dioxybenzone, ensulizole, homosalate, meradimate, octinoxate, octisalate, octocrylene, oxybenzone, padimate O, sulisobenzone, titanium dioxide, trolamine salicylate, or zinc oxide, alone or in combination. The provisions do not apply to sunscreen products marketed under approved new drug applications or abbreviated new drug applications.

(a) *Principal display panel.* In addition to the statement of identity in paragraph (b) of this section, the following labeling shall be prominently placed on the principal display panel:

(1) *Effectiveness claim.* (i) *For products that pass the broad spectrum test in paragraph (j) of this section.* (A) The labeling states ''Broad Spectrum SPF [insert numerical SPF value resulting from testing under paragraph (i) of this section]''.

(B) *Prominence.* The Broad Spectrum SPF statement shall appear as continuous text with no intervening text or graphic. The entire text shall appear in the same font style, size, and color with the same background color.

(ii) *For sunscreen products that do not pass the broad spectrum test in paragraph (j) of this section.* The labeling states ''SPF [insert numerical SPF value resulting from testing under paragraph (i) of this section]''. The entire text shall appear in the same font style, size, and color with the same background color.

(2) *Water resistance statements.* (i) *For products that provide 40 minutes of water resistance according to the test in paragraph (i)(7)(i) of this section.* The labeling states ''Water Resistant (40 minutes)''.

(ii) *For products that provide 80 minutes of water resistance according to the test in paragraph (i)(7)(ii) of this section.* The labeling states ''Water Resistant (80 minutes)''.

(b) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the drug as a ''sunscreen.''

(c) *Indications.* The labeling of the product states, under the heading ''Uses,'' the phrases listed in this paragraph (c), as appropriate. Other truthful and nonmisleading statements, describing only the uses that have been established and listed in this paragraph (c), may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) relating to misbranding and the prohibition in section 301(d) of the FD&C Act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the FD&C Act.

(1) For all sunscreen products, the following indication statement must be included under the heading ''Uses'': ''[Bullet] helps prevent sunburn''. See § 201.66(b)(4) of this chapter for definition of bullet.

(2) For sunscreen products with a Broad Spectrum SPF value of 15 or higher according to the tests in paragraphs (i) and (j) of this section, the labeling may include the following statement in addition to the indication in § 201.327(c)(1): ''[Bullet] if used as directed with other sun protection measures (see Directions [in bold italic

font]), decreases the risk of skin cancer and early skin aging caused by the sun''.

(3) Any labeling or promotional materials that suggest or imply that the use, alone, of any sunscreen reduces the risk of or prevents skin cancer or early skin aging will cause the product to be misbranded under section 502 of the FD&C Act (21 U.S.C. 352).

(d) *Warnings.* The labeling of the product contains the following warnings under the heading ''Warnings''.

(1) *For all sunscreen products.* (i) The labeling states ''Do not use [bullet] on damaged or broken skin''.

(ii) The labeling states ''When using this product [bullet] keep out of eyes. Rinse with water to remove.''

(iii) The labeling states ''Stop use and ask a doctor if [bullet] rash occurs''.

(2) *For sunscreen products that are broad spectrum with SPF values of at least 2 but less than 15 according to the SPF test in paragraph (i) of this section or that do not pass the broad spectrum test in paragraph (j) of this section.* The first statement under the heading ''Warnings'' states ''Skin Cancer/Skin Aging Alert [in bold font]; Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not [in bold font] skin cancer or early skin aging.''

(e) *Directions.* The labeling of the product contains the following statements, as appropriate, under the heading ''Directions.'' More detailed directions applicable to a particular product formulation may also be included.

(1) *For all sunscreen products.* (i) As an option, the labeling may state ''For sunscreen use:''.

(ii) The labeling states ''[bullet] apply [select one of the following: 'Liberally' or 'generously'] [and, as an option: 'And evenly'] 15 minutes before sun exposure''.

(iii) As an option, the labeling may state ''[bullet] apply to all skin exposed to the sun''.

(iv) The labeling states ''[bullet] children under 6 months of age: Ask a doctor''.

(2) *For sunscreen products with a Broad Spectrum SPF value of 15 or higher according to the tests in paragraphs (i) and (j) of this section.* The labeling states ''[bullet] Sun Protection Measures. [in bold font] Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: [Bullet] limit time in the sun, especially from 10 a.m.–2 p.m. [bullet] wear long-sleeved shirts, pants, hats, and sunglasses''.

(3) *For products that satisfy the water resistance test in paragraph (i)(7) of this section.* The labeling states ''[bullet] reapply: [Bullet] after [select one of the following determined by water resistance test: '40 minutes of' or '80 minutes of'] swimming or sweating [bullet] immediately after towel drying [bullet] at least every 2 hours''.

(4) *For products that do not satisfy the water resistance test in paragraph (i)(7) of this section.* The labeling states ''[bullet] reapply at least every 2 hours [bullet] use a water resistant sunscreen if swimming or sweating''.

(f) *Other information.* The labeling of the product contains the following statement under the heading ''Other information:'' ''[bullet] protect the product in this container from excessive heat and direct sun''.

(g) *False and misleading claims.* There are claims that would be false and/or misleading on sunscreen products. These claims include but are not limited to the following: ''Sunblock,'' ''sweatproof,'' and ''waterproof.'' These or similar claims will cause the product to be misbranded under section 502 of the FD&C Act (21 U.S.C. 352).

(h) *Labeling of products containing a combination of sunscreen and skin protectant active ingredients.* Statements of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable. Labeling provisions in § 347.50(e) of this chapter shall not apply to these products.

(i) *SPF test procedure.* (1) *UV source (solar simulator).* (i) *Emission spectrum.* A single port or multiport solar simulator should be filtered so that it provides a continuous emission spectrum from 290 to 400 nanometers (nm) with a limit of 1,500 Watts per square meter (W/m^2) on total irradiance for all wavelengths between 250 and 1,400 nm.

(A) The solar simulator should have the following percentage of erythema-effective radiation in each specified range of wavelengths:

SOLAR SIMULATOR EMISSION SPECTRUM

Wavelength range (nm)	Percent erythemal contribution [1]
< 290	< 0.1
290–300	1.0–8.0
290–310	49.0–65.0
290–320	85.0–90.0
290–330	91.5–95.5
290–340	94.0–97.0
290–400	99.9–100.0

[1] Calculation of erythema action spectrum described in § 201.327(i)(1)(ii) of this section.

(B) In addition, UVA II (320–340 nm) irradiance should equal or exceed 20 percent of the total UV (290–400 nm) irradiance. UVA I (340–400 nm) irradiance should equal or exceed 60 percent of the total UV irradiance.

(ii) *Erythema action spectrum.* (A) Calculate the erythema action spectrum weighting factor (V_i) at each wavelength λ:

(*1*) $V_i(\lambda) = 1.0$ ($250 < \lambda \leq 298$ nm)

(*2*) $V_i(\lambda) = 10^{0.094 * (298 - \lambda)}$ ($298 < \lambda \leq 328$ nm)

(*3*) $V_i(\lambda) = 10^{0.015 * (140 - \lambda)}$ ($328 < \lambda$ 400 nm)

(B) Calculate the erythema-effective UV dose (E) delivered by a solar simulator as follows:

$$E = \sum_{250}^{400} V_i(\lambda) * I(\lambda) * t$$

Where $V_i(\lambda)$ = erythema action spectrum weighting factor at each wavelength λ
$I(\lambda)$ = irradiance (Watts per square meter) at each wavelength λ
t = exposure time (seconds)

Erythema-effective dose (E) is expressed as effective Joules per square meter (J/m^2-eff).

(C) The emission spectrum must be determined using a handheld radiometer with a response weighted to match the spectrum in ISO 17166 CIE S 007/E entitled ''Erythemal reference action spectrum and standard erythema dose,'' dated 1999 (First edition, 1999–12–15; corrected and reprinted 2000–11–15), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from the ISO Copyright Office, Case Postale 56, CH–1211, Geneva 20, Switzerland, telephone +41–22–749–01–11 or fax +41–22–74 -09–47. *http://www.iso.org.* You may inspect a copy at the Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 22, Silver Spring, MD 20993, call 301–796–2090, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://*

www/archives.gov/federal_register/code_offederal_regulations/ibr_locations.html. The solar simulator output should be measured before and after each phototest or, at a minimum, at the beginning and end of each test day. This radiometer should be calibrated using side-by-side comparison with the spectroradiometer (using the weighting factors determined according to paragraph (i)(1)(ii)(A) of this section) at the time of the annual spectroradiometric measurement of the solar simulator as described in paragraph (i)(1)(iv) of this section.

(iii) *Operation.* A solar simulator should have no significant time-related fluctuations (within 20 percent) in radiation emissions after an appropriate warm-up time and demonstrate good beam uniformity (within 20 percent) in the exposure plane. The delivered dose to the UV exposure site must be within 10 percent of the expected dose.

(iv) *Periodic measurement.* To ensure that the solar simulator delivers the appropriate spectrum of UV radiation, the emission spectrum of the solar simulator should be measured at least annually with an appropriate and accurately calibrated spectroradiometer system (results should be traceable to the National Institute for Standards and Technology). In addition, the solar simulator must be recalibrated if there is any change in the lamp bulb or the optical filtering components (*i.e.,* filters, mirrors, lenses, collimating devices, or focusing devices). Daily solar simulator radiation intensity should be monitored with a broadband radiometer with a response weighted to match the erythema action spectrum in ISO 17166 CIE S 007/E entitled ''Erythemal reference action spectrum and standard erythema dose,'' which is incorporated by reference in paragraph (i)(1)(ii)(C) of this section. If a lamp must be replaced due to failure or aging during a phototest, broadband device readings consistent with those obtained for the original calibrated lamp will suffice until measurements can be performed with the spectroradiometer at the earliest possible opportunity.

(2) *SPF standard.* (i) *Preparation.* The SPF standard should be a formulation containing 7-percent padimate O and 3-percent oxybenzone.

COMPOSITION OF THE PADIMATE O/OXYBENZONE SPF STANDARD

Ingredients	Percent by weight
Part A:	
Lanolin	4.50
Cocoa butter	2.00
Glyceryl monostearate	3.00
Stearic acid	2.00
Padimate O	7.00
Oxybenzone	3.00
Part B:	
Purified water USP	71.60
Sorbitol solution	5.00
Triethanolamine, 99 percent	1.00
Methylparaben	0.30
Propylparaben	0.10
Part C:	
Benzyl alcohol	0.50
Part D:	
Purified water USP	QS [1]

[1] Quantity sufficient to make 100 grams.

Step 1. Add the ingredients of Part A into a suitable stainless steel kettle equipped with a propeller agitator. Mix at 77 to 82 °C until uniform.

Step 2. Add the water of Part B into a suitable stainless steel kettle equipped with a propeller agitator and begin mixing at 77 to 82 °C. Add the remaining ingredients of Part B and mix until uniform.

Step 3. Add the batch of Step 1 to the batch of Step 2 and mix at 77 to 82 °C until smooth and uniform. Slowly cool the batch to 49 to 54 °C.

Step 4. Add the benzyl alcohol of Part C to the batch of Step 3 at 49 to 54 °C. Mix until uniform. Continue to cool batch to 35 to 41 °C.

Step 5. Add sufficient water of Part D to the batch of Step 4 at 35 to 41 °C to obtain 100 grams of SPF standard. Mix until uniform. Cool batch to 27 to 32 °C.

(ii) *HPLC assay.* Use the following high performance liquid chromatography (HPLC) procedure to verify the concentrations of padimate O and oxybenzone in the SPF standard:

(A) *Instrumentation.* (*1*) Equilibrate a suitable liquid chromatograph to the following or equivalent conditions:

(*i*) Column	C–18, 250 millimeters (mm) length, 4.6 mm inner diameter (5 microns)
(*ii*) Mobile Phase.	85:15:0.5 methanol: water: acetic acid
(*iii*) Flow Rate	1.5 milliliters (mL) per minute
(*iv*) Temperature.	Ambient
(*v*) Detector	UV spectrophotometer at 308 nanometers
(*vi*) Attenuation.	As needed

(*2*) Use HPLC grade reagents for mobile phase.

(B) *Preparation of the HPLC reference standard.* (*1*) Weigh 0.50 gram (g) of oxybenzone USP reference standard into a 250-mL volumetric flask. Dissolve and dilute to volume with isopropanol. Mix well.

(*2*) Weigh 0.50 g of padimate O USP reference standard into a 250-mL volumetric flask. Dissolve and dilute to volume with isopropanol. Mix well.

(*3*) Pipet 3.0 mL of the oxybenzone solution and 7.0 mL of the padimate O solution into a 100-mL volumetric flask. Dilute to volume with isopropanol and mix well.

(C) *HPLC system suitability.* (*1*) Make three replicate 10-microliter injections of the HPLC reference standard (described in paragraph (i)(2)(ii)(B) of this section). The relative standard deviation in peak areas should not be more than 2.0 percent for either oxybenzone or padimate O.

(*2*) Calculate the resolution (R) between the oxybenzone and padimate O peaks from one chromatogram as follows:

$$R = \frac{2 * (to - tp)}{Wo + Wp}$$

Where t_o = retention time for oxybenzone
t_p = retention time for padimate O
W_o = oxybenzone peak width at baseline
W_p = padimate O peak width at baseline

If the resolution (R) is less than 3.0, adjust the mobile phase or replace the column.

(D) *SPF standard assay.*

(*1*) The SPF standard is diluted to the same concentration as the HPLC reference standard according to the following steps:

(i) Step 1. Weigh 1.0 g of the SPF standard (described in paragraph (i)(2)(i) of this section) into a 50-mL volumetric flask.

(ii) Step 2. Add approximately 30 mL of isopropanol and heat with swirling until contents are evenly dispersed.

(iii) Step 3. Cool to room temperature (15 to 30 °C) and dilute to volume with isopropanol. Mix well.

(iv) Step 4. Pipet 5.0 mL of the preparation into a 50-mL volumetric flask and dilute to volume with isopropanol. Mix well.

(*2*)(*i*) Inject 10-microliter of diluted SPF standard from paragraph (i)(2)(D)(*1*) of this section and calculate the amount of oxybenzone and padimate O as follows:

$$\text{Percent Oxybenzone} = \frac{\text{Peak area of oxybenzone in sunscreen standard}}{\text{Peak area of oxybenzone in HPLC reference standard}} * 100$$

$$\text{Percent Padimate O} = \frac{\text{Peak area of padimate O in sunscreen standard}}{\text{Peak area of padimate O in HPLC reference standard}} * 100$$

(ii) The percent of oxybenzone and padimate O in the SPF standard should be between 95 and 105.

(3) *Test subjects.* (i) *Number of subjects.* A test panel should include enough subjects to produce a minimum of 10 valid test results. A maximum of three subjects may be rejected from this panel based on paragraph (i)(5)(v)) of this section.

(ii) *Medical history.* (A) Obtain a medical history from each subject with emphasis on the effects of sunlight on the subject's skin. Determine that each subject is in good general health with skin type I, II, or III as follows:

(*1*) Always burns easily; never tans (sensitive).

(*2*) Always burns easily; tans minimally (sensitive).

(*3*) Burns moderately; tans gradually (light brown) (normal).

(*4*) Burns minimally; always tans well (moderate brown) (normal).

(*5*) Rarely burns; tans profusely (dark brown) (insensitive).

(*6*) Never burns; deeply pigmented (insensitive).

(B) Skin type is based on first 30 to 45 minutes of sun exposure after a winter season of no sun exposure. Determine that each subject is not taking topical or systemic medication that is known to alter responses to UV radiation. Determine that each subject has no history of sensitivities to topical products and/or abnormal responses to sunlight, such as a phototoxic or photoallergic response.

(iii) *Physical examination.* Conduct a physical examination to determine the presence of sunburn, suntan, scars, active dermal lesions, and uneven skin tones on the areas of the back to be tested. A suitable source of low power UVA, such as a Woods lamp, is helpful in this process. If any of these conditions are present, the subject is not qualified to participate in the study. The presence of nevi, blemishes, or moles will be acceptable if, in the physician's judgment, they will neither compromise the study nor jeopardize a subject's safety. Subjects with dysplastic nevi should not be enrolled. Excess hair on the back is acceptable if the hair is clipped. Shaving is unacceptable because it may remove a significant portion of the stratum corneum and temporarily alter the skin's response to UV radiation.

(iv) *Informed consent.* Obtain legally effective written informed consent from all test subjects.

(4) *Sunscreen application.* (i) *Test site.* Test sites are locations on each subject's back, between the beltline and the shoulder blades (scapulae) and lateral to the midline, where skin responses to UV radiation are determined. Responses on unprotected skin (no test material applied) and protected skin (sunscreen test product(s) or SPF standard applied) are determined at separate unprotected and protected test sites, respectively. Test sites should be randomly located in a blinded manner. Each test site should be a minimum of 30 square centimeters and outlined with indelible ink.

(ii) *Test subsite.* Test subsites are the locations to which UV radiation is administered within a test site. At least five test subsites should receive UV doses within each test site. Test subsites should be at least 0.5 square centimeters (cm^2) in area and should be separated from each other by at least 0.8 cm. Each test subsite should be outlined with indelible ink.

(iii) *Applying test materials.* Apply the sunscreen test product and the SPF standard at 2 milligrams per square centimeter (mg/cm^2) to their respective test sites. Use a finger cot compatible with the sunscreen to spread the product as evenly as possible.

(iv) *Waiting period.* Wait at least 15 minutes after applying a sunscreen product before exposing the test sites to UV radiation as described in paragraph (i)(5)) of this section. For water resistant sunscreen products, proceed with the water resistance testing procedure described in paragraph (i)(7) of this section after waiting at least 15 minutes.

(5) *UV exposure.* (i) *Definition of minimal erythema dose (MED).* The minimal erythema dose (MED) is the smallest UV dose that produces perceptible redness of the skin (erythema) with clearly defined borders at 16 to 24 hours after UV exposure. The MED for unprotected skin (MED_u) is determined on a test site that does not have sunscreen applied. The MED for protected skin (MED_p) is determined on a test site that has sunscreen applied. An MED_p is determined for the SPF standard ($ssMED_p$). An MED_p is determined for the sunscreen test product ($tpMED_p$).

(ii) *UV exposure for initial* MED_u. For each test subject, administer a series of UV radiation doses expressed as J/m^2-eff (as determined according to paragraph (a)(2) of this section) to the test subsites within an unprotected test site using an accurately calibrated solar simulator. Select doses that are a geometric series represented by 1.25^n (*i.e.,* each dose is 25 percent greater than the previous dose).

(iii) *UV exposure for final* MED_u, $ssMED_p$, and $tpMED_p$. For each subject, determine the final MED_u, $ssMED_p$, and $tpMED_p$ by administering a series of five UV doses to the appropriate test sites. The middle dose (X) in each of these dose series (*i.e.,* the third dose) should equal the initial MED_u times the expected SPF. Note that the expected SPF equals 1 and 16.3 for the final MED_u and $ssMED_p$, respectively. The remaining UV doses in the series depend upon the expected SPF value of the sunscreen test product(s).

For products with an expected SPF less than 8, administer UV doses that increase by 25 percent with each successive dose (*i.e.,* 0.64X, 0.80X, 1.00X, 1.25X, and 1.56X). For products with an expected SPF from 8 to 15, administer UV doses that increase by 20 percent with each successive dose (*i.e.,* 0.69X, 0.83X, 1.00X, 1.20X, and 1.44X). For products with an expected SPF higher than 15, administer UV doses that increase by 15 percent with each successive dose (*i.e.,* 0.76X, 0.87X, 1.00X, 1.15X, and 1.32X).

(iv) *Evaluation of test subsites.* In order that the person who evaluates the test subsites is not biased, he/she should not be the same person who applied the sunscreen drug product to the test site or administered the UV doses. After UV doses are administered, all immediate responses should be recorded. These may include an immediate darkening or tanning, typically grayish or purplish in color, which fades in 30 to 60 minutes; an immediate reddening at the subsite, due to heating of the skin, which fades rapidly; and an immediate generalized heat response, spreading beyond the subsite, which fades in 30 to 60

minutes. After the immediate responses are noted, each subject should shield the exposed area from further UV radiation until the MED is determined. Determine the MED 16 to 24 hours after UV exposure. Because erythema is evaluated 16 to 24 hours after UV exposure, the final MED_u, $ssMED_p$, and $tpMED_p$ are typically determined the day following determination of the initial MED_u. Evaluate the erythema responses of each test subsite using either tungsten or warm white fluorescent lighting that provides at least 450 lux of illumination at the test site. For the evaluation, the test subject should be in the same position as when the test site was irradiated.

(v) *Invalid test data.* Reject test data for a test subject if erythema is not present on either the unprotected or protected test sites; or erythema is present at all subsites; or the responses are inconsistent with the series of UV doses administered; or the subject was noncompliant (*e.g.,* the subject withdraws from the test due to illness or work conflicts or does not shield the exposed testing sites from further UV radiation until the MED is determined).

(6) *Determination of SPF.* (i) Calculate an SPF value for each test subject (SPF_i) as follows:

$$SPFi = \frac{MEDp}{MEDu}$$

(ii) Calculate the mean

$$SPF\ (\overline{SPF})$$

and the standard deviation (s) from the SPF_i values. Calculate the standard error (SE), which equals $s/\sqrt{n}$ (where n equals the number of subjects who provided valid test results). Obtain the t value from Student's t distribution table corresponding to the upper 5-percent point with n—1 degrees of freedom. Determine the labeled SPF value, which equals the largest whole number less than

$$\overline{SPF} - (t * SE).$$

In order for the SPF determination of a test product to be considered valid, the SPF value of the SPF standard should fall within the standard deviation range of the expected SPF (*i.e.,* 16.3 ± 3.43).

(7) *Determination of water resistance.* The following procedure should be performed in an indoor fresh water pool, whirlpool, and/or hot tub maintained at 23 to 32 °C. Fresh water is clean drinking water that meets the standards in 40 CFR part 141. The pool and air temperature and the relative humidity should be recorded.

(i) *Water resistance (40 minutes).* The labeled SPF should be determined after 40 minutes of water immersion using the following procedure:

(A) Step 1: Apply the sunscreen as described in paragraph (d) of this section.

(B) Step 2: Perform moderate activity in water for 20 minutes.

(C) Step 3: Rest out of water for 15 minutes. Do not towel test site(s).

(D) Step 4: Perform moderate activity in water for 20 minutes.

(E) Step 5: Allow test sites to dry completely without toweling.

(F) Step 6: Apply the SPF standard as described in paragraph (d) of this section.

Step 1. Expose test sites to UV doses as described in paragraph (e) of this section.

(ii) *Water resistance (80 minutes).* The labeled SPF should be determined after 80 minutes of water immersion using the following procedure:

(A) Step 1: Apply the sunscreen as described in paragraph (d) of this section.

(B) Step 2: Perform moderate activity in water for 20 minutes.

(C) Step 3: Rest out of water for 15 minutes. Do not towel test site(s).

(D) Step 4: Perform moderate activity in water for 20 minutes.

(E) Step 5: Rest out of water for 15 minutes. Do not towel test site(s).

(F) Step 6: Perform moderate activity in water for 20 minutes.

(G) Step 7: Rest out of water for 15 minutes. Do not towel test site(s).

(H) Step 8: Perform moderate activity in water for 20 minutes.

(I) Step 9: Allow test sites to dry completely without toweling.

(J) Step 10: Apply the SPF standard as described in paragraph (d) of this section.

(K) Step 11: Expose test sites to UV doses as described in paragraph (e) of this section.

(j) *Broad spectrum test procedure.* (1) *UV Spectrometry.* (i) *Plate.* Use optical-grade polymethylmethacrylate (PMMA) plates suitable for UV transmittance measurements. The plate should be roughened on one side to a three dimensional surface topography measure (Sa) between 2 and 7 micrometers and must have a rectangular application area of at least 16 square centimeters (with no side shorter than 4 cm).

(ii) *Sample holder.* The sample holder should hold the PMMA plate in a horizontal position to avoid flowing of the sunscreen drug product from one edge of the PMMA plate to the other. It should be mounted as close as possible to the input optics of the spectrometer to maximize capture of forward scattered radiation. The sample holder should be a thin, flat plate with a suitable aperture through which UV radiation can pass. The PMMA plate should be placed on the upper surface of the sample holder with the roughened side facing up.

(iii) *Light source.* The light source should produce a continuous spectral distribution of UV radiation from 290 to 400 nanometers.

(iv) *Input optics.* Unless the spectrometer is equipped with an integrating sphere, an ultraviolet radiation diffuser should be placed between the sample and the input optics of the spectrometer. The diffuser will be constructed from any UV radiation transparent material (*e.g.,* Teflon® or quartz). The diffuser ensures that the radiation received by the spectrometer is not collimated. The spectrometer input slits should be set to provide a bandwidth that is less than or equal to 1 nanometer.

(v) *Dynamic range of the spectrometer.* The dynamic range of the spectrometer should be sufficient to measure transmittance accurately through a highly absorbing sunscreen product at all terrestrial solar UV wavelengths (290 to 400 nm).

(2) *Sunscreen product application to PMMA plate.* The accuracy of the test depends upon the application of a precisely controlled amount of sunscreen product with a uniform distribution over the PMMA plate. The product is applied at 0.75 mg per square centimeter to the roughened side of the PMMA plate. The sunscreen product should be applied in a series of small dots over the entire PMMA plate and then spread evenly using a gloved finger. Spreading should be done with a very light spreading action for approximately 30 seconds followed by spreading with greater pressure for approximately 30 seconds. The plate should then be allowed to equilibrate for 15 minutes in the dark before the pre-irradiation described in paragraph (c) of this section.

(3) *Sunscreen product pre-irradiation.* To account for lack of photostability, apply the sunscreen product to the PMMA plate as described in paragraph (b) of this section and then irradiate with a solar simulator described in section 352.70(b) of this chapter. The irradiation dose should be 4 MEDs which is equivalent to an erythemal effective dose of 800 J/m^2 (*i.e.,* 800 J/m^2-eff).

(4) *Calculation of mean transmittance values.* After pre-irradiation described in paragraph (c) of this section, mean transmittance values should be

determined for each wavelength λ over the full UV spectrum (290 to 400 nanometers). The transmittance values should be measured at 1 nanometer intervals. Measurements of spectral irradiance transmitted for each wavelength λ through control PMMA plates coated with 15 microliters of glycerin (no sunscreen product) should be obtained from at least 5 different locations on the PMMA plate [C1(λ), C2(λ), C3(λ), C4(λ), and C5(λ)]. In addition, a minimum of 5 measurements of spectral irradiance transmitted for each wavelength λ through the PMMA plate covered with the sunscreen product will be similarly obtained after pre-irradiation of the sunscreen product [P1(λ), P2(λ), P3(λ), P4(λ), and P5(λ)]. The mean transmittance for each wavelength,

$$\overline{T(\lambda)},$$

is the ratio of the mean of the C(λ) values to the mean of the P(λ) values, as follows:

$$\overline{T(\lambda)} = \frac{\sum_1^n P(\lambda)/n}{\sum_1^n C(\lambda)/n}$$

Where n ≥ 5

(5) *Calculation of mean absorbance values.* (i) Mean transmittance values,

$$\overline{T(\lambda)},$$

are converted into mean absorbance values,

$$\overline{A(\lambda)},$$

at each wavelength by taking the negative logarithm of the mean transmittance value as follows:

$$\overline{A(\lambda)} = -\log \overline{T(\lambda)}$$

(ii) The calculation yields 111 monochromatic absorbance values in 1 nanometer increments from 290 to 400 nanometers.

(6) *Number of plates.* For each sunscreen product, mean absorbance values should be determined from at least three individual PMMA plates. Because paragraph (d) of this section requires at least 5 measurements per plate, there should be a total of at least 15 measurements.

(7) *Calculation of the critical wavelength.* The critical wavelength is identified as the wavelength at which the integral of the spectral absorbance curve reaches 90 percent of the integral over the UV spectrum from 290 to 400 nm. The following equation defines the critical wavelength:

$$\int_{290}^{\lambda c} A(\lambda)d\lambda = 0.9 \int_{290}^{400} A(\lambda)d\lambda$$

Where λc = critical wavelength
A(λ) = mean absorbance at each wavelength
dλ = wavelength interval between measurements

A mean critical wavelength of 370 nm or greater is classified as broad spectrum protection.

PART 310—NEW DRUGS

■ 4. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b–263n.

■ 5. Section 310.545 is amended by revising paragraphs (a)(29) and (d)(31) and by adding new paragraph (d)(40) to read as follows:

§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

(a) * * *

(29) *Sunscreen drug products.*

(i) *Ingredients.*

Diethanolamine methoxycinnamate

Digalloyl trioleate

Ethyl 4-[bis(hydroxypropyl)] aminobenzoate

Glyceryl aminobenzoate

Lawsone with dihydroxyacetone

Red petrolatum

(ii) Any ingredients labeled with any of the following or similar claims. Instant protection or protection immediately upon application.

Claims for ''all-day'' protection or extended wear claims citing a specific number of hours of protection that is inconsistent with the directions for application in 21 CFR 201.327.

* * * * *

(d) * * *

(31) December 31, 2002, for products subject to paragraph (a)(29)(i) of this section.

* * * * *

(40) June 18, 2012, for products subject to paragraph (a)(29)(ii) of this section. June 17, 2013, for products with annual sales less than $25,000.

Dated: June 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–14766 Filed 6–14–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 310

[Docket No. FDA–2010–D–0509]

Draft Guidance for Industry on Enforcement Policy for Over-the-Counter Sunscreen Drug Products Marketed Without an Approved Application; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Enforcement Policy—OTC Sunscreen Drug Products Marketed Without an Approved Application.'' The draft guidance is intended to inform manufacturers of over-the-counter (OTC) sunscreen products about our enforcement policy for certain OTC sunscreen products marketed without an approved new drug application. The draft guidance describes our intended approach to enforcement for certain OTC sunscreen products prior to an effective final monograph.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers all comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 16, 2011. Submit written comments on the proposed collection of information by August 16, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Reynold Tan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New

Hampshire Ave., Bldg. 22, rm. 5411, Silver Spring, MD 20993–0002, 301–796–2090.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Enforcement Policy—OTC Sunscreen Drug Products Marketed Without an Approved Application.'' Certain OTC sunscreen products without an approved new drug application [1] have been marketed under our enforcement discretion while we work to establish a final monograph for OTC sunscreen products. These products are not yet the subject of an effective final monograph.

We continue to evaluate information to determine appropriate conditions for OTC sunscreen products to be generally recognized as safe and effective (GRASE) and not misbranded. In a final rule published elsewhere in this issue of the **Federal Register**, we establish in § 201.327 (21 CFR 201.327) and § 310.545 (21 CFR 310.545) labeling and testing requirements for OTC sunscreen products that contain certain active ingredients and are marketed without approved applications. We are also publishing a proposed rule elsewhere in this issue of the **Federal Register** that would, if finalized, limit the maximum labeled sun protection factor (SPF) value for OTC sunscreen products to ''50 +''or ''50 plus.'' In addition to both rules mentioned previously, we are publishing an ANPRM where we are asking sunscreen manufacturers and other interested parties to submit data on OTC sunscreen drug products marketed without approved applications that are formulated in certain dosage forms. For spray dosage forms, we are requesting data to resolve specific questions about both effectiveness and safety. We are also inviting comment on possible labeling and testing requirements for spray dosage forms.

Because of this complex regulatory backdrop, we are developing a guidance to clarify our enforcement policy towards certain OTC sunscreen products before a final monograph becomes effective. The draft guidance applies only to OTC sunscreen products marketed without an approved application that contain only active ingredients or combinations of active ingredients identified as GRASE in a 1999 sunscreen final rule published in the **Federal Register** of May 21, 1999 (64 FR 27666) (the 1999 final rule) that was stayed before becoming effective (69 FR 53801, September 3, 2004);

The draft guidance states our intention to continue to exercise enforcement discretion for these types of products under certain circumstances. The draft guidance addresses OTC sunscreen products subject to the final rule codified in § 201.327 (i.e., products with Broad Spectrum SPF values of 15 or higher, products that do not provide broad spectrum protection, and products with Broad Spectrum SPF values between 2 and 14). The draft guidance also indicates the Agency's enforcement approach for sunscreen products labeled with specific SPF values higher than 50, sunscreens formulated in various dosage forms, and products that contain an insect repellent active ingredient registered with the Environmental Protection Agency. In addition, the draft guidance addresses enforcement policy with regard to the continued labeling of certain OTC sunscreens with SPF values determined using the SPF test methods contained in either the Agency's 1999 final rule (64 FR 27666 at 27689 through 27693) or a proposed rule that published in the **Federal Register** of August 27, 2007 (the 2007 proposed rule) (72 FR 49070 at 49114 through 49119).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on ''Enforcement Policy—OTC Sunscreen Drug Products Marketed Without an Approved Application.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance discusses our intended enforcement policy for OTC sunscreen products marketed without approved applications, including recommendations for labeling and testing of these products. Certain of these provisions are subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). These provisions are discussed further in the following paragraphs.

The draft guidance also references submissions under 21 CFR 330.14. The information collections provisions of that regulation have been submitted to OMB for approval, in accordance with the PRA (76 FR 6801, February 8, 2011).

Under the PRA, Federal Agencies must obtain approval from OMB for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, (44 U.S.C. 3506(c)(2)(A)), requires Federal Agencies to provide a 60-day notice in the **Federal Register** for each proposed collection of information before submitting the collection to OMB for approval.

This draft guidance refers to labeling and testing requirements applicable to certain OTC sunscreen products under § 201.327. Elsewhere in this issue of the **Federal Register**, in accordance with section 3506(c)(2)(A) of the PRA, we are publishing a 60-day notice soliciting public comment on the collections of information in that regulation and will then submit these information collection provisions to OMB for approval. These requirements will not be effective until we obtain OMB approval.

This draft guidance also contains additional information collection provisions that are not addressed by the notice regarding the provisions of § 201.327. To comply with the requirements of the PRA, we are publishing this notice of the additional proposed collection of information set forth in this guidance document and inviting comments on the following topics: (1) Whether the proposed information collected is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimated burden of the proposed information collected, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of information collected on the respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Information Collections Applicable to Sunscreens That Choose To Defer Retesting of SPF Values and Continue Labeling With a Previously-Calculated SPF Value

As already noted, the information collection provisions resulting from

[1] See section 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355). Approved applications under section 505 include both new drug applications (NDAs) and abbreviated new drug applications (ANDAs).

§ 201.327 addressed in this draft guidance are the subject of a 60-day PRA notice published elsewhere in this issue of the **Federal Register**. This draft guidance proposes to temporarily modify that information collection by stating that we do not intend to initiate enforcement action before June 17, 2013, if an OTC sunscreen subject to § 201.327 that was initially marketed prior to June 17, 2011, the date of publication of the 2011 final rule, continues to include an SPF value in its labeling that was determined prior to that date according to either the SPF test method described in the 1999 final rule (64 FR 27666 at 27689 through 27693) or the SPF test method described in the 2007 proposed rule (72 FR 49070 at 49114 through 49119). We believe that the majority of currently-marketed sunscreen formulations will meet this standard and, therefore, may defer their conduct of new SPF testing. However, this one-time testing will need to be conducted within 2 years after publication of the 2011 final rule (§ 201.327), which is within the period addressed in the PRA notice for that regulation. We, therefore, do not expect this draft guidance will alter the burden calculated for SPF testing under 201.327(i) or calculated for developing the PDP (principal display panel) label in compliance with 201.327(a)(1), as indicated in that document.

Under the draft guidance, manufacturers who do choose to delay SPF testing in accordance with 201.327(i) would nonetheless be expected to include on their product's PDP the effectiveness statement required by 201.327(a)(1)—either ''Broad Spectrum SPF'' or ''SPF'', as applicable—followed by the numerical SPF value resulting from prior testing. This creates a burden for third-party disclosure. With respect to the 2011 final rule, we estimated that there are approximately 100 manufacturers of sunscreens (respondents) and we anticipated that it would require no more than 0.5 hours per stock keeping units (SKU) for these manufacturers to prepare and review labeling that inserts the SPF value into the effectiveness statement provided by 201.327(a)(1).[2] We anticipate that manufacturers will choose to avail themselves of the delay of SPF testing provided for under the guidance for as many as half (1,175) of the 2,350 formulations estimated in the 2011 final rule. Based on the estimate that there are about 1.53 SKUs for every formulation, we estimate that as many as 1,798 SKUs may have to be re-labeled. For these 1,798 SKUs, we estimate that it will take no more than 0.5 hours per SKU to prepare and review labeling that inserts a previously derived SPF value into the effectiveness (SPF) statement required under 201.327(a)(1). Therefore, the total burden is estimated be 899 hours (1,798 SKUs times 0.5 hours per SKU).

The final rule becomes effective 1 year after its date of publication, so that firms that seek to fall within the enforcement policy described in the guidance will need to begin labeling products with their previously-derived SPF value within the first year after publication of the rule. (Under the enforcement policy guidance, labeling bearing a previously derived SPF value will have to be discontinued and replaced by the labeling required by 201.327(a)(1) no later than 2 years after the date of publication of the final rule.) We therefore assume that the entire burden of labeling products with previously derived SPF values will be incurred in the first year, with no recurrence. This burden estimate is presented in table 1 of this document.

[2] By the terms of our enforcement policy, such manufacturers would be employing an existing test value, and thus would not incur any additional burden of testing associated with this information collection provision.

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN[1]

Activity	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Create PDP labeling statement "Broad Spectrum SPF [fill in value]" based on existing SPF test results[2]	100	17.98	1,798	0.5	899
Total first-year burden					899

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] First-year burden.

We conclude that other labeling recommendations of the draft guidance are not subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The labeling statements for additional directions and warnings recommended in the guidance for sunscreens formulated as sprays are a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)) and, therefore, are not collections of information.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: June 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–14767 Filed 6–14–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 352

[Docket No. FDA–1978–N–0018; formerly Docket No. 1978N–0038]

RIN 0910–ZA40

Sunscreen Drug Products for Over-the-Counter Human Use; Request for Data and Information Regarding Dosage Forms

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; request for data and information.

SUMMARY: We (Food and Drug Administration or FDA) are asking sunscreen manufacturers and other interested parties to submit data on over-the-counter (OTC) sunscreen drug products marketed without approved applications that are formulated in certain dosage forms. These data are necessary to address questions about these dosage forms. For spray dosage forms, we are requesting data to resolve specific questions about both effectiveness and safety. We are also inviting comment on possible labeling and testing requirements for spray dosage forms. This information will be used in establishing monograph conditions, including dosage forms, for sunscreens that are generally recognized as safe and effective (GRASE) and not misbranded.

DATES: Submit data and information either electronically or in writing by September 15, 2011.

ADDRESSES: You may submit comments, identified by docket number FDA–1978–N–0018 (formerly Docket No. 1978N–0038) and/or RIN number 0910–ZA40, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Fax:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and docket number FDA–1978–N–0018 and RIN 0910–ZA40 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided if not marked as confidential.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov,* insert the docket numbers, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Reynold Tan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Mail Stop 5411, Silver Spring, MD 20993, 301–796–2090.

SUPPLEMENTARY INFORMATION:

I. Purpose of This Document

FDA is requesting additional data necessary to establish monograph conditions for sunscreens, including specification of certain dosage forms. In this document, we discuss those dosage forms that we consider currently to be part of the OTC Drug Review, and thus eligible for potential inclusion in a sunscreen monograph, and those dosage forms that we do not consider eligible. For the dosage forms that are eligible, we seek to ensure that the record is complete, so as to support a future monograph identifying conditions, including dosage forms and appropriate testing and labeling, for sunscreens to be GRASE and not misbranded. Finally, as explained below, sunscreens in certain dosage forms such as wipes, towelettes, powders, body washes, and shampoos are not currently considered eligible for inclusion in the sunscreen monograph, and even if their eligibility were established, they lack a sufficient record to support inclusion in the sunscreen monograph.

Although spray dosage forms are among those dosage forms we consider potentially eligible for inclusion in the final sunscreen monograph, they currently lack a record comparable to other dosage forms that could be included in the sunscreen monograph. Considering the greatly increasing number of sunscreen products formulated as sprays, it is critical that the safety and effectiveness of this dosage form be adequately supported. From their existing marketing of spray sunscreens, manufacturers may have the necessary data, but to date these data have not been submitted to FDA. To further encourage submission of data and allow us to move to a proposed rule as quickly as possible, we have developed possible labeling and testing specific to sprays, for which we solicit comment.

Although at this time we expect to receive the necessary data, if we do not obtain sufficient data to support monograph conditions for sunscreen products formulated in certain dosage forms, these products may not be included in the future OTC sunscreen monograph. Any sunscreen product not included in a future final monograph could obtain approval to market by submitting new drug applications (NDAs) under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). These products might in the future be able to submit NDA deviations in accordance with 21 CFR 330.11, limiting the scope of review necessary to obtain approval. It should be noted that, where a final monograph exists, the content of an NDA that deviates only in limited respects from the monograph may omit all information except that pertinent to the deviation.

II. Enforcement Policy

In the absence of an effective final monograph for OTC sunscreen products, questions may arise regarding FDA's enforcement policy for OTC sunscreen products in various dosage forms that are marketed without approved applications. For clarification, we are issuing a draft guidance document that explains the Agency's intended enforcement policy on the various dosage forms for OTC sunscreen products that are marketed during the absence of an effective sunscreen final monograph. This draft guidance document is being published elsewhere in this issue of the **Federal Register**. We are also publishing elsewhere in this issue of the **Federal Register** a final rule for OTC sunscreen products containing certain ingredients and marketed without approved applications that specifies labeling and testing requirements, without regard to dosage form.

III. Dosage Forms Currently Eligible for Inclusion in a Sunscreen Monograph

We have not explicitly stated in previous rulemakings which dosage forms of OTC sunscreen drug products we would consider to be GRASE and not misbranded. However, in 21 CFR 352.52(d), we identified several dosage forms, including sprays, for the purposes of labeling: ''(*e.g.,* cream, gel,

lotion, oil, spray, *etc.*).'' In 21 CFR 352.72(e), we further identified oils, lotions, creams, gels, butters, and pastes and ointments for the purposes of testing. We also identified sticks in the August 25,1978, advanced notice of proposed rulemaking (ANPR) (43 FR 38206 at 38207, 38223, 38224, 38229, and 38239) as lip protectants, which are allowed to contain sunscreen active ingredients and are formulated as sticks (existing 21 CFR 352.60).

For a drug product to be eligible for review, the drug product must either be a product that can be substantiated to have been marketed OTC before the OTC Drug Review began in 1972, or it must be determined to be eligible through submission of a time and extent application (21 CFR 330.14). With respect to OTC sunscreen drug products, the following dosage forms are eligible for review and potential inclusion in the monograph:

- Oils
- Lotions
- Creams
- Gels
- Butters
- Pastes
- Ointments
- Sticks
- Sprays

On the existing record, we anticipate that all of these listed dosage forms, except sprays, would be included in the future OTC sunscreen monograph as GRASE and not misbranded under the labeling and testing established in new 21 CFR 201.327. However, the record does not yet contain comparable safety and effectiveness data and information for spray dosage forms.

Although we have information about how sunscreens in eligible dosage forms other than sprays are applied, including data on the amounts of oils, creams, and lotions consumers typically apply (Refs. 1 and 2), spray dosage forms are sufficiently different from other eligible dosage forms identified during the course of development of the sunscreen monograph that the data and information for these dosage forms are not directly applicable. The nature of other eligible dosage forms identified during the course of development of the sunscreen monograph (oils, creams, lotions, gels, butters, pastes, ointments, sticks) requires that consumers dispense the product into their hand or directly onto their skin and rub these products into the skin to some extent, with most of the amount dispensed applied. Sprays, however, in particular aerosolized sprays, are dispensed in a more diffuse manner even when applied directly to the body. Due to the different modes of dispensing and application between sprays and the other dosage forms, we do not know if consumers obtain the same protection with sprays as these other dosage forms. With sprays, we also do not know how much of the typical dispensed amount is effectively transferred to the skin. Adequate, uniform coverage of sprays may also be difficult to assess, because some sprays are applied in a thin, clear layer which is more difficult to visualize than other dosage forms. Some spray products are similarly meant to be rubbed into the skin, but we do not know if consumers typically rub these spray products into the skin. Thus, upon review of the record, we have determined that additional data or information (as outlined below) are necessary, and must be sufficient to support appropriate monograph conditions (e.g., testing and labeling specific to sprays) to be included in the future final monograph. Thus, we are soliciting data to address the following questions to build a record comparable to other dosage forms such as lotions:

- What amounts of sunscreen spray do consumers typically dispense and what amounts are effectively transferred to the skin?)
- How uniform is the sunscreen application across the sun-exposed area of skin?
- How frequently do consumers reapply the product?
- If a product is labeled with a direction to rub it into the skin, do consumers typically follow this direction?
- How does rubbing the product into the skin change the effectiveness?
- How do the protection levels (SPF values) when typical amounts are applied compare with those under laboratory conditions?
- Should the SPF and broad spectrum tests be modified to address sprays? If so, how?

In addition to answering these questions for spray dosage forms, it would be useful if studies also directly compared spray dosage forms to the other eligible dosage forms previously identified during the course of development of the sunscreen monograph. We are interested in whether use of sunscreen sprays differs enough from use of other eligible sunscreen dosage forms that the SPF values on sunscreen sprays are not comparable to those on other sunscreens. We are also interested in whether use differs among sunscreen spray products. Some sunscreen sprays are dispensed by pumps rather than as aerosolized sprays. Other sprays may turn into a foam upon contact with the skin. We would be interested in data and information that helps us assess how our concerns about sunscreen sprays in general apply to different types of sunscreen sprays. (See section *V. ''Submission of Data and Information''* for information on submitting these data.)

As we have done previously for other spray OTC products, we are also requesting data to understand the possibility and consequences of unintentional inhalation of spray sunscreens, an issue not presented by the other eligible dosage forms because they are applied directly to the skin:

- What are the risks associated with inhalation of sunscreen active ingredients and propellants?
- What are typical particle size distributions for sunscreen spray products?
- Are animal toxicity studies necessary for determining the potential for toxicity resulting from inhalation?
- Is the labeling discussed in this document adequate to prevent unintentional inhalation? If not, please provide alternative labeling.

In responding to the first question, (What are the risks associated with inhalation of sunscreen active ingredients and propellants?), we request submission of any reports of adverse events associated with unintentional inhalations of currently marketed sunscreen spray products.

To encourage submission and in anticipation of receiving this necessary data/information, we have used the available data and information on sprays to develop possible labeling and testing for comment. To address the possibility that inhalation of aerosolized particulates could cause adverse health effects, we are considering proposing a warning for sunscreen spray products that reads:

- ''*When using this product* keep away from face to avoid breathing it.''

We are also considering specific directions for sunscreen spray products that read:

- ''hold container 4 to 6 inches from the skin to apply''
- ''do not spray directly into face. Spray on hands then apply to face.''
- ''do not apply in windy conditions''
- ''use in a well-ventilated area''

Sunscreen spray products would be required to be labeled with these warnings and directions in addition to the other warnings and directions required for all sunscreen products.

We are also considering a proposal to modify a directions statement to ensure that sunscreen products in spray dosage forms are applied comparably to sunscreen products in other dosage forms. The sun protection factor (SPF)

and broad spectrum test procedures in the 2011 final rule (published elsewhere in this issue of the **Federal Register**) require that test products be applied in an amount of 2 milligrams per square centimeter (mg/cm^2) and 0.75 mg/cm^2, respectively, and then spread evenly by hand (21 CFR 201.327(i)(4)(iii) and (j)(2)). Comparable product application during testing, as required by these standard testing conditions, is necessary to ensure consistent and comparable test values between sunscreen products. However, valid comparison of SPF test values and broad spectrum test results between products further requires comparable product application during actual use. Therefore, we are considering proposing directions for the application of sprays to more closely follow the way they are applied in SPF and broad spectrum testing. The modified directions statement would read:

- ''spray [select one of the following: 'liberally' or 'generously'] and spread evenly by hand 15 minutes before sun exposure.''

We invite comment on all of the labeling statements we are considering. If there are other labeling statements that should be considered, in order for us to propose them for inclusion in a final monograph, we will need adequate data supporting the alternative labeling, just as we are requesting data to support the labeling we have already developed for consideration. In developing any alternative labeling for consideration, we advise submitters that the directions for application should reflect how the SPF and broad spectrum test procedures are performed.

We are considering adding the following sentence to the SPF and broad spectrum test procedures (21 CFR 201.327(i) and (j), respectively) to require the following regarding application of test material: ''For spray formulations, dispense the product into a weighing vessel and then apply the appropriate weight of liquid.'' This revision is based upon the one public test modification for a sunscreen spray product that we are aware of (Ref. 3). However, the information regarding the test method did not contain validation of the test as it relates to sprays. To support proposing this modification as a monograph condition, we need data to validate the modified test method; we also remain open to any other testing alternative that is supported by sufficient data to demonstrate that it would be an appropriate monograph condition for sprays. To support a testing alternative, data would need to show that testing a spray product according to the alternative test produces SPF and broad spectrum test results that can be validly compared to SPF and broad spectrum test results for other dosage forms. We solicit comment on whether this test modification would be appropriate for all spray dosage forms and whether modifications are needed to address differences in dispensing and application between spray dosage forms. For example, some current spray labels direct the user to spray directly onto skin and some also direct the user to rub in. As noted, we are soliciting comment on directions calling for spray products to be spread by hand, as is done under the current test method. If spray manufacturers instead seek labeling indicating that spray application is alone sufficient (*e.g.,* ''no-rub'' labeling), we seek validated testing to support this labeling. We invite manufacturers to discuss possible methods and validations with us.

The foregoing discussion concentrates on specific dosage forms that we have concluded are eligible for potential inclusion in the sunscreen monograph. Although we particularly solicit specific data regarding sprays, we welcome the submission of any additional information relevant to the safety and effectiveness of other eligible dosage forms. We also invite submitters to identify any additional dosage forms that may be eligible for inclusion in the OTC monograph based on marketing prior to the outset of the OTC drug review in 1972, and to provide information to support their eligibility. If eligible, any additional dosage forms will also require a sufficient record to support finding them to be generally recognized as safe and effective if they are to be proposed for inclusion in the OTC sunscreen monograph. See 21 CFR 330.10 for information regarding the types of information to be submitted to support eligibility and inclusion in an OTC drug monograph.

IV. Dosage Forms Not Eligible for Inclusion in a Sunscreen Monograph

In response to the August 27, 2007, proposed rule for OTC sunscreen products (72 FR 49070), several submissions recommended that we include the following dosage forms in the final sunscreen monograph (Ref. 4):

- Wipes
- Towelettes
- Powders
- Body washes
- Shampoos

We currently do not consider these dosage forms eligible for review under the OTC monograph process. We were unable to identify any sunscreen products in wipe, towelette, powder, body wash, or shampoo dosage forms that were marketed OTC before the OTC Drug Review began. To determine eligibility for the OTC Drug Review, we must have actual product labeling or a facsimile of labeling that documents the conditions of marketing of the product prior to May 1972 (21 CFR 330.10(a)(2)). Conditions include active ingredient, dosage form, dosage strength, route of administration, and specific OTC use of the product (21 CFR 330.14(a)). These are the same criteria used to establish that OTC drugs initially marketed in the United States after the OTC Drug Review began or without U.S. marketing experience meet the ''material extent'' or ''material time'' provisions of the FD&C Act's ''new drug'' definition (21 U.S.C. part 201, section 201(p)(2)) and are eligible for the OTC Drug Review (21 CFR 330.14(c)(3)). We also have not received any time and extent applications for OTC sunscreen products formulated as wipes, towelettes, powders, body washes or shampoos. Therefore, sunscreens formulated as wipes, towelettes, powders, body washes, or shampoos are not currently eligible for review under the OTC sunscreen monograph. If their eligibility is to be established, the required information must be submitted in the form of a time and extent application (21 CFR 330.14). Determination of eligibility would not itself be sufficient for inclusion in the OTC sunscreen monograph. As discussed in 21 CFR 330.14(e), we would publish a notice of eligibility if the dosage form was found eligible and then we would request data to demonstrate the safety and effectiveness of the dosage form for its intended OTC use (21 CFR 330.14(f)).

V. Submission of Data and Information

Interested persons may submit data and information as described under the **ADDRESSES** heading at the beginning of this document. Submit a single copy of electronic submissions or two paper copies of any mailed submissions, except that individuals may submit one paper copy. Submissions are to be identified with the docket number found in brackets in the heading of this document. Received submissions may be viewed electronically at *http://www.regulations.gov* or by visiting the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**), under docket number FDA–1978–N–0018

(formerly Docket No. 1978N–0038) unless otherwise noted, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Neale *et al., Archives of Dermatology,* 138:1319–25, 2002.

2. Autier *et al., British Journal of Dermatology,* 144:288–91, 2001.

3. Docket No. FDA–1978–N–0018 (formerly Docket No. 1978N–0038): C712, Schering Plough.

4. Docket No. FDA–1978–N–0018 (formerly Docket No. 1978N–0038): FDA List of Docket Submissions Regarding Dosage Forms Issues: C683, C712, C716, EC2720.

This ANPR is issued under 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264 and under the authority of the Commissioner of Food and Drugs.

Dated: June 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–14768 Filed 6–14–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. FDA–1978–N–0018; formerly Docket No. 1978N–0038]

RIN 0910–AF43

Revised Effectiveness Determination; Sunscreen Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to limit the maximum labeled SPF value for over-the-counter (OTC) sunscreen drug products to ''50+.'' We are issuing this proposed rule after reviewing data and information we received on the safety and effectiveness of OTC sunscreen drug products after publication of our 2007 proposed rule. The record does not currently contain sufficient data to indicate that there is additional clinical benefit above SPF 50. This proposal is part of FDA's ongoing review of these products to ensure their safety and effectiveness.

DATES: Submit either electronic or written comments on the proposed rule by September 15, 2011. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (the PRA) by July 18, 2011, (see the ''Paperwork Reduction Act of 1995'' section of this document). See section VII of this document for the proposed effective date of a final rule based on this proposal.

ADDRESSES: You may submit comments, identified by Docket No. FDA–1978–N–0018 and RIN number 0910–AF43, by any of the following methods, except that comments on information collection issues under the PRA must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Fax:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name, Docket No. FDA–1978–N–0018, and RIN 0910–AF43 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov,* insert the docket numbers, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Reynold Tan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5411, Silver Spring, MD 20993–0002, 301–796–2090.

SUPPLEMENTARY INFORMATION:

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I. Overview of This Document

A. Summary of Proposal

This document proposes to specify one of the conditions under which OTC sunscreen products are considered to be generally recognized as safe and effective (GRASE) and not misbranded. We are proposing a maximum labeled sun protection factor (SPF) value of ''50+'' for all monograph sunscreen products. In a final monograph issued in 1999, and stayed prior to becoming effective, we determined that the maximum SPF permitted under the monograph should be ''30+'' (64 FR 27666 at 27674 through 27675, May 21, 1999). In a 2007 proposed rule, we proposed to amend the sunscreen monograph in part 352 to permit products marketed under the monograph to be labeled with SPF values up to ''50+,'' and we expressed particular concern that sunscreen products with SPF test values above 50 could not be tested with acceptable accuracy and reproducibility (72 FR 49070 at 49085 through 49087, August 27, 2007) (the 2007 proposed rule). Although submissions in response to the 2007 proposed rule demonstrated the accuracy and reproducibility of such tests at values as high as SPF 80, we are again proposing a maximum labeled SPF value of ''50+'' for sunscreen products marketed without approved applications, because the record continues to lack data demonstrating that sunscreen products with SPF values above 50 provide additional clinical benefit compared to SPF 50 products. In this document, we are inviting the submission of data demonstrating additional clinical benefit provided by sunscreen products with SPF values greater than 50.

B. Enforcement Policy

Elsewhere in this issue of the **Federal Register**, we are issuing a final regulation establishing effectiveness

testing and labeling requirements for OTC sunscreen products containing specified active ingredients and marketed without approved applications. This regulation will become effective 1 year after its date of publication in the **Federal Register**. However, because we are considering certain active ingredient safety issues further, there is not yet a sunscreen final monograph in effect that specifies which sunscreen active ingredients may be included in a sunscreen product that is determined to be GRASE and not misbranded. Our further consideration of these active ingredient issues does not preclude us from identifying in this document an additional condition that is necessary for a sunscreen product to be GRASE and not misbranded. In a forthcoming rulemaking, we intend to request additional data regarding the safety of the individual sunscreen active ingredients. The issuance of the final labeling rule for certain OTC sunscreen products marketed without approved applications combined with the absence of an effective final monograph for OTC sunscreen products may give rise to questions regarding FDA's enforcement policy for OTC sunscreen products marketed without approved applications. To clarify expectations for industry, we are issuing a draft guidance document explaining our intended enforcement policy for these products in the absence of an effective sunscreen final monograph.

II. Maximum Labeled SPF

In this document, we propose to set an upper limit for labeled SPF values at ''50+,'' as proposed in the 2007 proposed rule. This limit would permit sunscreen products with SPF test results above 50 to be labeled with a ''50+'' value, but would not allow the specific values above 50 to be listed on the label. The remainder of this section of the document summarizes the public submissions regarding the maximum SPF value, most of which support this maximum specific SPF value of 50. We also summarize how the maximum SPF value has increased over the history of sunscreen rulemakings and discuss the two criteria for allowing these increases:

- *First Criteria:* Does the SPF test provide accurate and reproducible results for sunscreen products with higher SPF values?
- *Second Criteria:* Do sunscreen products with higher SPF values provide additional clinical benefit?

The first criterion has been met for sunscreen products with SPF values up to 80. However, we are proposing that the maximum specific labeled SPF be 50, unless we receive data to meet the second criterion that products with SPF values higher than 50 provide additional clinical benefit. These data are critical to show that SPF values measured in the laboratory setting correspond to additional clinical benefit in actual use conditions. We do not have sufficient data to establish that products with SPF values higher than 50 provide additional clinical benefit over SPF 50 sunscreen products. We describe the types of additional studies that would need to be submitted to support increasing the maximum specific SPF value above 50.

A. Summary of Public Submissions

In response to the 2007 proposed rule, we received 13 submissions concerning the upper limit for the SPF value (Ref. 1):

- Four submissions disagreed with the proposed upper limit of ''50+'' and argued that the upper limit should be decreased to ''30+''
- Six submissions supported raising the upper limit from 30 to ''50+''
- Three submissions disagreed with the proposed upper limit of ''50+'' and argued that FDA should not specify an upper limit

The submissions requesting that the upper limit be decreased to ''30+'' argued that consumers would not benefit significantly from the availability of higher SPF sunscreen products. The submissions noted that consumers might reapply higher SPF sunscreen products less frequently than SPF 30+ sunscreen products and, therefore, would not derive the additional protection that higher SPF products are claimed to provide. One of the submissions provided data showing that increases in the concentrations of ingredients in higher SPF products might lead to increases in skin sensitization and/or irritation problems. Another one of the submissions submitted data to demonstrate that an increase in SPF value from 28 to 50 requires roughly twice the amount of active ingredients in a sunscreen product and suggested that this result may lead to increases in skin sensitization and/or irritation problems. The submission argued that the safety risks associated with increased exposure to sunscreen active ingredients were not justified in light of what it defined as a small increase in UV protection.

The submissions that support our raising the proposed upper limit from 30+ to 50+ came from the American Academy of Dermatology, the American Society of Dermatologic Surgery, two sunscreen manufacturers, the Personal Care Products Council, and a consumer. These submissions collectively made the following arguments:

- The increased protection provided by an SPF 50 sunscreen product compared to an SPF 30 sunscreen product is important and necessary for some consumers (*e.g.,* those with skin type I, a history of skin cancer, or an immunosuppression condition).
- Increasing the upper limit from ''30+'' to ''50+'' compensates for inadequate application of sunscreen by consumers.
- The SPF test has been validated to ensure accuracy and reproducibility for sunscreen products with SPF 50, but not for sunscreen products with SPF above 50.
- An SPF upper limit of ''50+'' is harmonized with many other countries, including Japan and those in the European Union.
- An SPF 50 sunscreen product provides the maximum protection needed by consumers.

The submissions requesting that FDA not establish an upper limit on the SPF value argued that some consumers may need more sun protection than that provided by SPF 50 sunscreen products (*e.g.,* lifeguards and athletes who cannot reapply sunscreen products frequently). Two of the submissions submitted data that they argue support an upper limit for SPF values above 50. One submission included data intended to validate that the SPF test can accurately and reproducibly measure sunburn protection for sunscreen products with SPF values as high as 80. The other submission included data intended to demonstrate that sunscreen products with SPF values above 50 provide additional protection under actual use conditions.

B. Discussion of Maximum SPF Values in Previous Sunscreen Rulemakings

We have addressed the issue of establishing maximum SPF values in many earlier sunscreen rulemakings. We have raised the maximum SPF value over time in the rulemakings in accordance with the two previously mentioned criteria:

- Does the SPF test provide accurate and reproducible results for sunscreen products with higher SPF values?
- Do sunscreen products with higher SPF values provide additional clinical benefit?

Maximum SPF values were first addressed in an advance notice of proposed rulemaking (ANPRM) published in 1978 (43 FR 38206 at 38213 through 38214, August 25, 1978). A panel of sunscreen experts recommended categorizing products based upon the protection they

provided against sunburn. Products that provided the most protection from sunburn were those with SPF values of 15 or higher. The panel recommended the use of these higher SPF products for individuals with skin types that always burn easily. In the 1993 proposed rule, we considered raising the maximum SPF value to a value higher than 15 (58 FR 28194 at 28221 through 28225, May 12, 1993). Based on the data available at that time, we stated that sunscreen products with SPF values higher than 15 are beneficial to consumers and proposed increasing the maximum value to 30. We focused on the question of whether there was additional benefit from these sunscreen products with higher SPF values. We were not concerned about the accuracy of SPF testing because available data demonstrated that the SPF test was accurate and reproducible for sunscreen products with SPF values as high as 30.

In the stayed 1999 final rule, we considered increasing the SPF maximum value from 30 to 50 (64 FR 27666 at 27674 through 27675). We discussed both the question of additional benefit and the question of testing accuracy and reproducibility in deciding not to increase the maximum SPF value to 50. We expressed concern about the ''extremely small'' additional sunburn protection afforded by an SPF 50 sunscreen product compared to an SPF 30 sunscreen product (64 FR 27666 at 27675). We explained that the increase in sunburn protection becomes increasingly small with increasing SPF values. We stated that this nonlinear nature of SPF rating system is difficult to translate to labeling. We also expressed concern about the ''ability of current testing methods to accurately and reproducibly determine SPF values for high SPF products'' (64 FR 27666 at 27675). The higher UV test doses required to test high SPF products can make it difficult to obtain accurate and reproducible results. Therefore, because we did not have data validating testing for SPF 50 sunscreen products, we retained a maximum SPF value of 30 in the 1999 final rule, which is currently stayed.

In the 2007 proposed rule, we proposed increasing the maximum labeled SPF value to ''50+'' based on our receipt of sufficient supporting data (72 FR 49070 at 49085 through 49087). Our decision to limit the labeled SPF values to 50+ was based primarily on concerns about expected increased SPF test variability for sunscreen products with SPF values higher than 50 and the lack of validation data for these products. We stated that we would consider SPF values above 50 upon receipt of validation data demonstrating that accurate and reproducible test results could be obtained. We further specified that these data should include SPF test results from multiple laboratories testing the same sunscreen formulations with statistical analyses of the overall results. We also discussed the clinical benefits provided by SPF 50 sunscreen products for ''those sun-sensitive consumers who require such products based upon personal knowledge, planned sun exposure, geographical location, or advice of a health professional'' (72 FR 49070 at 49086). We explained in the 2007 proposed rule that SPF 50 sunscreen products are expected to provide additional benefit by compensating for inadequate application and infrequent reapplication of sunscreen products (72 FR 49070 at 49086).

C. Validity of Testing Sunscreen Products With SPF Values Higher Than 50

We now have data demonstrating that the SPF test can be accurately and reproducibly performed for sunscreen products with SPF values as high as 80. The data were included in one of the submissions requesting an upper limit above SPF 50 (Ref. 2). Multiple laboratories, testing multiple sunscreen formulations, determined the same SPF values for the same sunscreen products.

D. Insufficient Evidence of Additional Benefit at SPF Values Higher Than 50

Despite the new testing, the record does not contain adequate data demonstrating that a sunscreen product with an SPF value over 50 provides an increase in clinical benefit over a sunscreen product with an SPF value of 50. For reasons explained in the remainder of this section, it is critical that the data demonstrate that SPF values measured in the laboratory setting correspond to additional clinical benefit in actual use conditions. Consumers have become familiar with SPF values because SPF values have appeared on sunscreen product labels for many decades. Consumers have learned to associate higher SPF values with greater sun protection. Consumers would likely assume that a product with an SPF value higher than 50 provides greater protection than a product with an SPF value of 50 (*e.g.,* assume that an SPF 80 sunscreen provides greater protection than an SPF 50 sunscreen). However, we lack evidence that a product with an SPF value higher than 50 provides additional clinical benefit compared to a product with an SPF value of 50. In the absence of data demonstrating additional clinical benefit, we are concerned that labeling a product with a specific SPF value higher than 50 would be misleading to the consumer.

It is important to understand that SPF values are determined in a laboratory where human subjects are given ultraviolet (UV) radiation doses produced by a solar simulator (*i.e.,* a UV lamp). Under those circumstances, products with increasingly higher SPF values are shown to prevent sunburn against increasingly higher UV doses produced by the solar simulator. However, because the solar simulator can produce far higher UV radiation doses than a consumer would ever receive even under the most severe sun exposure situations (*i.e.,* locations and times associated with the most intense sun exposure), the theoretical increase in protection implied by higher SPF values generated in the lab does not necessarily correspond to meaningful additional sunburn protection for consumers in actual use conditions, where a consumer may be receiving effectively maximal protection against their actual UV exposure with a lower SPF product.

We are only aware of one study that examined the relative effectiveness of sunscreen products with SPF values of 50 compared to products with SPF values above 50. Russak *et al.* compared the sunburn protection provided by an SPF 85 sunscreen product compared to an SPF 50 sunscreen product (Ref. 3). In the double-blind study, each subject was randomly assigned to apply the SPF 85 product to one side of the face and the SPF 50 product to the other. Following a one-time morning application, subjects went skiing or snowboarding during a bright, sunny day at a well-known ski resort.

Nine of 56 subjects, who averaged 5 hours of sun exposure, developed sunburn. Eight of the sunburned subjects developed sunburn on the SPF 50 product side of the face but not on the SPF 85 side of the face. The remaining sunburned subject developed sunburn on both sides of the face. The study authors concluded that these results demonstrate that an SPF 85 sunscreen product provides significantly better sunburn protection than an SPF 50 sunscreen product. However, this single study summary is not an adequate basis upon which we may conclude that sunscreen products with SPF values above 50 provide additional sun protection compared to an SPF 50 sunscreen product. For example, we cannot determine from the study summary the amounts of sunscreen products applied, length of sun exposure for individual subjects, or

the time of day during which subjects were exposed to the sun. Furthermore, although current sunscreen directions instruct consumers to reapply sunscreen products no less frequently than every two hours, the subjects in this study were explicitly told not to reapply sunscreen products. Therefore, we do not have adequate data to conclude that sunscreen products with SPF values above 50 provide additional clinical benefit when compared to SPF 50 sunscreen products.

The requirement that higher SPF sunscreen products provide additional clinical benefit when compared to lower SPF sunscreen products also flows from the principle that the GRASE determination requires consideration of the benefit-to-risk ratio for the drug (21 CFR 330.10(a)(4)(ii) and (iii)). If the addition of ingredients to a drug does not provide additional clinical benefit, but potentially increases the risk associated with the drug (*e.g.,* increased skin irritation), then this benefit-risk calculation shifts, and the drug is not GRASE. For the reasons noted above, the record does not currently contain sufficient data to indicate that there is additional clinical benefit above SPF 50.

Our combination policy also illustrates this principle. As stated in 21 CFR 330.10(a)(4)(iv), active ingredients should not be combined in a drug product unless ''each active ingredient makes a contribution to the claimed effect(s).'' An active ingredient should not be added to a drug product unless the combination with the active ingredient has additional benefit. Similarly, increased concentrations of active ingredients should not be included in sunscreen products unless there is evidence that these increases result in improved effectiveness under conditions of actual use. Therefore, we are requiring data sufficient to support a general conclusion that sunscreen products with specific SPF values above 50 provide additional protection over SPF 50 sunscreen products. If we receive such data, and sufficient accompanying data regarding accuracy and reproducibility of testing, we may be able to allow those specific SPF values to be included in labeling. For example, as we now have data addressing the reproducibility of SPF testing up to SPF 80, if we received sufficient clinical data demonstrating additional clinical benefit for products with specific SPF values between 50 and 80, we may include those products under the monograph. However, the final determination may also depend on safety data on those products, and the question of whether the benefit-risk calculation remains favorable to finding them GRASE.

E. Data Necessary To Demonstrate Additional Benefit

To increase the maximum specific SPF value above 50, we would need data demonstrating that sunscreen products with SPF values above 50 provide additional clinical benefit relative to SPF 50 sunscreen products. The study by Russak *et al.* described earlier in this section of the document is one type of study that we would accept for consideration, if it would have contained the detail required to make a determination of its adequacy. There may be other types of studies that would support such an increase. However, it is important that any such studies be well-designed so that we can draw conclusions from them. We recommend that anyone interested in conducting these types of studies contact FDA before beginning the studies.

We recognize that sunscreen products with SPF values above 50 could have utility for consumers in certain settings, such as skiing at high altitudes, or with certain conditions that predispose them to developing skin cancer. If such products are needed in unique situations but not in typical situations of sunscreen use (*e.g.,* beach or gardening), it is possible that different labeling may be necessary for these unique situations. Possibly, sunscreen products with specific SPF values above 50 should be labeled only for certain situations or populations, while sunscreen products with SPF 50 or lower could contain the labeling included in the 2011 final rule published elsewhere in this issue of the **Federal Register**. Additional data would enable us to identify the appropriate target population (*e.g.,* high altitude skiers or people diagnosed with skin cancer) for sunscreen products with SPF values above 50.

F. Alternatives for Addressing Maximum SPF Value

In this and prior rulemakings, we have proposed monograph conditions addressing SPF labeling, which would have the effect of limiting the maximum SPF value that can be declared on the label of a sunscreen under the monograph. As we have described, we are concerned that in the absence of data supporting additional clinical benefit for products with specific SPF values above 50 (but below 80, the current limit of validated testing), declaring specific SPF values higher than 50 would mislead consumers into thinking that they are obtaining superior protection from these products, which has not been substantiated. Similarly, we solicit comment on whether, absent data demonstrating additional clinical benefit, allowing a product with a tested SPF value above 50 to be labeled as ''SPF 50 plus'' is itself misleading, in suggesting a greater level of protection than a product labeled simply as ''SPF 50.''

In addition to our proposals to limit the maximum SPF value stated in labeling to ''50'' or ''50 plus,'' we solicit comment on whether we should establish a maximum SPF value for sunscreen formulations marketed under the monograph. If a maximum SPF value were established, a product with a tested SPF above that value would no longer be permitted to be marketed under the monograph. For example, if the maximum SPF value were set at 50, then a product with a tested SPF value of 65 would no longer be permitted under the monograph, even if labeled as ''SPF 50 plus'' or ''SPF 50.'' We seek comment on this alternative because, as noted previously, FDA's general approach to combination drugs prohibits the inclusion of additional active ingredients if they do not provide additional benefit. More specifically, if having an SPF above 50 does not confer additional clinical benefit in a sunscreen, the risk benefit-assessment for these sunscreens may no longer be favorable. Manufacturers may have economic incentives to limit their formulations to the minimum necessary active ingredients if they were limited to labeling their product as ''50'' or ''50 plus.'' However, we solicit comment on whether FDA should address this issue through a direct limit on product formulation rather than through labeling. We also solicit comment and data on how to establish the maximum SPF value as a formulation limit (if one were to be set).

III. Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). OMB has determined that this proposed rule is a significant regulatory action as defined by Executive Order 12866. Consistent

with Executive Order 13563, the approach taken here maintains ''flexibility and freedom of choice for the public,'' above all by providing ''information for the public in a form that is clear and intelligible.''

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule would lead to at most a small one-time relabeling cost for some small businesses, the Agency proposes to certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

A. Background

This proposed rule would require that ''SPF 50+'' be the maximum labeled SPF value for sunscreens marketed under the monograph because products with SPF values above 50 have not been shown to provide additional clinical benefit. Currently, about 2 percent of all products are labeled with SPF values above 50. Manufacturers of broad spectrum products that have products labeled with SPF values greater than 50 will have to relabel the SPF value on their products to ''50+.''

The science regarding the sun's harmful effects on skin has evolved in recent years, and we now know that protection from sunburn is not enough to prevent harmful or undesirable long-term effects from too much sun exposure, such as skin cancer and premature skin aging. We also now have evidence to demonstrate that when used as directed with other sun protection measures, products with Broad Spectrum SPF values of 15 or higher reduce the risk of skin cancer and premature skin aging, as well as helping prevent sunburn. No evidence, however, indicates that SPF values above 50 provide additional protection.

B. Cost To Relabel SPF 50+ Products

Broad spectrum products labeled with SPF values greater than 50 would have to relabel the SPF value to ''50+''. We estimate that about 2 percent of the SKUs, or a total of 72, have SPF values greater than 50 (Ref. 4). We used the new FDA labeling cost model to estimate the costs of relabeling these products. The estimated total one-time costs for relabeling, range from about $200,000 to $650,000 (see table 1 of this document).

TABLE 1—TOTAL COST TO RELABEL SPF 50+ PRODUCTS

	Low	Medium	High
SKUs relabeling SPF 50+	72	72	72
Total Costs ($)	$208,327	$381,287	$657,108

The principal alternative to this proposed rule would be allowing claimed SPF values as high as 80, which would reduce costs by 80 percent or more because most marketed products labeled with SPF values higher than 50 are in the 50 to 80 range. The SPF test has not been validated for values over 80. Another problem with this alternative is that we lack the evidence of additional clinical benefit from these higher SPF ratings.

C. Small Business Analysis

Most major suppliers of sunscreen products are drug manufacturers, for which the Small Business Administration (SBA) defines a small entity as having fewer than 750 employees. The U.S. Census, however, classifies sunscreen firms as Toilet Preparation Manufacturers under code number 325620 under the North American Industry Classification System (NAICS), where the SBA's definition of a small business is fewer than 500 employees. Census data from 2002 indicate that about 97 percent of the establishments in NAICS 325620 would be considered small using the SBA definition. A casual analysis of the sunscreen manufacturers suggests, however, that there are a higher percentage of large firms manufacturing sunscreens than indicated by using all manufacturers classified in NAICS 325620. We estimate that about 78 of 100 manufacturers of sunscreen products would be considered small under the SBA definitions. Some of these firms may be currently marketing products that would have to be relabeled as a result of this rule. If the relabeling cannot be coordinated with scheduled labeling changes, the FDA labeling cost model estimates the one-time labeling cost per Universal Product Code (UPC) to range from $3,028 to $9,555. If labeling changes can be coordinated with other scheduled changes, the cost per UPC ranges from $140 to $270. Because small manufacturers would on average be marketing few affected UPCs and only 72 UPCs in all would need changing, FDA concludes that this proposed rule would not have a significant economic impact on a substantial number of small entities. FDA requests comments on this tentative conclusion.

IV. Paperwork Reduction Act of 1995

This proposed rule contains certain information collection provisions addressing SPF labeling and associated testing that are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). Specifically, if finalized, this rule would modify the information collection associated with § 201.327(a)(1), which is based on testing in § 201.327(i), by requiring that products with tested SPF values above 50 be labeled as ''50+'' or ''50 plus,'' rather than with the specific numerical SPF value that results from the testing under § 201.327(i) (21 CFR 201.327(i)). Elsewhere in this issue of the **Federal Register**, in accordance with section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)), we are publishing a 60-day notice soliciting public comment on the collections of information resulting from § 201.327(a)(1) and (i) as established in the 2011 final rule published elsewhere in this issue of the **Federal Register** and will then submit these information collection provisions to OMB for approval. Those requirements will not be effective until we obtain OMB approval.

A description of the information collection provisions in this proposed rule, which would modify those resulting from § 201.327(a)(1) and (i), is

given in this section with an estimate of the annual third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

We invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

SPF Labeling and Testing Requirements for OTC Sunscreen Products With SPF Values Greater Than 50

In this proposed rule, we propose that the maximum labeled SPF value for any product marketed under the OTC monograph for sunscreens be ''50+'' or ''50 plus.'' Under § 201.327(a)(1), a final rule published elsewhere in this issue of **Federal Register** which will be become effective 1 year after its date of publication, these products are required to be labeled with the numerical SPF value resulting from testing under § 201.327(i)), resulting in a third party disclosure. If the proposal included in this document is finalized, that requirement would be amended so that products with tested SPF values above 50 would no longer include that specific numerical SPF value in their labeling, but instead would substitute the statement ''SPF 50+'' or ''Broad Spectrum SPF 50+'', as applicable.

We believe that this proposed rule, if finalized, would modify the information collection associated with the present version of § 201.327, in that currently marketed sunscreens labeled with specific SPF values above 50 would be required to make a one-time revision to their labeling to replace the specific SPF value with the ''50+'' statement. In our PRA estimate for the current version of § 201.327(a)(1), we estimate that manufacturers would require 0.5 hours per SKU to insert the tested SPF value, and we believe this is therefore also an appropriate estimate of the time that would be required to revise those labels to include the term ''50 plus''. We estimate that there are a total of 3,600 currently marketed SKUs, of which 2 percent, or a total of 72, are products with SPF values above 50. We estimate that these 72 SKUs are manufactured by 50 firms (respondents). While manufacturers would need to examine all their products in order to determine which ones to revise, we estimate that the amount of time needed to accomplish this review is negligible, as SPF values would be apparent on the face of existing labels, and manufacturers are likely to have existing data compiled for their own business needs on which of their products are labeled with SPF values above 50. As a result, we include in our estimate of burden only the labels actually requiring revision. We annualize this one-time burden of 36 hours (0.5 hours per label times 72 labels) across the 3-year period for which we are seeking approval, for an annualized burden of 12 hours.

We note that no additional product testing under § 201.327(i) would be required to support this relabeling; existing products would merely reexamine their prior test values in light of the new labeling requirement.

With respect to new sunscreen products entering the market after the effective date of a final rule based on this proposal, we believe that the effect of this rule would be either to leave unchanged or slightly reduce the information collection burden associated with § 201.327(a)(1). The burden of SPF testing of all new formulations in order to ascertain the content of the SPF labeling statement (third party disclosure) is already accounted for in the estimate of burden for the 2011 final rule and would not be changed by this rule. If this proposal is finalized, new products with tested SPF values above 50 will simply create labeling that states ''SPF 50+'' or ''Broad Spectrum SPF 50+'' instead of including their specific tested value. We estimate that approximately 60 new products will be introduced each year, and based on currently marketed products, that 2 percent of these will have SPF values greater than 50, for a total of 1 such product per year. This labeling is estimated to require no more than the 0.5 hours estimated for creating labeling bearing a specific SPF value, which is already included in the estimate for the 2011 final rule.

In sum, we estimate the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN[1]

Activity	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Labeling new sunscreen products with SPF values greater than 50 with ''Broad Spectrum SPF 50 plus'' or ''SPF 50 plus'' in lieu of specific SPF values	1	1	1	0.5	0.5
Reexamining/relabeling of effectiveness statement on existing sunscreen PDPs to replace specific SPF values above 50 with the phrase ''50+'' or ''50 plus'' in accordance with revisions to 201.327(a)(1)[2]	17	1.4	24	0.5	12
Total					12.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Actual first year burden hours have been divided by 3 to avoid double counting in OMB's tracking system.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), we have submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection by (see **DATES**) to the Office of Information and Regulatory Affairs, OMB. To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, *Fax:* 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the

title ''SPF Labeling and Testing Requirements for OTC Sunscreen Products with SPF Values Greater Than 50.''

V. Environmental Impact

We have determined under 21 CFR 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' The sole statutory provision giving preemptive effect to the proposed rule is section 751 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379r).

We believe that the preemptive effect of this proposed rule, if finalized, would be consistent with Executive Order 13132. Through the publication of this proposed rule, we are providing notice and an opportunity for State and local officials to comment on this rulemaking.

VII. Proposed Effective Date

Any final rule based on this proposal would become effective 1 year after the date of its publication in the **Federal Register.**

VIII. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**), under Docket No. FDA–1978–N–0018 (formerly Docket No. 1978N–0038) unless otherwise noted, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. We have verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register.**

1. FDA List of Docket Submissions Addressed in This Proposed Rule.

2. Comment C716 from Playtex Products, Inc., Docket No. FDA–1978–N–0018.

3. Russak, J. E. *et al.,* ''A Comparison of Sunburn Protection of High-Sun Protection Factor (SPF) Sunscreens: SPF 85 Sunscreen Is Significantly More Protective Than SPF 50,'' *Journal of the American Academy of Dermatology,* 62:348–9, 2010.

4. Eastern Research Group, ''Sunscreen Drug Formulations for Over-the-Counter Human Use,'' Task Order No. 21, Contract No. 223–03–8500, 2010.

List of Subjects in 21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 201, as amended June 17, 2011, effective June 18, 2012, be further amended as follows:

PART 201—LABELING

1. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg-360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

2. Section 201.327 is amended by revising paragraph (a) introductory text and paragraphs (a)(1)(i)(A) and (a)(1)(ii) to read as follows:

§ 201.327 Over-the-counter sunscreen drug products; required labeling based on effectiveness testing.

* * * * *

(a) Principal display panel. In addition to the statement of identity in paragraph (b) of this section, the following statements shall be prominently placed on the principal display panel:

(1) *Effectiveness claim.*—(i) *For products that pass the broad spectrum test in paragraph (j) of this section.* (A) The labeling states ''Broad Spectrum SPF [insert numerical SPF value resulting from testing under paragraph (i) of this section. For values over 50, insert ''50+'' or ''50 plus'']. ''

* * * * *

(ii) *For sunscreen products that do not pass the broad spectrum test in paragraph (j) of this section.* The labeling states ''SPF [insert numerical SPF value resulting from testing under paragraph (i) of this section. For values over 50, insert ''50+'' or ''50 plus'']. '' The entire text shall appear in the same font style, size, and color with the same background color.

* * * * *

Dated: June 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–14769 Filed 6–14–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 310

[Docket No. FDA–2011–N–0449]

SPF Labeling and Testing Requirements and Drug Facts Labeling for Over-the-Counter Sunscreen Drug Products; Agency Information Collection Activities; Proposed Collection

AGENCY: Food and Drug Administration, HHS.

ACTION: Comment request.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on SPF labeling and testing requirements for over-the-counter (OTC) sunscreen products containing specified ingredients and marketed without approved applications, and on compliance with Drug Facts labeling requirements for all OTC sunscreen products.

DATES: Submit either electronic or written comments on the collection of information by August 16, 2011.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined

in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

SPF Labeling and Testing Requirements for OTC Sunscreen Products Containing Specified Active Ingredients and Marketed Without Approved Applications, and Drug Facts Labeling for All OTC Sunscreen Products—21 CFR 201.327(a)(1) and (i), 21 CFR 201.66(c) and (d)—(OMB 0910–New)

Elsewhere in this issue of the **Federal Register**, we (FDA) are publishing a final rule establishing labeling and effectiveness testing requirements for certain OTC sunscreen products containing specified active ingredients and marketed without approved applications (2011 sunscreen final rule; § 201.327 (21 CFR 201.327)). The rule also lifts the delay of implementation date of the Drugs Facts regulation (21 CFR 201.66) for all OTC sunscreens. This rule is not yet in effect. It is intended to be effective June 18, 2012.

SPF Labeling and Testing for OTC Sunscreens Containing Specified Active Ingredients and Marketed Without Approved Applications

Section 201.327(a)(1) requires the principal display panel (PDP) labeling of a sunscreen covered by the rule to include the SPF value determined by conducting the SPF test outlined in § 201.327(i). Therefore, this provision will result in an information collection with a third-party disclosure burden for manufacturers of OTC sunscreens covered by the rule. Products need only complete the testing and labeling required by the rule one time, and then continue to utilize the resultant labeling (third-party disclosure) going forward, without additional burden.

In a draft guidance published elsewhere in this issue of the **Federal Register**, we state that we do not intend to initiate enforcement action before June 17, 2013 if an OTC sunscreen subject to § 201.327 that was initially marketed prior to June 17, 2011, the date of publication of the final rule, continues to include an SPF value in its labeling that was determined prior to that date according to either the SPF test method described in the May 21, 1999, final rule (64 FR 27666 at 27689 through 27693) or the SPF test method described in the August 27, 2007, proposed rule (72 FR 49070 at 49114 through 49119). We believe that the majority of currently-marketed OTC sunscreen formulations will meet this standard and, therefore, may defer their conduct of new SPF testing. However, this one-time testing will nonetheless need to be conducted within the first 3 years after publication of the 2011 final rule for all OTC sunscreens covered by that rule. We therefore do not anticipate that the draft guidance will alter the annualized burden associated with §§ 201.327(a)(1) and (i) as estimated here. We provide a separate PRA analysis in the notice of availability for the draft guidance to address the information collections provisions that result from it.

Our estimate of third-party disclosure burden includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information. We have estimated that there are approximately 100 manufacturers of OTC sunscreen drug products. We estimate that these 100 manufacturers are currently producing as many as 2,350 OTC sunscreen formulations and that these formulations are available in approximately 3,600 stock keeping units (SKUs) (see 2010 sunscreen final rule—indicating recent data supports estimate of up to 2,348 formulations and 3,591 SKUs).[1]

Our estimates on the conduct of SPF testing are based on the estimated number of formulations because, if the same formulation is sold under different SKUs, the formulation will only have to be retested one time in order to develop the labeling for multiple marketed SKUs. However, our estimates on labeling are based on the number of SKUs because, although each SKU will not need to be tested to establish its SPF value, the labeling of each SKU has to be considered.

To determine the SPF value required in § 201.327(a)(1), manufacturers will have to conduct SPF tests according to § 201.327(i). We estimate that all 100 manufacturers will have to retest currently marketed sunscreen formulations. We estimate that there are approximately 2,350 existing sunscreen formulations that will require retesting. We further estimate that it will take 24 hours (*i.e.,* three 8-hour days) to complete SPF testing for each of the formulations. This estimate assumes SPF testing of a high SPF sunscreen that includes 80 minutes of water resistance testing, which reflects products requiring the most time to test. Therefore, a total of 56,400 hours will be required as the one-time burden to retest existing sunscreen products in accordance with § 201.327(i) to provide the SPF value required to be disclosed to the public in labeling under § 201.327(a)(1). In accordance with FDA's enforcement policy guidance, retesting of currently marketed sunscreen products should be completed within 2 years after the date of publication of the final rule, so if this one-time burden is annualized across that time period, the result is a burden of 28,200 hours in each of the first 2 years to complete retesting of existing sunscreen products.

Once manufacturers have tested their products to determine the SPF value to comply with the third-party disclosure (labeling) requirements in § 201.327(a)(1), the manufacturers will need to insert the SPF value after the term ''SPF'' in either the statement ''SPF'' or ''Broad Spectrum SPF,'' as applicable. We estimate that each of the 100 manufacturers will spend no more than 0.5 hours per SKU to prepare, complete, and review the labeling for each of 3,600 currently marketed SKUs. Therefore, we estimate that a total of no more than 1,800 hours will be required as a one time burden to relabel currently marketed OTC sunscreens containing specified ingredients and marketed without approved applications (3,600 SKUs times 0.5 hours per SKU). In accordance with FDA's enforcement policy guidance, relabeling of currently marketed sunscreen products should be completed within 2 years after the date of publication of the final rule, so if this one-time burden is annualized across that time period, the result is a burden

[1] Document No. FDA–1978–N–0018–0693 in Docket No. FDA–1978–N–0018.

of 900 hours in each of the first 2 years to complete relabeling of existing sunscreen products.

In addition, new products may also be introduced each year, and these products will have to be tested and labeled with the SPF value determined in the test. We estimate that as many as 60 new OTC sunscreen products (SKUs) may be introduced each year. As discussed in this section of the document, there are currently approximately 1.53 SKUs marketed for every sunscreen formulation (3,600 SKUs divided by 2,350 formulations). Therefore, we estimate that the 60 new sunscreen SKUs will represent 39 new formulations annually. We expect the burden of testing the 39 new formulations marketed each year will require 936 hours per year (39 formulations times 24 hours testing per formulation). We estimate that labeling of the 60 new SKUs marketed each year will require 30 hours per year (60 SKUs times 0.5 hours per SKU).

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Conduct SPF testing in accordance with § 201.327(i) for existing sunscreen formulations [2]	100	11.75	1,175	24	28,200
Conduct SPF testing in accordance with § 201.327(i) for new sunscreen formulations	20	1.95	39	24	936
Create PDP labeling in accordance with § 201.327(a)(1) for existing sunscreen SKUs [2]	100	180	1,800	0.5	900
Create PDP labeling in accordance with § 201.327(a)(1) for new sunscreen SKUs	20	3	60	0.5	30
Total burden in years one and two					30,066
Total burden in each subsequent year					966

[1] There are no capital, operating or maintenance costs associated with this collection of information.
[2] Burden for each of first and second years for currently marketed OTC sunscreens.

Drug Facts Labeling for OTC Sunscreens

Because the 2011 final rule also lifts the delay of implementation date for Drug Facts regulations (21 CFR 201.66) for OTC sunscreens, the rule will also modify the information collection associated with § 201.66 (currently approved under OMB control number 0910–0340) and result in additional third-party disclosure burden resulting from requiring OTC sunscreen products to comply with Drug Facts regulations. In the **Federal Register** of March 17, 1999 (64 FR 13254), we amended our regulations governing requirements for human drug products to establish standardized format and content requirements for the labeling of all marketed OTC drug products, codified in 21 CFR 201.66 (the 1999 Drug Facts labeling final rule). Section 201.66 sets requirements for the Drug Facts portion of labels on OTC drug products, requiring such labeling to include uniform headings and subheadings, presented in a standardized order, with minimum standards for type size and other graphical features. In the **Federal Register** of September 3, 2004 (69 FR 53801), we delayed the § 201.66 implementation date for OTC sunscreen products indefinitely, pending future rulemaking to amend the substance of labeling for these products. The 2011 sunscreen final rule lifts this stay for OTC sunscreens. Therefore, currently marketed OTC sunscreen products will incur a one-time burden to comply with the requirements in 21 CFR 201.66 (c) and (d).

We estimate that there are 3,600 currently marketed OTC sunscreen drug product SKUs, and we assume for purposes of this estimate that none of them have yet complied with the 1999 Drug Facts labeling final rule. These 3,600 SKUs will need to implement the new labeling format by the implementation date included in the sunscreen final rule. We estimate that these 3,600 SKUs are marketed by 100 manufacturers and that approximately 12 hours will be spent on each label. The number of hours per label (response) is based on the most recent estimate used for other OTC drug products to comply with the 1999 Drug Facts labeling final rule, including public comments received on this estimate in 2010 that addressed sunscreens. If an average of 12 hours is spent preparing, completing, and reviewing each of the estimated 3,600 sunscreen SKUs, the total number of hours dedicated to the one-time relabeling of currently marketed OTC sunscreen products, as necessary to comply with § 201.66 would be 43,200 (3,600 SKUs times 12 hours/SKU).

In addition to this one-time burden, we estimate that 60 new sunscreen SKUs marketed each year will have a third-party disclosure burden to comply with Drug Facts regulations equal to 720 hours annually (60 SKUs times 12 hours/SKU). We estimate that these new SKUs will be marketed by 20 manufacturers. We do not expect any OTC sunscreens to apply for exemptions or deferrals of the Drug Facts regulations 21 CFR 201.66(e).

We estimate the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Format labeling in accordance with 201.66(c) and (d) for existing sunscreen SKUs [2]	100	36	3,600	12	43,200

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]—Continued

Activity	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Format labeling in accordance with 201.66(c) and (d) for new sunscreen SKUs	20	3	60	12	720
Total first year burden					43,920
Total burden for each subsequent year					720

[1] We estimate a one-time medium capital cost of $6.1 million dollars will result from preparing labeling content and format for OTC sunscreens in accordance with § 201.66. There are no operating or maintenance costs associated with this collection of information.
[2] First-year burden for currently marketed OTC sunscreens.

With the exception of the PDP statement of SPF value in § 201.327(a)(1), the labeling requirements in § 201.327(a) through (h), which provide other elements of the PDP, as well as specific content for indications, directions, and warnings, are a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)) and, therefore, are not collections of information. These provisions are thus not subject to OMB review under the PRA.

Dated: June 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–14771 Filed 6–14–11; 8:45 am]

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Part V

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 485
Medicare Program; Conditions of Participation (CoPs) for Community Mental Health Centers; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 485

[CMS–3202–P]

RIN 0938–AP51

Medicare Program; Conditions of Participation (CoPs) for Community Mental Health Centers

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish, for the first time, conditions of participation (CoPs) that community mental health centers (CMHCs) would have to meet in order to participate in the Medicare program. These proposed CoPs would focus on the care provided to the client, establish requirements for staff and provider operations, and encourage clients to participate in their care plan and treatment. The new CoPs would enable CMS to survey CMHCs for compliance with health and safety requirements.

DATES: To be assured consideration, comments must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. on August 16, 2011.

ADDRESSES: In commenting, please refer to file code CMS–3202–P. Because of staff and resource limitations, we cannot accept comments by facsimile (Fax) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address *only:*

Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–3202–P, P.O. Box 8010, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address *only:*

Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–3202–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments *only* to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Mary Rossi-Coajou, (410) 786–6051.

Maria Hammel, (410) 786–1775.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244, on Monday through Friday of each week from 8:30 a.m. to 4 p.m. E.S.T. To schedule an appointment to view public comments, phone 1–800–743–3951.

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through *GPO Access,* a service of the U.S. Government Printing Office. Free public access is available on a Wide Area Information Server (WAIS) through the Internet and via asynchronous dial-in. Internet users can access the database by using the World Wide Web (the Superintendent of Documents' home page address is *http://www.gpoaccess.gov/index.html*), by using local WAIS client software, or by telnet to *swais.access.gpo.gov,* then login as guest (no password required). Dial-in users should use communications software and modem to call (202) 512–1661; type swais, then login as a guest (no password required).

I. Background

A. Introduction

In 2007, 224 certified Community Mental Health Centers (CMHCs) billed Medicare for partial hospitalization services for 25,087 Medicare beneficiaries. Currently, there are no Conditions of Participation (CoPs) in place for Medicare-certified CMHCs. As such, no regulatory basis exists to ensure basic levels of quality and safety for CMHC care. The Federal government, as the single largest payer of health care services in the United States, administers many statutory and regulatory requirements on the delivery and quality of health care furnished under its programs. Therefore, we are proposing for the first time a set of requirements that Medicare-certified CMHCs must meet in order to participate in the Medicare program. The CoPs that we are proposing would help to ensure the quality and safety of CMHC care for all clients served by the CMHC, regardless of payment source.

These requirements would focus on a short term, client-centered, outcome-oriented process that promotes quality client care. Requirements for CMHC services would encompass—(1) Personnel qualifications; (2) client rights; (3) admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client; (4) treatment team, active treatment plan, and coordination of services; (5) quality assessment and performance improvement; and (6) organization, governance, administration of services, and partial hospitalization services. Overarching the proposed CMHC

requirements would be a quality assessment and performance improvement program that would build on a provider's own quality management system to improve client care performance. We would expect CMHCs to furnish health care that met the essential health and quality standards that would be established by this rule; therefore, a CMHC would use its own quality management system to monitor and improve its own performance and compliance. To achieve this objective, we are proposing new CMHC requirements.

B. Current Requirements for CMHCs

Section 1832(a)(2)(J) of the Social Security Act (the Act) established coverage of partial hospitalization services for Medicare beneficiaries. Section 1861(ff)(2) of the Act defines partial hospitalization services as a broad range of mental health services ''that are reasonable and necessary for the diagnosis or active treatment of the individual's condition, reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization, and furnished pursuant to such guidelines relating to frequency and duration of services as the Secretary shall by regulation establish''.

Section 4162 of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990) (Pub. L. 101–508) amended sections 1832(a)(2) and 1861(ff)(3) of the Act to allow CMHCs to provide partial hospitalization services. Under the Medicare program, CMHCs are recognized as Medicare providers only for partial hospitalization services (see 42 CFR 410.110).

A CMHC, in accordance with section 1861(ff)(3)(B) of the Act, is an entity that meets applicable licensing or certification requirements for CMHCs in the State in which it is located and provides the set of services specified in section 1913(c)(1) of the Public Health Service Act (PHS Act). However, CMS has learned that most States either do not have a certification or licensure program for these types of facilities, or have regulatory regimens that apply only to CMHCs that receive state funding.

A CMHC may receive Medicare payment for partial hospitalization services only if it demonstrates two key components:

(1) The CMHC meets each of the following core requirements identified at 42 CFR 410.2:

- Provides outpatient services, including specialized outpatient services for children, elderly individuals, individuals with chronic mental illness, and residents of the CMHC's mental health service area that have been discharged from inpatient treatment at a mental health facility.
- Provides 24 hour-a-day emergency care services.
- Provides day treatment, partial hospitalization services, or psychosocial rehabilitation services.
- Provides screening for clients being considered for admission to State mental health facilities to determine the appropriateness of such admission. (Section 1861(ff)(3)(B)(i)(II) of the Act allows CMHCs to provide these services by contract if State law precludes the entity from directly providing the screening services.)
- Provides at least 40 percent of its services to individuals who are not eligible for benefits under Medicare.

(2) The CMHC, in accordance with regulations at 42 CFR 424.24(e), provides partial hospitalization program (PHP) services that are:

- Furnished under the general supervision of a physician;
- Subject to certification or recertification by a physician that the individual would require inpatient psychiatric care if partial hospitalization services were not provided; and
- Furnished under an individualized plan of treatment that is periodically reviewed and meets the requirements of 42 CFR 424.24(e)(2).

When the partial hospitalization program benefit was first enacted, CMHCs were certified based on self-attestation. Currently, CMHCs are Medicare-certified and Medicare-enrolled based on a CMS Regional Office determination that the provider meets the definition of a CMHC at section 1861(ff)(3)(B)(i) of the Act and provides the core services described in section 1913(c)(1) of the PHS Act. CMS has received complaints regarding CMHCs such as: ceasing to provide services once the CMHC has been certified, physically mistreating clients, and providing fragmented care. As there are no CoPs in place for CMHCs, many participating CMHCs have never had an onsite survey visit by CMS after their initial certification. Furthermore, there are currently only limited circumstances in which CMS can terminate a facility based on the result of a complaint investigation. Without such health and safety standards in place, CMS' oversight of CMHCs is severely limited.

C. Rationale for Proposing CMHC CoPs

Medicare is responsible for establishing requirements to promote the health and safety of care provided to its beneficiaries. We believe that basic health and safety standards should be established for CMHCs in order to protect patients and their families. Once our rules have been established, CMS will be able to survey providers, through State survey and certification agencies, to ensure that the care being furnished meets the standards. These CoPs would enable CMS to establish a survey process to promote the safety and quality of client care provided by Medicare-certified CMHCs. At this time, we are not proposing to amend our regulations at 42 CFR 488.6 to grant deeming authority for CMHCs to accrediting organizations. We are specifically soliciting public comment regarding this issue.

These proposed CoPs are part of CMS' overall effort to improve the safety and quality of all care provided to Medicare beneficiaries, regardless of the setting in which the care is provided. To that end, CMS has issued new and revised regulations for end-stage renal disease facilities, hospices, hospitals, nursing homes, transplant hospitals, organ procurement organizations, ambulatory surgery centers, and other providers. The proposed CMHC CoPs would adopt relevant provisions (for example, those related to client rights) from these other provider types to ensure that clients receive consistent protections as they move from one type of care to another.

D. Principles Applied in Developing the Proposed CMHC CoPs

We developed the proposed CMHC requirements based on the following principles:

- A focus on the continuous, integrated, mental health care process that a client experiences across all CMHC services.
- Activities that center around client assessment, the active treatment plan, and service delivery.
- Use of a client-centered, interdisciplinary approach that recognizes the contributions of various skilled professionals and other support personnel and their interaction with each other to meet the client's needs.
- Promotion and protection of client rights.

Based on these principles, we are proposing the following six CoPs: (1) Personnel qualifications; (2) client rights; (3) admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client; (4) treatment team, active treatment plan, and coordination of services; (5) quality assessment and performance improvement; and (6) organization, governance, administration of services, and partial hospitalization services.

The ''Personnel qualifications'' CoP would establish staff qualifications for the CMHC.

The ''Client rights'' CoP would emphasize a CMHC's responsibility to respect and promote the rights of each CMHC client.

The ''Admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client'' CoP would reflect the critical nature of a comprehensive assessment in determining appropriate treatments and accomplishing desired health outcomes.

The ''Treatment team, active treatment plan, and coordination of services'' CoP would incorporate a client-centered interdisciplinary team approach, in consultation with the client's primary health care provider (if any).

The ''Quality assessment and performance improvement'' CoP would challenge each CMHC to build and monitor its own quality management system to monitor and improve client care performance.

The ''Organization, governance, administration of services, and partial hospitalization services'' CoP would charge each CMHC with the responsibility for creating and implementing a governance structure that focuses on and enhances its coordination of services to better serve its clients.

Two of the proposed CoPs, ''Admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client'' and ''Treatment team, active treatment plan, coordination of services,'' would establish a cycle of individualized client care. The client's care needs would be comprehensively assessed, enabling the interdisciplinary team, with the client, to establish an active treatment plan. The active treatment plan would be implemented, and the results of the care would be evaluated by updating the comprehensive assessment and active treatment plan.

These proposed CoPs present an opportunity for CMHCs, States, and CMS to join in a partnership for improvement. When implemented, CMHC programming will reflect a client-centered approach that will affect how State survey and certification agencies and CMS manage the survey process. We believe that this approach will provide opportunities for improvement in client care.

II. Provisions of the Proposed Regulations

A. Proposed Requirements

We are proposing to establish a new subpart J under the regulations at 42 CFR part 485 to incorporate the proposed CoPs for CMHCs. We are proposing that the effective date of these provisions would be 12 months after the publication of the final rule. Delaying the effective date for 12 months after the date of publication of the final rule would allow CMHCs time to educate staff, initiate their quality assessment and performance improvement (QAPI) program, and implement the new set of CoPs. The new subpart J would include the basis and scope of the subpart, definitions, and the six CoPs and standards. Below we discuss each proposed section in detail.

Basis and Scope (Proposed § 485.900)

In proposed § 485.900, we are proposing to cite the statutory authority for CMHCs to provide services that are payable under Medicare Part B. In addition, we would describe the scope of provisions in the proposed subpart J.

Definitions (Proposed § 485.902)

In proposed § 485.902, we are proposing to include the following definitions for terms used in the CoPs for CMHCs under the proposed subpart J:

''Active treatment plan'' would mean an individualized client plan that focuses on the provision of care and treatment services that address the client's physical, psychological, psychosocial, emotional, and therapeutic needs and goals as identified in the comprehensive assessment. This proposed definition was established by reviewing 42 CFR 424.24(e)(2) and The Joint Commission Accreditation Manual for Behavioral Health Care definition of ''planning of care.''

''Community mental health center (CMHC)'' would mean the entity type defined at 42 CFR 410.2.

''Comprehensive assessment'' would mean a thorough evaluation of the client's physical, psychological, psychosocial, emotional, and therapeutic needs related to the diagnosis under which care is being furnished by the CMHC. This proposed definition was derived from the home health and hospice assessment CoPs under 42 CFR parts 484 and 418, respectively. Clients served by home health and hospice agencies have comprehensive and complex needs, and the comprehensive assessment requirements for these providers capture the key elements we believe are also essential for assessing a CMHC client.

''Employee of a CMHC'' would mean an individual—(a) Who works for the CMHC and with respect to whom the CMHC is required to issue a W–2 form; or (b) for whom an agency or organization issues a W–2 form, and who is assigned to the CMHC if the CMHC is a subdivision of such agency or organization.

''Initial evaluation'' would mean an immediate care and support assessment of the client's physical, psychosocial, and therapeutic needs (including a screen for harm to self or others), related to the client's psychiatric illness and related conditions for which care is being furnished by the CMHC. This proposed definition is derived from the hospice CoPs at part 418, but with the addition of the term ''psychiatric illness.'' We added the term ''psychiatric illness'' to the definition to ensure that the client's needs relate to the care and services provided by the CMHC. Similar to hospice clients, we believe that the CMHC client's immediate care needs should be assessed and addressed as soon as possible. The initial evaluation is the vehicle that identifies a client's immediate needs and initiates the care planning process.

''Representative'' would mean an individual who has the authority under State law to authorize or terminate medical care on behalf of a client who is mentally or physically incapacitated. This would include a legal guardian. This proposed definition is consistent with the definition of this term found in the CoPs for hospices at 42 CFR 418.3. We do not propose to regulate the relationship between a client and his or her authorized representative. However, we believe reference to such representatives is necessary due to the potential instability of some CMHC clients, and the need to ensure that decisions related to the client's care and active treatment plan are made appropriately. We recognize that clients may refuse to participate in their care and active treatment or, in documented circumstances, be unable to be present. There is no implication that clients will or will not have representatives.

''Restraint'' would mean—(a) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a client to move his or her arms, legs, body, or head freely, not including devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a client for the purpose of conducting routine physical examinations or tests, or to protect the client from falling out of bed, or to permit the client to participate in activities without the risk of physical harm (this does not include a client

being physically escorted); or (b) a drug or medication when it is used as a restriction to manage the client's behavior or restrict the client's freedom of movement, and which is not a standard treatment or dosage for the client's condition.

''Seclusion'' would mean the involuntary confinement of a client alone in a room or an area from which the client is physically prevented from leaving.

The proposed definitions for ''restraint'' and ''seclusion'' are used in other Medicare-certified provider CoPs such as those for hospices at § 418.3 and hospitals at 42 CFR 482.13(e)(1), and are in accordance with section 3207 of the Children's Health Act (Pub. L. 106–310).

''Volunteer'' would mean an individual who—(a) Is an unpaid worker of the CMHC; or (b) if the CMHC is a subdivision of an agency or organization, is an unpaid worker of the agency or organization and is assigned to the CMHC. All volunteers would have to meet the standard training requirements under 42 CFR 485.918(d).

CMHC CoP: Personnel Qualifications (Proposed § 485.904)

We are proposing to add a new CoP at § 485.904 to establish staff qualifications for CMHCs. In proposed § 485.904(a), ''Standard: General qualification requirements,'' we are proposing to require that all professionals who furnish services directly, under an individual contract, or under arrangements with a CMHC, be legally authorized (licensed, certified or registered) in accordance with applicable Federal, State and local laws, and be required to act only within the scope of their State licenses, certifications, or registrations. All personnel qualifications would have to be kept current at all times.

In proposed § 485.904(b), ''Standard: Personnel qualifications for certain disciplines,'' we are proposing to require staff qualifications to be consistent with, or similar to, those set forth in CoPs for other provider types in the Medicare regulations.

''Administrator of a CMHC'' would mean a CMHC employee that meets the education and experience requirements established by the CMHC governing body for that position and who is responsible for the day-to-day operation of the CMHC. This proposed definition is similar to the definition used in the hospice CoPs at part 418. We believe this proposed qualification would allow for provider flexibility to establish requirements based on the services provided by individual CMHCs.

''Clinical psychologist'' would mean an individual who meets the qualifications at 42 CFR 410.71(d). This proposed definition by CMS is used as a basis for payment for services.

''Clinical social worker'' would mean an individual who meets the qualifications at 42 CFR 410.73(a). This proposed definition also is currently in use for CMHC services paid by Medicare.

''Mental health counselor'' would mean a professional counselor who is certified and/or licensed by the State (as applicable) and has the skills and knowledge to provide mental health services to clients. The mental health counselor would provide services in areas such as psychotherapy, substance abuse, crisis management, psychoeducation and prevention programs. Information contained in The Joint Commission Accreditation Behavioral Health Care Manual contributed to the development of these proposed qualifications. These counselors have an essential role in the care of CMHC clients, and we believe that it is necessary to define this role to ensure that CMHCs use a variety of appropriate personnel to care for CMHC clients.

''Occupational therapist'' would mean an individual who meets the requirements for ''occupational therapist'' set forth at 42 CFR 484.4. This proposed definition was established in the November 27, 2007, ''Revision to Payment Policies Under the Physician Fee Schedule, and Other part B Payment Policies for 2008'' final rule (72 FR 66222) that applied the same requirements for occupational therapists to a variety of provider types; we believe that this definition is appropriate for the CMHC environment.

''Physician'' would mean an individual who meets the qualifications and conditions as defined in section 1861(r) of the Act and provides the services as specified at § 410.20 of this chapter and would have experience providing mental health services to clients. This proposed definition is consistent with the definition of the term ''physician'' in the requirements for other providers such as hospices and hospitals, with the addition of having experience with clients receiving mental health services. While we believe experience is important, we are proposing that through the CMHC's policies and procedures, the CMHC would determine the level and range of experience appropriate to care for CMHC clients.

''Psychiatric registered nurse'' would mean a registered nurse that is a graduate of an approved school of professional nursing, who is licensed as a registered nurse by the State in which he or she is practicing, and has at least 2 years of education and/or training in psychiatric nursing. This proposed definition is similar to that used for other Medicare-certified providers. We are proposing to add the additional requirement of 2 years of education and/or training in psychiatric nursing due to the sensitive and complex needs of the CMHC client.

''Psychiatrist'' would mean an individual who specializes in assessing and treating persons having psychiatric disorders, is certified by the American Board of Psychiatry and Neurology or has documented equivalent education, training or experience, and is fully licensed to practice medicine in the State in which he or she practices. Information contained in The Joint Commission Accreditation Behavioral Health Care Manual contributed to the development of these proposed qualifications.

CMHC CoP: Client Rights (Proposed § 485.910)

We are proposing to add a new CoP at § 485.910 to set forth certain rights to which CMHC clients would be entitled, and to require that CMHCs inform each client verbally of these rights in a language and manner that the client or client's representative (if appropriate) or surrogate understands. The client's representative or surrogate, who could be a family member or friend that accompanies the client, may act as a liaison between the client and the CMHC to help the client communicate, understand, remember, and cope with the interactions that take place during the visit, and explain any instructions to the client that are delivered by the CMHC staff. If a client is unable to fully communicate directly with CMHC staff, then the CMHC may give client rights information to the client's representative or surrogate. The client also has the choice of using an interpreter of his or her own or one supplied by the CMHC. A professional interpreter is not considered to be a client's representative or surrogate. Rather, it is the professional interpreter's role to pass information from the CMHC to the client.

We also propose to require that the client be provided a written copy of client rights information. This must be provided in English, for present or future reference or translation by the client's representative or surrogate. We recommend, but do not propose requiring, that a written translation be provided in languages that non-English speaking clients can read, particularly

for languages that are most commonly used by non-English-speaking clients of the CMHC.

In proposed § 485.910(a)(1), the notice of rights and responsibilities would be given to the client, the client's representative or surrogate, as appropriate, during the initial evaluation, as described at proposed § 485.914(b). Ensuring that clients are aware of their rights and how to exercise them are vital components of improving overall CMHC quality and client satisfaction.

While we propose this standard under the authority of section 1832(a)(2)(F)(i) of the Act, we are also guided by Title VI of the Civil Rights Act of 1964. Our proposed requirement has been designed to be compatible with guidance on Title VI. The Department of Health and Human Services (HHS) guidance related to Title VI of the Civil Rights Act of 1964, ''Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons'' (August 8, 2003, 68 FR 47311) applies to those entities that receive Federal financial assistance from HHS, including CMHCs. This guidance may assist CMHCs in ensuring that client rights information is provided in a language and manner the client understands.

At proposed § 485.910(b), ''Standard: Exercise of rights and respect for property and person,'' we are proposing that a client would be able to exercise his or her rights, have his or her property and person respected, voice grievances, and not be subjected to discrimination or reprisal for exercising his or her rights. Furthermore, in proposed § 485.910(c), the client would have the right to—(1) Participate in the active treatment planning process; (2) refuse care or treatment; (3) have his or her records kept confidential; (4) be free from mistreatment, neglect, abuse, and misappropriation of his or her personal property; (5) receive information about limitations on CMHC services; and (6) not be compelled to perform services for the CMHC. If services are performed by clients for the CMHC, the wages received by the clients would have to be commensurate with prevailing wages for the nature of services performed and the clients' abilities.

In proposed § 485.910(d), ''Standard: Addressing violations of client rights,'' we are proposing that CMHCs report all complaints of alleged violations of clients' rights to the CMHC administrator. We are also proposing that the CMHC would immediately investigate all alleged violations, take intermediate actions to prevent further potential client rights violations during the investigation period, and take appropriate corrective action where necessary. Furthermore, we are proposing that the CMHC report verified violations of client rights to appropriate authorities having jurisdiction within five working days of the CMHC becoming aware of the violation.

The proposed client rights CoP would act as a safeguard of client health and safety. Open communication between CMHC staff and the client, and client access to information are vital to enhancing the client's participation in his or her coordinated active treatment plan. All CMHCs also would be required to comply with Federal rules concerning the privacy of individually identifiable health information set out at 45 CFR parts 160 and 164.

In proposed § 485.910(e), ''Standard: Restraint and seclusion,'' we are proposing that all clients would have the right to be free from physical or mental abuse, and corporal punishment. Since accidental injuries and deaths have been documented in medical facilities due to the use of restraint and seclusion, we strongly discourage the use of restraints or seclusion in a CMHC environment where the clients are receiving services on an outpatient basis. However, we are aware that under extremely rare instances their application may be warranted for brief periods of time, and only while awaiting transport of the client to a hospital. In response to accidental injuries and deaths, we published new hospital restraint and seclusion requirements on December 8, 2006 (71 FR 71378) that included a new standard at § 482.13. The hospital restraint and seclusion CoP is the basis for the proposed CMHC restraint and seclusion CoP, with modifications to the regulatory requirements to accommodate this outpatient setting.

We are proposing that a CMHC restraint and/or seclusion could only be imposed to ensure the immediate physical safety of the client, staff, or other individuals while awaiting transfer of the client to a hospital. A transfer to a hospital immediately is necessary because the CMHC has limited staff and resources available to safely monitor a restrained or secluded client. Additionally, the safety of the patient, other clients and the staff may be in jeopardy. The hospital would be able to safely monitor the client and assess the cause of the client's behavior. We are proposing this in order to implement the restraint and seclusion language in section 3207 of the Children's Health Act (CHA), Public Law 106–310, codified at section 591 of the Public Health Service Act (42 U.S.C. 290ii). The CHA provisions apply to any health care facility that receives support in any form from any program supported in whole or in part with funds appropriated from any Federal agency, which clearly includes all providers that participate in Medicare or Medicaid. The CHA was enacted to protect and promote every client's right to be free from ''any restraints or involuntary seclusions imposed for purposes of discipline or convenience.'' The CHA clearly describes the circumstances in which restraints or seclusion may be appropriate.

Based on discussions with the CMHC industry and The Joint Commission, we believe restraints or seclusion are rarely, if ever, used in a CMHC setting and that there are very few deaths (if any) that occur due to restraints or seclusion in CMHCs. However, there are no data available regarding this issue. The use of restraint or seclusion would be considered contrary to targeted client outcomes and therefore we would consider the use of restraint or seclusion an adverse client event that would be tracked as part of the QAPI program (Quality assessment and performance improvement: proposed § 485.917). During the survey process the surveyors would review all reports on adverse client events and the actions taken as part of the QAPI review. We believe that including these proposed requirements in the CMHC CoPs would promote the safe use of restraint or seclusion in the rare occurrence that clients posed an immediate physical threat to themselves or others. Providing for safe use of restraints would, we believe, prevent accidental injury or death.

In order to ensure the safety of the CMHC client during the rare event of the need for restraint or seclusion pending transport to the hospital, the CMHC would be required to continuously monitor the restrained or secluded client using trained staff that met the requirements at paragraph (f) of this section. Continuously monitoring the client would include, but would not be limited to, respiratory and circulatory status, skin integrity, vital signs, and any other elements as specified by CMHC policy.

In proposed § 485.910(e)(2) through (e)(4), we are proposing that a physician or other licensed practitioner authorized by State law would be required to order the use of restraint or seclusion. A single order for seclusion or restraint would not be permitted to exceed 1 hour in duration. In the exceptionally rare circumstance that transport to the hospital did not occur within the

original 1 hour timeframe, the CMHC would obtain another order, if clinically warranted. At the time of the restraint or seclusion order, the CMHC would be required to obtain a separate order for transfer of the client to the hospital. Finally, we would require that orders for restraint or seclusion could never be written as standing orders or on an as needed (PRN) basis.

In proposed § 485.910(f), ''Standard: Restraint or seclusion: Staff training requirements,'' we have focused on the proper use of restraint and seclusion, the need for appropriate CMHC personnel to receive training and education in the proper use of restraint and seclusion applications and techniques, and the need for CMHC personnel to receive training and education in alternative methods for handling emergency situations that may arise. We emphasize that restraint or seclusion may only be used to protect the client or others from immediate harm, and would trigger immediate transportation to a hospital. We believe restraints or seclusion are rarely, if ever, used in a CMHC setting; therefore, the use of restraint or seclusion is an adverse event for a CMHC and should be used as part of the CMHC's quality assessment and performance improvement program, as outlined in 485.917(a). We also emphasize that staff training requirements on restraint and seclusion would focus on training and education on alternative methods for handling behavior, symptoms, and interventions in emergency situations. Restraint or seclusion would be used only when less restrictive interventions were determined to be ineffective.

In proposed § 485.910(g), ''Standard: Death reporting requirements,'' we are proposing a death reporting requirement in the unlikely circumstance that a death would occur at a CMHC due to restraint and seclusion. If a client's death was attributed to restraint or seclusion while the client was awaiting transfer to a hospital, the CMHC would be required to report the death to CMS promptly. CMS could initiate an onsite investigation and complaint survey of the CMHC in accordance with the existing complaint investigation processes and would inform the federally-mandated Protection and Advocacy Organizations for its state or territory. We encourage the public to comment on this proposed standard.

CMHC CoP: Admission, Initial Evaluation, Comprehensive Assessment and Discharge or Transfer of the Client (Proposed § 485.914)

We are proposing to add a new CoP at § 485.914 to establish requirements for admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client. These requirements reflect our view that a client-centered, interdisciplinary, and systematic client assessment is essential to quality client care. A client-specific, comprehensive assessment identifies the client's physical, psychological, psychosocial, emotional and therapeutic needs. The care needs identified in the initial evaluation would include, but would not be limited to, those necessary for treatment and management of the psychiatric illness. The initial assessment would be completed within 24 hours of the client admission to the CMHC. The comprehensive assessment would build from the initial evaluation and be completed by the physician-led interdisciplinary team in consultation with the client's primary health care provider, if any. The interdisciplinary team would be composed of a doctor of medicine, osteopathy or psychiatry, a psychiatric registered nurse, clinical psychologist, a clinical social worker, an occupational therapist, and other licensed mental health counselors, as necessary, pursuant to § 485.916(a)(2). Each member of the team would provide input within the scope of that individual's practice. The comprehensive assessment would be completed within 3 working days after the admission to the CMHC. We believe the current practices of the mental health industry support a client-specific assessment. This requirement would, therefore, support standards currently in place at other facilities serving mental health clients.

The information generated from an interdisciplinary, comprehensive assessment is critical in determining the individual care and support needs of each client. This information is used to develop each CMHC client's active treatment plan. As a result of updates of the comprehensive assessment, a CMHC would be able to track a client's progress towards achieving the desired care outcomes. Where progress did not occur, the interdisciplinary treatment team would consider appropriate changes to the client's active treatment plan.

The proposed comprehensive assessment requirements would guide CMHC staff in thoroughly assessing their clients by identifying the general areas that would be included in each assessment and by identifying timeframes for the completion of each assessment.

We believe that the broad assessment outline we are proposing would encourage CMHCs to exercise flexibility in determining how best to achieve positive outcomes. We believe that this approach is consistent with currently accepted practices in CMHCs.

In proposed § 485.914(a), ''Standard: Admission,'' we are proposing that each CMHC would have to determine whether a client was appropriate for its services as specified in the definition of a CMHC at § 410.2. If the client was admitted to receive partial hospitalization services, the CMHC would also have to meet separate requirements specified at proposed § 485.918(f).

In proposed § 485.914(b), ''Standard: Initial evaluation,'' we are proposing that a CMHC psychiatric registered nurse or clinical psychologist would be required to complete an initial evaluation to determine the client's immediate clinical care and support needs, including an admitting diagnosis and other diagnoses; the source of the referral; the reason for admission as stated by the client or others significantly involved; identification of the client's immediate care needs; a list of current prescriptions and over-the-counter medications, as well as other substances that the client may be taking; and for partial hospitalization services only, an explanation as to why the client would be at risk for hospitalization if the partial hospitalization services were not provided. We would require that the initial evaluation be completed within 24 hours after admission to the CMHC.

In proposed § 485.914(c), ''Standard: Comprehensive assessment,'' we are proposing that the CMHC physician-led interdisciplinary treatment team, in consultation with the client's primary care provider (if any), be required to complete the comprehensive assessment in a timely manner consistent with the client's immediate needs, but no later than 3 working days after admission to the CMHC. In proposed § 485.914(c)(3) and (c)(4), we are proposing the requirements for the content of the comprehensive assessment that we believe are critical to quality CMHC care. These content requirements are at the core of CMHC care and are needed to evaluate the client's physical, psychological, psychosocial, medical, emotional, therapeutic and other needs related to psychiatric illness and the reason for admission. Therefore, we are proposing that the comprehensive assessment take into consideration the following factors outlined in proposed § 485.914(c)(4)(i) through (xiii):

In proposed § 485.914(c)(4)(i), we are proposing to require the CMHC to identify the reason for the client's admission to the CMHC. This identification would include the reason

for admission and the admitting diagnosis as stated by the referral source, the client, and the CMHC. We believe that this information is necessary to ensure that the CMHC and client are clear about the reason for the client's treatment at the CHMC.

In proposed § 485.914(c)(4)(ii) through (c)(4)(ix), we are proposing to require the comprehensive assessment to address client preferences regarding what is important to, and important for the client. The comprehensive assessment would also include a psychiatric evaluation; information concerning previous and current mental status, including but not limited to, previous therapeutic interventions and hospitalizations; information regarding the onset of symptoms of the illness and circumstances leading to the admission; a description of attitudes and behavior, such as the client's non-verbal presentation; cultural factors that may affect care planning; an assessment of intellectual functions, memory and orientation; complications and risk factors that may affect care planning; functional status, including the client's ability to understand and participate in his or her own care, and the client's strengths and goals; and factors affecting client safety or the safety of others, including behavioral and physical factors.

In proposed § 485.914(c)(4)(x), we are proposing that the client's comprehensive assessment include a review of the client's current medications, including prescription and over-the-counter medications, herbal remedies, and other alternative treatments or substances that could affect drug therapy. The review and accompanying documentation would include identification of the following items:

- Effectiveness of drug therapy.
- Drug side effects.
- Actual or potential drug interactions.
- Duplicate drug therapy.
- Drug therapy requiring laboratory monitoring.

As part of the update of the comprehensive assessment, as proposed in § 485.914(d), this review would have to be repeated as often as necessary to ensure that the client continued to receive drug therapy that was effective and appropriate for his or her needs. A review of a client's drug therapy would be included in the comprehensive assessment and in the development of the active treatment plan. This review could occur at any time, as well as at the time of the comprehensive assessment. We believe it would be most appropriate when a client was prescribed or began to take any new drug and/or when use of a drug was discontinued.

In proposed § 485.914(c)(4)(xi), we are proposing that CMHCs would be required to assess each client's need for referrals to appropriate health professionals unrelated to the client's mental illness and beyond the scope of the CMHC, such as care related to additional medical conditions and/or co-morbidities. This would include consultation of the CMHC with the client's primary health care provider, if any.

In proposed § 485.914(c)(4)(xii), we are proposing to require the CMHC to consider discharge planning options at the time of the comprehensive assessment. We believe that it is important for continuity of care that the discharge planning process begin as the CMHC assesses the client's current health care needs, living environment, support systems, and therapy goals.

In proposed § 485.914(c)(4)(xiii), we are proposing that the CMHC be required to identify the client's current support system. We believe that a smooth transition between care settings would be more likely to occur if the discharge planning process were initiated early to determine the availability of resources to assist the client after discharge from the CMHC.

In proposed § 485.914(d), ''Standard: Update of the comprehensive assessment,'' we are proposing that the CMHC update the comprehensive assessment via the physician-led interdisciplinary treatment team, in consultation with the client's primary health care provider (if any), no less frequently than every 30 days, and when changes in the client's status, response to treatment, or goals have occurred. The update would have to include information on the client's progress toward desired outcomes, a reassessment of the client's response to care and therapies, and the client's goals. We believe that these frequent reviews are necessary since clients with ongoing mental illness may be subject to frequent and/or rapid changes in status, needs, acuity, and circumstances, and the client's treatment goals may change, thereby affecting the type and frequency of services that should be furnished. The physician-led interdisciplinary treatment team would use assessment information to guide necessary reviews and/or changes to the client's active treatment plan.

In proposed § 485.914(e), ''Standard: Discharge or transfer of the client,'' we are proposing to require the CMHC to complete a discharge summary and forward it to the receiving facility/provider, if any, within 48 hours of discharge or transfer from the CMHC. If the client is being discharged due to non-compliance with the treatment plan, the CMHC would forward the discharge summary and, if requested, other pertinent clinical record information to the client's primary health care provider (if any). The discharge summary would be required to include—(1) A summary of the services provided while a client of the CMHC, including the client's symptoms, treatment and recovery goals and preferences, treatments, and therapies; (2) the client's current active treatment plan at the time of discharge; (3) the client's most recent physician orders; and (4) any other documentation that would assist in post-discharge continuity of care. Furthermore, under the discharge or transfer standard, the CMHC would have to adhere to all Federal and State-related requirements pertaining to medical privacy and the release of client information. We believe this standard would help ensure that the information flow between the CMHC and the receiving entity is smooth, and that the appropriate care continues without being compromised (where applicable).

We welcome public comments on our proposed timeframes and content for the initial assessment, comprehensive assessment, updated comprehensive assessment, and discharge or transfer requirements.

CMHC CoP: Treatment Team, Client-Centered Active Treatment Plan, and Coordination of Services (Proposed § 485.916)

We are proposing to add a new CoP at § 485.916 to establish requirements for the treatment team, active treatment plan, and coordination of services. This proposed CoP would contain five standards that reflect an interdisciplinary team approach to CMHC care delivery.

As proposed, each client would have a written active treatment plan developed by the CMHC physician-led interdisciplinary team that would specify the CMHC care and services necessary to meet the client-specific needs identified in the initial, comprehensive, and updated assessments. All CMHC services furnished to clients would have to follow each client-specific written active treatment plan.

In proposed § 485.916(a), ''Standard: Delivery of services,'' we are proposing that the CMHC designate a physician-led interdisciplinary team for each client, which would include either a psychiatric registered nurse, clinical psychologist, or clinical social worker,

who would be a coordinator responsible, with the client, for directing, coordinating and managing the care and services provided to the client. The team would be composed of individuals who would work together to meet the physical, medical, psychosocial, emotional, and therapeutic needs of CMHC clients. The interdisciplinary team would include, but would not be limited to the following:

- A doctor of medicine, osteopathy or psychiatry.
- A psychiatric registered nurse.
- A clinical social worker.
- A clinical psychologist.
- An occupational therapist.
- Other licensed mental health professionals, as necessary.

We believe that the role of the interdisciplinary treatment team is paramount in directing and monitoring client care. Each discipline brings forth a unique perspective, that together creates a well thought-out and thorough active treatment plan. We understand that there are instances where two of the interdisciplinary team member's roles could be covered by one person. For example, a nurse who also holds a qualifying degree in social work, could represent both the nurse and social worker interdisciplinary treatment team. This team of medical professionals works in unison to provide comprehensive care for the client. For example, the physician/psychiatrist (depending on his or her licenses) would, at a minimum, address medication management. The psychiatric nurse would bring forth issues related to care and implementation of the active treatment plan, and the social worker would bring forth issues related to the social aspects of the client and family care. The CMHC would designate a psychiatric registered nurse, clinical psychologist or clinical social worker who was a member of the interdisciplinary treatment team to coordinate care, ensure the continuous assessment of each client's needs, and ensure the implementation and revision of the active treatment plan. Depending on the number and/or type of clients served by the CMHC, the CMHC may have more than one interdisciplinary team. If so, the CMHC is required to designate a treatment team responsible for establishing policies governing the day-to-day provision of CMHC care and services.

In proposed § 485.916(b), ''Standard: Active treatment plan,'' we are proposing to require that all CMHC services furnished to clients follow a written active treatment plan established within 3 working days after the client's admission to the CMHC by the CMHC physician-led interdisciplinary treatment team and the client (and representative, if any), in accordance with the client's psychiatric needs and goals. The CMHC would have to ensure that each client and, if relevant, primary caregiver(s) received education and training that was consistent with the client's and caregiver's responsibilities, as identified in the client-specific active treatment plan. Education is necessary to ensure that the client and caregiver understand the services and treatments contained in the active treatment plan and their roles in actively participating in and following the plan.

In proposed § 485.914(c), ''Standard: Content of the active treatment plan,'' we are proposing to require that each client's active treatment plan reflect client goals and interventions for problems identified in the comprehensive and updated assessments. This proposed requirement would ensure that care and services were appropriate to the level of each client's specific needs. The active treatment plan would include all of the services necessary for the care and management of the psychiatric illness, including the following:

- Client diagnoses;
- Treatment goals, based on what is important to and appropriate for the client, and the client's recovery goals;
- Interventions;
- A detailed statement of the type, duration and frequency of services, including social work, counseling, psychiatric nursing and therapy services, as well as services furnished by other staff trained to work with psychiatric clients, necessary to meet the specific client needs;
- Drugs, treatments, and individual and/or group therapies;
- Family psychotherapy with the primary focus on the treatment of the client's conditions (or if no family was available for such psychotherapy, we would expect the CMHC to document this in the client's clinical record); and
- The interdisciplinary treatment team's documentation of the client's and representative's (if any) understanding, involvement, and agreement with the active treatment plan, in accordance with the CMHC's own policies. This would include information about the client's need for services and supports, and treatment goals and preferences.

The client and/or representative would need to understand the importance of their roles in implementing elements of the active treatment plan. We believe that the client's participation and agreement regarding care is essential in developing an effective relationship with the CMHC. Some clients would require supports to participate effectively in the planning process. While it remains important to actively engage client representatives, representative participation could not substitute for client participation, unless there was a documented reason, such as a safety risk. We would expect a CMHC to document the client's and the representative's understanding of, and agreement with, the active treatment plan in accordance with its own policies. This could include an attestation signed by the client and representative, a note in the clinical record, and/or another form of documentation decided upon by the CMHC governing body.

In proposed § 485.916(d), ''Standard: Review of the active treatment plan,'' we are proposing to require that a revised active treatment plan be updated with current information from the client's comprehensive assessment and information concerning the client's progress toward achieving outcomes and goals specified in the active treatment plan. The active treatment plan would have to be reviewed at intervals specified in the plan, but no less frequently than every 30 calendar days. We believe that it is essential to include this requirement because it would establish the linkage between assessment information, evaluation of treatment results, and active treatment plan modification.

In proposed § 485.916(e), ''Standard: Coordination of services,'' we are proposing to require that the CMHC maintain a system of communication and integration to enable the interdisciplinary treatment team to ensure the overall provision of care and the efficient implementation of day-to-day policies. This proposed standard would also make it easier for the CMHC to ensure that the care and services were provided in accordance with the active treatment plan, and that all care and services provided were based on the comprehensive and updated assessments of the client's needs. An effective communication system would also enable the CMHC to ensure the ongoing sharing of information among all disciplines providing care and services, whether the care and services were being provided by employees or by individuals under contract with the CMHC.

We believe that this proposed standard is appropriate because a CMHC client typically encounters many services delivered at different times by a variety of individuals with different

skills. Communication and integration of services and observations among members of the interdisciplinary treatment team and others providing care is essential to meet and respond to the client's needs in a timely manner. Additionally, this would ensure that the CMHC actively coordinated the care that they were providing with the care being furnished by other providers, including a client's primary health care provider (if any).

We recognize the value of an interdisciplinary approach to the delivery of CMHC services. This approach reflects actual industry practice, and as a result, we believe the proposed requirement is in step with accepted standards of practice.

We are specifically soliciting public comment on the proposed requirements for delivery of services, content of the active treatment plan, the time frames for review of the active treatment plan, and the coordination of services standard.

CMHC CoP: Quality Assessment and Performance Improvement (Proposed § 485.917)

We are proposing to add a new CoP at § 485.917 to specify the requirements for a quality assessment and performance improvement program. During the last decade, the health care industry has begun to address quality issues preemptively. In this proposed rule, we have outlined the scope of the proposed quality assessment and performance improvement (QAPI) requirement, the guidelines for identifying performance improvement activities, and the individuals responsible for ensuring that a CMHC has a QAPI program. In this rule, we are proposing that each CMHC develop, implement, and maintain an effective, continuous QAPI program that stimulates the CMHC to constantly monitor and improve its own performance, and to be responsive to the needs and satisfaction levels of the clients it serves.

The desired overall outcome of the proposed QAPI CoP is that the CMHC would drive its own quality improvement activities and improve its provision of services. With an effective QAPI program in place and operating properly, the CMHC could better identify the activities that led to poor client outcomes, and take actions to improve performance.

This proposed condition would require the CMHC to develop, implement and maintain an effective data-driven QAPI program. The program would establish a planned approach to quality improvement and would take into account the complexity of the CMHC's organization and services, including those provided directly or under contract. The CMHC would have to take all actions necessary to implement improvements in its performance as identified by its QAPI program. The CMHC would also be responsible for ensuring that the professional services it offered were carried out within current clinical practice guidelines as well as professional practice standards applicable to CMHC care.

In proposed § 485.917(a), ''Standard: Program scope,'' we are proposing that the CMHC's QAPI program include, but not be limited to, an ongoing program that is able to show measureable improvement in indicators linked to improving client care outcomes and behavioral health support services. We expect that a CMHC would use standards of care and the findings made available in current literature to select indicators to monitor its program. The CMHC would have to measure, analyze, and track quality indicators, including areas such as adverse client events and other aspects of performance that assess processes of care, CMHC services and operations. The term ''adverse client events,'' as used in the field, refers to occurrences that are harmful or contrary to the targeted client outcomes, including sentinel events. The use of restraint and seclusion is contrary to targeted client outcomes; therefore, we would consider the use of restraint and seclusion to be an adverse client event that would be tracked and analyzed as part of the QAPI program.

In proposed § 485.917(b), ''Standard: Program data,'' we are proposing to require the CMHC QAPI program to incorporate quality indicator data, including client care data and other relevant data, into its QAPI program. A fundamental barrier in identifying quality care is lack of measurement tools. Measurement tools can identify opportunities for improving medical care and examining the impact of interventions.

We are not proposing to require that CMHCs use any particular process, tools or quality measures. However, a CMHC that used available quality measures could expect an enhanced degree of insight into the quality of its services and client satisfaction than if it began the quality measure development process anew.

The CMHC could also develop its own data elements and measurement process as part of its program. A CMHC would be free to develop a program that met its needs. We recognize the diversity of provider needs and concerns with respect to QAPI programs. As such, a provider's QAPI program would not be judged against a specific model.

The proposed program data standard would require the CMHC to monitor the effectiveness of its services and target areas for improvement. The main goal of the proposed standard would be to identify and correct ineffective and/or unsafe care. We expect CMHCs to assess their potential client load and identify circumstances that could lead to significant client care issues, and concentrate their energies in these areas.

In proposed § 485.917(c), ''Standard: Program activities,'' we are proposing to require a CMHC to set priorities for its performance improvement activities that focus on high risk, high volume or problem-prone areas; consider the prevalence and severity of identified problems; and give priority to improvement activities that affect client safety, and quality of client outcomes. We expect that a CMHC would take immediate action to correct any identified problems that would directly or potentially threaten the care and safety of clients. Prioritizing areas of improvement is essential for the CMHC to gain a strategic view of its operating environment and to ensure consistent quality of care over time.

We are also proposing to require the CMHC to track adverse client events, analyze their causes, and implement preventive actions that include feedback and learning throughout the CMHC. In implementing its QAPI program, a CMHC is expected to treat staff and clients/representatives as full partners in quality improvement. Staff members and clients/representatives are in a unique position to provide the CMHC with structured feedback on, and suggestions for, improving the CMHC's performance. We expect the CMHC to demonstrate how the staff and clients have contributed to its quality improvement program.

In proposed § 485.917(d), ''Standard: Performance improvement projects,'' we are proposing to require that the number and scope of improvement projects conducted annually reflect the scope, complexity, and past performance of the CMHC's services and operations. The CMHC would have to document what improvement projects were being conducted, the reasons for conducting them, and the measurable progress achieved on these projects.

As part of its QAPI program, a CMHC could use an IT performance improvement project that allowed the CMHC to invest in information technology; that is, we would allow CMHCs to undertake a program of

investment and development of an IT system that was geared to improvements in patient safety and quality, as a QAPI project. In recognition of the time required to develop and implement this type of system, we would not require that such activities have a demonstrable benefit in their initial stages, but we would expect that quality improvement goals and their achievement would be incorporated in the plan for the program. Initial stages of development would include activities such as installation of hardware and software, testing of an installed system, training of staff, piloting the system, and CMHC-wide implementation of the system. Upon implementation of the system, monitoring would begin and data would be collected over time as part of the process to evaluate the impact of the new system on patient safety and quality. We believe that recognizing an investment in IT as part of QAPI demonstrates this Administration's deep commitment to patients, high quality care, and flexibility. This approach would allow CMHCs the flexibility to invest appropriate efforts in their quality program and the freedom to make decisions about the best way to improve the quality of care. We believe that giving CMHCs the flexibility to review their own organizations and QAPI programs would improve the effectiveness and efficiency of their services, the outcomes of care they provided, and client satisfaction with their services.

In proposed § 485.917(e), ''Standard: Executive responsibilities,'' we are proposing to require that the CMHC's governing body be responsible and accountable for ensuring that the ongoing quality improvement program is defined, implemented and maintained, and evaluated annually. The governing body would be required to appoint one or more individuals responsible for operating the QAPI program, and would have to ensure that the program addressed priorities for improved quality of client-centered care and client safety. The governing body would also have to specify the frequency and level of detail of the data collection and ensure that all quality improvement actions were evaluated for effectiveness. The governing body's most important role would be to ensure that staff was furnishing, and clients were receiving, the most appropriate level of care. Therefore, it would be incumbent on the governing body to lend its full support to agency quality improvement and performance improvement efforts.

CMHC CoP: Organization, Governance, Administration of Services, and Partial Hospitalization Services. (Proposed § 485.918)

We are proposing to add a new CoP at § 485.918 that would require the CMHC to set out the CMHC's administrative and governance structure and would clarify performance expectations for the governing body. The overall goal of this CoP would be to ensure that the management structure was organized and accountable.

In this proposed organization and administration of services CoP, we would list the services that the statute (section 1861(ff)(3) of the Act) requires CMHCs to furnish. We are also proposing a standard that would require a CMHC to provide in-service training to all employees and staff, including those under contract or under arrangements, who have client contact. This requirement would assist in ensuring that all staff serving CMHC clients were up to date on current standards of practice. The CMHC would be required to have written policies and procedures describing its methods for assessing staff skills and competency, and to maintain a written description of in-service training offered during the previous 12 months.

In proposed § 485.918(a), ''Standard: Governing body and administrator,'' we are proposing to emphasize the responsibility of the CMHC governing body (or designated persons so functioning) for managing all CMHC facilities and services, including fiscal operations, quality improvement, and the appointment of the administrator. The administrator would be responsible for the day-to-day operation of the CMHC and would report to the governing body. The administrator would have to be a CMHC employee and meet the education and experience requirements established by the CMHC's governing body. The specifics of the administration of the CMHC would be left to the discretion of the governing body, thereby affording the CMHC's management with organizational flexibility. The proposed governing body standard reflects our goal of promoting the effective management and administration of the CMHC as an organizational entity without dictating prescriptive requirements for how a CMHC must meet that goal.

In proposed § 485.918(b), ''Standard: Provision of services,'' we are proposing to specify a comprehensive list of services that a CMHC would be required to provide. At § 485.918(b)(1)(v), we are proposing to require the CMHC to provide at least 40 percent of its services to individuals who are not eligible for benefits under title XVIII of the Act (Medicare). This proposed requirement would track the changes to 42 CFR § 410.2 set out in the November 24, 2010 Outpatient Prospective Payment System final rule (OPPS) (75 FR 71800, 72259). Both this CMHC proposed rule and the OPPS final rule changes implement the statutory changes made by section 1301(a) of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152).

Enactment of section 1301(a) of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (HCERA 2010) revised the definition of a CMHC set forth at section 1861(ff)(3)(B) of the Act by adding a provision to the existing requirements for CMHCs, effective on the first day of the first calendar quarter that begins at least 12 months after the date of enactment (that is, April 1, 2011). As of that date, a CMHC must provide at least 40 percent of its services to individuals who are not eligible for benefits under Title XVIII of the Act (Medicare).

We are proposing to measure whether a CMHC is providing ''at least 40 percent of its services'' by the amount of reimbursement for all services furnished. This is only one of several possible approaches to implementing this measurement, and we are seeking public comment on this approach. Alternatives we considered included calculating whether at least 40 percent of the CMHC's units of service were furnished to non-Medicare patients, the number of non-Medicare patients served by the CMHC, or the dollar amount of services billed overall by the CMHC. We believe that the percentage of total revenues received by the CMHC that are payments from Medicare versus other payers is an approach that can be measured efficiently.

Accordingly, the CMHC would be required to demonstrate to the Medicare program that it is receiving no less than 40 percent of its reimbursement from payers other than Medicare, including but not limited to commercial entities, Medicaid and CHIP. Additionally, we propose to measure the 40 percent of its services on an annual basis. We are seeking public comment on whether we should determine if a CMHC meets the 40 percent requirement annually or at some other interval. We are seeking comment on both the definition of terms used in any approach to measuring the 40 percent threshold and the data sources for that measurement. Specifically, since the measure proposed to determine the 40 percent threshold is total reimbursement from Medicare, we are interested in

comments on how we should define reimbursement.

We are interested in comments addressing whether such a calculation should include uncompensated care or any other aspect of reimbursement. For example, the denominator would include total reimbursement received, including co-payments/co-insurance paid by Medicare beneficiaries and private patients and reimbursement received by Medicare for bad-debt. The numerator would include reimbursement by non-Medicare payers, which would include co-pays/co-insurance from privately insured individuals, reimbursement from Medicaid, other reimbursement from States, private pay and charity/uncompensated care. If instead we choose to measure based on service increment, we are interested in receiving comments on the specific definition for the services to be included in the calculation and how they would be counted. We are also interested in receiving comments regarding data sources for the metrics that comprise the components of a measure of the 40 percent threshold. In addition, we are interested in seeking comment on whether CMS should require the CMHCs to attest to whether they meet the 40 percent requirement, or whether we should subject them to verification auditing.

Furthermore, we are interested in receiving comments on any other definitions of what constitutes a measure of the 40 percent threshold. For example, if there is a way to use a combined metric relying in part on reimbursement and in part on beneficiary/patient counts, and in part on service use. Finally, we are interested in seeking comments on how this measurement would be accomplished; for example, we would be interested in hearing commenters' ideas on how each of these measures would be included in the metric calculation and the best data sources for the calculation. We stress that we are concerned that the implementation of this provision not negatively impact access to care, and are seeking additional comment on strategies that would correctly balance the implementation of this new requirement with access concerns.

We will carefully consider all public comments received on this provision, and would respond to public comments in the final rule. We intend to issue sub-regulatory guidance implementing this requirement after the publication of the final rule.

We want to clarify that although we have proposed an approach to calculating the 40 percent threshold, we are broadly seeking comments on the proposed approach as well as any other approaches that commenters think might be appropriate as a basis for determining whether a CMHC meets the requirement of providing at least 40 percent of its services to non-Medicare patients. We are also seeking comment on any aspect of how this requirement would be implemented at the provider level, what operational changes might be needed and whether there is a need for any additional financial/management document(s) to enable assessment of whether a CMHC meets the 40 percent threshold. For example, we would be interested in hearing commenters' views about whether or not a CMHC should use an independent auditing agency to review its financial statements and certify whether the CMHC meets the 40 percent threshold. We expect to draw on the comments received and make a final decision about the definition of what constitutes 40 percent in the final regulation.

Medicare-certified CMHCs are already required to provide most of the services set out in this proposed provision through the existing CMS payment rules (42 CFR 410.2, 410.110, and 424.24(e)). It is essential for CMHCs to have sufficient numbers of appropriately educated and trained staff to meet these service expectations. For example, CMHCs that provide partial hospitalization services could provide the services of ''other staff trained to work with psychiatric clients'' (42 CFR 410.43(a)(3)(iii)). Non-specified staff might be responsible for supervising clients and ensuring a safe environment. CMHCs would be expected to have a sufficient number of appropriately-trained staff to meet these responsibilities at all times.

In proposed § 485.918(c), ''Standard: Professional management responsibility,'' we are proposing to require that where services are furnished by other than CMHC staff, a CMHC would have to have a written agreement with another agency, individual, or organization that furnishes the services. Under this agreement, the CMHC would retain administrative and financial management and oversight of staff and services for all arranged services. The CMHC would have to have a written agreement that specified that all services would have to be authorized by the CMHC, be furnished in a safe and effective manner, and be delivered in accordance with established professional standards, the policies of the CMHC and the client's active treatment plan. As part of retaining financial management responsibility, the CMHC would retain all payment responsibility for services furnished under arrangement on its behalf.

In proposed § 485.918(d), ''Standard: Staff training,'' which would apply to all employees, staff under contract, and volunteers, we are proposing to require a CMHC to take steps to develop appropriate in-service programs, including initial orientation for each new employee or volunteer furnishing services. The new employee orientation would address specific job duties. The CMHC could also provide staff training under arrangement.

We would not require a specific staff in-service training program; rather, we would expect each CMHC to determine the scope of its own program, including the manner in which it chose to assess competence levels, determine training content, determine the duration and frequency of training for all employees, and track the training on a yearly basis.

In proposed § 485.918(e)(1), ''Environmental conditions,'' and (e)(2), ''Building,'' would require the CMHC to provide services in an environment that was safe, functional, sanitary, comfortable, and in compliance with all Federal, State, and local health and safety standards, as well as State health care occupancy regulations. These proposed requirements would help to ensure that CMHC services were provided in a physical location that was both safe and conducive to meeting the needs of CMHC clients.

In proposed § 485.918(e)(3), ''Infection control,'' we are proposing to address the seriousness and potential hazards of infectious and communicable diseases. We would require a CMHC to develop policies, procedures, and monitoring, as well as take specific actions to address the prevention and control of infections and disease.

We believe that a CMHC should follow nationally accepted infection control standards of practice and ensure that all staff know and use current best preventive practices. Periodic training is one way to assure staff understanding, and we would expect the CMHC to establish a method to ensure that all staff receives appropriate training. Where infection and/or communicable diseases are identified, we would expect aggressive actions be taken to protect all the clients and staff.

This proposed CoP would allow the CMHC to have flexibility in meeting its infection control, prevention and education objectives. For example, the extent of training in infection control that would be necessary for the CMHC's personnel would depend on the client mix and experience of the staff. One

example of ''current best practices'' is the standard precautionary use of gloves when handling blood or blood products. While we would expect that established best practices be followed, we are not proposing any specific approaches to meeting this requirement. We would expect to see clear evidence that the CMHC sought to minimize the spread of disease and infection through the use of effective techniques by its staff and through its efforts to help clients understand what can and should be done for infection control purposes.

In proposed § 485.918(e)(4), ''Therapy sessions,'' we are proposing that the CMHCs ensure that all individual and group therapy sessions be conducted in a manner that maintains client privacy and dignity. We believe that a safe, private environment would enhance the effectiveness of the therapy sessions.

In proposed § 485.918(f), ''Standard: Partial hospitalization services,'' we are proposing that all partial hospitalization services would be required to meet all applicable requirements of 42 CFR parts 410 and 424.

In proposed § 485.918(g), ''Standard: Compliance with Federal, State, and local laws and regulations related to the health and safety of clients,'' we are proposing that the CMHC and its staff would be required to operate and furnish services in compliance with all applicable Federal, State, and local laws and regulations related to the health and safety of clients. If State or local law provided for licensing of CMHCs, the CMHC would have to be licensed. In addition, the CMHC staff would have to follow the CMHC's policies and procedures.

B. Health Disparities

In 1985, the Secretary of the Department of Health and Human Services (HHS) issued a landmark report which revealed large and persistent gaps in health status among Americans of different racial and ethnic groups and served as an impetus for addressing health inequalities for racial and ethnic minorities in the U.S. This report led to the establishment of the Office of Minority Health (OMH) within HHS, with a mission to address these disparities within the Nation. National concerns for these differences, termed health disparities, and the associated excess mortality and morbidity have been expressed as a high priority in national health status reviews, including Healthy People 2000 and 2010.

Since that time, research has extensively documented the pervasiveness of racial and ethnic disparities in health care and has led to the acknowledgement of racial and ethnic disparities as a national problem. As a result, more populations have been identified as vulnerable, which necessitated the development of programs and strategies to reduce disparities for vulnerable populations, and the emergence of new leadership to address such disparities. Currently, vulnerable populations can be defined by race/ethnicity, socio-economic status, geography, gender, age, disability status, risk status related to sex and gender, and other populations identified to be at-risk for health disparities. Other populations at risk may include persons with visual or hearing problems, cognitive perceptual problems, language barriers, pregnant women, infants, and persons with disabilities or special health care needs.

Although there has been much attention at the national level to ideas for reducing health disparities in vulnerable populations, we remain vigilant in our efforts to improve health care quality for all persons by improving health care access and by eliminating real and perceived barriers to care that may contribute to less than optimal health outcomes for vulnerable populations. For example, we are aware that immunization rates remain low among some minorities. Despite the long-term implementation of some strategies like the use of language translators in hospitals, health literacy and its impact on health care outcomes continues to be in the forefront.

We are always seeking better ways to address the needs of vulnerable populations; therefore, we are specifically requesting comments in regard to how our proposed requirements could be used to address disparities.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of the issues for the information collection requirements (ICRs) discussed below.

A. ICRs Related to Condition of Participation: Client Rights (§ 485.910)

Proposed § 485.910(a) would require that the CMHC develop a notice of rights statement to be provided to each client. We estimate that it would require 8 hours on a one-time basis to develop this notice, and the CMHC administrator would be responsible for this task, at a cost of $424 per CMHC and $94,976 for all CMHCs nationwide. In addition, this standard would require that the CMHC provide each client and client's representative or surrogate with a verbal and written notice of the client's rights and responsibilities during the initial evaluation visit, in advance of furnishing care. The CMHC would also be required to obtain the client's and client representative's (if appropriate) signature confirming that he or she has received a copy of the notice of rights and responsibilities. The CMHC would have to retain the signed documentation showing that it complied with the requirements and that the client and the client's representative demonstrated an understanding of these rights. We estimate the burden for the time associated with disclosing the information would be 2.5 minutes per client or approximately 4.67 hours per CMHC. Similarly, we estimate that the burden for the CMHC to document the information would take 2.5 minutes per client or approximately 4.67 hours per CMHC. At an average of 5 minutes (.0833 hours) per client to complete both tasks, we estimate that all CMHCs would use 2,090 hours to comply with this proposed requirement (.0833 hours per client × 25,087 clients). The estimated cost associated with these requirements would be $75,240, based on a psychiatric nurse performing this function (2,090 hours × $36 per hour).

We note that we do not impose any new language translation or interpretation requirements. Under Title VI of the Civil Rights Act of 1964, recipients of Federal financial assistance, such as CMHCs, have long been prohibited from discriminating on the basis of race, color, or national origin. Language interpretation is required under some circumstances under that statute and the HHS regulations at 45 CFR part 80 (see

previous discussion of Office for Civil Rights guidance issued in 2003). Because we impose no new requirements not fully encompassed in that regulation and guidance, we have estimated no paperwork burden.

Proposed § 485.910(d)(2) would require a CMHC to document a client's or client representative's complaint of the alleged violation and the steps taken by the CMHC to resolve it. The burden associated with this proposed requirement is the time it would take to document the necessary aspects of the issues. In late 2007, the American Association of Behavioral Health and The Joint Commission informed us that we could anticipate 52 complaints per year per CMHC and that it would take the administrator 30 minutes per complaint at the rate of $53/hr to document the complaint and resolution activities, for an annual total of 26 hours per CMHC or 5,824 hours for all CMHCs. The estimated cost associated with this requirement is $308,672.

Proposed § 485.910(d)(4) would require the CMHC to report all confirmed violations to the State and local bodies having jurisdiction within 5 working days of becoming aware of the violation. We anticipate that it would take the administrator 5 minutes per complaint to report, for an annual total of 4.3 hours per CMHC or 971 hours for all CMHCs. The estimated cost associated with this requirement is $51,463.

Proposed § 485.910(e)(2)(v) would require written orders for a physical restraint or seclusion, and proposed § 485.910(e)(5)(v) would require physical restraint or seclusion be supported by a documentation of the client's response or outcome in the client's clinical record. The burden associated with this requirement would be the time and effort necessary to document the use of physical restraint or seclusion in the client's clinical record. We estimate that it would take 45 minutes per event to document this information. Similarly, we estimate that there will be 1 occurrence of the use of physical restraint or seclusion per CMHC. The estimated annual burden associated with this requirement for all CMHCs would be 168 hours. The estimated cost associated with this burden for all CMHCs is $6,048.

Proposed § 485.910(f) would specify restraint or seclusion staff training requirements. Specifically, § 485.910(f)(1) would require that all client care staff working in the CMHC be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a client in restraint or seclusion and on the use of alternative methods to restraint and seclusion. Proposed § 485.910(f)(4) would require that a CMHC document in the personnel records that each employee successfully completed the restraint and seclusion training and demonstrated competency. We estimate that it would take 35 minutes per CMHC to comply with these requirements. The estimated total annual burden associated with these requirements would be 131 hours. The estimated cost associated with this requirement would be $4,704.

Proposed § 485.910(g) would require the CMHC to report any death that occurred while a CMHC client was in restraint or seclusion in the CMHC while awaiting transfer to a hospital. We have a parallel requirement in all other CMS rules dealing with programs and providers where restraint or seclusion may be used (*e.g.,* in our hospital conditions of participation). Based on informal discussions with the CMHC industry and The Joint Commission, we believe restraints and seclusion are rarely if ever used in CMHCs and that there are very few deaths (if any) that occur due to restraint and seclusion in a CMHC. For purposes of the PRA, we estimate the annual number of deaths to be zero. However, there are no data available regarding this issue. We are soliciting public comment, thus allowing the CMHC provider community the opportunity to provide feedback on this issue. With the number of deaths estimated at zero, under 5 CFR 1320.3(c)(4), this proposed requirement is not subject to the PRA as it would affect fewer than 10 entities in a 12-month period.

B. ICRs Related to Condition of Participation: Admission, Initial Evaluation, Comprehensive Assessment, and Discharge or Transfer of the Client (§ 485.914)

Proposed § 485.914(b) through (d) would require each CMHC to conduct and document in writing an initial evaluation and a comprehensive client-specific assessment; maintain documentation of the assessment and any updates; and coordinate the discharge or transfer of the client. The burden associated with these proposed requirements would be the time required to record the initial evaluation and comprehensive assessment, including changes and updates. We believe that documenting a client's initial evaluation and comprehensive assessment is a usual and customary business practice under 5 CFR 1320.3(b)(2) and, as such, the burden associated with it is exempt from the PRA.

Proposed § 485.914(e) would require that, if the client were transferred to another facility, the CMHC would be required to forward a copy of the client's CMHC discharge summary and clinical record, if requested, to that facility. If a client is discharged from the CMHC because of noncompliance with the treatment plan or refusal of services from the CMHC, the CMHC would be required to provide a copy of the client's discharge summary and clinical record, if requested, to the client's attending physician. The burden associated with this proposed requirement would be the time it takes to forward the discharge summary and clinical record, if requested. This proposed requirement is considered to be a usual and customary business practice under § 1320.3(b)(2) and, as such, the burden associated with it is exempt from the PRA.

C. ICRs Related to Condition of Participation: Treatment Team, Active Treatment Plan, and Coordination of Services (§ 485.916)

Proposed § 485.916(b) would require all CMHC care and services furnished to clients and their families to follow a written active treatment plan established by the CMHC physician-led interdisciplinary treatment team. The CMHC would be required to ensure that each client and representative receives education provided by the CMHC as appropriate to the care and services identified in the active treatment plan.

The proposed provisions at § 485.916(c) specify the minimum elements that the active treatment plan would include. In addition, in proposed § 485.916(d), the physician-led interdisciplinary team would be required to review, revise, and document the active treatment plan as frequently as the client's condition requires, but no less frequently than every 30 calendar days. A revised active treatment plan would include information from the client's updated comprehensive assessment, and would document the client's progress toward the outcomes specified in the active treatment plan. The burden associated with these proposed requirements would be the time it would take to document the active treatment plan (approximately 45 minutes) estimated to be a total $3,024 per CMHC or $677,376 nationally. Additionally, we estimate any revisions to the active treatment plan (approximately 15 minutes) would cost $1008 per CMHC or $225,792 nationally.

Proposed § 485.916(e) would require a CMHC to develop and maintain a

system of communication and integration to ensure compliance with the requirements contained in § 485.916(e)(1) through (e)(5). The burden associated with this proposed requirement would be the time and effort required to develop and maintain the system of communication in accordance with the CMHC's policies and procedures. While this proposed requirement is subject to the PRA, the associated burden would be considered to be usual and customary business practice as stated in 5 CFR 1320.3(b)(2).

D. ICRs Related to Condition of Participation: Quality Assessment and Performance Improvement (§ 485.917)

Proposed § 485.917 would require a CMHC to develop, implement, and maintain an effective ongoing CMHC-wide data-driven quality assessment and performance improvement (QAPI) program. The CMHC's governing body would have to ensure that the program reflected the complexity of its organization and services; involved all CMHC services, including those services furnished under contract or arrangement; focused on indicators related to improved behavioral health outcomes and support services provided; and demonstrated improvement in the CMHC's performance. The CMHC would be required to maintain and demonstrate evidence of its quality assessment and performance improvement program and be able to demonstrate its operation to CMS.

The CMHC would be required to take actions aimed at performance improvement and, after implementing those actions, must measure its success and track its performance to ensure that improvements were sustained.

The CMHC would be required to document what quality improvement projects were being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

The burden associated with these requirements would be the time it would take to document the development of the quality assessment and performance improvement and associated activities. We estimate that it would take each CMHC administrator an average of 24 hours per year at the rate of $53/hr to comply with these requirements for a total of 5,376 hours annually. The estimated cost associated with this requirement is $284,928.

E. ICRs Related to Condition of Participation: Organization, Governance, Administration of Services, and Partial Hospitalization Services (§ 485.918)

Proposed § 485.918(c) would list the CMHC's professional management responsibilities. A CMHC could enter into a written agreement with another agency, individual, or organization to furnish any services under arrangement. The CMHC would be required to retain administrative and financial management, and oversight of staff and services for all arranged services, to ensure the provision of quality care. The burden associated with this proposed requirement is the time and effort necessary to develop, draft, execute, and maintain the written agreements. We believe these proposed written agreements are part of the usual and customary business practices of CMHCs under 5 CFR 1320.3(b)(2) and, as such, the burden associated with them is exempt from the PRA.

Proposed § 485.918(d) describes the proposed standard for training. In particular, § 485.918(d)(2) would require a CMHC to provide an initial orientation for each employee, contracted staff member, and volunteer who addresses the employee's or volunteer's specific job duties. Proposed § 485.918(d)(3) would require a CMHC to have written policies and procedures describing its method(s) of assessing competency. In addition, the CMHC would be required to maintain a written description of the in-service training provided during the previous 12 months. These proposed requirements are considered to be usual and customary business practices under 5 CFR 1320.3(b)(2) and, as such, the burdens associated with them are exempt from the PRA.

Proposed § 485.918(e)(3) would require the CMHC to maintain policies, procedures, and monitoring of an infection control program for the prevention, control and investigation of infection and communicable diseases. The burden associated with this proposed requirement would be the time it would take to develop and maintain policies and procedures and document the monitoring of the infection control program. We believe this proposed documentation is part of the usual and customary medical and business practices of CMHCs and, as such, is exempt from the PRA under 5 CFR 1320.3(b)(2).

Table 1 below summarizes the estimated annual reporting and recordkeeping burdens for this proposed rule.

TABLE 1—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDENS

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/maintenance Costs ($)	Total cost ($)
§ 485.910(a)(1)	0938–New	224	224	8	1,792	53	94,976	0	94,976
§ 485.910(a)(3)	0938–New	224	25,087	.0833	2,090	36	75,240	0	75,240
§ 485.910(d)(2)	0938–New	224	11,648	.5	5,824	53	308,672	0	308,672
§ 485.910(d)(4)	0938–New	224	11,648	.0833	971	53	51,463	0	51,463
§ 485.910(e)(4)(v)	0938–New	224	224	.75	168	36	6,048	0	6,048
§ 485.910(f)(4)	0938–New	224	224	.583	131	36	4,704	0	4,704
§ 485.916(c)	0938–New	224	25,087	.75	18,815	36	677,340		677,340
§ 485.916(d)	0938–New	224	25,087	.25	6,272	36	225,792	0	225,792
§ 485.917	0938–New	224	224	24	5,376	53	284,928	0	284,928
Total		224	99,453		41,439				1,729,163

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, CMS–3202–P.

Fax: (202) 395–6974; or

E-mail: *OIRA_submission@omb.eop.gov.*

IV. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). The overall economic impact for all proposed new Conditions of Participation in this rule is estimated to be $4.1 million in the first year of implementation and $2.6 million after the first year of implementation and annually thereafter. Therefore, this is not an economically significant or major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Individuals and States are not included in the definition of a small entity. For purposes of the RFA, most CMHCs are considered to be small entities, either by virtue of their nonprofit or government status or by having revenues of less than $10 million in any one year (for details, see the Small Business Administration's Web site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=2465b064ba6965cc1fbd2eae60854b11&rgn=div8&view=text&node=13:1.0.1.1.16.1.266.9&idno=13*). We estimate there are approximately 224 CMHCs with average admissions of approximately 112 clients per CMHC (based on the number of Medicare clients in 2007 divided by the number of CMHCs in 2007). However, we cannot estimate the full impact of this rule because we do not know the total number of non-Medicare patients served by CMHCs. Therefore, we are requesting information on the total number of non-Medicare clients served. We are also soliciting data on the potential effect of this rule on patients' access to services, as well as comments regarding whether specific data exists measuring availability of necessary services to this patient population.

We estimate that implementation of this proposed rule would cost CMHCs approximately $4.1 million, or $18,475 per average CMHC, in the first year of implementation and $2.6 million, or $11,566 per average CMHC, after the first year of implementation and annually thereafter. Therefore, the Secretary has determined that this rule would not have a significant impact on a substantial number of small entities, because the cost impact of this rule is less than 1 percent of total CMHC Medicare revenue.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We believe that this rule would not have a significant impact on the operations of a substantial number of small rural hospitals since there are few CMHC programs in those facilities. Therefore, the Secretary has determined that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately $136 million. This rule would not have an impact on the expenditures of State, local, or tribal governments in the aggregate, or on the private sector of $136 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule has no Federalism implications.

B. Anticipated Effects on CMHCs

We are proposing to establish a new subpart J under the regulations at 42 CFR part 485 to incorporate the proposed CoPs for CMHCs (which would be effective 12 months after the publication of the final rule). The new subpart J would include sections on the basis and scope of the subpart, definitions, and six conditions. For purposes of this section of this proposed rule, we have assessed the impact of all proposed CoPs that may present a burden to a CMHC.

We have made several assumptions and estimates in order to assess the time that it would take for a CMHC to comply with the proposed provisions and the associated costs of compliance. CMHC client data from outside sources are limited; therefore, our estimates are based on available Medicare data. We have detailed these assumptions and estimates in Table 2 below. We have also detailed many, but not all, of the proposed standards within each proposed CoP, and have noted whether or not there is an impact for each in the section below. However, the requirements contained in many of the proposed CoPs are already standard medical or business practices and as a result do not pose an additional burden on CMHCs.

TABLE 2—ASSUMPTIONS AND ESTIMATES USED THROUGHOUT THE IMPACT ANALYSIS SECTION ON CMHCS

Number of Medicare CMHCs nationwide	224
Number of Medicare CMHC clients nationwide	25,087
Number of Medicare clients per average CMHC	112
Hourly rate of psychiatric nurse	$36
Hourly rate of clinical psychologist	$48
Hourly rate of administrator	$53

TABLE 2—ASSUMPTIONS AND ESTIMATES USED THROUGHOUT THE IMPACT ANALYSIS SECTION ON CMHCS—Continued

Hourly rate of clinical social worker	$28

Note: All salary estimates include benefits package worth 30 percent of the fringe base salary. Salary estimates were obtained from *http://www.bls.gov/.*

As stated earlier, we estimate that implementation of the six CoPs that we are proposing would not significantly impact CMHCs. We estimate that implementation of this proposal would cost CMHCs approximately $4.1 million, or $18,475 per average CMHC, in the first year of implementation and $2.6 million, or $11,566 per average CMHC, annually thereafter. We have detailed below many, but not all, of the proposed standards within each proposed CoP, and have noted whether or not there is an impact for each. However, the requirements contained in many of the proposed provisions are already standard medical or business practices. These proposed requirements would, therefore, not pose additional burden to CMHCs because they are already standards of practice. The CoP that we are proposing for client rights would set forth the rights of CMHC clients, ensure that client and client's representative or surrogate are educated about their rights, establish a process for the investigation and reporting of client rights violations, and establish requirements governing the use of restraint and seclusion methods in CMHCs.

In proposed § 485.910(a), ''Standard: Notice of rights and responsibilities,'' we are proposing that during the initial evaluation, the CMHC would have to provide the client and the client's representative (if appropriate) or surrogate with verbal and written notice of the client's rights and responsibilities in a language and manner that the individual understands. Communicating with the clients, and their representative or surrogate, including the provision of a written notice of rights, in a manner that meets their communication needs is a standard practice in the health care industry. Similar requirements already exist for many other health care provider types, including hospice providers, long term care facilities, ambulatory care surgery centers, and end-stage renal disease facilities. Because we are proposing a requirement that is fully compatible with existing civil rights requirements and guidance, we believe that this proposed standard will impose no additional costs.

This standard would require a CMHC to develop a notice of rights statement to be provided to each CMHC client. We estimate that it would require 8 hours on a one-time basis to develop this notice, and that the CMHC administrator would be responsible for this task, at a cost of $424 per CMHC and $94,976 for all CMHCs nationwide. In addition, this standard would require a CMHC to provide each CMHC client and representative verbal and written notification of the CMHC client's rights, and obtain a signature certifying that they received such notification at the time of the initial evaluation. We estimate the burden for the time associated with disclosing the information would be 2.5 minutes per client or approximately 4.67 hours per CMHC. Similarly, we estimate that the burden for the CMHC to document the information would take 2.5 minutes per client or approximately 4.67 hours per CMHC. At an average of 5 minutes (.0833 hours) per client to complete both tasks, we estimate that all CMHCs would use 2090 hours to comply with this proposed requirement (.0833 hours per client × 25,087 clients). The estimated cost associated with these requirements would be $75,240, based on a psychiatric nurse performing this function (2090 hours × $36 per hour).

With respect to the proposed CoP for client rights, the proposed standard addressing violations of client rights would require a CMHC to investigate alleged client rights violations, take corrective actions when necessary and appropriate, and report verified violations to State and local bodies having jurisdiction. We estimate that the CMHC administrator would spend, on average, 30 minutes investigating each alleged client rights violation. For purposes of our analysis, we assume that an average CMHC would investigate 1 alleged violation per week, for a total of 26 hours annually, at a cost of $1,378 annually per CMHC. All CMHCs nationwide would require 5,824 hours at an estimated cost of $308,672.

In addition, we are proposing three standards under the CoP for client rights pertaining to restraint and seclusion, staff training requirements for restraints and seclusion, and death reporting requirements. These proposed standards would include requirements that guide the appropriate use of seclusion and restraint interventions in CMHCs when necessary to ensure the physical safety of the client and others while awaiting transport to a hospital. They are adapted to reflect the clients' rights CoP for hospitals published as a final rule in the **Federal Register** on December 8, 2006 (71 FR 71378), and codified at § 482.13.

While we anticipate that CMHCs would be impacted by these proposed standards, we do not have access to several key pieces of information to estimate the burden. For example, we do not have reliable data on the prevalence of restraint and seclusion use, the volume of staff in CMHCs, or the varying levels and qualifications of CMHC staff who may use restraint seclusion. Factors such as size, services rendered, staffing, and client populations vary as well. We are hesitant to make impact estimates in this proposed rule that may not account for these and other unforeseen variations. Therefore, we reserve the right to provide estimates when feasible. Below we discuss the anticipated effects on providers of the standards related to restraints and seclusion.

The proposed restraint and seclusion standards would set forth the client's rights in the event he or she is restrained or secluded, and would limit when and by whom restraint or seclusion could be implemented. We recognize that there would be some impact associated with performing client assessment and monitoring to ensure that seclusion or restraint are only used when necessary to protect the client and others from immediate harm, pending transport to the hospital and are implemented in a safe and effective manner. However, client assessment and monitoring are standard components of client care, and this requirement does not pose a burden to a CMHC.

We are proposing to specify elements at § 485.910(e)(4)(v) regarding the documentation that must be included in the client's clinical record when the client is restrained or secluded. We estimate on average that it would take 45 minutes per event for a nurse to document this information. Similarly, we estimate that there will be 1 occurrence of the use of restraint and seclusion per CMHC per year. Based on the nurses hourly rate the total cost for documenting restraint and seclusion would be $27 per CMHC.

The proposed standard on staff training for restraint or seclusion that we are proposing to codify in § 485.910(f) would set out the training requirements for all appropriate client care staff involved in the use of

seclusion and restraint in the CMHC. Training is important for the provision of safe and effective restraint or seclusion use. We would require that, before staff apply restraints, implement seclusion, perform associated monitoring and assessment of the restrained or secluded client, or provide care for a restrained or secluded client, the staff be trained and able to demonstrate competency in the performance of these actions. The proposed staff training requirements would address the following broad areas: training intervals; training contents; trainer requirements; and training documentation.

To reduce regulatory burden and create a reasonable requirement while assuring client safety, we would mandate that only those staff who would be involved in the application of restraint or seclusion or performing associated monitoring and assessment of, or providing care for, restrained or secluded clients would be required to have this training. While we would expect physicians to be trained in the proper use of restraint or seclusion, we do not expect that they would be trained with the other CMHC staff. Therefore, we have not included physicians in the burden associated with these requirements. Instead, we would require that the appropriate CMHC staff who have direct contact with clients must be trained in restraint or seclusion use.

In this proposed rule, we are proposing broad topics to be covered in training, and would not require that staff be trained by an outside organization. We believe that in-house training could be more economical than sending staff off site for instruction. However, CMHCs would have the option of sending either selected or all staff to outside training if they believe this is warranted.

Therefore, we have based our burden estimate on a CMHC nurse being trained by an outside organization (for example, we refer readers to *http://www.crisisprevention.com,* below) to provide such training. We believe that most CMHCs then would have this nurse function as a program developer and as a trainer of the appropriate CMHC staff. In addition, we believe in most instances this professional would be a psychiatric nurse.

Train-the-trainer programs are the way many CMHCs provide staff instruction. For example, the 4-day instructor certification program given by the Crisis Prevention Institute (CPI, Inc.) costs $1,529 for tuition plus travel, lodging, and participant salary. More detailed information regarding the train-the-trainer programs can be found on CPI, Inc.'s Web site at *http://www.crisisprevention.com.*

We estimate, on average, that the cost to train one nurse would include the following expenses: (1) Round trip travel at approximately $400 to cover the need for either local or distant travel; (2) lodging for 3 nights (at $120 per night) for approximately $360; and (3) meals and incidental expenses for 4 days (at $50 per day) for approximately $200, depending upon the location within the particular State. Therefore, we anticipate the cost to train one nurse would be approximately $2,489 plus the nurse's total salary of $1,152 for 4 days (at $288 per day). The total estimated training cost for all CMHCs would be approximately $815,584.

We believe that CMHCs would add seclusion and restraint training onto their existing in-service training programs. The train-the-trainer program described above would provide CMHCs with the necessary personnel and materials to implement a staff-wide seclusion and restraint training program. We estimate that developing this staff-wide training program would require 40 hours of the trainer's time on a one-time basis for all affected CMHCs, at a cost of $1,440 per CMHC.

We would require that each individual who could potentially be involved in restraint and seclusion of a client have training in the proper techniques. According to the National Association of Psychiatric Health Systems (NAPHS), initial training in de-escalation techniques, restraint and seclusion policies and procedures, and restraint and seclusion techniques range from 7 to 16 hours of staff and instructor time.

Due to a lack of data on the average number of employees in a CMHC, for purposes of this analysis only, we assume that an average CMHC would need to train 7 employees in seclusion and restraint techniques. Based on 1 nurse trainer conducting an 8-hour training course for 7 CMHC staff members, we estimate that this requirement would cost $2,248 as calculated below.

- 8 trainer hours at $36/hr = $288
- 56 trainee hours at $35/hr = $1,960
- $288 trainer cost + $1,960 trainee costs = $2,248

We are also proposing to require that each individual receive documented, updated training. Again, according to National Association of Psychiatric Health Systems (NAPHS), annual updates involve about 4 hours of staff and instructor time per employee who has direct client contact. We assume an average size CMHC has 7 employees with direct client contact who must be trained in de-escalation techniques. Therefore, we estimate that it would cost $1,124 annually to update each person's training as shown below.

- 4 trainer hours at $36/hr = $144
- 28 trainee hours at $35/hr = $980
- $144 trainer costs + $980 trainee costs = $1,124

Additionally, we are proposing to require recordkeeping for documenting in each trained individual's personnel record that he or she successfully completed training. We estimate that it would take the trainer 5 minutes per trainee to document each participant's completion of the training. As described above, we estimate that 7 CMHC staff members would require such documentation and have calculated below the estimated total annual cost for this proposed requirement for all CMHCs.

- 5 minutes per trainee × 7 trainees = 35 minutes annually
- 35 minutes × $36/hr = $21 annually
- 35 minutes per CMHC × 224 CMHCs = 130.6 hours nationwide
- 130.6 hours industry wide × $36/hr = $4,701.60 nationwide

We would require that each CMHC revise its training program annually as needed. We estimate this task, which would be completed by the trainer, to take approximately 4 hours annually per CMHC and have calculated below the estimated total annual cost for all CMHCs.

- 4 hours × $36/hr = $144 per CMHC
- $144 per CMHC × 224 CMHCs = $32,256 nationwide

Finally, the proposed standard for reporting client deaths applies to all deaths associated with the use of restraint or seclusion throughout the CMHC. A CMHC would be required to report to CMS each death that occurs while a client is in restraint or seclusion at the CMHC.

Each death would require reporting to CMS by telephone no later than the close of business the next business day following the facility's learning of the client's death. We have no data on which to base an estimate of the number of deaths in CMHCs that may be related to the use of seclusion and restraint. However, based on a lack of complaints to State agencies and CMS, we believe such deaths to be rare occurrences. Although our goals are to ensure the safe and appropriate use of seclusion and restraint and to reduce associated deaths, we are aware that the actual number of reported deaths from seclusion and restraint may increase due to these reporting requirements. Therefore, we anticipate there would be a burden associated with this proposed requirement due to the increased

number of deaths that would be reported by CMHCs. Given the lack of historical data, we assume the number of reports certainly should average less than one per CMHC per year. We believe the impact associated with this proposed provision (that is, making a telephone call and filling in a written report) to be negligible.

Tables 3 and 4 below show the initial year (one-time) and annual estimated CMHC burden, respectively, associated with the proposed standards for the client rights CoP.

TABLE 3—CLIENT RIGHTS BURDEN ASSESSMENT (FIRST YEAR)

Standard	Time per average CMHC (hours)	Total time (in hours)	Cost per average CMHC	Total cost
Client rights form development	8	1,792	$424	$94,976
Client rights notification, signature, and documentation	9.3	2,090	336	75,240
Addressing violations	26	5,824	1,378	308,672
Reporting violations	4.3	971	228	51,463
Documenting Restraint and Seclusion	0.75	168	27	6,048
4 day trainer training	32	7,168	3,641	815,584
Staff training program development	40	8,960	1,440	322,560
Staff training	64	14,336	2,248	503,552
Staff training records	0.58	130.6	21	4,702
Totals 1st year	184.93	41,439.6	9,743	2,182,797

TABLE 4—CLIENT RIGHTS BURDEN ASSESSMENT (ANNUAL)

Standard	Time per average CMHC	Total time (in hours)	Cost per average CMHC	Total cost
Client rights notification, signature, and documentation	9.3 hours	1090	$336	$75,240
Addressing violations	26 hours	5,824	1,378	308,672
Reporting violations	4.3 hours	971	228	51,463
Documenting Restraint and Seclusion	0.75 hours	168	27	6,048
Staff training update	32 hours	7,168	1,124	251,776
Staff training records	35 minutes	130.6	21	4,704
Staff training program update	4 hours	896	144	32,256
Totals Annually	76.85 hours	17,247.6	3,258	730,159

With respect to the proposed CoP for admission, initial evaluation, comprehensive assessment and discharge or transfer of the client, we believe that several of the proposed standards associated with the CoP are unlikely to impose a burden on CMHCs. Specifically, the proposed requirement for admitting a client is standard medical practice; therefore, this requirement would not impose a burden upon a CMHC.

Similarly, the proposed requirement to initially evaluate a client to collect basic information (for example, the admitting diagnosis and referral source) and to determine his or her immediate care and support needs is standard medical practice. Therefore, this requirement would not impose an additional burden upon a CMHC. We believe that this evaluation, conducted by a psychiatric nurse or clinical psychologist, would take 30 to 45 minutes per client.

While we are also proposing to require a comprehensive assessment of each client's needs, this is standard medical practice; therefore, this requirement would not impose a burden upon a CMHC. We believe that each discipline involved in the CMHC interdisciplinary treatment team (physician, psychiatric nurse, clinical social worker, clinical psychologist, occupational therapist, and any other licensed mental health counselors), in coordination with the client's primary care provider (if any), would complete their respective portions of the comprehensive assessment. We estimate that each discipline would spend 20 to 30 minutes completing its portion of the comprehensive assessment, for a total of 2 to 3 hours per client.

Moreover, we do not believe that the proposed requirement to update the comprehensive assessment would impose a burden upon CMHCs. Currently, all CMHCs are required by CMS payment rules (§ 424.24(e)(3)) to recertify a Medicare client's eligibility for partial hospitalization services. Therefore, the 25,087 Medicare beneficiaries who received partial hospitalization services in 2007 have already received an updated assessment in order for the CMHC to recertify their eligibility. In addition, updating client assessments is part of standard medical practice to ensure that care is furnished to meet current client needs and treatment goals. Therefore, we believe that this requirement would not impose a burden upon a CMHC. We estimate that updating the comprehensive assessment would require 30 minutes per client.

Further, as part of the CMHC care model, it is assumed that clients will eventually be discharged or transferred from the CMHC's care. As such, CMHCs routinely plan for and implement client discharges and transfers. Therefore, we believe that the proposed standard for the discharge or transfer of the client is part of a CMHC's standard practice and would not pose additional burden to CMHCs.

Under the CoP for treatment team, active treatment plan, and coordination of services, we assessed the potential impact of the following proposed standards on CMHCs: Delivery of services, active treatment plan, content of the active treatment plan, review of the active treatment plan, and

coordination of services. First, the standard for delivery of services would set forth the required members of each CMHC's active treatment team and would require these members to work together to meet the needs of each CMHC client. We believe it is standard practice within the CMHC industry to include these identified members in an active treatment team and, therefore, this requirement would not pose a burden.

Furthermore, this standard would require a psychiatric nurse, clinical psychologist, or clinical social worker who is a member of the interdisciplinary treatment team to be designated for each client as a care coordinator. The designated individual would be responsible for coordinating an individual client's care, including ensuring that the client's needs are fully assessed and reassessed in a timely manner and that the client's active treatment plan is fully implemented. CMHCs may choose to assign a single individual to perform this function for all clients of the CMHC or it may divide this duty between several individuals, assigning specific clients to specific individuals. While we believe that CMHCs already actively work to coordinate client assessment, care planning, and care implementation, we also believe that designating specific individuals to perform this function may be new to CMHCs. We estimate that, on average, designated CMHC staff would spend 20 to 30 minutes per week (37 to 56 hours annually) overall to fulfill this requirement. The annual cost per CMHC associated with this requirement would be $1,332 to $2,016 for a psychiatric registered nurse, $1,776 to $2,688 for a clinical psychologist, or $1,036 to $1,568 for a clinical social worker. The aggregate annual cost for all CMHCs would be $298,368 to $451,584 if a psychiatric registered nurse is used; $397,824 to $602,112 if a clinical psychologist is used, or $232,064 to $351,232, if a clinical social worker is used. This estimated burden is shown in Table 5 below.

Finally, subsection (a)(3) of this standard would require a CMHC that has more than one interdisciplinary treatment team to designate a single team that is responsible for establishing policies and procedures governing the day-to-day provision of CMHC care and services. We believe that using multiple disciplines to establish client care policies and procedures is standard practice and does not pose a burden.

The proposed active treatment plan standard and its content would set forth the requirements for each client's active treatment plan. The written active treatment plan would be established by the client and interdisciplinary treatment team. It would address the client's needs as they were identified in the initial evaluation and subsequent comprehensive assessment. The treatment plan would include several required elements (for example, an identification of a client's treatment goals and his or her prescribed drugs), all of which are considered to be standard practice in the mental health care industry. We estimate that establishing the first comprehensive active treatment plan would require 45 minutes of the interdisciplinary treatment team's time. The burden associated with this proposed requirements would be the time it would take to document the active treatment plan in the clinical record. We estimate that compliance with the requirements at § 485.916(c) would require a nurse a total of 45 minutes per client, for a total of 84 hours per CMHC. Based on the nurses' hourly rate, the total cost would be $3,024 per CMHC.

The proposed standard for review of the active treatment plan would require the interdisciplinary treatment team to review and revise the active treatment plan as necessary, but no less frequently than every 30 calendar days. The revised treatment plan would include several required elements, such as the client's progress toward the treatment goals identified in the previous treatment plan. We estimate that updating the active treatment plan would require 15 minutes of the interdisciplinary treatment team's time. The burden associated with this proposed requirement would be the time it would take to update the active treatment plan as a client's care progresses (estimated to be 15 minutes). Therefore, we estimate that compliance with the requirements at § 485.916(d) would require a nurse a total of 15 minutes per client, for a total of 28 hours per CMHC. Based on the nurses' hourly rate, the total cost would be $1,008 per CMHC.

In addition, the proposed coordination of services standard would require a CMHC to have and maintain a system of communication, in accordance with its own policies and procedures, to ensure the integration of its services and systems. This communication would be required to, among other things, ensure that information is shared among all disciplines providing care and services for each client and ensure that information is shared with other health care providers, including the client's primary care provider (if any) that care for CMHC clients as necessary and appropriate. We believe that active communication within health care providers, including CMHCs, is standard practice; therefore, this requirement would not impose a burden.

Table 5 below shows the annual estimated CMHC burden associated with the proposed standards for the treatment team, active treatment plan, and coordination of services CoP.

TABLE 5—TREATMENT TEAM, ACTIVE TREATMENT PLAN, AND COORDINATION OF SERVICES BURDEN ASSESSMENT

	Time per average CMHC (in hours)	Total time (in hours)	Cost per average CMHC	Total cost
Psychiatric Registered Nurse Coordinator.	37 to 56	8,288 to 12,544	$1,332 to $2,016	$298,368 to $451,584
	Average: 47	Average: 10,416	Average: $1,674	Average: $374,976
Clinical Psychologist	37 to 56	8,288 to 12,544	$1,776 to $2,688	$397,824 to $602,112
	Average: 47	Average: 10,416	Average: $2,232	Average: $499,968
Clinical Social Worker	37 to 56	8,288 to 12,544	$1,036 to $1,568	$232,064 to $351,232
	Average: 47	Average: 10,416	Average: $1,302	Average: $291,648
** Total Average (for all disciplines).	Total Average: 47	Total Average Range: 8,288–10,416.	Total Average Range: $1,381–$2,613.	Total Average Range: $309,418–$468,309
		Total Average: 9,352	Total Average: $1,736	Total Average: $388,864
Development of the Active Treatment Plan.	84 hours	18,816 hours	$3,024	$677,376
Review and Update of the Active treatment Plan.	28 hours	6,272 hours	$1008	$225,792

TABLE 5—TREATMENT TEAM, ACTIVE TREATMENT PLAN, AND COORDINATION OF SERVICES BURDEN ASSESSMENT—Continued

	Time per average CMHC (in hours)	Total time (in hours)	Cost per average CMHC	Total cost
Total	159 hours	34,440 hours	$5,768	$1,292,032

* **Note:** CMHC will choose one of the providers in table 5 to coordinate each client care.
** **Note:** The Total columns represent an average of all 3 provider type.

Quality Assessment and Performance Improvement (§ 485.917)

The proposed rule would provide guidance to the CMHC on how to establish a quality assessment and performance improvement program. Based on an annual census of 112 Medicare beneficiaries per CMHC, it is estimated that a CMHC would spend approximately 24 hours a year to implement a quality assessment and performance improvement program. Many providers are already using comprehensive quality assessment and performance improvement programs for accreditation or independent improvement purposes. For those providers who choose to develop their own quality assessment and performance improvement program, we estimate that it would take 12 hours to create a program. We also estimate that CMHCs would spend 4 hours a year collecting and analyzing data. In addition, we estimate that CMHC would spend 3 hours a year training their staff and 5 hours a year implementing performance improvement activities. Both the program development and implementation would most likely be managed by that CMHC's administration. Based on an administrator's hourly rate, the total cost of the quality assessment and performance improvement condition of participation would be $1,272 per CMHC.

$53 per hour × 24 hours = $1,272

We believe that these estimates may not be a complete reflection of the impact that this CoP may have on CMHCs, because we do not know the total number of clients served by CMHCs. Therefore, we are requesting public comment regarding the total number of all clients served by CMHCs annually and the length of time on service.

(a) Standard: Program scope. This standard would require that the CMHC assess its organization and develop a formal quality assessment and performance improvement program that is capable of showing measurable improvement through the use of quality indicator data.

(b) Standard: Program data. The proposed rule would require the use of quality indicator data in a quality assessment and performance improvement program, but would not require any specific data collection or utilization, nor would it require CMHCs to report the collected data. CMHCs would, therefore, be provided flexibility with minimal burden. The CMHC must use the data to monitor the effectiveness and safety of services and quality of care. As part of the monitoring process, the data must be used to assist in the prioritization of the aforementioned opportunities for improvement.

(c) Standard: Program activities. This standard would identify certain areas that would be required to be covered in a CMHC's customized quality assessment and performance improvement program. The categories would be sufficiently broad to allow for a vast range of acceptable compliance methods. This would minimize burden.

Table 6 below shows the annual estimated CMHC burden associated with the proposed standards for the quality assessment and performance improvement CoP.

TABLE 6—QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT BURDEN ASSESSMENT

Standard	Time per CMHC (hours)	Total time (hours)	Cost per CMHC	Total cost
QAPI development	12	2688	$636	$142,464
QAPI implementation	12	2688	636	142,464
Total annually	24	5376	1272	284,928

Under the proposed CoP for organization, governance, administration of services, and partial hospitalization services, we assessed the potential impact of the following proposed standards on CMHCs: governing body and administration, provision of services, professional management responsibility, staff training, and physical environment. The proposed governing body and administration standard would require a CMHC to have a designated governing body that assumes full legal responsibility for management of the CMHC. This standard would also require the CMHC governing body to appoint an administrator, in accordance with its own education and experience requirements, who is responsible for the day-to-day operations of the CMHC. Having a governing body and a designated administrator are standard business practices; therefore, this requirement would not impose a burden.

The proposed provision of services standard would set forth a comprehensive list of services that CMHCs are currently required by statute and regulation to furnish. This standard would also require the CMHC and all individuals furnishing services on its behalf to meet applicable State licensing and certification requirements. As this standard is a compilation of requirements that CMHCs must already meet, it would not impose a burden.

In addition, the proposed professional management responsibility standard would require that, if a CMHC chooses to provide certain services under agreement, it must ensure that the agreement is written. This standard would also require the CMHC to retain full professional management responsibility for the services provided under arrangement on its behalf. Full

professional management responsibility would include paying for the arranged services and ensuring that the services are furnished in a safe and effective manner. Having a written agreement and retaining professional management of all care and services provided is standard practice in the health care industry. Therefore, this requirement would not impose a burden.

Further, the proposed staff training standard would require a CMHC to educate all staff who have contact with clients and families about CMHC care and services. It would also require a CMHC to provide an initial orientation for each staff member that addresses his or her specific job duties. Educating staff about the nature of CMHC care and their particular job duties are standard practices that would not impose a burden upon CMHCs.

This standard also would require a CMHC to assess the skills and competency of all individuals furnishing client and family care in accordance with its own written policies and procedures. Finally, this standard would require a CMHC to provide and document its in-service training program. This proposed standard does not prescribe the content or format of the CMHC's skills assessment and in-service training programs. Rather, it would allow CMHCs to establish their own policies and procedures to meet their individual needs and goals. Due to this inherent flexibility, we cannot estimate the impact of this proposed provision at this time; therefore, we specifically invite comments on this issue.

The proposed physical environment standard would require CMHCs to furnish services in a safe, comfortable, and private environment that meets all Federal, State, and local health and safety requirements and occupancy rules. We believe that this proposed requirement would not impose a burden on CMHCs as it is considered standard practice to provide services in a physical location that is both safe and conducive to meeting the needs of CMHC clients.

This proposed standard would also require a CMHC to have an infection control program. While basic precautions such as thorough hand washing and proper disposal of medical waste are standard practice, developing a comprehensive infection control program may impose a burden on CMHCs. We estimate that an administrator would spend 8 hours on a one-time basis developing infection control policies and procedures and 2 hours per month conducting follow up efforts. The estimated cost associated with this proposed provision would be $424 to develop the infection control program and $1,272 annually to follow-up on infection control issues in the CMHC. We believe that staff education regarding infection control will be incorporated into the CMHC's in-service training program, described above.

Table 7 below shows the initial year (one-time) and annual estimated CMHC burden, respectively, associated with the proposed standards for the organization, governance, administration of services, and partial hospitalization services CoP.

TABLE 7—ORGANIZATION, GOVERNANCE, ADMINISTRATION OF SERVICES, AND PARTIAL HOSPITALIZATION SERVICES BURDEN ASSESSMENT

	Time per average CMHC (in hours)	Total time (in hours)	Cost per average CMHC	Total cost
Infection control policies and procedures	8	1,792	$424	$94,976
Infection control follow-up	24	5,376	1,272	284,928
Total 1st year	32	7,168	1,696	379,904
Total annually	24	5,376	1,272	284,928

Table 8 below shows the initial year (one-time) and annual estimated CMHC burden, respectively, associated with all requirements in this proposed CMHC rule.

TABLE 8—TOTAL BURDEN ASSESSMENT FOR ALL REQUIREMENTS IN THE FIRST YEAR COP

	Total time (hours) per average CMHC	Total industry time	Total cost per average CMHC	Total industry cost
Client rights	1st year: 184.93 Annual: 76.85	1st year: 41,439.6 Annual: 17,247.6	1st year: $9,743 Annual: $3,258	1st year: $2,182,797 Annual: $730,159
Treatment team. Active Treatment Plan, and Coordination of Services.	Range: 37–56 Average: 47 Total: 159	Range: 8,288–12,544 Average: 10,416 Total: 34,440	Range: $1,381–$2,613. Average: $1,736 $5,768	Range: $309,418–$468,309 Average: $388,864 Total: 1,292,032
Quality Assessment and Performance Improvement.	24	5,376	$1,272	$284,928
Organization, Governance, Administration of Services.	1st year: 32 Annual: 24	1st year: 7,168 Annual: 5,376	1st year: $1,696 Annual: $1,272	1st year: $379,904 Annual: $284,928
Totals	1st year: 399.93 Annual: 283.93	1st year: 88,423.6 Annual: 62,439.6	1st year: $18,479 Annual: $11,570	1st year: $4,139,661 Annual: $2,592,047

All first year costs include the annual burden for Treatment team, Active Treatment Plan, and Coordination of Services and Quality Assessment and Performance Improvement CoPs.

We believe that the burden associated with this rule is reasonable and necessary to ensure the health and safety of all CMHC clients.

1. Estimated Effects of Proposed CoPs for CMHCs on Other Providers

We do not expect the proposed CoPs for CMHCs included in this proposed rule to affect any other providers.

2. Estimated Effects of Proposed CoPs for CMHCs on the Medicare and Medicaid Programs

The costs to the Medicare and Medicaid programs resulting from implementation of the proposed CoPs for CMHCs included in this proposed rule would be negligible.

C. Alternatives Considered

We considered not proposing CoPs for CMHCs. These providers have been operating without federally-issued health and safety requirements since the 1990 inception of Medicare coverage of partial hospitalizations services in CMHCs. In place of Federal standards, we have relied upon State certification and licensure requirements to ensure the health and safety of CMHC clients. However, CMS has learned that most States either do not have certification or licensure requirements for CMHCs or that States do not apply such certification or licensure requirements to CMHCs that are for-profit, privately owned, and/or not receiving State funds. Due to the significant gaps in State requirements to ensure the health and safety of CMHC clients, we chose to propose a core set of health and safety requirements that would apply to all CMHCs receiving Medicare funds, regardless of the State in which the CMHC is located. These requirements would ensure a basic level of services provided by qualified staff.

We also considered proposing a comprehensive set of CoPs for CMHCs. Such a comprehensive set of CoPs would go beyond the requirements in this proposed rule to address other areas of CMHC services and operations, such as the specific contents of a CMHC's quality assessment and performance improvement program, and its specific clinical record content and procedures. While we believe that these areas are important and may warrant additional consideration in future rulemaking, we do not believe that it is appropriate to begin with an expansive set of CoPs. A comprehensive set of CoPs may be difficult for CMHCs to manage, considering that many CMHCs are not currently required to meet any health and safety standards. Rather than potentially overwhelming CMHCs with a substantial number of new requirements at one time, we chose to focus on a set of requirements and allow for the option of additional CoPs in the future.

D. Conclusion

As stated earlier, we estimate that the changes that we are proposing in this proposed rule to implement CoPs for CMHCs will not have a significant economic effect on Medicare payments to CMHCs. We estimate that this proposal would cost CMHCs approximately $4.1 million, or $18,475 per average CMHC, in the first year of implementation and approximately $2.6 million, or $11,566 per average CMHC, annually. We believe that the burden that would be associated with this rule is reasonable and necessary to ensure the health and safety of all CMHC clients.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

List of Subjects in 42 CFR Part 485

Grant programs—Health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

1. The authority citation for part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395 (hh)).

2. Add a new subpart J to part 485 to read as follows:

Subpart J—Conditions of Participation: Community Mental Health Centers (CMHCs)

Sec.

Subpart J—Conditions of Participation: Community Mental Health Centers (CMHCs)

§ 485.900 Basis and scope.

(a) *Basis.* This subpart is based on the following sections of the Social Security Act:

(1) Section 1832(a)(2)(J) of the Act specifies that payments may be made under Medicare Part B for those partial hospitalization services furnished by a community mental health center (CMHC) that are defined in section 1861(ff)(2)(B) of the Act.

(2) Section 1861(ff) of the Act describes the items and services that are covered under Medicare Part B as ''partial hospitalization services'' and the conditions under which the items and services must be provided. In addition, section 1861(ff) of the Act specifies that the entities authorized to provide partial hospitalization services under Medicare Part B include CMHCs and defines that term.

(3) Section 1866(e)(2) of the Act specifies that a provider of services for purposes of provider agreement requirements includes a CMHC as defined in section 1861(ff)(3)(B) of the Act, but only with respect to providing partial hospitalization services.

(b) *Scope.* The provisions of this subpart serve as the basis of survey activities for the purpose of determining whether a CMHC meets the specified requirements that are considered necessary to ensure the health and safety of clients; and for the purpose of determining whether a CMHC qualifies for a provider agreement under Medicare.

§ 485.902 Definitions.

As used in this subpart, unless the context indicates otherwise—

Active treatment plan means an individualized client plan that focuses on the provision of care and treatment services that address the client's physical, psychological, psychosocial, emotional, and therapeutic needs and

goals as identified in the comprehensive assessment.

Community mental health center (CMHC) means an entity as defined in § 410.2 of this chapter.

Comprehensive assessment means a thorough evaluation of the client's physical, psychological, psychosocial, emotional, and therapeutic needs related to the diagnosis under which care is being furnished by the CMHC.

Employee of a CMHC means an individual—

(1) Who works for the CMHC and for whom the CMHC is required to issue a W–2 form on his or her behalf; or

(2) For whom an agency or organization issues a W–2 form, and who is assigned to such CMHC if the CMHC is a subdivision of an agency or organization.

Initial evaluation means an immediate care and support assessment of the client's physical, psychosocial (including a screen for harm to self or others), and therapeutic needs related to the psychiatric illness and related conditions for which care is being furnished by the CMHC.

Representative means an individual who has the authority under State law to authorize or terminate medical care on behalf of a client who is mentally or physically incapacitated. This includes a legal guardian.

Restraint means—

(1) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a client to move his or her arms, legs, body, or head freely, not including devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a client for the purpose of conducting routine physical examinations or tests, or to protect the client from falling out of bed, or to permit the client to participate in activities without the risk of physical harm (this does not include a client being physically escorted); or

(2) A drug or medication when it is used as a restriction to manage the client's behavior or restrict the client's freedom of movement, and which is not a standard treatment or dosage for the client's condition.

Seclusion means the involuntary confinement of a client alone in a room or an area from which the client is physically prevented from leaving.

Volunteer means an individual who is an unpaid worker of the CMHC; or if the CMHC is a subdivision of an agency or organization, is an unpaid worker of the agency or organization and is assigned to the CMHC. All volunteers must meet the standard training requirements under § 485.918(d).

§ 485.904 Condition of participation: Personnel qualifications.

(a) *Standard: General qualification requirements.* All professionals who furnish services directly, under an individual contract, or under arrangements with a CMHC, must be legally authorized (licensed, certified or registered) in accordance with applicable Federal, State and local laws, and must act only within the scope of their State licenses, certifications, or registrations. All personnel qualifications must be kept current at all times.

(b) *Standard: Personnel qualifications for certain disciplines.* The following qualifications must be met:

(1) *Administrator of a CMHC.* A CMHC employee who meets the education and experience requirements established by the CMHC's governing body for that position and who is responsible for the day-to-day operation of the CMHC.

(2) *Clinical psychologist.* An individual who meets the qualifications at § 410.71(d) of this chapter.

(3) *Clinical social worker.* An individual who meets the qualifications at § 410.73(a) of this chapter.

(4) *Mental health counselor.* A professional counselor who is certified and/or licensed by the State in which he or she practices and has the skills and knowledge to provide a range of behavioral health services to clients. The mental health counselor provides services in areas such as psychotherapy, substance abuse, crisis management, psychoeducation, and prevention programs.

(5) *Occupational therapist.* A person who meets the requirements for the definition of ''occupational therapist'' at § 484.4 of this chapter.

(6) *Physician.* An individual who meets the qualifications and conditions as defined in section 1861(r) of the Act and provides the services at § 410.20 of this chapter and has experience providing mental health services to clients.

(7) *Psychiatric registered nurse.* A registered nurse, who is a graduate of an approved school of professional nursing, is licensed as a registered nurse by the State in which he or she is practicing, and has at least 2 years of education and/or training in psychiatric nursing.

(8) *Psychiatrist.* An individual who specializes in assessing and treating persons having psychiatric disorders; is certified by the American Board of Psychiatry and Neurology or has documented equivalent education, training or experience, and is fully licensed to practice medicine in the State in which he or she practices.

§ 485.910 Condition of participation: Client rights.

The client has the right to be informed of his or her rights. The CMHC must protect and promote the exercise of these client rights.

(a) *Standard: Notice of rights and responsibilities.*

(1) During the initial evaluation, the CMHC must provide the client, the client's representative (if appropriate) or surrogate with verbal and written notice of the client's rights and responsibilities. The verbal notice must be in a language and manner that the client or client's representative or surrogate understands. Written notice must be provided, at a minimum, in English.

(2) During the initial evaluation, the CMHC must inform and distribute written information to the client concerning its policies on filing a grievance.

(3) The CMHC must obtain the client's and/or the client representative's signature confirming that he or she has received a copy of the notice of rights and responsibilities.

(b) *Standard: Exercise of rights and respect for property and person.*

(l) The client has the right to—

(i) Exercise his or her rights as a client of the CMHC.

(ii) Have his or her property and person treated with respect.

(iii) Voice grievances and understand the CMHC grievance process; including but not limited to grievances regarding mistreatment and treatment or care that is (or fails to be) furnished.

(iv) Not be subjected to discrimination or reprisal for exercising his or her rights.

(2) If a client has been adjudged incompetent under State law by a court of proper jurisdiction, the rights of the client are exercised by the person appointed in accordance with State law to act on the client's behalf.

(3) If a State court has not adjudged a client incompetent, any legal representative designated by the client in accordance with State law may exercise the client's rights to the extent allowed under State law.

(c) *Standard: Rights of the client.* The client has a right to—

(1) Be involved in developing his or her active treatment plan.

(2) Refuse care or treatment.

(3) Have a confidential clinical record. Access to or release of client information and the clinical record

client information is permitted only in accordance with 45 CFR parts 160 and 164.

(4) Be free from mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of client property.

(5) Receive information about specific limitations on services that he or she will be furnished.

(6) Not be compelled to perform services for the CMHC, and to be compensated by the CMHC for any work performed for the CMHC at prevailing wages and commensurate with the client's abilities.

(d) *Standard: Addressing violations of client rights.* The CMHC must adhere to the following requirements:

(1) Ensure that all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of client property by anyone, including those furnishing services on behalf of the CMHC, are reported immediately by CMHC employees and contracted staff to the CMHC's administrator.

(2) Immediately investigate all alleged violations involving anyone furnishing services on behalf of the CMHC and immediately take action to prevent further potential violations while the alleged violation is being verified. Investigations, and documentation, of all alleged violations must be conducted in accordance with procedures established by the CMHC.

(3) Take appropriate corrective action in accordance with State law if the alleged violation is verified by the CMHC's administration or verified by an outside entity having jurisdiction, such as the State survey and certification agency or the local law enforcement agency; and

(4) Ensure that, within 5 working days of becoming aware of the violation, verified violations are reported to State and local entities having jurisdiction (including the State survey and certification agency).

(e) *Standard: Restraint and seclusion.*

(1) All clients have the right to be free from physical or mental abuse, and corporal punishment. All clients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion, defined in § 485.902, may only be imposed to ensure the immediate physical safety of the client, staff, or other individuals.

(2) The use of restraint or seclusion must be in accordance with the written order of a physician or other licensed independent practitioner who is authorized to order restraint or seclusion in accordance with State law and must not exceed a duration of 1 hour per order.

(3) The CMHC must obtain a corresponding order for the client's immediate transfer to the hospital when restraint or seclusion is ordered.

(4) Orders for the use of restraint or seclusion must never be written as a standing order or on an as-needed basis.

(5) When a client becomes an immediate threat to the physical safety of themselves, staff or other individuals, the CMHC must adhere to the following requirements:

(i) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the client or other individuals from harm.

(ii) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the client or other individuals from harm.

(iii) The use of restraint or seclusion must be implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by State law.

(iv) The condition of the client who is restrained or secluded must be continuously monitored by a physician or by trained staff who have completed the training criteria specified in paragraph (f) of this section.

(v) When a restraint or seclusion is used, there must be documentation in the client's clinical record of the following:

(A) A description of the client's behavior and the intervention used.

(B) Alternatives or other less restrictive interventions attempted (as applicable).

(C) The client's condition or symptom(s) that warranted the use of the restraint or seclusion.

(D) The client's response to the intervention(s) used, including the rationale for continued use of the intervention.

(E) The name of the hospital to which the client was transferred.

(f) *Standard: Restraint or seclusion: Staff training requirements.* The client has the right to safe implementation of restraint or seclusion by trained staff. Application of restraint or seclusion in a CMHC must only be imposed when a client becomes an immediate physical threat to themselves, staff or other individuals.

(1) *Training intervals.* All appropriate client care staff working in the CMHC must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a client in restraint or seclusion and use of alternative methods to restraint and seclusion as follows:

(i) Before performing any of the actions specified in this paragraph (f).

(ii) As part of orientation.

(iii) Subsequently on a periodic basis, consistent with the CMHC's policy.

(2) *Training content.* The CMHC must require all appropriate staff caring for clients to have appropriate education, training, and demonstrated knowledge based on the specific needs of the client population in at least the following:

(i) Techniques to identify staff and client behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion.

(ii) The use of nonphysical intervention skills.

(iii) Choosing the least restrictive intervention based on an individualized assessment of the client's medical and behavioral status or condition.

(iv) The safe application and use of all types of restraint or seclusion used in the CMHC, including training in how to recognize and respond to signs of physical and psychological distress.

(v) Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.

(vi) Monitoring the physical and psychological well-being of the client who is restrained or secluded, including, but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by the CMHC's policy.

(3) *Trainer requirements.* Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address clients' behaviors.

(4) *Training documentation.* The CMHC must document in the staff personnel records that the training and demonstration of competency were successfully completed.

(g) *Standard: Death reporting requirements.* The CMHC must report deaths associated with the use of seclusion or restraint.

(1) The CMHC must report to CMS each death that occurs while a client is in restraint or seclusion awaiting transfer to a hospital.

(2) Each death referenced in paragraph (g)(1) of this section must be reported to CMS Regional Office by telephone no later than the close of business the next business day following knowledge of the client's death.

(3) Staff must document in the client's clinical record the date and time the death was reported to CMS.

§ 485.914 Condition of participation: Admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client.

The CMHC must ensure that all clients admitted into its program are appropriate for the services the CMHC furnishes in its facility.

(a) *Standard: Admission.*

(1) The CMHC must determine that each client is appropriate for the services it provides as specified in § 410.2 of this chapter.

(2) For clients assessed and admitted to receive partial hospitalization services, the CMHC must also meet separate requirements as specified in § 485.918(f).

(b) *Standard: Initial evaluation.*

(1) The CMHC's psychiatric registered nurse or clinical psychologist must complete the initial evaluation within 24 hours of the client's admission to the CMHC.

(2) The initial evaluation, at a minimum, must include the following:

(i) The admitting diagnosis as well as other diagnoses.

(ii) The source of referral.

(iii) The reason for admission as stated by the client or other individuals that are significantly involved.

(iv) Identification of the client's immediate clinical care needs related to the psychiatric diagnosis.

(v) A list of current prescriptions and over-the-counter medications, as well as other substances that the client may be taking.

(vi) For partial hospitalization services only, include an explanation as to why the client would be at risk for hospitalization if the partial hospitalization services were not provided.

(c) *Standard: Comprehensive assessment.*

(1) The comprehensive assessment must be completed by a CMHC physician-led interdisciplinary treatment team, in consultation with the client's primary health care provider (if any).

(2) The comprehensive assessment must be completed in a timely manner, consistent with the client's immediate needs, but no later than 3 working days after admission to the CMHC.

(3) The comprehensive assessment must identify the physical, psychological, psychosocial, emotional, therapeutic, and other needs related to the client's psychiatric illness. The CMHC must ensure that the active treatment plan is consistent with the findings of the comprehensive assessment.

(4) The comprehensive assessment, at a minimum, must include the following:

(i) The reasons for the admission.

(ii) A psychiatric evaluation, completed by a psychiatrist or psychologist with physician counter signature, that includes the medical history and severity of symptoms.

(iii) Information concerning previous and current mental status, including but not limited to, previous therapeutic interventions and hospitalizations.

(iv) Information regarding the onset of symptoms of the illness and circumstances leading to the admission.

(v) A description of attitudes and behavior, including cultural factors that may affect the client's treatment plan.

(vi) An assessment of intellectual functioning, memory functioning, and orientation.

(vii) Complications and risk factors that may affect the care planning.

(viii) Functional status, including the client's ability to understand and participate in his or her own care, and the client's strengths and goals.

(ix) Factors affecting client safety or the safety of others, including behavioral and physical factors.

(x) A drug profile that includes a review of all of the client's prescription and over-the-counter medications; herbal remedies; and other alternative treatments or substances that could affect drug therapy. The profile must provide documentation that includes, but is not limited to, the effectiveness of drug therapy; drug side effects; actual or potential drug interactions; duplicate drug therapy; and drug therapy requiring laboratory monitoring.

(xi) The need for referrals and further evaluation by appropriate health care professionals, including the client's primary health care provider (if any), when warranted.

(xii) Factors to be considered in discharge planning.

(xiii) Identification of the client's current social and health care support systems.

(d) *Standard: Update of the comprehensive assessment.*

(1) The CMHC must update the comprehensive assessment via the CMHC physician-led interdisciplinary treatment team in consultation with the client's primary health care provider (if any), when changes in the client's status, responses to treatment, or goals have occurred.

(2) The assessment must be updated no less frequently than every 30 days.

(3) The update must include information on the client's progress toward desired outcomes, a reassessment of the client's response to care and therapies, and the client's goals.

(e) *Standard: Discharge or transfer of the client.*

(1) If the client is transferred to another facility, the CMHC must, within 48 hours, forward to the facility, a copy of—

(i) The CMHC discharge summary.

(ii) The client's clinical record, if requested.

(2) If a client refuses the services of a CMHC, or is discharged from a CMHC due to noncompliance with the treatment plan, the CMHC must forward to the primary health care provider (if any) a copy of—

(i) The CMHC discharge summary.

(ii) The client's clinical record, if requested.

(3) The CMHC discharge summary must include—

(i) A summary of the services provided, including the client's symptoms, treatment and recovery goals and preferences, treatments, and therapies.

(ii) The client's current active treatment plan at time of discharge.

(iii) The client's most recent physician orders.

(iv) Any other documentation that will assist in post-discharge continuity of care.

(4) The CMHC must adhere to all Federal and State-related requirements pertaining to the medical privacy and the release of client information.

§ 485.916 Condition of participation: Treatment team, client-centered active treatment plan, and coordination of services.

The CMHC must designate a physician-led interdisciplinary treatment team that is responsible, with the client, for directing, coordinating, and managing the care and services furnished for each client. The interdisciplinary treatment team is composed of individuals who work together to meet the physical, medical, psychosocial, emotional, and therapeutic needs of CMHC clients.

(a) *Standard: Delivery of services.*

(1) A physician-led interdisciplinary treatment team must provide the care and services offered by the CMHC.

(2) The CMHC must designate a psychiatric registered nurse, clinical psychologist, or clinical social worker, who is a member of the interdisciplinary team, to coordinate care and treatment decisions with each client, to ensure that each client's needs are assessed and to ensure that the active treatment plan is implemented as indicated. The interdisciplinary

treatment team must include, but is not limited to, individuals who are licensed, and in compliance with State law, to practice in the following professional roles:

(i) A doctor of medicine, osteopathy or psychiatry (who is an employee of or under contract with the CMHC).

(ii) A psychiatric registered nurse.

(iii) A clinical social worker.

(iv) A clinical psychologist.

(v) An occupational therapist.

(vi) Other licensed mental health professionals, as necessary.

(3) If the CMHC has more than one interdisciplinary team, it must designate the treatment team responsible for establishing policies and procedures governing the coordination of services and the day-to-day provision of CMHC care and services.

(b) *Standard: Active treatment plan.* All CMHC care and services furnished to clients must be consistent with an individualized, written, active treatment plan that is established by the CMHC physician-led interdisciplinary treatment team and the client, in accordance with the client's psychiatric needs and goals, within 3 working days of admission to the CMHC. The CMHC must ensure that each client and the client's primary caregiver(s), as applicable, receive education and training provided by the CMHC that are consistent with the client's and caregiver's responsibilities as identified in the active treatment plan.

(c) *Standard: Content of the active treatment plan.* The CMHC must develop an individualized active treatment plan for each client. The active treatment plan must take into consideration client goals and the issues identified in the comprehensive assessment. The active treatment plan must include all services necessary to assist the client in meeting his or her recovery goals, including the following:

(1) Client diagnoses.

(2) Treatment goals.

(3) Interventions.

(4) A detailed statement of the type, duration, and frequency of services, including social work, psychiatric nursing, counseling, and therapy services, necessary to meet the client's specific needs.

(5) Drugs, treatments, and individual and/or group therapies.

(6) Family psychotherapy with the primary focus on treatment of the client's conditions.

(7) The interdisciplinary treatment team's documentation of the client's and representative's (if any) understanding, involvement, and agreement with the plan of care, in accordance with the CMHC's policies.

(d) *Standard: Review of the active treatment plan.* The CMHC interdisciplinary treatment team must review, revise, and document the individualized active treatment plan as frequently as the client's condition requires, but no less frequently than every 30 calendar days. A revised active treatment plan must include information from the client's initial evaluation and comprehensive assessments, the client's progress toward outcomes and goals specified in the active treatment plan, and changes in the client's goals. The CMHC must also meet partial hospitalization program requirements specified under § 424.24(e) of this chapter.

(e) *Standard: Coordination of services.* The CMHC must develop and maintain a system of communication that assures the integration of services in accordance with its policies and procedures and, at a minimum, would do the following:

(1) Ensure that the interdisciplinary treatment team maintains responsibility for directing, coordinating, and supervising the care and services provided.

(2) Ensure that care and services are provided in accordance with the active treatment plan.

(3) Ensure that the care and services provided are based on all assessments of the client.

(4) Provide for and ensure the ongoing sharing of information among all disciplines providing care and services, whether the care and services are provided by employees or those under contract with the CMHC.

(5) Provide for ongoing sharing of information with other health care providers, including the primary health care provider, furnishing services to a client for conditions unrelated to the psychiatric condition for which the client has been admitted.

§ 485.917 Condition of participation: Quality assessment and performance improvement.

The CMHC must develop, implement, and maintain an effective, ongoing, CMHC-wide data-driven quality assessment and performance improvement program (QAPI). The CMHC's governing body must ensure that the program: reflects the complexity of its organization and services; involves all CMHC services (including those services furnished under contract or arrangement); focuses on indicators related to improved behavioral health or other healthcare outcomes; and takes actions to demonstrate improvement in CMHC performance. The CMHC must maintain documentary evidence of its quality assessment and performance improvement program and be able to demonstrate its operation to CMS.

(a) *Standard: Program scope.* (1) The CMHC program must be able to demonstrate measurable improvement in indicators related to improving behavioral health outcomes and CMHC services.

(2) The CMHC must measure, analyze, and track quality indicators, adverse client events, including the use of restraint and seclusion, and other aspects of performance that enable the CMHC to assess processes of care, CMHC services, and operations.

(b) *Standard: Program data.* (1) The program must use quality indicator data, including client care, and other relevant data, in the design of its program.

(2) The CMHC must use the data collected to do the following:

(i) Monitor the effectiveness and safety of services and quality of care.

(ii) Identify opportunities and priorities for improvement.

(3) The frequency and detail of the data collection must be approved by the CMHC's governing body.

(c) *Standard: Program activities.* (1) The CMHC's performance improvement activities must:

(i) Focus on high risk, high volume, or problem-prone areas.

(ii) Consider incidence, prevalence, and severity of problems.

(iii) Give priority to improvements that affect behavioral outcomes, client safety, and client-centered quality of care.

(2) Performance improvement activities must track adverse client events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the CMHC.

(3) The CMHC must take actions aimed at performance improvement and, after implementing those actions, the CMHC must measure its success and track performance to ensure that improvements are sustained.

(d) *Standard: Performance improvement projects.* CMHCs must develop, implement and evaluate performance improvement projects.

(1) The number and scope of distinct performance improvement projects conducted annually, based on the needs of the CMHC's population and internal organizational needs, must reflect the scope, complexity, and past performance of the CMHC's services and operations.

(2) The CMHC must document what performance improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

(e) *Standard: Executive responsibilities.* The CMHC's governing body is responsible for ensuring the following:

(1) That an ongoing QAPI program for quality improvement and client safety is defined, implemented, maintained, and evaluated annually.

(2) That the CMHC-wide quality assessment and performance improvement efforts address priorities for improved quality of care and client safety, and that all improvement actions are evaluated for effectiveness.

(3) That one or more individual(s) who are responsible for operating the QAPI program are designated.

§ 485.918 Condition of participation: Organization, governance, administration of services, and partial hospitalization services.

The CMHC must organize, manage, and administer its resources to provide CMHC services, including specialized services for children, elderly individuals, individuals with serious mental illness, and residents of its mental health services area who have been discharged from an inpatient mental health facility.

(a) *Standard: Governing body and administrator.*

(1) A CMHC must have a designated governing body (or designated person(s)) that assumes full legal authority and responsibility for the management of the CMHC, the services it furnishes, its fiscal operations, and continuous quality improvement.

(2) The CMHC's governing body must appoint an administrator who reports to the governing body and is responsible for the day-to-day operation of the CMHC. The administrator must be a CMHC employee and meet the education and experience requirements established by the CMHC's governing body.

(b) *Standard: Provision of services.*

(1) A CMHC must be primarily engaged in providing the following care and services to all clients served by the CMHC regardless of payer type, and must do so in a manner that is consistent with the following accepted standards of practice:

(i) Provides outpatient services, including specialized outpatient services for children, elderly individuals, individuals with chronic mental illness, and residents of its mental health services area who have been discharged from inpatient mental health facilities.

(ii) Provides 24-hour-a-day emergency care services.

(iii) Provides day treatment, partial hospitalization services other than in an individual's home or in an inpatient or residential setting, or psychosocial rehabilitation services.

(iv) Provides screening for clients being considered for admission to State mental health facilities to determine the appropriateness of such services, unless otherwise directed by State law.

(v) Provides at least 40 percent of its items and services to individuals who are not eligible for benefits under title XVIII of the Act, as measured by the total revenues received by the CMHC that are payments from Medicare versus payers other than Medicare.

(vi) Provides individual and group psychotherapy utilizing a psychiatrist, psychologist, or other licensed mental health counselor, to the extent authorized under State law.

(vii) Provides physician services.

(viii) Provides psychiatric nursing services.

(ix) Provides clinical social work services.

(x) Provides family counseling services, with the primary purpose of treating the individual's condition.

(xi) Provides occupational therapy services.

(xii) Provides services of other staff trained to work with psychiatric clients.

(xiii) Provides drugs and biologicals furnished for therapeutic purposes that cannot be self-administered.

(xiv) Provides client training and education as related to the individual's care and active treatment.

(xv) Provides individualized therapeutic activity services that are not primarily recreational or diversionary.

(xvi) Provides diagnostic services.

(2) The CMHC and individuals furnishing services on its behalf must meet applicable State licensing and certification requirements.

(c) *Standard: Professional management responsibility.* A CMHC that has a written agreement with another agency, individual, or organization to furnish any services under arrangement must retain administrative and financial management and oversight of staff and services for all arranged services. As part of retaining financial management responsibility, the CMHC must retain all payment responsibility for services furnished under arrangement on its behalf. Arranged services must be supported by a written agreement which requires that all services be as follows:

(1) Authorized by the CMHC.

(2) Furnished in a safe and effective manner.

(3) Delivered in accordance with established professional standards, the policies of the CMHC, and the client's active treatment plan.

(d) *Standard: Staff training.*

(1) A CMHC must provide education about CMHC care and services, and client-centered planning to all employees, volunteers, and staff under contract who have contact with clients and their families.

(2) A CMHC must provide an initial orientation for each individual furnishing services that addresses the specific duties of his or her job.

(3) A CMHC must assess the skills and competence of all individuals furnishing care and, as necessary, provide in-service training and education programs where indicated. The CMHC must have written policies and procedures describing its method(s) of assessing competency and must maintain a written description of the in-service training provided during the previous 12 months.

(e) *Standard: Physical environment.*

(1) *Environmental conditions.* The CMHC must provide a safe, functional, sanitary, and comfortable environment for clients and staff that is conducive to the provision of services that are identified in paragraph (b) of this section.

(2) *Building.* The CMHC services must be provided in a location that meets Federal, State, and local health and safety standards and State health care occupancy regulations.

(3) *Infection control.* There must be policies, procedures, and monitoring for the prevention, control, and investigation of infection and communicable diseases with the goal of avoiding sources and transmission of infection.

(4) *Therapy sessions.* The CMHC must ensure that individual or group therapy sessions are conducted in a manner that maintains client privacy and ensures client dignity.

(f) *Standard: Partial hospitalization services.* A CMHC providing partial hospitalization services must—

(1) Provide services as defined in § 410.2 of this chapter.

(2) Provide the services and meet the requirements specified in § 410.43 of this chapter.

(3) Meet the requirements for coverage as described in § 410.110 of this chapter.

(4) Meet the content of certification and plan of treatment requirements as described in § 424.24(e) of this chapter.

(g) *Standard: Compliance with Federal, State, and local laws and regulations related to the health and safety of clients.* The CMHC and its staff must operate and furnish services in compliance with all applicable Federal, State, and local laws and regulations related to the health and safety of clients. If State or local law provides for

licensing of CMHCs, the CMHC must be licensed. The CMHC staff must follow the CMHC's policies and procedures.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: May 26, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: June 3, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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