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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, September 14, 2010
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

Animal and Plant Health Inspection Service

9 CFR Parts 102, 103, 104, 108, 112, 113, 114, 116, and 124

[Docket No. APHIS–2009–0069]

Viruses, Serums, Toxins, and Analogous Products and Patent Term Restoration; Nonsubstantive Amendments

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: On April 21, 2010, the Animal and Plant Health Inspection Service published a direct final rule. (See 75 FR 20771–20773.) The direct final rule notified the public of our intention to amend the Virus-Serum-Toxin Act regulations concerning veterinary biological products to update the addresses provided for units within the Center for Veterinary Biologics and to make several nonsubstantive technical changes to the regulations to update information concerning the number of copies of Outlines of Production and labeling to submit, and to provide information concerning using the Internet to obtain forms and apply for veterinary biologics permits. We did not receive any written adverse comments or written notice of intent to submit adverse comments in response to the direct final rule.

DATES: *Effective Date:* The effective date of the direct final rule is confirmed as June 21, 2010.

FOR FURTHER INFORMATION CONTACT: Dr. Albert P. Morgan, Chief of Operational Support Section, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231; (301) 734–8245.

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 8th day of July 2010.

Kevin Shea

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2010–17076 Filed 7–13–10: 1:33 pm]

BILLING CODE 3410–34–S

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2009–1190; Airspace Docket No. 09–ANM–27]

Establishment of Class E Airspace; Kemmerer, WY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action will establish Class E airspace at Kemmerer, WY to accommodate aircraft using a new Area Navigation (RNAV) Global Positioning System (GPS) Standard Instrument Approach Procedures (SIAPs) at Kemmerer Municipal Airport. This will improve the safety and management of Instrument Flight Rules (IFR) operations at the airport.

DATES: Effective date, 0901 UTC, September 23, 2010. The Director of the Federal Register approves this incorporation by reference action under 1 CFR Part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

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:

History

On March 11, 2010, the FAA published in the **Federal Register** a notice of proposed rulemaking to amend controlled airspace at Kemmerer, WY (75 FR 11477). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6002 and 6005, respectively, of FAA Order 7400.9T signed August 27, 2009, and effective September 15, 2009, which is incorporated by reference in 14 CFR Part 71.1. The Class E airspace designations listed in this document will be published subsequently in that Order.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) Part 71 by establishing Class E surface airspace, and amending Class E airspace extending upward from 700 feet above the surface by amending the geographic coordinates to coincide with the FAA's National Aeronautical Charting Office for Kemmerer Municipal Airport. This action will accommodate IFR aircraft executing new RNAV (GPS) SIAPs at the airport. This action is necessary for the safety and management of IFR operations.

The FAA has determined this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this 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 rule, when promulgated, will 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 discusses the authority of 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 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 Kemmerer Municipal Airport, Kemmerer, WY.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air)

Adoption of the Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends 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 Part 71.1 of the Federal Aviation Administration Order 7400.9T, Airspace Designations and Reporting Points, signed August 27, 2009, and effective September 15, 2009 is amended as follows:

Paragraph 6002 Class E airspace designated as surface areas.

* * * * *

ANM WY, E2 Kemmerer, WY [New]

Kemmerer Municipal Airport, WY
(Lat. 41°49′27″ N., long. 110°33′25″ W.)

Within a 4.3-mile radius of the Kemmerer Municipal Airport, and within 1 mile each side of the 360° bearing from the airport, extending from the 4.3-mile radius to 7 miles north of the airport. This Class E 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.

* * * * *

ANM WY, E5 Kemmerer, WY [Amend]

Kemmerer Municipal Airport, WY
(Lat. 41°49′27″ N., long. 110°33′25″ W.)

That airspace extending upward from 700 feet above the surface within the 8-mile radius of the Kemmerer Municipal Airport, and within 4 miles each side of the 174° bearing from the Kemmerer Airport extending from the airport 11 miles south of the airport, and within 3.6 miles each side of the 354° bearing from the Kemmerer Airport extending from the airport to 16.1 miles northwest of the airport; and that airspace extending upward from 1,200 feet above the surface bounded by a line beginning at lat. 41°30′00″ N., long. 111°00′00″ W.; to lat. 42°10′00″ N., long. 111°00′00″ W.; to lat. 42°10′00″ N., long. 110°00′00″ W.; to lat. 41°30′00″ N., long. 110°00′00″ W.; to lat. 41°15′00″ N., long. 110°23′00″ W.; to point of origin; and excluding that airspace within Federal airways; and the Fort Bridger, WY, Class E airspace areas.

Issued in Seattle, Washington, on June 30, 2010.

John Warner,

Manager, Operations Support Group, Western Service Center.

[FR Doc. 2010–17006 Filed 7–13–10; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 95

[Docket No. 30733; Amdt. No. 488]

IFR Altitudes; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This document adopts miscellaneous amendments to the required IFR (instrument flight rules) altitudes and changeover points for certain Federal airways, jet routes, or direct routes for which a minimum or maximum en route authorized IFR altitude is prescribed. This regulatory action is needed because of changes occurring in the National Airspace System. These changes are designed to provide for the safe and efficient use of the navigable airspace under instrument conditions in the affected areas.

DATES: *Effective Date:* 0901 UTC, July 29, 2010.

FOR FURTHER INFORMATION CONTACT: Harry Hodges, Flight Procedure Standards Branch (AMCAFS–420), Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK 73125) telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This amendment to part 95 of the Federal Aviation Regulations (14 CFR part 95) amends, suspends, or revokes IFR altitudes governing the operation of all aircraft in flight over a specified route or any portion of that route, as well as the changeover points (COPs) for Federal airways, jet routes, or direct routes as prescribed in part 95.

The Rule

The specified IFR altitudes, when used in conjunction with the prescribed changeover points for those routes, ensure navigation aid coverage that is adequate for safe flight operations and free of frequency interference. The reasons and circumstances that create the need for this amendment involve matters of flight safety and operational efficiency in the National Airspace System, are related to published aeronautical charts that are essential to the user, and provide for the safe and efficient use of the navigable airspace. In addition, those various reasons or circumstances require making this amendment effective before the next scheduled charting and publication date of the flight information to assure its timely availability to the user. The effective date of this amendment reflects those considerations. In view of the close and immediate relationship between these regulatory changes and safety in air commerce, I find that notice and public procedure before adopting this amendment are impracticable and contrary to the public interest and that good cause exists for making the amendment effective in less than 30 days.

Conclusion

The FAA has determined that this 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. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 95

Airspace, Navigation (air).

Issued in Washington, DC, on July 7, 2010.

John M. Allen,

Director, Flight Standards Service.

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me by the Administrator, part 95 of the Federal Aviation Regulations (14 CFR part 95) is amended as follows effective at 0901 UTC, July 29, 2010.

■ 1. The authority citation for part 95 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44719, 44721.

■ 2. Part 95 is red to read as follows:

REVISIONS TO IFR ALTITUDES & CHANGEOVER POINTS

[Amendment 488 effective date July 29, 2010]

From	To	MEA	MAA
§ 95.3000 LOW ALTITUDE RNAV ROUTES			
§ 95.3227 RNAV ROUTE T227 IS AMENDED TO READ IN PART			
FIPSU, AK FIX	CUGOB, AK FIX	**11000	17500
*7000—MCA CUGOB, AK FIX, S BND			
*10300—MOCA			
§ 95.3228 RNAV ROUTE T228 IS AMENDED TO READ IN PART			
SHISHMAREF, AK NDB	ECIPI, AK FIX	*10000	17500
*2000—MOCA			
ECIPI, AK FIX	JAPKI, AK FIX	*8000	17500
*3800—MOCA			
JAPKI, AK FIX	PODKE, AK FIX	*13000	17500
*4200—MOCA			
PODKE, AK FIX	CIRSU, AK FIX	3800	17500
CIRSU, AK FIX	BARROW, AK VOR/DME	2000	17500
BARROW, AK VOR/DME	DEADHORSE, AK VOR/DME	*2000	17500
*1500—MOCA			
DEADHORSE, AK VOR/DME	ROCES, AK FIX	*2000	17500
*1300—MOCA			

From	To	MEA
§ 95.6001 VICTOR ROUTES–U.S.		
§ 95.6001 VOR FEDERAL AIRWAY V1 IS AMENDED TO READ IN PART		
ASHES, NC FIX	LAYZE, NC FIX	5000
GRAYM, MA FIX	BOSTON, MA VOR/DME	*4000
*2500—MOCA		
*3000—GNSS MEA		
§ 95.6003 VOR FEDERAL AIRWAY V3 IS AMENDED TO READ IN PART		
#MODENA, PA VORTAC	BIGGY, NJ FIX	*2500
*2500—GNSS MEA		
#MODENA R–056 UNUSABLE.		
§ 95.6012 VOR FEDERAL AIRWAY V12 IS AMENDED TO READ IN PART		
DRAKE, AZ VORTAC	OATES, AZ FIX	10100
OATES, AZ FIX	WINSLOW, AZ VORTAC	10800
§ 95.6025 VOR FEDERAL AIRWAY V25 IS AMENDED TO READ IN PART		
RED BLUFF, CA VORTAC	HOMAN, CA FIX	*4000
*4000—MOCA		
MUREX, CA FIX	KLAMATH FALLS, OR VORTAC	
N BND		*8500
S BND		*11000
*8500—MOCA		
§ 95.6037 VOR FEDERAL AIRWAY V37 IS AMENDED TO READ IN PART		
COLUMBIA, SC VORTAC	RICHE, SC FIX	*4000
*2300—MOCA		
§ 95.6044 VOR FEDERAL AIRWAY V44 IS AMENDED TO READ IN PART		
MARTINSBURG, WV VORTAC	WOOLY, MD FIX	3200
WOOLY, MD FIX	BALTIMORE, MD VORTAC	2600
PALEO, MD FIX	SPEAK, MD FIX	*13500
*2000—GNSS MEA		
PAWLING, NY VOR/DME	ATHOS, NY FIX	3100
ATHOS, NY FIX	GROUP, NY FIX	*8000
*3000—GNSS MEA		
GROUP, NY FIX	ALBANY, NY VORTAC	*6000
*2300—MOCA		

From	To	MEA
*2800—GNSS MEA		
§ 95.6054 VOR FEDERAL AIRWAY V54 IS AMENDED TO READ IN PART		
HARRIS, GA VORTAC	DILLA, GA FIX	7500
DILLA, GA FIX	RESTS, SC FIX	*8000
*6800—MOCA		
RESTS, SC FIX	CLEVA, SC FIX	5000
CLEVA, SC FIX	SPARTANBURG, SC VORTAC	*4000
*3300—GNSS MEA		
§ 95.6056 VOR FEDERAL AIRWAY V56 IS AMENDED TO READ IN PART		
MACON, GA VORTAC	MISTY, GA FIX	*6000
*2200—MOCA		
§ 95.6066 VOR FEDERAL AIRWAY V66 IS AMENDED TO READ IN PART		
GREENWOOD, SC VORTAC	RICHE, SC FIX	*4000
*2100—MOCA		
*2500—GNSS MEA		
RICHE, SC FIX	SANDHILLS, NC VORTAC	*8000
*2300—MOCA		
*2500—GNSS MEA		
§ 95.6070 VOR FEDERAL AIRWAY V70 IS AMENDED TO READ IN PART		
GRAND STRAND, SC VORTAC	#WILMINGTON, NC VORTAC	*3100
*3100—GNSS MEA		
#WILMINGTON R–240 UNUSABLE		
WILMINGTON, NC VORTAC	BEULA, NC FIX	*8000
*5000—GNSS MEA		
§ 95.6071 VOR FEDERAL AIRWAY V71 IS AMENDED TO READ IN PART		
NATCHEZ, MS VOR/DME	MONROE, LA VORTAC	2000
§ 95.6091 VOR FEDERAL AIRWAY V91 IS AMENDED TO READ IN PART		
PLATTSBURGH, NY VORTAC	U.S. CANADIAN BORDER	*6000
*3200—MOCA		
*3500—GNSS MEA		
§ 95.6093 VOR FEDERAL AIRWAY V93 IS AMENDED TO READ IN PART		
CHESTER, MA VOR/DME	KEENE, NH VORTAC	*4000
*3500—GNSS MEA		
§ 95.6097 VOR FEDERAL AIRWAY V97 IS AMENDED TO READ IN PART		
ATLANTA, GA VORTAC	BAPPY, GA FIX	*4000
*3300—MOCA		
BAPPY, GA FIX	NELLO, GA FIX	5000
NELLO, GA FIX	MELLS, GA FIX	*10000
*5800—GNSS MEA		
MELLS, GA FIX	*HINDE, TN FIX	7400
*6600—MCA HINDE, TN FIX, S BND		
HINDE, TN FIX	TALLA, TN FIX	6600
§ 95.6123 VOR FEDERAL AIRWAY V123 IS AMENDED TO READ IN PART		
*WIGAN, NY FIX	GROUP, NY FIX	**8000
*4500—MRA		
**3000—GNSS MEA		
GROUP, NY FIX	ALBANY, NY VORTAC	*6000
*2300—MOCA		
*2800—GNSS MEA		
§ 95.6140 VOR FEDERAL AIRWAY V140 IS AMENDED TO READ IN PART		
IBAAH, OK FIX	TULSA, OK VORTAC	3300
§ 95.6153 VOR FEDERAL AIRWAY V153 IS AMENDED TO READ IN PART		
LAKE HENRY, PA VORTAC	GROWS, NY FIX	4500

From	To	MEA
GROWS, NY FIX	GEORGETOWN, NY VORTAC	*4500
*3800—MOCA		
*4000—GNSS MEA		
§ 95.6155 VOR FEDERAL AIRWAY V155 IS AMENDED TO READ IN PART		
SINCA, GA FIX	BEYLO, GA FIX	*5000
*2400—MOCA		
*2400—GNSS MEA		
§ 95.6157 VOR FEDERAL AIRWAY V157 IS AMENDED TO READ IN PART		
HAARP, CT FIX	KINGSTON, NY VOR/DME	*7000
*2800—MOCA		
*4000—GNSS MEA		
*WIGAN, NY FIX	GROUP, NY FIX	**8000
*4500—MRA		
**3000—GNSS MEA		
GROUP, NY FIX	ALBANY, NY VORTAC	*6000
*2300—MOCA		
*2800—GNSS MEA		
§ 95.6185 VOR FEDERAL AIRWAY V185 IS AMENDED TO READ IN PART		
SUGARLOAF MOUNTAIN, NC VORTAC	MUMMI, NC FIX	7000
§ 95.6190 VOR FEDERAL AIRWAY V190 IS AMENDED TO READ IN PART		
LAKEY, AZ FIX	GRINE, AZ FIX	
NE BND		*9000
SW BND		*6000
*5300—MOCA		
GRINE, AZ FIX	PEAKS, AZ FIX	*10000
*6700—MOCA		
TEDDI, AZ FIX	ST JOHNS, AZ VORTAC	*13000
*11000—MOCA		
*11000—GNSS MEA		
§ 95.6213 VOR FEDERAL AIRWAY V213 IS AMENDED TO READ IN PART		
GRAND STRAND, SC VORTAC	#WILMINGTON, NC VORTAC	*3100
*3100—GNSS MEA		
#WILMINGTON R–240 UNUSABLE		
WILMINGTON, NC VORTAC	WALLO, NC FIX	*8000
*5000—GNSS MEA		
*WEETS, NY FIX	ALBANY, NY VORTAC	**10000
*6000—MRA		
**6100—MOCA		
**8000—GNSS MEA		
§ 95.6214 VOR FEDERAL AIRWAY V214 IS AMENDED TO READ IN PART		
MARTINSBURG, WV VORTAC	WOOLY, MD FIX	3200
WOOLY, MD FIX	BALTIMORE, MD VORTAC	2600
§ 95.6225 VOR FEDERAL AIRWAY V225 IS AMENDED TO READ IN PART		
MARCI, FL FIX	LEE COUNTY, FL VORTAC	2100
§ 95.6232 VOR FEDERAL AIRWAY V232 IS AMENDED TO READ IN PART		
CHARDON, OH VOR/DME	FRANKLIN, PA VOR	3300, MAA—15000
§ 95.6260 VOR FEDERAL AIRWAY V260 IS AMENDED TO READ IN PART		
CHARLESTON, WV VORTAC	MONTS, WV FIX	3400
MONTS, WV FIX	RAINELLE, WV VOR	5100
§ 95.6264 VOR FEDERAL AIRWAY V264 IS AMENDED TO READ IN PART		
DRAKE, AZ VORTAC	OATES, AZ FIX	10100
OATES, AZ FIX	WINSLOW, AZ VORTAC	10800

From	To	MEA
§ 95.6286 VOR FEDERAL AIRWAY V286 IS AMENDED TO READ IN PART		
DERIN, WV FIX	TEAKK, VA FIX	6900
§ 95.6290 VOR FEDERAL AIRWAY V290 IS AMENDED TO READ IN PART		
*MONTEBELLO, VA VOR/DME *6000—MCA MONTEBELLO, VA VOR/DME, SE BND	ROMAN, VA FIX	6300
ROMAN, VA FIX	ARVON, VA FIX	4000
ARVON, VA FIX *2200—GNSS MEA #FLAT ROCK R–297 UNUSABLE.	#FLAT ROCK, VA VORTAC	*5000
§ 95.6296 VOR FEDERAL AIRWAY V296 IS AMENDED TO READ IN PART		
RAPVY, NC FIX *5000—GNSS MEA	WILMINGTON, NC VORTAC	*8000
§ 95.6300 VOR FEDERAL AIRWAY V300 IS AMENDED TO READ IN PART		
U.S. CANADIAN BORDER *5900—MOCA *5900—GNSS MEA	CAMPO, ME FIX	*9000
CAMPO, ME FIX *6000—MOCA *6000—GNSS MEA	WRAPT, ME FIX	*9000
WRAPT, ME FIX *5900—MOCA *5900—GNSS MEA	MILLINOCKET, ME VOR/DME	*7000
§ 95.6335 VOR FEDERAL AIRWAY V335 IS AMENDED TO READ IN PART		
GLASS, MO FIX *2200—MOCA *3500—GNSS MEA	NIKEL, IL FIX	*4500
§ 95.6364 VOR FEDERAL AIRWAY V364 IS AMENDED TO READ IN PART		
WEAKS, NC FIX *7700—MOCA *7700—GNSS MEA	UNICO, TN FIX	*9000
§ 95.6375 VOR FEDERAL AIRWAY V375 IS AMENDED TO READ IN PART		
PROSE, VA FIX	ROMAN, VA FIX	6500
ROMAN, VA FIX	GORDONSVILLE, VA VORTAC	4000
§ 95.6419 VOR FEDERAL AIRWAY V419 IS AMENDED TO READ IN PART		
BOSTON, MA VOR/DME *2500—MOCA *3000—GNSS MEA	BRADLEY, CT VORTAC	*4000
BIGGY, NJ FIX *2500—GNSS MEA #MODENA R–056 UNUSABLE.	#MODENA, PA VORTAC	*2500
§ 95.6424 VOR FEDERAL AIRWAY V424 IS AMENDED TO READ IN PART		
NAPOLEON, MO VORTAC	MACON, MO VOR/DME	2900
§ 95.6451 VOR FEDERAL AIRWAY V451 IS AMENDED TO READ IN PART		
LA GUARDIA, NY VOR/DME *4000—MRA **1700—MOCA **2000—GNSS MEA	*NESSI, CT FIX	**4000
§ 95.6452 VOR FEDERAL AIRWAY V452 IS AMENDED TO READ IN PART		
KLAMATH FALLS, OR VORTAC	TULIP, CA FIX	9000
TULIP, CA FIX	BACHS, CA FIX	.....
S BND	.....	*14000
N BND	.....	*9000
*11000—GNSS MEA		
BACHS, CA FIX	HALLE, NV FIX	*14000

From	To	MEA
*10200—MOCA *11000—GNSS MEA HALLE, NV FIX *9600—MOCA	MUSTANG, NV VORTAC	*11000
§ 95.6483 VOR FEDERAL AIRWAY V483 IS AMENDED TO READ IN PART		
KINGSTON, NY VOR/DME *6000—MRA **3000—GNSS MEA	*WEETS, NY FIX	**4000
§ 95.6511 VOR FEDERAL AIRWAY V511 IS AMENDED TO READ IN PART		
HALLR, FL FIX *1700—MOCA *5000—GNSS MEA	THNDR, FL FIX	*7000

From	To	MEA	MAA
§ 95.7001 JET ROUTES			
§ 95.7003 JET ROUTE J3 IS AMENDED TO DELETE IN PART			
SPOKANE, WA VORTAC	U.S. CANADIAN BORDER	18000	45000
§ 95.7181 JET ROUTE J181 IS AMENDED TO READ IN PART			
HALLSVILLE, MO VORTAC	BAYLI, IL FIX	18000	23000
BAYLI, IL FIX	BRADFORD, IL VORTAC	18000	45000
§ 95.7190 JET ROUTE J190 IS AMENDED TO READ IN PART			
SLATE RUN, PA VORTAC	BINGHAMTON, NY VORTAC	18000	38000

Airway Segment		Changeover Points	
From	To	Distance	From
§ 95.8003 VOR FEDERAL AIRWAY CHANGEOVER POINTS V12 IS AMENDED TO ADD CHANGEOVER POINT			
DRAKE, AZ VORTAC	WINSLOW, AZ VORTAC	39	DRAKE
V153 IS AMENDED TO MODIFY CHANGEOVER POINT			
LAKE HENRY, PA VORTAC	GEORGETOWN, NY VORTAC	51	LAKE HENRY
V264 IS AMENDED TO ADD CHANGEOVER POINT			
DRAKE, AZ VORTAC	WINSLOW, AZ VORTAC	39	DRAKE
V300 IS AMENDED TO ADD CHANGEOVER POINT			
SHERBROOKE, VORTAC	MILLINOCKET, ME VOR/DME	61	
SHERBROOKE			
V419 IS AMENDED TO ADD CHANGEOVER POINT			
BOSTON, MA VOR/DME	BRADLEY, CT VORTAC	49	BOSTON
V54 IS AMENDED TO ADD CHANGEOVER POINT			
HARRIS, GA VORTAC	SPARTANBURG, SC VORTAC	52	HARRIS
V66 IS AMENDED TO ADD CHANGEOVER POINT			
GREENWOOD, SC VORTAC	SANDHILLS, NC VORTAC	64	
GREENWOOD			

[FR Doc. 2010–17133 Filed 7–13–10; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2010–0613]

Safety Zones: Annual Events Requiring Safety Zones in the Captain of the Port Buffalo Zone

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zones for annual fireworks displays in the Captain of the Port Buffalo Zone from July 2, 2010 through July 31, 2010. This action is necessary to protect the safety of life and property on navigable waters during these events. During the enforcement period, no person or vessel may enter the safety zones without the permission of the Captain of the Port Buffalo.

DATES: This notice provides information about enforcement of safety zones in 33 CFR Part 165.939 enforced from July 2, 2010 at 9:30 p.m. through July 25, 2010 at 10 p.m.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or e-mail MST2 Jessica Seguin, Marine Events Coordinator, Coast Guard Sector Buffalo, 1 Fuhrmann Blvd., Buffalo, NY 14203; Coast Guard telephone 716–843–9353, e-mail *Jessica.L.Seguin@USCG.Mil.*

SUPPLEMENTARY INFORMATION:

The Coast Guard will enforce the following safety zones listed in 33 CFR 165.939:

1. Boldt Castle 4th of July Fireworks on the St. Lawrence River, Heart Island, NY in 33 CFR 165.939(a)(1) on July 4, 2010 from 9 p.m. to 10 p.m.

2. French Festival Fireworks on the St. Lawrence River, Cape Vincent, NY in 33 CFR 165.939(a)(3) on July 10, 2010 from 9:30 p.m. to 10:30 p.m.

3. Brewerton Fireworks on Oneida River near Lake Ontario, Brewerton, NY in 33 CFR 165.939(a)(4) on July 3, 2010 from 9:30 p.m. to 10 p.m.

4. Seneca River Days on the Seneca River, Baldwinsville, NY in 33 CFR 165.939(a)(7) on July 9, 2010 from 9 p.m. to 10 p.m.

5. Oswego Harborfest on Lake Ontario, Oswego, NY in 33 CFR 165.939(a)(8) on July 24, 2010 from 9:30 p.m. to 10 p.m.

6. Village Fireworks on Sodus Bay, Sodus Point, NY in 33 CFR 165.939(a)(9) on July 3, 2010 from 10 p.m. to 10:30 p.m.

7. City of Syracuse Fireworks Celebration on Onondaga Lake, Syracuse, NY in 33 CFR 165.939(a)(10) on July 2, 2010 from 9:30 p.m. to 10:30 p.m.

8. Tom Graves Memorial on Port Bay, Wolcott, NY in 33 CFR 165.939(a)(11) on July 3, 2010 from 9:30 p.m. to 10 p.m.

9. North Tonawanda Fireworks Display on the East Niagara River, North Tonawanda, NY in 33 CFR 165.939(a)(13) on July 4, 2010 from 9 p.m. to 10 p.m.

10. Tonawanda's Canal Fest Fireworks, on the East Niagara River, Tonawanda, NY in 33 CFR 165.393(a)(14) on July 25, 2010 from 9:30 p.m. to 10 p.m.

11. Fairport Harbor Mardi Gras Fireworks on Lake Erie, Fairport Harbor Beach, OH in 33 CFR 165.939(a)(17) on July 5, 2010 from 10 p.m. to 10:30 p.m.

12. Mentor Harbor Yacht Club Fireworks Celebration on Lake Erie, Mentor Harbor, OH in 33 CFR 165.939(a)(19) on July 3, 2010 from 10 p.m. to 10:30 p.m.

13. City of Cleveland 4th of July Fireworks in Cleveland Harbor and Lake Erie, Cleveland, OH in 33 CFR 165.939(a)(21) on July 4, 2010 from 10 p.m. to 10:20 p.m.

14. Lorain 4th of July Celebration in Lorain Harbor, Lorain, OH in 33 CFR 165.939(a)(25) on July 4, 2010 from 10 p.m. to 11 p.m.

These regulations can be found in 73 Fed. Reg. 28704 (May 19, 2008).

Under the provisions of 33 CFR 165.23, entry into, transiting, or anchoring within these safety zones is prohibited unless authorized by the Captain of the Port Buffalo or his designated representative. Vessels that wish to transit through the safety zones may request permission from the Captain of the Port Buffalo. Requests must be made in advance and approved by the Captain of Port before transits will be authorized. Approvals will be granted on a case-by-case basis. The Captain of the Port may be contacted via U.S. Coast Guard Sector Buffalo on channel 16, VHF–FM. The Coast Guard will give notice to the public via a Broadcast to Mariners that the regulation is in effect.

This notice is issued under authority of 33 CFR 165.939 and 5 U.S.C. 552 (a). If the District Commander, Captain of the Port, or other official authorized to do so, determines that the regulated area need not be enforced for the full duration stated in this notice, he or she may use a Broadcast Notice to Mariners to grant general permission to enter the safety zone.

Dated: June 28, 2010.

R.S. Burchell,

Captain, U. S. Coast Guard, Captain of the Port Buffalo.

[FR Doc. 2010–17168 Filed 7–13–10; 8:45 am]
BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2010–0514; FRL–9172–3]

Revisions to the California State Implementation Plan, Sacramento Metropolitan Air Quality Management District and South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve revisions to the Sacramento Metropolitan Air Quality Management District (SMAQMD) and South Coast Air Quality Management District (SCAQMD) portions of the California State Implementation Plan (SIP). These revisions concern volatile organic compound (VOC) from vanishing oils, rust inhibitors, plastic coatings, rubber coatings, glass coatings, and aerospace operations. We are approving local rules that regulate these emission sources under the Clean Air Act as amended in 1990 (CAA or the Act).

DATES: This rule is effective on September 13, 2010 without further notice, unless EPA receives adverse comments by August 13, 2010. If we receive such comments, we will publish a timely withdrawal in the **Federal Register** to notify the public that this direct final rule will not take effect.

ADDRESSES: Submit comments, identified by docket number [EPA–R09–OAR–2010–0514], by one of the following methods:

1. *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the online instructions.

2. *E-mail: steckel.andrew@epa.gov*.

3. *Mail or deliver:* Andrew Steckel (Air-4), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Instructions: All comments 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 Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *http://www.regulations.gov* or e-mail. *http://www.regulations.gov* is an "anonymous access" system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send e-mail directly to EPA, your e-mail address will be automatically captured and included as part of the public comment. 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: The index to the docket for this action is available electronically at *http://www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material), and some may not be publicly available in either location (*e.g.,* CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Nicole Law, EPA Region IX, (415) 947–4126, *law.nicole@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, "we," "us," and "our" refer to EPA.

Table of Contents

I. The State's Submittal

A. What rules did the State submit?

Table 1 lists the rules we are approving with the dates that they were adopted by the local air agencies and submitted by the California Air Resources Board (CARB).

TABLE 1—SUBMITTED RULES

Local agency	Rule No.	Rule title	Adopted/ amended	Submitted
SCAQMD	1144	Vanishing Oils and Rust Inhibitors	03/06/09	05/17/10
SCAQMD	1145	Plastic, Rubber, Leather, and Glass Coatings	12/04/09	05/17/10
SMAQMD	456	Aerospace Assembly and Component Coating Operations	10/23/08	09/15/09

On June 8, 2010, EPA determined that the submittal for SCAQMD 1144 and SCAQMD 1145 met the completeness criteria in 40 CFR Part 51 Appendix V, which must be met before formal EPA review.

On January 21, 2010, EPA determined that the submittal for SMAQMD 456 met the completeness criteria in 40 CFR Part 51 Appendix V, which must be met before formal EPA review.

B. Are there other versions of these rules?

There are no previous versions of SCAQMD Rule 1144 in the SIP. We approved an earlier version of SCAQMD Rule 1145 into the SIP on May 4, 1999 (64 FR 23774). The SCAQMD adopted revisions to the SIP-approved version on December 3, 2004 and December 4, 2009 and CARB submitted them to us on March 17, 2009 and May 17, 2010. An earlier version of SMAQMD Rule 456 was approved into the SIP on November 9, 1998 (63 FR 60214) and the SMAQMD adopted a revision to that version on October 23, 2008. CARB submitted it to us on September 15, 2009. While we can act on only the most recently submitted version, we have reviewed materials provided with previous submittals.

C. What is the purpose of the submitted rules and rule revisions?

VOCs help produce ground-level ozone and smog, which harm human health and the environment. Section 110(a) of the CAA requires States to submit regulations that control VOC emissions. SCAQMD Rule 1144 will regulate vanishing oils and rust inhibitors at industrial facilities. SCAQMD Rule 1145 lowers VOC content limits and begins to regulate the leather coatings. SMAQMD Rule 456 lowers an exemption threshold and the VOC content limit for cleaning solvents. EPA's technical support documents (TSD) have more information about these rules.

II. EPA's Evaluation and Action

A. How is EPA evaluating the rules?

Generally, SIP rules must be enforceable (see section 110(a) of the Act), must require Reasonably Available Control Technology (RACT) for each category of sources covered by a Control Techniques Guidelines (CTG) document as well as each major source in nonattainment areas (see sections 182(a)(2) and (b)(2)), and must not relax existing requirements (see sections 110(l) and 193). The SCAQMD and SMAQMD regulate ozone nonattainment areas (see 40 CFR part 81), so the districts must implement RACT for appropriate source categories.

Guidance and policy documents that we use to evaluate enforceability and RACT requirements consistently include the following:

1. "Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations," EPA, May 25, 1988 (the Bluebook).
2. "Guidance Document for Correcting Common VOC & Other Rule Deficiencies," EPA Region 9, August 21, 2001 (the Little Bluebook).
3. "Model Volatile Organic Compound Rules for Reasonable Available Control Technology," EPA-Staff Working Document, June 1992.
4. "Control Techniques Guidelines for Miscellaneous Metal and Plastic Parts Coatings," EPA–453/R–08–003, September 2008.
5. "Surface Coating Operations at Aerospace Manufacturing & Rework Operations," EPA–453/R–97–004, December 1997.

B. Do the rules meet the evaluation criteria?

We believe these rules are consistent with the relevant policy and guidance regarding enforceability, RACT, and SIP relaxations. SMAQMD Rule 456 has RACT deficiencies, but the rule is not subject to RACT because the one facility

in the district under this category emits less than 25 tons of VOC per year. The TSDs have more information on our evaluation.

C. EPA Recommendations to Further Improve the Rules

The TSDs describe additional rule revisions that we recommend for the next time the local agencies modify the rules.

D. Public Comment and Final Action

As authorized in section 110(k)(3) of the Act, EPA is fully approving the submitted rules because we believe they fulfill all relevant requirements. We do not think anyone will object to this approval, so we are finalizing it without proposing it in advance. However, in the Proposed Rules section of this **Federal Register**, we are simultaneously proposing approval of the same submitted rules. If we receive adverse comments by August 13, 2010, we will publish a timely withdrawal in the **Federal Register** to notify the public that the direct final approval will not take effect and we will address the comments in a subsequent final action based on the proposal. If we do not receive timely adverse comments, the direct final approval will be effective without further notice on September 13, 2010. This will incorporate the rules into the federally enforceable SIP.

Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

III. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act 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 Clean Air Act. 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 Clean Air Act; 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.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register.** A major rule cannot take effect until 60 days after it is published in the **Federal Register.** This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 13, 2010. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the Proposed Rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements (*see* section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: June 18, 2010.

Jared Blumenfeld,

Regional Administrator, Region IX.

■ Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. Section 52.220, is amended by adding paragraphs (c)(377) (i)(A)(*3*) and (379) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(377) * * *

(i) * * *

(A) * * *

(*3*) Rule 456, "Aerospace Assembly and Component Coating Operations," amended on October 23, 2008.

* * * * *

(379) New and amended regulations for the following APCDs were submitted on May 17, 2010 by the Governor's designee.

(i) Incorporation by Reference.

(A) South Coast Air Quality Management District.

(*1*) Rule 1144, "Vanishing Oils and Rust Inhibitors," adopted on March 6, 2009.

(*2*) Rule 1145, "Plastic, Rubber, Leather, and Glass Coatings," amended on December 4, 2009.

* * * * *

[FR Doc. 2010–17077 Filed 7–13–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0533; FRL–8833–2]

Residues of Quaternary Ammonium Compounds, N-Alkyl (C_{12-14}) Dimethyl Ethylbenzyl Ammonium Chloride; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends an existing exemption from the requirement of a tolerance for residues of n-alkyl (C_{12-14}) dimethyl ethylbenzyl ammonium chloride on food contact surfaces when applied/used in public eating places, dairy processing equipment, and/or food processing equipment and utensils. The regulation will exempt from the requirement of tolerance residues in food resulting from contact with surfaces treated with antimicrobial solutions where the end-use concentration of active quaternary compound does not exceed 400 parts per million (ppm).

DATES: This regulation is effective July 14, 2010. Objections and requests for hearings must be received on or before September 13, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0533. 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., Confidential Business Information (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 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 Docket Facility is open 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: Velma Noble, Antimicrobials Division (7510P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–6233; e-mail address: *noble.velma@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are dairy cattle milk producer, food manufacturer, or beverage manufacturer. Potentially affected entities may include, but are not limited to:

- Dairy cattle milk production (NAICS code 11212).
- Food manufacturing (NAICS code 311).
- Beverage manufacturing (NAICS code 3121).

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**.

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0533 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before September 13, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2008–0533, 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.

II. Summary of Petitioned-For Exemption

In the **Federal Register** of November 28, 2007 (72 FR 67299) (FRL–8141–1), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 8F7323) by Stepan Company, 22 West Frontage Rd., Northfield, IL 60093. The petition requested that 40 CFR 180.940(a) be amended by increasing concentration limits for n-alkyl (C_{12-14}) dimethyl ethylbenzyl ammonium chloride in end-use solutions eligible for tolerance exemption. That notice referenced a summary of the petition prepared by Stepan Company, the registrant, which is available in the docket, *http://www.regulations.gov*.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue."

Consistent with section 408(c)(2)(A) of FFDCA, and the factors specified in section 408(c)(2)(B) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for residues of n-alkyl (C_{12-14}) dimethyl ethylbenzyl ammonium chloride on food contact surfaces when applied/used in public eating places, dairy processing equipment, and/or food processing equipment and utensils. EPA's assessment of exposures and risks associated with amending the exemption from the requirement for a tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by n-alkyl (C_{12-14}) dimethyl ethylbenzyl ammonium chloride as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

The alkyl dimethyl benzyl ammonium chlorides (ADBAC) chemical case is comprised of 24 compounds that are structurally similar and are a subgroup of the class of chemicals known as quaternary ammonium compounds. Quaternary ammonium compounds are a class of salts derived from ammonium in which nitrogen atom is attached to four organic groups. ADBAC is characterized by having a positively charged nitrogen atom covalently bonded to three alkyl group substituents (two methyls and R component) and a benzyl substituent. The R component represents the different number of hydrocarbon carbon moieties delineated by different percentages (e.g., Alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}) dimethyl benzyl ammonium chloride). In finished form, these quaternary ammonium compounds are salts with the positively charged nitrogen (cation) balanced by a negatively charged anion. The most common anion for the quaternary ammonium compounds in this cluster is chloride. However, other anions, such as saccharide and bromide are also used. The Agency clustered these chemicals together because variance in the length and conformation of alkyl carbon chains between 12 and 18 does not appear to significantly affect the toxicity or fate of the ADBAC compound. In all ADBACs, it is the positive entity (quaternized nitrogen) that is of relevance from toxicology and exposure perspectives. The negative part of ADBAC (counter ion) is a relatively non-toxic entity (chloride). Alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}) dimethyl benzyl ammonium chloride (PC code 069105) was chosen by the Agency as the representative chemical for the ADBAC subgroup of quaternary ammonium compounds, and the toxicology database for alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}) dimethyl benzyl ammonium chloride is considered representative of the hazard for the ADBAC subgroup. The individual exposure scenarios in the ADBAC assessments (as well as the aggregate assessment in the RED) were developed by assuming that an ADBAC compound was used on 100% of the surfaces authorized on the label that could result in human exposure and summing the percent active ingredients on the labels for all of the ADBAC compounds when used in combination.

Quaternary ammonium compounds are corrosive on contact with the skin and eyes. They typically cause highly-irritating localized effects which occur at the portals of entry. On the other hand, ADBACs are only moderately toxic systemically by oral, dermal, and inhalation routes of exposure. Systemic toxicity occurs after absorption and distribution of the chemical to tissues in the body. Such toxicity is dependent on physiological factors within the tissue/organ, and also how the body eliminates the chemical (Kinetics). These chemicals are classified as "not likely" to be human carcinogens based on negative carcinogenicity studies in both rats and mice. There is no evidence of these chemicals being associated with increased susceptibility to developmental toxicity or reproductive toxicity based on two developmental toxicity studies and a 2–generation reproductive study. Lastly, they are negative for mutagenicity and neurotoxicity. Specific information on the studies received and the nature of the toxic effects caused by ADBAC, can be found at *http://www.regulations.gov*. Docket ID Number EPA–HQ–OPP–2005–0339, Alkyl dimethyl benzyl ammonium chloride (ADBAC)- Report of Antimicrobials Division Toxicity Endpoint Committee (ADTC) and the Hazard Identification Assessment Review Committee (HIARC).

B. Toxicological Points of Departure/Levels of Concern

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. The Level of Concern (LOC) is a reference value expressed as either a reference dose/population adjusted dose (RfD/PAD) or margin of exposure (MOE). Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by

dividing the POD by all applicable uncertainty/safety factors. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded. For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of a cancer occurrence greater than that expected in a lifetime. Generally, cancer risks are considered non-threshold. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for ADBAC used for human risk assessment is shown in Table 1 of this unit.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ADBAC USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (general population, females 13+, infants and children)	An acute dietary endpoint was not identified in the database.		
Chronic dietary (all populations)	NOAEL = 44 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.44 mg/kg/day cPAD = 0.44 mg/kg/day	Chronic toxicity/carcinogencity-rat MRID 41947501 LOAEL = 88 mg/kg/day based on decreased body weight and weight gain
Incidental oral short-term (1 to 30 days)	NOAEL = 10 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Developmental Toxicity-Rat MRID 42351501 LOAEL = 30 mg/kg/day based on clinical signs and decrease body weight gain
Incidental oral intermediate-term (1 to 6 months)	NOAEL = 10 mg/kg/day UF_A = 10x UF_H = 10 x FQPA SF = 1x	LOC for MOE = 100	Developmental Toxicity-Rat MRID 42351501 LOAEL = 30 mg/kg/day based on clinical signs and decrease body weight gain
Dermal short-term (1 to 30 days) (Formulated product (4% ai.))	Dermal study NOAEL = 20 mg/kg/day (333 ug/cm^2)[b] UF_A = 3x UF_H = 3x FQPA SF = 1x	LOC for MOE = 10[d]	21-day dermal toxicity-guinea pigs MRID 41105801 LOAEL = 40 mg/kg/day based on denuded non-vascularized epidermal layer
Dermal intermediate-term (technical grade a.i.) (1 to 6 months)	Dermal study NOAEL= 20 mg/kg/day (80 ug/cm^2)[c] UF_A = 3x UF_H = 3x FQPA SF = 1x	LOC for MOE = 10[d]	90-day dermal in rats MRID 41499601 LOAEL = 20 mg/kg/day based on highest doest tested before irritation became significant. Irritation not observed until day 43
Dermal Short-term (technical grade a.i)	No endpoint identified from the available data on dermal irritation. Dermal irritation in the 90-day dermal toxicity study was not evident until day 43 (MRID 41499601)[d]		
Long-term Dermal (technical grade a.i.)	No appropriate endpoint identified. No systemic effects observed up to 20 mg/kg/day, highest dose of technical that could be tested without irritation effects.[d]		
Inhalation (all exposures)	Oral study NOAEL = 3 mg/kg/day 100% UF_A = 10x UF_H = 10x FQPA SF = 10x (UF_{db})[a]	LOC for MOE = 1000	Developmental Toxicity-rabbit MRID 42392801 LOAEL = 9 mg/kg/day based on clinical signs of toxicity in maternal animals

UF_A = extrapolation from animal to human (interspecies).
UF_H = potential variation in sensitivity among members of the human population (intraspecies).
FQPA SF = FQPA Safety Factor.
PAD = population adjusted dose (a = acute, c = chronic).
RfD = reference dose.
MOE = margin of exposure.

[a] An additional uncertainity factor of 10x is applied for use of an oral endpoint for route-to-route extrapolation in the absence of an inhalation toxicity study.

[b] Formulated-based dermal endpoint = (20 mg/kg guinea pig x 0.43 kg guinea pig x 1,000 ug/mg)/25.8cm^2 area of guinea pig dosed = 33 ug/cm^2.

[c] TGAI-based dermal endpoint = (20 mg/kg rat x 0.2 kg rat x 1000 ug/mg)/ 50 cm^2 area of rate dosed = 80 ug/cm^2.

[d] For dermal exposures, irritation as the effect was selected for the short-term endpoint and a reduced margin of exposure (MOE) was used to characterize the risk. The use of irritation as a toxic endpoint for assessment of dermal risk is appropriate in this case, as dermal exposure that results in primarily an irritation response is considered a self-limiting type of exposure that is not expected to last for any length of time, and variability in the response is not expected to be as great as systemic toxic responses. For ADBAC, the MOE for short-term dermal risk is reduced to a total factor of 10x (3x for interspecies extrapolation, 3x for intraspecies variation.)

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to n-alkyl (C_{12-14}) dimethyl ethylbenzyl ammonium chloride, EPA considered exposure under the petitioned-for exemption as well as all existing ADBAC exemptions or tolerances in 40 CFR 180.940(a), and (c). EPA assessed dietary exposures from ADBAC in food as follows:

ADBACs are to be used as a sanitizer on counter tops, utensils, appliances, tables, refrigerators, food packaging, and beverage bottling. The use of these actives in antimicrobial products for use on food or feed contact surfaces, agricultural commodities, and application to food-grade eggs may result in pesticide residues in human food. Residues from treated surfaces, such as utensils, countertops, equipment, and appliances can migrate to food coming into contact with the treated and rinsed surfaces and can be ingested by humans.

The Agency assessed chronic dietary exposures from the use of ADBAC as a disinfectant and food contact sanitizer on utensils, countertops, and in food/beverage processing facilities. The assessment calculated the Daily Dietary Dose (DDD) and the Estimated Daily Intake (EDI) using modified Food and Drug Administration (FDA) methodologies for utensils and Indirect Dietary Residential Exposure Model software (IDREAM) for countertops. IDREAM incorporates consumption data from U.S. Department of Agriculture (USDA) Continuing Surface of Food Intakes by Individuals (CSFII) for 1994–1996, and 1998. The 1994–1996, and 1998 data are based on the reported consumption of more than 20,000 individuals over 2 non-consecutive survey days.

The Estimated Daily Intake (EDI) calculations presented in this assessment for treated indirect dietary exposures resulting from sanitizing utensils assumed that food would contact 4,000 cm^2 (which represents contact with treated silverware, china, and glass used by an individual who regularly eats three meals per day at an institutional or public facility) and that the residual solution remaining on the surface or pesticide migration fraction is 1 mg per square centimeter of treated area. The body weights used for this assessment were 70 kilogram (kg) for an adult male, 60 kg for an adult woman, and 10 kg for an infant. Based on data provided in a new residue study, Transferability Equivalence among Quats and Measured Food Surrogate Transfer Efficiency (MRID 46870703), a conservative transfer rate of 43% was used to estimate the amount of residues on the surface that will be transferred to food and subsequently ingested. The maximum application rate for ADBAC on utensils is 0.0033 lbs a.i per gallon of treatment solution.

There are two levels of refinement for assessing dietary exposure to antimicrobial products used on countertops. The Tier 2 approach, a refined exposure estimate in comparison to the Tier 1, was utilized for this assessment. This conservative approach uses food consumption and preparation patterns as well as data and assumptions that are not chemical-specific. Food ingredients are separated into nine categories based on food preparation, food physical properties, and potential, or likelihood of contact with treated countertops. The nine food categories are liquids, fruit, bread, cheese, vegetable, meat, purees (e.g., pudding, oatmeal), pieces (foods normally consumed in small pieces), and powders (foods normally used in powder/granular forms). Assumed countertop residues are converted to estimated residues contacting the countertops using a translation factor for each food category, and default residue transfer efficiency for a representative food. Therefore, IDREAM combines the estimated countertop residues for surface treatment products, CSFII consumption data, food-specific conversion factors that relate the surface area contacting a countertop with corresponding weight of the food item, and the transfer efficiency of residues from countertops to food. Conservative assumptions for these analyses include: All disinfectants registered to disinfect kitchen countertops are included; all foods are prepared on treated countertops; all prepared foods will come in contact with treated countertops at the maximum active ingredient (a.i.) residues; these residues will not diminish over time (i.e., residue reduction will not occur from cooking or preparation processes); there is a 100% likelihood of contact to account for both commercial and residential scenarios; all commercial facilities and households use the same disinfectant product; all foods are prepared and consumed.

When assessing the food bottling/packaging use, EPA assumed a 100% transfer rate because the food is potentially in contact with the treated surfaces for very long periods of time. The maximum application rate for ADBAC for bottling/packing of food is 0.0103 lbs a.i per gallon of treatment solution. EDI values were calculated using an approach similar to that used for treated food utensils. Exposure was assumed to occur through the ingestion of three food products that might be packaged in treated material: milk, egg products, and beverages (alcoholic and non-alcoholic). A calorie intake modification factor of 0.64 was applied to the EDI for a child to account for the differences between intake values among children and adults.

2. *Dietary exposure from drinking water.* ADBAC is applied to nursery ornamentals and turf as an bactericide and fungicide. The Tier 1 surface water and groundwater model was used to assess Estimated Drinking Water Concentrations (EDWCs). EPA modeled the ornamental plant use because this use has the highest application rate of all labeled uses — 302 lbs. a.i/Acre, and a maximum of 3 applications per year. The EDWCs determined for the nursery ornamental use are also protective of all other uses with lower application rates. The EDWC for surface water is 331 ug/L and groundwater is 5.4 ug/L. There were no major degradates of ADBAC in the laboratory studies.

ADBAC is also used for mosquito control and as an algaecide in decorative ponds and pools. Because the mosquito control and algaecide uses are both periodic in nature and are restricted to a limited use area, EPA expects drinking water exposures from these uses to be minimal in comparison to the ornamental plant exposure estimate for drinking water using the Tier 1 surface and ground water model.

Additionally, antisapstain and cooling water tower uses for ADBAC are potential exposures to drinking water. These uses are also expected to result in minimal exposure in comparison to the modeled EDWCs for the ornamental use taking into account that the Tier 1 model assumed that ADBAC was applied at 302 lbs./Acre across the entire watershed.

Specific information on the dietary and drinking water exposure assessments for ADBAC can be found at *http://www.regulations.gov*. Docket ID Number EPA–HQ–OPP–2006–0339, Dietary Risk Assessment on ADBAC and Tier 1 Drinking Water Assessment for Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) & Didecyl Dimethyl Ammonium Chloride (DDAC).

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

ADBAC is currently registered for the following residential non-dietary sites: Homes, swimming pools, humidifiers. EPA assessed residential exposure using the following assumptions: Residential exposure may occur during the application as well as post application of ADBAC to indoor hard surfaces (e.g., mopping, wiping, trigger pump sprays), carpets, swimming pools, wood as a preservative, textiles (e.g., diaper treated during washing and clothes treated with fabric spray), and humidifiers. The residential handler scenarios were assessed to determine dermal and inhalation exposures. Residential post application scenarios such as children exposure to treated toys and floors were also assessed to determine dermal and incidental oral exposures. Surrogate dermal and inhalation unit exposure values were estimated using Pesticide Handler Exposure Database (PHED) data and the Chemical Manufactures Association Antimicrobial Exposure Assessment Study (USEPA, 1999), and the SWIMODEL 3.0 was utilized to conduct exposure assessments of pesticides found in swimming pools and spas (Versar, 2003). Note that for this assessment, EPA assumed that residential users complete all elements of an application (mix/load/apply) without the use of personal protective equipment.

The duration for most residential exposures is believed to be best represented by the short-term duration (1 to 30 days). The short-term duration was chosen for this assessment because the residential handler and post-application scenarios are assumed to be performed on an episodic, not daily basis.

Specific information on the residential exposure assessment for ADBAC Quaternaries can be found at *http://www.regulations.gov*. Docket ID Number EPA–HQ–OPP–2006–0339 Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) Occupational and Residential Exposure Assessment.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA's risk assessment for any individual ADBAC is based on an assessment of the cumulative exposure to all ADBACs. The individual exposure scenarios in the ADBAC assessments (as well as the aggregate assessment in the RED) were developed by assuming that an ADBAC compound was used on 100% of the surfaces authorized on the label that could result in human exposure and summing the percent active ingredients on the labels for all of the ADBACs when used in combination. Thus, because the risk assessment for ADBAC accounts for exposures to all of the ADBACs, there is no need for a separate cumulative risk assessment for those compounds. The Agency has not identified any other substances as sharing a common mode of toxicity with ADBAC. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemical, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional (10X) tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA SF value based on the use of traditional UFs and/or FQPA SFs, as appropriate.

2. *Prenatal and postnatal sensitivity*. There is no evidence that ADBAC result in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2–generation reproduction study.

3. *Conclusion*. EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA SF to 1X. That decision is based on the following findings:

i. The toxicity database for ADBAC is complete.

ii. There is no indication that ADBAC is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that ADBAC results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2–generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. Conservative ground and surface water modeling estimates were used. Similarly conservative residential standard operating procedures (SOPs) were used to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by ADBAC.

E. Aggregate Risks and Determination of Safety

The chronic dietary aggregate risk assessment includes direct and indirect food contact uses as well as drinking water exposures. Based on the results of the chronic aggregate assessment, the estimated chronic risks for adults and children are 8.4% and 40.9% of the cPAD. Therefore, the chronic dietary aggregate risks are not of concern (i.e., less than 100% of cPAD).

Short-term and intermediate-term aggregate risks were calculated using the total MOE approach. Only the short-term aggregate is presented here because the endpoints for incidental oral as well as inhalation are identical for the short- and intermediate-term durations. The aggregate risks are not of concern for adults for any of the three routes of exposure. The aggregate adult MOEs are 1,200 for oral, 480 for dermal, and 2,000 for inhalation, which are greater than the target MOE of 100 for the oral, 1,000 for inhalation, and 10 for dermal. For children, the aggregate risk estimate for each of the routes of exposure are also above the target MOEs of 100 for the oral, 1,000 for inhalation, and 10 for dermal (MOE=140 for the oral route,

1,200 for the dermal route, and are thus not of concern). There were no inhalation risks identified.

Based on the toxicological and exposure data discussed in this preamble, EPA concludes that will not pose a risk under reasonably foreseeable circumstances. Accordingly, EPA finds that there is a reasonable certainty of no harm will result to the general population, or to infants and children from aggregate exposure to ADBAC residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An analytical method for food is not needed. Food contact sanitizers are typically regulated by the State health departments to ensure that the food industry is using products in compliance with the regulations in 40 CFR 180.940. The end-use solution that is applied to the food contact surface is analyzed not food items that may come into contact with treated surface. An analytical method is available to analyze the use dilution that is applied to food contact surfaces. A titration method is used to determine the total amount of quaternary compound. If the use solution is a mixture of ADBAC and didecyl dimethyl ammonium chloride (DDAC), then High Pressure Liquid Chromatogram–Ultraviolet Visible (HPLC-UV) is used to determine the amount of ADBAC. The amount of DDAC is determined by calculating the difference between the total amount of quaternary compounds and ADBAC.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/ World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for n-alkyl (C_{12-14}) dimethyl ethylbenzyl ammonium chloride.

C. Response to Comments

EPA received no comments in response to the notice of filing for the petition to amend the tolerance exemption for the ADBAC compound addressed in this rulemaking, n-alkyl (C_{12-14}) dimethyl ethylbenzyl ammonium chloride. However, in October, 2008, EPA received comments on a final rule amending the tolerance exemption for a similar ADBAC compound, n-alkyl (C_{12-18}) dimethyl benzyl ammonium chloride. (73 FR 49101) (August 20, 2008). The commenter mistakenly assumed that this final rule was a "proposed EPA action" and urged that EPA require submission of new data on ADBAC, review studies that have recently become available on ADBAC, and conduct a revised risk assessment for the chemical. Because the petition for the current action was pending at the time that the comments on the related final rule were received, EPA considered those comments in ruling on the petition addressed in this action.

The commenter raised several concerns with regard to the earlier tolerance action as to an ADBAC compound: (1) ADBAC and other quaternary ammonium compounds may be reproductive and genetic toxicants; (2) quaternary ammonium compounds are linked with increased occupational asthma and immune system sensitization; and (3) quaternary ammonium compounds are persistent in the environment. The commenter also raised various environmental concerns with the quaternary ammonium compounds but these concerns are relevant only to EPA's decision to register ADBAC under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. 136 *et seq.*, and not tolerance actions under section 408 of the FFDCA. EPA has prepared a detailed response to each of the commenter's arguments and included that document in the record for this action. EPA's response as to the FFDCA-related comments is summarized below.

EPA does not believe that ADBAC poses unacceptable reproductive risks. In the ADBAC risk assessment, the Agency relied on available, reliable, quantitative animal data to characterize hazards associated with uses of ADBAC including reproductive function and effects on the developing mammalian fetus. In the developmental studies with rats (range-finding MRID 42645101 and main study MRID 42351501) and rabbits (range-finding MRID 42734401 and main study MRID 42392801), there was no increased sensitivity of developing fetuses to ADBAC compared to adult animals. In a 2–generation reproductive toxicity study (MRID 41385001), effects on rat pups were observed in the absence of statistically significant maternal toxicity, but only at the highest dose (160 mg/kg/day). The effects observed were considered to be nonspecific (decreased pup body weight and weight gain during lactation) and there were no effects of ADBAC on reproductive indices. It is important to note that the endpoints selected from the rat oral developmental toxicity study (NOAEL = 10 mg/kg/day) or the 21–day dermal toxicity studies (NOAEL = 20 mg/kg/day) are well below the dose causing these nonspecific effects. Therefore, the endpoints used in risk assessment are protective of infants and children. The commenter relied on a scientific literature article in which a researcher speculated that a severe decline in the fertility of the researcher's laboratory mouse population was due to exposure to quaternary ammonium compounds. EPA concludes that the results of the specific studies designed to examine the reproductive effects of pesticides outweigh the speculative article.

EPA does not believe ADBAC is a genetic toxicant. In evaluating ADBAC's potential mutagenicity, EPA relied on testing results in a battery of mutagenicity studies, including an HGPRT/CHO forward mutation assay (MRID 42290801, reformat of MRID 41012701), an *in vivo* bone marrow chromosomal aberration assay (MRID 40311101, supplement MRID 43037701), and an unscheduled DNA synthesis (UDS) assay (MRID 42290802, reformat of 41012601), all of which demonstrated that ADBAC did not induce mutagenic effects. Further support for this conclusion is provided by carcinogenicity testing in long-term studies using both rats (MRID 41947501) and mice (MRID 41765201). In both studies, ADBAC was tested at adequate dose levels and found to be negative for induction of tumors. In contrast, the commenter relies on the result in an *in vitro* mutagenicity test. The weight of the evidence clearly supports EPA's conclusion. *In vivo* mutagenicity testing (as does carcinogenicity testing in rodents) carries far greater weight than *in vitro* testing because *in vivo* testing is much more likely to simulate the detoxifying effects present in the living animal.

Finally, although EPA would agree that the chemical properties of ADBAC indicate that it will only degrade slowly in the environment, these properties were taken into account in estimating exposure to humans to ADBAC in drinking water in assessing ADBAC

risks. Accordingly, ADBAC's persistence does not render it unsafe.

V. Conclusion

Therefore, the exemption from the requirement of a tolerance in 40 CFR 180.940(a) for Quaternary Ammonium Compounds: n-alkyl (C_{12-14}) dimethyl ethylbenzyl ammonium chloride (CAS Reg. No. 85409–23–0) is amended to increase from 200 ppm to 400 ppm the level of the end-use concentration of all quaternary chemicals that may be present in solution when the solution is ready for use.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 8, 2010.

Joan Harrigan-Farrelly,

Director, Antimicrobials Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.940 is amended by revising the following entry in the table in paragraph (a) to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

* * * * *

(a) * * *

Pesticide Chemical	CAS Reg. No.	Limits
	* * * *	*
Quaternary Ammonium Compounds: n-alkyl (C_{12-14}) dimethyl ethylbenzyl ammonium chloride, average molecular weight (in amu), 377 to 384.	85409–23–0	When ready for use, the end-use concentration of all quaternary chemicals in solution is not to exceed 400 ppm of active quaternary compound.
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BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0561;FRL–8833–8]

Acetic Acid; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the existing tolerance exemption for acetic acid by establishing an exemption from the requirement of a tolerance for residues of acetic acid, also known as vinegar in or on all food crops resulting from unintentional spray and drift to non-target vegetation including non-food, food and feed crops when used as a non-selective contact herbicide spray. SummerSet Products c/o SciReg, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of acetic acid, also known as vinegar.

DATES: This regulation is effective July 14, 2010. Objections and requests for hearings must be received on or before September 13, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0561. 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., Confidential Business Information (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 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 Docket Facility is open 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: Cheryl Greene, Biopesticides and Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–0352; e-mail address: *greene.cheryl@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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**.

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2010–0561 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before September 13, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2010–0561, 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.

II. Background and Statutory Findings

In the **Federal Register** of November 19, 2008, (FR 69635) (FRL–8389–6), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 8F7319) by SummerSet Products c/o SciReg, Inc., 130 Columbia Court, Chaska, MN 55318. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of acetic acid. This notice referenced a summary of the petition prepared by the petitioner SummerSet Products, which is available in the docket, *http://www.regulations.gov*. One anonymous comment was received on the notice of filing. However, EPA was unable to address the comment because it was not specific to this action, focusing instead on the registration of pesticides generally, and therefore was not a significant comment.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ." Additionally, section 408(b)(2)(D) of FFDCA requires that the Agency consider "available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity's.

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Acetic acid is a substance found or produced naturally in most plants and animals, including primates and humans. It is also naturally produced during the fermentation process in a wide range of foods. In plants and animals, it is generally produced biologically by bacteria from the genus *Acetobacter*. Acetic acid has a fundamental role in cellular metabolism, particularly in the tricarboxylic acid cycle, also known as the citric acid (Ref. 1.) or krebs cycle (Ref. 2.), which is the chemical activity in all cells that utilize oxygen as part of their respiration process. The krebs cycle is carried out in the mitochondria of the cells of plants and animals including humans. Acetic acid plays a key role in the production of carbon dioxide and is a chemical rich in adenosine triphosphate (ATP). Acetic acid occurs naturally in many commonly consumed food items such as coffee, chick peas, edible plants, brown sugar, fruits, and vegetables where it forms during post-harvest fermentation. As an organic chemical, acetic acid is readily metabolized by the tissues of the body and is used in plants and animals to synthesize proteins, carbohydrates and fatty acids. In animals, including humans, acetic acid is produced naturally as consumed sugars and alcohol containing foods or liquids such as alcoholic beverage undergo fermentation.

Acetic acid has been used as a food additive in most cultures throughout recorded history. Historical reports suggest that the first dietary consumption of acetic acid was in wine, beer and similar brewed beverages and fermented food items such as sauerkraut. Acetic acid also has a long history of use as a food additive. Acetic acid is a component of white distilled vinegar at 4%. In the form of vinegar, it is historically consumed in a wide range of commonly used condiments such as food seasonings, pickled food items, dried, preserved, canned and processed fruits and vegetables. It is also added to or found naturally in many dairy based foods including yogurt, chocolate milk and eggnog. It is included as an additive in many contemporary common foods including breakfast cereals, processed meats, prepared table top sweeteners, sports and energy drinks (CODEX GSFA, 2009) (Ref. 3.) and is used in pharmaceutical products such as antibiotics, antibacterials and antimicrobials. Acetic acid is also the main acid in vinegars, and it is the acid in vinegar that gives vinegar its characteristic odor. In commonly consumed vinegars such as white (distilled), cider, balsamic, malt, red wine, white wine, rice and sherry the percentage of acetic acid generally ranges between 3% and 8%. The Food and Drug Administration (FDA) classifies acetic acid as "Generally Recognized as Safe (GRAS)" under 21 CFR 184.1005 as a direct food substance and under 21 CFR 582.1005 as a general purpose food additive.

As a pesticide, acetic acid is registered for use as a non-selective contact herbicide for combating a wide range of weeds and some grasses. Upon contact with targeted weed and weed grasses, acetic acid destroys or damages the cell membrane of the plants which causes rapid dehydration of the plant tissues. This process is called "burnout" or "burndown" and can result in the death of the targeted plant or injury sufficient to slow the growth and reproduction of the targeted plant.

In a final rule dated August 3, 2005, (70 FR 44483) (FRL–7717–2), EPA established an exemption from the requirement of a tolerance for residues of acetic acid when used as an active ingredient as a preservative on post-harvest agricultural commodities intended for animal feed, including alfalfa, barley grain, bermuda grass; bluegrass, brome grass, clover, corn grain, cowpea hay, fescue, lespedeza, lupines, oat grain, orchard grass, peanut grass, Timothy, vetch, and wheat grain, or commodities described as grain or hay. Acetic acid is also approved for use on growing crops or raw agricultural commodities after harvest as an inert ingredient in pesticide products under 40 CFR 180.1258.

In support of the request to amend the existing exemption from the requirement of a tolerance, the Agency has reviewed all information submitted in support of this action. This petition is supported by information from open scientific literature and cited studies which are discussed in detail in this unit. When used as an indirect spray to control weeds and weed grasses according to the required label instructions, significant dietary residues of acetic acid are unlikely because direct exposure to food plants would be accidental or due to spray drift. Additionally, acetic acid rapidly biodegrades in the environment; it is non-toxic at pesticidal use concentrations; it is readily metabolized in the body; it is ubiquitous in food and the environment. Moreover, pesticidal uses of acetic acid are not expected to contribute significantly to the overall exposure of the general population, and information from the open literature indicates that acetic acid has little or no toxicity from an acute oral perspective (toxicity category III; median lethal dose (LD_{50} 3,310 milligrams/kilogram (mg/kg). (Ref. 4.)

A. Acute Toxicity

Acute toxicity information submitted to support the exemption from the requirement of a tolerance for acetic

acid confirms a low toxicity profile and reflects the Agency's findings that acetic acid poses no significant human health risk with regard to food commodities. As a biochemical pesticide, products containing acetic acid would be used to control herbaceous broadleaf weeds and weed grasses that may damage or otherwise compromise the production of food crops. Products containing acetic acid are not intended for direct use on food crops. Moreover, any food crops exposed to acetic acid when used as a biochemical pesticide would be destroyed or significantly damaged. Such exposure would most likely be accidental or from spray drift and would render the plant unsuitable or less suitable for marketing. The low toxicological profile of acetic acid when used as an herbicide provides additional justification for this exemption from the requirement of a tolerance. Further, published literature (discussed in this unit) concerning low toxicity and the extensive history of acetic acid used in foods supports this exemption from the requirement of a tolerance.

The primary routes of exposure to the general population have been determined to be through consumption of food and inhalation of air in workplaces. (Ref. 5.)

1. *Acute oral toxicity*. The acute oral median LD_{50} for acetic acid in rats was greater than 3,310 mg/kg in rats and 4,960 mg/kg in mice, which confirmed negligible toxicity through oral exposure. (Ref. 6.) The lowest observed adverse effect level (LOAEL) was determined to be 390 mg/kg and the no observed adverse effect level (NOAEL) was determined to be 195 mg/kg (Ref. 7.) Acedic acid is a toxicity category III for acute oral toxicity.

2. *Acute dermal toxicity*.The acute dermal LD_{50} for acetic acid in rats was 1,060 mg/kg, (MRID 47330503) which confirmed moderate dermal toxicity, (MRID 47330503) the requirement of sub-acute toxicity data was waived because the use pattern and personal protection equipment (PPE) requirements of products containing acetic acid mitigate any risk from dermal exposure. Specifically, acetic acid as a biopesticide is only intended for use in spray products formulated for use as contact herbicides on broadleaf weeds and grasses; the Agency requires appropriate signal word (DANGER) and corresponding precautionary language on all labels containing acetic acid as a biochemical pesticide; and the Agency requires all applicators and handlers of such products to wear PPE that includes protective eyewear, long-sleeved shirt, long pants, socks and shoes. Given these considerations, the Agency believes that repeated dermal and inhalation exposure is not expected to occur. Acetic acid is a toxicity category II for acute dermal toxicity.

3. *Acute inhalation toxicity*. The acute inhalation median LC_{50} was greater than 11.4 milligrams per liter (mg/L) in rats and showed little to no inhalation toxicity or irritation (MRID 47330503). Acetic acid is toxicity category IV for acute inhalation toxicity.

4. *Primary eye irritation*. A primary eye study showed significant potential for eye irritation. Eye corneal damage can occur from exposure to acetic acid and clarity of vision is not reversed within seven days (MRID 47330503). As such, the Agency has determined that acetic acid is Toxicity Category I for acute eye irritation. (PPE requirements of products containing acetic acid will mitigate any risk associated with the products).

5. *Acute dermal/skin sensitization*. An acute dermal irritation/skin sensitization study showed that acetic acid is corrosive at very high (60%) concentrations (MRIDs 47330503) and (47330504). However, due to the use pattern and PPE requirements of biopesticidal products containing acetic acid (see Unit III.A.2., in this unit, regarding the use pattern and PPE requirements), and a required default restricted-entry interval (REI) of 48 hours following application of products containing acetic acid, exposure risks associated with products containing acetic acid will be mitigated. Acetic acid is a Toxicity category I for acute dermal irritation/skin sensitization.

B. Subchronic Toxicity

Based on its acute toxicity profile, use pattern and biodegradation properties, residues of acetic acid are not expected to result in significant dietary exposure beyond the levels expected in background dietary exposures. Nonetheless, a subchronic oral, dermal and inhalation toxicity study satisfied the data requirements for subchronic toxicity and indicated that acetic acid has no subchronic toxicological effect.

1. *90–day oral toxicity*. A 90–day oral toxicity study (Ref. 8.) found no toxicological effects regarding mortality, clinical observations, neurotoxicity assessment, hematology, clinical chemistry, organ weights, and macroscopic or microscopic observations. Weight loss was observed in test subjects administered up to 390 mg/kg body weight (bw/day) acetic acid in drinking water for 2-4 months. The reduction in weight gain is likely attributed to reduced appetite and food consumption observed in the study. No other effects were reported. The LOAEL was determined to be 390 mg/kg bw/day, and the NOAEL was determined to be 195 mg/kg bw/day.

2. *90–day dermal toxicity*. Requirement of a 90–day dermal toxicity study has been waived. Considering the use pattern and PPE requirements of pesticide products containing acetic acid (see Unit III.A.2., in this unit, regarding the use pattern and PPE requirements), repeated dermal and inhalation exposure is not expected to occur. Additionally, the Agency does not expect significant dermal exposure since uses of acetic acid as a contact biopesticide will not involve purposeful application to the skin, nor will it result in prolonged dermal exposure to the product when label directions are followed. Moreover, acute toxicity testing of the two proposed end-use products in which acetic acid will be used as an herbicide have indicated that the products are non-irritating to slightly-irritating to the skin. Applicators are required to wear protective eye-wear, long-sleeved shirts, long pants, socks and shoes. Additionally, a REI of 48 hours has been added to these labels.

3. *90–day inhalation toxicity*. Requirements for a 90–day inhalation toxicity study have also been waived. Herbicide products containing acetic acid are liquids and it is therefore, unlikely that significant levels of repeated inhalation will occur from the use of these products. Based on the results of toxicity testing cited above, proposed herbicide products containing acetic acid are placed into Toxicity Category IV for acute inhalation toxicity and to further mitigate exposure, a REI of 48 hours has been added to these labels.

C. Developmental Toxicity

Developmental toxicity data submitted to the Agency demonstrate a clear lack of developmental toxicity for acetic acid and supports the Agency's conclusion that there is no risk of developmental toxicity associated with new food uses for acetic acid.

A prenatal developmental toxicity study (MRID 47330503) found no significant treatment-related reproductive effects. The study showed abnormalities of soft or skeletal tissue of the test group, but the abnormalities did not differ from those found in the control group. The study established a LOAEL of 1,600 mg/kg bw/day. The NOAEL is equal to 1,600 mg/kg bw/day. A second prenatal developmental toxicity study (MRID 47330503) also, found no significant treatment related to reproductive effects or fetal abnormalities. Based on this

information, the Agency believes that there is no risk of developmental toxicity associated with new food uses for acetic acid.

D. Mutagenicity

A mutagenicity study using acetic acid as the test substance was conducted. The reverse mutation assays performed (MRID 47330503) were negative for mutagenicity to bacteria exposed to concentrations of acetic acid from 0 micrograms per plate to 10,000 micrograms per plate with and without metabolic activation. In the *in-vitro* Chinese hamster tests (MRID 47330503), results were also negative for mutagenicity. Results showed that acetic acid is not mutagenic at levels less than or equal to 16 micromoles. The Agency has determined that these data are sufficient to confirm that there are no expected dietary or non-occupational risks of mutagenicity with regard to new food uses of acetic acid.

E. Endocrine Effects

There is no available evidence demonstrating that acetic acid is an endocrine disruptor in humans. As a result, the Agency is not requiring information on the endocrine effects of acetic acid at this time. However, the Endocrine Disruption Screening Program (EDSP) has established a protocol, which guides the Agency in selecting suspect ingredients for review, and the Agency reserves the right to require new information should the program require it. Presently, based on the lack of exposure and the negligible toxicity profile of acetic acid, no adverse effects to the endocrine system are known or expected. Overall, the lack of evidence of endocrine disruption is consistent with the low toxicity profile of acetic acid and supports this exemption from the requirement of a tolerance.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). The Agency has determined that there is reasonable certainty that no harm to the U.S. population will result from aggregate exposure to residues of acetic acid. This includes all exposures for which there is reliable information. The Agency arrived at this conclusion based on the low level of toxicity of the chemical, low anticipated dietary and non-dietary exposures, worker protection requirements on the label (PPE and REI requirements) and the already widespread exposure without any reported adverse effects on human health. The risks from aggregate exposure via oral, dermal and inhalation exposure are negligible.

A. Dietary Exposure

The use of acetic acid as a pesticide is not intended as a direct spray to food commodities and will not be directly applied to food commodities intended for human consumption. Therefore, the Agency anticipates negligible to no residues present at the time of consumption.

1. *Food*. The Agency expects that food commodities will only be exposed to acetic acid by accidental application or spray drift. The Agency believes that any unintentional application or drift of products containing acetic acid would kill or substantially damage food crops, making them undesirable for human consumption. However, even in the event of indirect spray to food crops, the Agency is not concerned with potential residues due to low toxicity of acetic acid and the fact that acetic acid is a weak acid that rapidly degrades into a base composed of an acetate ion and hydrogen. Finally, the Agency believes that because acetic acid biodegrades rapidly under both anaerobic and aerobic conditions in the environment, residues of toxicological concern are not expected.

2. *Drinking water exposure*. Pesticide products containing acetic acid are not applied directly to water; applications are made directly to terrestrial non food crops, and as such, drinking water exposure of humans to acetic acid from pesticidal use is unlikely. Moreover, the Agency believes that any potential exposure to surface water would be negligible because of the low application rates and rapid biodegradation of acetic acid. Therefore, drinking water exposure is not expected to pose any quantifiable risk due to a lack of residues of toxicological concern.

B. Other Non-Occupational Exposure—Non-Dietary Exposure-Dermal and Inhalation Exposure

The potential for non-dietary exposure of the general population, including infants and children, is limited based on the use patterns of acetic acid (see Unit III.A.2., in this unit, regarding the use pattern and PPE requirements) and REI requirements (48 hours) on product labels, and the lack of anticipated residues of toxicological concern. Non-dietary exposures would not be expected to pose any quantifiable risk to the general population.

1. *Dermal exposure*. Non-occupational dermal exposures to acetic acid when used as an indirect non-selective herbicide are expected to be negligible based on the use patterns of acetic acid (see Unit III.A.2., in this unit, regarding the use patterns).

2. *Inhalation exposure*. Non occupational exposures to acetic acid when used as a selective herbicide are expected to be negligible because acetic acid products are limited to targeted weeds and grasses in proximity to food crops.

V. Cumulative Effects from Substances with a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found acetic acid to share a common mechanism of toxicity with any other substances, and acetic acid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that acetic acid does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

VI. Determination of Safety for U.S. Population, Infants and Children

The Agency has considered acetic acid in light of the relevant safety factors in FQPA and FIFRA. A determination has been made that no unreasonable adverse effects to the U.S. population in general, and to infants and children in particular, will result from the use of acetic acid when label instructions are followed.

A. U.S. Population

A determination has been made that no unreasonable adverse effects to the U.S. population in general will result from the use of acetic acid when used as an indirect spray to control weeds and weed grasses when label instructions are followed. This conclusion is based on the unlikelihood of significant dietary residues of acetic acid because direct exposure to food

plants would be accidental or due to spray drift. Additionally, acetic acid rapidly biodegrades in the environment; it is non-toxic at pesticidal use concentrations; it is readily metabolized in the body; and, it is ubiquitous in food and the environment. Moreover, pesticidal uses of acetic acid are not expected to contribute significantly to the overall exposure of the general population, and information from the open literature indicates that acetic acid has little or no toxicity from an acute oral perspective (toxicity category III; median LD_{50} 3,310 mg/kg).

The Agency is reasonably certain that there will be no harm to residential and/or commercial workers and applicators using herbicide products containing acetic acid based on the low application rates of end-use products, the low toxicity of acetic acid, and the rapid biodegradation of acetic acid in the environment. Precautionary labeling language, personal protective equipment and a 48 hour rentry interval for contact herbicides containing acetic acid adds an additional level of assurance of no harm to residential and commercial workers using such pesticide products.

B. Infants and Children

In examining exposures to sensitive subpopulations, FFDCA section 408 directs EPA to apply an additional tenfold margin of exposure (MOE) (safety) for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database, unless EPA determines that a different MOE will be protective for infants and children. MOE are often referred to as uncertainty or safety factors. For the proposed pesticidal uses, based on all the available information, the Agency concludes that acetic acid is practically non-toxic (with the exception of severe eye irritation) to mammals, including infants and children. Acetic acid is found in many foods already consumed by infants and children, and there is no information available indicating an appreciable difference in risk between adults and infants and children from exposure to acetic acid when used as a contact herbicide. As a result, EPA has not used a MOE approach to assess the safety of acetic acid. When used as proposed, EPA expects that the contact herbicides containing acetic acid as an active ingredient would not result in residue levels that are of toxicological concern. Thus, there are no threshold effects of concern. As such, an additional margin of safety is not necessary.

VII. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with internal standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codes), as required by FFDCA section 408(b)(4). The Codex is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex Level. The Codex has not established a MRL for acetic acid.

VIII. Conclusions

The Agency concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of acetic acid when used as an herbicide to control broadleaf weeds and grasses. Therefore, an exemption is established for residues of the biochemical acetic acid when used as a non selective, indirect contact herbicide spray for broadleaf weeds and weed grasses on all food crops.

IX. References

1. MRIDs 47350604 through 47350609).

2. MRIDs 47330501, 47330505, 47330510–47330512 and 47775901).

3. “Acetic Acid”. Codex General Standards for Food Additives Online Database. 2010. GSFA Online. January 13, 2010 *http://www.codexalimentarius.net/gsfaonline/additives/details.html?id=170.*

4. MRIDs 47350601 through 47350603 and 47776001.

5. “Acetic Acid”. Hazardous Substances Data Base. 2010. National Library of Medicine January 13, 2010 *http://www.toxnet.nlm.nih.gov/cgibin/sis/search/f?./temp/~SWRBRt:1.*

6. MRIDs 47330503, 47330504, 47330507, 47330508 and 47330513-47330518).

7. Joint FAO/WHO Expert Committee on Food Additives. “Toxicological Evaluation of Some Microbials, Antioxidants, Emulsifiers, Stabilizers, Flour-Treatment Agents, Acids and Bases.” 1967. WHO/Food Add. January 13, 2010 *http://www.inchem.org/documents/jecfa/jecmono/40abcj37.htm.*

8. EPA Memorandum R.S. Jones to D. Benmhend. “Science Review in Support of the Registration of Eastman Acetic Acid® P Grain and Hay Preservative. . . .”. April 12, 2004.

X. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of

power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

XI. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 30, 2010.

W. Michael McDavit,

Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In subpart D, revise §180.1258 to read as follows:

§ 180.1258 Acetic acid; exemption from the requirement of a tolerance.

(a) An exemption from the requirement of a tolerance is established for residues of the biochemical pesticide acetic acid when used as a preservative on post-harvest agricultural commodities intended for animal feed, including Alfalfa, seed; alfalfa, hay; barley, grain; bermudagrass, hay; bluegrass, hay; bromegrass, hay; clover, hay; corn, field, grain; corn, pop, grain; cowpea, hay; fescue, hay; lespedeza, hay; lupin; oat, grain; orchardgrass, hay; peanut, hay; timothy, hay; vetch, hay; and wheat, grain, or commodities described as grain or hay.

(b) An exemption from the requirement of a tolerance is established for residues of acetic acid in or on all food crops resulting from unintentional spray and drift to non-target vegetation including non-food, food and feed crops when used as a non-selective contact herbicide spray.

[FR Doc. 2010–17163 Filed 7–13–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0325; FRL–8833–6]

Hexythiazox; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation revises tolerances for combined residues of hexythiazox in or on stone fruit. Gowan Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 14, 2010. Objections and requests for hearings must be received on or before September 13, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0325. 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., Confidential Business Information (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 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 Docket Facility is open 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: Olga Odiott, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9369; e-mail address: *odiott.olga@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide 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**.

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions

provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2009–0325 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before September 13, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2009–0325, 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.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of August 19, 2009 (74 FR 41898) (FRL–8426–7), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9F7556) by Gowan Company, 370 South Main Street, Yuma, AZ 85364. The petition requested that 40 CFR 180.448 be amended by revising tolerances for residues of the insecticide hexythiazox, (trans-5-(4-chlorophenyl)-*N*-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide) and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3- thiazolidine moiety, as follows: Revising the tolerance "fruit, stone, group 12, except plums" to read " fruit, stone, group 12; removing the existing separate tolerance for fresh, prune, plums at 0.1 parts per million (ppm); revising the tolerance in or on plum, prune, dried from 0.4 to 1.3 ppm; and by revising the tolerance in or on grapes from 0.75 to 1.0 ppm. That notice referenced a summary of the petition prepared by Gowan Company, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA issued a notice in the **Federal Register** of March 17, 2010 (75 FR 12691) (FRL–8813–7), revising the tolerance for grapes and revising the tolerance expression for hexythiazox. In that notice the Agency also announced that the residue chemistry data were insufficient to support the proposed revisions of the tolerances for the stone fruit use. Gowan Company, the registrant, has submitted additional data to adequately support the requested revisions to the stone fruit tolerances. This action addresses the updated aggregate risk assessment incorporating the revised dietary assessment on stone fruit.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for hexythiazox including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with hexythiazox follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Hexythiazox has a low order of acute toxicity by the oral, dermal and inhalation routes of exposure. It produces mild eye irritation, is not a dermal irritant, and is negative for dermal sensitization. Hexythiazox is not a developmental or reproductive toxicant. The toxicology database for hexythiazox provides no indication of increased susceptibility in rats or rabbits from *in utero* and postnatal exposure to hexythiazox. The database does not show any evidence of treatment-related effects on the nervous system or the immune system. Hexythiazox is classified as "Likely to be Carcinogenic to Humans." EPA has determined that a non-quantitative risk assessment approach (i.e., nonlinear, reference dose (RfD) approach) was appropriate and protective of all chronic effects including potential carcinogenicity of hexythiazox.

Specific information on the studies received and the nature of the adverse effects caused by hexythiazox as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found in the final rule published in the **Federal Register** of March 17, 2010 (75 FR 12691), and at *http://www.regulations.gov* in document "Hexythiazox. Human Health Risk Assessment to Support Amended Use on Stone Fruit Reducing the Preharvest Interval from 28–Days to 7–Days," p. 28 in docket ID number EPA–HQ–OPP–2009–0325.

B. Toxicological Points of Departure/ Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are

observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level – generally referred to as a population-adjusted dose (PAD) or a RfD – and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for hexythiazox used for human risk assessment can be found in the final rule published in the **Federal Register** of March 17, 2010 (75 FR 12691), and at *http://www.regulations.gov* in document "Hexythiazox. Human Health Risk Assessment to Support Amended Use on Stone Fruit Reducing the Preharvest Interval from 28–Days to 7–Days," p. 13 in docket ID number EPA–HQ–OPP–2009–0325.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to hexythiazox, EPA considered exposure under the petitioned-for tolerances as well as all existing hexythiazox tolerances in 40 CFR 180.448. EPA assessed dietary exposures from hexythiazox in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure.

No such effects were identified in the toxicological studies for hexythiazox; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the United States Department of Agriculture (USDA) 1994–1996 and 1998 CSFII. As to residue levels in food, EPA used tolerance level residues, assumed 100 percent crop treated (PCT), and incorporated default processing factors.

iii. *Cancer.* As discussed in this unit, EPA has determined that the chronic RfD is sufficient to evaluate all chronic risks for this chemical, including carcinogenic potential. Cancer risk was quantified using the same estimates as discussed in Unit III.C.1.ii., chronic exposure.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for hexythiazox. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for hexythiazox in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of hexythiazox. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) the estimated drinking water concentration (EDWC) of hexythiazox for chronic exposures for non-cancer and cancer assessments is estimated to be 4.1 parts per billion (ppb) for surface water. Since surface water residue values greatly exceed groundwater EDWCs, surface water residues were used in the dietary risk assessment.

The modeled estimate of drinking water concentrations was directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Hexythiazox is not currently registered for any specific use patterns that would result in residential exposure. However, the following uses that could result in residential exposures are pending registration in the near future and are included in this risk assessment: Turf, gardens, ornamental landscape plantings, ornamental plants, trees and vines in nurseries, residential fruit trees, nut trees and caneberries, and orchids.

Both adults and children may be exposed to hexythiazox residues from contact with treated lawns or treated plants. The exposure and risk assessment included risks to adult handlers from inhalation exposures. The exposure assessment for children included risks from incidental oral exposure resulting from transfer of residues from the hands or objects to the mouth, and from incidental ingestion of soil. Details of the residential exposure and risk assessment are contained in the final rule published in the **Federal Register** of March 17, 2010 (75 FR 12691), and at *http://www.regulations.gov* in document "Hexythiazox. Human Health Risk Assessment to Support Amended Use on Stone Fruit Reducing the Preharvest Interval from 28–Days to 7–Days," p. 19 in docket ID number EPA–HQ–OPP–2009–0325.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf*.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found hexythiazox to share a common mechanism of toxicity with any other substances, and hexythiazox does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that hexythiazox does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicology data base indicates no increased

susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to hexythiazox.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for hexythiazox is incomplete under the new 40 CFR part 158 data requirements for conventional pesticides, which requires certain generic testing, including acute and subchronic neurotoxicity studies and an immunotoxicity study. However, the toxicology database does not show any evidence of treatment-related effects on the nervous system or the immune system. The overall weight of evidence suggests that this chemical does not directly target either system. Although acute and subchronic neurotoxicity studies and an immunotoxicity study are required as a part of new data requirements in the 40 CFR part 158 for conventional pesticide registrations, the Agency does not believe that conducting these studies will result in a lower POD than any currently used for risk assessment, and therefore, a database uncertainty factor (UF_{DB}) is not needed to account for the lack of these studies.

ii. There is no indication that hexythiazox is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that hexythiazox results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2–generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. The dietary risk assessment is highly conservative and not expected to underestimate risk. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to hexythiazox in drinking water. These assessments will not underestimate the exposure and risks posed by hexythiazox.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk*. An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, hexythiazox is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to hexythiazox from food and water will utilize 49% of the cPAD for (children 1–2 years old) the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of hexythiazox is not expected.

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

There are potential short-term exposures from the pending residential uses for hexythiazox. The Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to hexythiazox.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 16,000 for adults and 2,000 for children. Because EPA's level of concern for hexythiazox is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

There are potential intermediate-term exposures from the pending residential uses for hexythiazox. The Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposure to hexythiazox.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs of 16,000 for adults and 2,200 for children. Because EPA's level of concern for hexythiazox is a MOE of 100 or below, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population*. As discussed in Unit III.A., and the **Federal Register** of March 17, 2010, (75 FR 12691), EPA concluded that regulation based on the chronic reference dose will be protective for both chronic and carcinogenic risks. As noted in this unit there are no chronic risks of concern.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to hexythiazox residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high performance liquid chromatography with ultra violet detection (HPLC/UV) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the U.S. is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Codex MRLs are established for residues of hexythiazox in or on cherry and peach at 1.0 ppm, and plum (including prune) at 0.2 ppm. There are no currently established Canadian or Mexican MRLs for residues of hexythiazox for these crops. The Agency

has harmonized the residue level with established Codex MRLs on cherry and peach, but notes that it is not possible to harmonize the tolerance expression at this time as the Codex MRL includes parent only. Additionally, it is not possible to harmonize with the codex MRL for plums as the established Codex MRL of 0.2 ppm is too low to cover residues that could result from the use of hexythiazox in the U.S.

V. Conclusion

Therefore, the tolerance for residues of hexythiazox, in or on plum, prune, dried is revised from 0.4 ppm to 1.3 ppm; and the tolerance for fruit, stone, group 12, except plum is revised to read fruit, stone, group 12. The established tolerances for plum and for plum, prune, fresh can be removed as these commodities are addressed by the stone fruit group tolerance.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 1, 2010.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.448, the table in paragraph (a) is amended as follows:

i. Remove the entry for plum at 0.10 ppm and for plum, prune, fresh at 0.10 ppm;

ii. Revise the entry for Fruit, stone, group 12, except plum; and

iii. Revise the entry for plum, prune, dried.

The revisions read as follows:

§ 180.448 Hexythiazox; tolerances for residues.

Commodity	Parts per million
* * * * *	
Fruit, stone, group 12	1.0
* * * * *	
Plum, prune, dried	1.3
* * * * *	

* * * * *

[FR Doc. 2010–17034 Filed 7–13–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0801; FRL–8833–1]

Cyazofamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyazofamid in or on Brassica, head and stem, subgroup 5A; Brassica, leafy greens, subgroup 5B; turnip, greens; spinach; and hop, dried cones. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 14, 2010. Objections and requests for hearings must be received on or before September 13, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION)**.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0801. 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., Confidential Business Information (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 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 Docket Facility is open 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: Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7390; e-mail address: *nollen.laura@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide 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**.

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2009–0801 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before September 13, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2009–0801, 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.

II. Summary of Petitioned-For Tolerances

In the **Federal Register** of January 6, 2010 (75 FR 864) (FRL–8801–5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E7615) by IR-4, 500 College Road East, Suite 201 W., Princeton, NJ 08540. The petition requested that 40 CFR 180.601 be amended by establishing tolerances for residues of the fungicide cyazofamid, 4-chloro-2-cyano-*N*,*N*-dimethyl-5-(4-methylphenyl)-1*H*-imidazole-1-sulfonamide, and its metabolite CCIM, 4-chloro-5-(4-methylphenyl)-1*H*-imidazole-2-carbonitrile, expressed as cyazofamid, in or on Brassica, head and stem, subgroup 5A at 1.2 parts per million (ppm); Brassica, leafy greens, subgroup 5B at 12.0 ppm; turnip, greens at 12.0 ppm; spinach at 9.0 ppm; and hops at 10.0 ppm. That notice referenced a summary of the petition prepared on behalf of IR-4 by ISK Biosciences, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

EPA has revised the tolerance expression for all established commodities to be consistent with current Agency policy. The reason for this change is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for cyazofamid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with cyazofamid follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity,

completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Cyazofamid has a low order of acute toxicity via the oral, dermal, and inhalation routes of exposure. It produces minimal but reversible eye irritation, is a slight dermal irritant, and is a weak dermal sensitizer. In subchronic toxicity studies in rats, the kidney appeared to be the primary target organ, with kidney effects including an increased number of basophilic kidney tubules and mild increases in urinary volume, pH, and protein. No adverse kidney effects were noted in chronic toxicity studies in rats. There were no toxicity findings up to the limit dose in a subchronic toxicity study in dogs; in the chronic dog toxicity study, increased cysts in parathyroids were observed in males at the highest dose tested (HDT).

There were no maternal or developmental effects observed in the prenatal developmental toxicity study in rabbits and no maternal, reproductive, or offspring effects in the 2-generation reproductive toxicity study in rats. There was evidence of increased susceptibility following *in utero* exposure of rats in the prenatal developmental toxicity study at the HDT; developmental effects, including an increased incidence of bent ribs, were observed in the absence of maternal toxicity.

There was no evidence of neurotoxicity in any study in the exposure database for cyazofamid. Skin lesions, which may be due to a systemic allergy, were observed in male mice in a carcinogenicity study. There was no evidence of carcinogenicity in the rat or mouse carcinogenicity studies and no evidence that cyazofamid is mutagenic in several *in vivo* and *in vitro* studies. Based on the results of these studies, EPA has classified cyazofamid as "not likely to be carcinogenic to humans."

Specific information on the studies received and the nature of the adverse effects caused by cyazofamid as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document: "Cyazofamid. Human Health Risk Assessment for Proposed Uses on Brassica (Cole) Leafy Vegetables Crop Group 5, Turnip Greens, Spinach, and Hops," pp 34-38 in docket ID number EPA–HQ–OPP–2009–0801.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level – generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) – and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for cyazofamid used for human risk assessment is shown in the following Table.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR CYAZOFAMID FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (General population including infants and children)	No adverse effects were observed which could be attributed to a single dose exposure for the general population.		
Acute dietary (Females 13–49 years of age)	NOAEL = 100 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 1.0 mg/kg/day aPAD = 1.0 mg/kg/day	Rat Prenatal Developmental Toxicity Study LOAEL = 1,000 mg/kg/day based on developmental toxicity findings of increased incidence of bent ribs.
Chronic dietary (All populations)	NOAEL= 94.8 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.948 mg/kg/day cPAD = 0.948 mg/kg/day	18-Month Mouse Oral Carcinogenicity Study LOAEL = 985 mg/kg/day based on increased skin lesions.
Incidental oral, short-term (1 to 30 days) and intermediate-term (1-6 months)	NOAEL= 30 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	90-day Rat Oral Toxicity Study LOAEL = 295 mg/kg/day based on increased number of basophilic tubules of the kidneys, increased urinary volume, pH, and protein.
Dermal, short-term (1 to 30 days) and intermediate-term (1-6 months)	For Children: No toxicity was found at 1,000 mg/kg/day in a 28–day dermal toxicity study; therefore, in the absence of hazard identified for this population, a dermal risk assessment is not necessary.		

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR CYAZOFAMID FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
	For Adults: Dermal (or oral) study NOAEL = 100 mg/kg/day (dermal absorption rate = 37 %) UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Rat Prenatal Developmental Toxicity Study LOAEL = 1,000 mg/kg/day based on developmental toxicity findings of increased incidence of bent ribs.
Cancer (Oral, dermal, inhalation)	Classification: "Not likely to be carcinogenic to humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to cyazofamid, EPA considered exposure under the petitioned-for tolerances as well as all existing cyazofamid tolerances in 40 CFR 180.601. EPA assessed dietary exposures from cyazofamid in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. EPA identified such an effect (increased incidence of bent ribs in the rat prenatal developmental toxicity study) for the population subgroup females 13 to 49 years old; however, no such effect was identified for the general population, including infants and children.

In estimating acute dietary exposure for females 13 to 49 years old, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994 to 1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed tolerance-level residues, Dietary Exposure Evaluation Model (DEEM) default processing factors and 100 percent crop treated (PCT) for all existing and proposed commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994 to 1996 and 1998 CSFII. As to residue levels in food, EPA assumed tolerance-level residues, DEEM default processing factors and 100 PCT for all existing and proposed commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that cyazofamid does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for cyazofamid. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for cyazofamid in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of cyazofamid. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Available environmental fate studies suggest cyazofamid is not very mobile and quickly degrades into a number of degradation products under different environmental conditions. Among the three major degradates for cyazofamid (CCIM, CCIM-AM and CTCA), the two terminal degradates are CCIM and CTCA. The highest estimated drinking water concentrations resulted from modeling which assumed application of 100% molar conversion of the parent into the terminal degradate CTCA. EPA used these estimates of CTCA in its dietary exposure assessments, a conservative approach that likely overestimates the exposure contribution from drinking water. Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) model for surface water and the Screening Concentration in Ground Water (SCI-GROW) model for ground water, the estimated drinking water concentrations (EDWCs) of CTCA for acute exposures are estimated to be 136 parts per billion (ppb) for surface water and 2.18 ppb for ground water. Chronic exposures for non-cancer assessments are estimated to be 133 ppb for surface water and 2.18 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 136 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 133 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Cyazofamid is currently registered for use on residential turf and ornamentals and on professionally managed turf areas, such as golf courses and college/professional sports fields. For the use of cyazofamid on professionally managed turf areas, short-term and intermediate-term postapplication dermal exposure was assessed for adult and youth golfers and adult athletes. However, because it is unlikely for an individual to experience a co-occurrence of activities within a single day, the scenarios of golfing and/or using recreational fields were not aggregated with the residential turf and ornamental scenarios.

For the use of cyazofamid on residential turf and ornamentals, application by homeowners is

prohibited; therefore, residential handler exposure is not expected and was not assessed. However, short-term and intermediate-term postapplication exposure is possible for adults and children. Adults were assessed for short-term and intermediate-term postapplication dermal exposure from contact with treated turf and ornamentals. The adult population of concern for dermal risk assessment is females of childbearing age (13+), based on the developmental toxicity findings of increased incidence of bent ribs; thus, the estimated risk for this population is protective of all adult population subgroups. Children were assessed for short-term and intermediate-term postapplication incidental oral exposure to treated residential turf and ornamentals, including hand-to-mouth activity, object-to-mouth activity, and soil ingestion. No POD was identified for dermal exposures to treated turf or ornamentals for children, since no toxicity was seen in the 28–day dermal toxicity study at the HDT (1,000 mg/kg/day); therefore, dermal postapplication exposure scenarios for children were not assessed.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found cyazofamid to share a common mechanism of toxicity with any other substances, and cyazofamid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that cyazofamid does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. The prenatal and postnatal toxicology database for cyazofamid includes rat and rabbit developmental toxicity studies and a 2-generation reproductive toxicity study in rats. There was no indication of increased susceptibility, as compared to adults, of rabbit fetuses to *in utero* exposure in a developmental study or of rat pups in the 2-generation reproductive toxicity study. There is evidence of increased quantitative susceptibility following *in utero* exposure of rats to cyazofamid in the prenatal developmental study; an increased incidence of bent ribs in fetuses at the HDT was noted in the absence of maternal effects.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

i. The toxicity database for cyazofamid is complete except for immunotoxicity and subchronic neurotoxicity testing. Recent changes to 40 CFR part 158 make immunotoxicity testing (OSCPP Harmonized Guideline 870.7800) and subchronic neurotoxicity testing (OSCPP Harmonized Guideline 158.500) required for pesticide registration; however, the available data for cyazofamid do not show potential for immunotoxicity. Further, there is no evidence of neurotoxicity in any study in the toxicity database for cyazofamid. EPA does not believe that conducting neurotoxicity and immunotoxicity studies will result in a NOAEL lower than the regulatory dose for risk assessment. Consequently, the EPA believes the existing data are sufficient for endpoint selection for exposure/risk assessment scenarios and for evaluation of the requirements under the FQPA, and an additional database uncertainty factor does not need to be applied.

ii. There is no indication that cyazofamid is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that cyazofamid results in increased susceptibility in rabbits in the prenatal developmental study or in young rats in the 2-generation reproductive toxicity study. Although there is evidence of increased quantitative susceptibility in the prenatal developmental study in rats, the Agency determined that concern is low because:

a. The developmental effect (increased bent ribs) is well identified with a clear NOAEL and LOAEL.

b. Increased bent ribs are considered a reversible variation rather than a malformation.

c. The effect was noted only at the limit dose of 1,000 mg/kg/day.

d. This endpoint was used to establish the acute reference dose (aRfD) for females 13–49.

e. The overall toxicity profile indicates that cyazofamid is not a very toxic compound.

Therefore, there are no residual concerns regarding developmental effects in the young.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to cyazofamid in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by cyazofamid.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-term, intermediate-term and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to cyazofamid will occupy 1.2% of the aPAD for females 13 to 49 years old, the population group of concern for acute effects. Cyazofamid is not expected to pose an acute risk to the general population, including infants and children.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to cyazofamid

from food and water will utilize 1.2% of the cPAD for infants less than 1 year old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of cyazofamid is not expected.

3. *Short-term and intermediate-term risk*. Short-term and intermediate-term aggregate exposure takes into account short-term and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Cyazofamid is currently registered for uses that could result in short-term and intermediate-term postapplication residential exposure to adults and children. The Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term and intermediate-term residential exposure to cyazofamid.

Using the exposure assumptions described in this unit for short-term and intermediate-term exposures, EPA has concluded the combined short-term and intermediate-term food, water, and residential exposures (treated residential turf and ornamentals) aggregated result in MOEs of 1,000 for the general U.S. population, 1,400 for children 3 to 5 years old, and 1,500 for children 6 to 12 years old. As the MOEs are greater than 100 for all population subgroups, short-term and intermediate-term aggregate exposure to cyazofamid is not of concern.

4. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, cyazofamid is not expected to pose a cancer risk to humans.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to cyazofamid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate analytical methodology is available to enforce the proposed tolerances. Cyazofamid and the metabolite CCIM are completely recovered (>80% recovery) using FDA's Multi-Residue Protocol D (without cleanup). In addition, a high performance liquid chromatography/ultraviolet detector (HPLC/UV) method is available for use as a single analyte confirmatory method. These methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There are currently no Codex or Canadian MRLs established for residues of cyazofamid in or on commodities associated with this petition.

C. Revisions to Petitioned-For Tolerances

The EPA has revised the tolerance expression to clarify: 1. That, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of cyazofamid not specifically mentioned; 2. That compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of cyazofamid, 4-chloro-2-cyano-*N*,*N*-dimethyl-5-(4-methylphenyl)-1*H*-imidazole-1-sulfonamide, and its metabolite 4-chloro-5-(4-methylphenyl)-1*H*-imidazole-2-carbonitrile, calculated as the stoichiometric equivalent of cyazofamid, in or on Brassica, head and stem, subgroup 5A at 1.2 ppm; Brassica, leafy greens, subgroup 5B at 12.0 ppm; turnip, greens at 12.0 ppm; spinach at 9.0 ppm; and hop, dried cones at 10.0 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq*., nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology

Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 1, 2010.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.601 is amended by:

i. Revising the introductory text and alphabetically adding the following commodities to the table in paragraph (a):

ii. Revising the introductory text in paragraph (c) to read as follows:

§ 180.601 Cyazofamid; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide cyazofamid, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only the sum of 4-chloro-2-cyano-*N*,*N*-dimethyl-5-(4-methylphenyl)-1*H*-imidazole-1-sulfonamide and its metabolite, 4-chloro-5-(4-methylphenyl)-1*H*-imidazole-2-carbonitrile, calculated as the stoichiometric equivalent of cyazofamid, in or on the following commodities:

Commodity	Parts per million
Brassica, head and stem, subgroup 5A	1.2
Brassica, leafy greens, subgroup 5B	12.0
* * * * * * *	
Hop dried cones	10.0
* * * * * * *	
Spinach	9.0
Turnip, greens	12.0
* * * * * * *	

* * * * *

(c) *Tolerances with regional registrations.* Tolerances with regional registrations are established for residues of the fungicide cyazofamid, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only the sum of 4-chloro-2-cyano-*N*,*N*-dimethyl-5-(4-methylphenyl)-1*H*-imidazole-1-sulfonamide and its metabolite, 4-chloro-5-(4-methylphenyl)-1*H*-imidazole-2-carbonitrile, calculated as the stoichiometric equivalent of cyazofamid, in or on the following commodities:

* * * * *

[FR Doc. 2010–17025 Filed 7–13–10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0231; FRL–8834–4]

Castor Oil, Ethoxylated, Oleate; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of castor oil, ethoxylated, oleate (CAS Reg. No. 220037–02–5) with a minimum number average molecular weight (in amu) of 1,600 when used as an inert ingredient in a pesticide chemical formulation under 40 CFR 180.960. SciReg. Inc. on behalf of Rhodia, Inc, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of castor oil, ethoxylated, oleate on food or feed commodities.

DATES: This regulation is effective July 14, 2010. Objections and requests for hearings must be received on or before September 13, 2010 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0231. 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., Confidential Business Information (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 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 Docket Facility is open 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: Karen Samek, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 347–8825; e-mail address: *samek.karen@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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**.

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2010–0231 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before September 13, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0231, 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.

II. Background and Statutory Findings

In the **Federal Register** of May 19, 2010 (75 FR 28009) (FRL–8823–2), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the receipt of a pesticide petition (PP 0E7692) filed by SciReg, Inc, on behalf of Rhodia Inc., 12733 Director's Loop, Woodbridge, VA 22192. The petition requested that the exemption from the requirement of a tolerance for castor oil, ethoxylated, oleate, minimum number average molecular weight (in amu) 2,000, (CAS Reg. No. 220037–02–5) when used as an inert ingredient in pesticide chemical formulations listed under 40 CFR 180.960 be amended to allow for a minimum number average molecular weight (in amu) of 1,200. That notice included a summary of the petition prepared by the petitioner and solicited comments on the petitioner's request. The Agency did not receive any comments.

Based upon review of the data supporting the petition, EPA has modified the exemption requested by limiting the minimum number average molecular weight (in amu) to 1,600. Therefore, the exemption from the requirement of a tolerance being established in this final rule is for residues of castor oil, ethoxylated, oleate (CAS Reg. No. 220037–02–5) with a minimum number average molecular weight (in amu) of 1,600.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and use in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing an exemption from the requirement of a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue..." and specifies factors EPA is to consider in establishing an exemption.

III. Risk Assessment and Statutory Findings

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be shown that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an

exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. In the case of certain chemical substances that are defined as polymers, the Agency has established a set of criteria to identify categories of polymers expected to present minimal or no risk. The definition of a polymer is given in 40 CFR 723.250(b) and the exclusion criteria for identifying these low-risk polymers are described in 40 CFR 723.250(d). Castor oil, ethoxylated, oleate conforms to the definition of a polymer given in 40 CFR 723.250(b) and meets the following criteria that are used to identify low-risk polymers.

1. The polymer is not a cationic polymer nor is it reasonably anticipated to become a cationic polymer in a natural aquatic environment.

2. The polymer does contain as an integral part of its composition the atomic elements carbon, hydrogen, and oxygen.

3. The polymer does not contain as an integral part of its composition, except as impurities, any element other than those listed in 40 CFR 723.250(d)(2)(ii).

4. The polymer is neither designed nor can it be reasonably anticipated to substantially degrade, decompose, or depolymerize.

5. The polymer is manufactured or imported from monomers and/or reactants that are already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

6. The polymer is not a water absorbing polymer with a number average molecular weight (MW) greater than or equal to 10,000 daltons.

Additionally, the polymer also meets as required the following exemption criteria specified in 40 CFR 723.250(e).

7. The polymer's number average MW of 1,600 daltons is greater than 1,000 and less than 10,000 daltons. The polymer contains less than 10% oligomeric material below MW 500 and less than 25% oligomeric material below MW 1,000, and the polymer does not contain any reactive functional groups.

Thus, castor oil, ethoxylated, oleate meets the criteria for a polymer to be considered low risk under 40 CFR 723.250. Based on its conformance to the criteria in this unit, no mammalian toxicity is anticipated from dietary, inhalation, or dermal exposure to castor oil, ethoxylated, oleate.

IV. Aggregate Exposures

For the purposes of assessing potential exposure under this exemption, EPA considered that castor oil, ethoxylated, oleate could be present in all raw and processed agricultural commodities and drinking water, and that non-occupational non-dietary exposure was possible. The number average MW of castor oil, ethoxylated, oleate is 1,600 daltons. Generally, a polymer of this size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since castor oil, ethoxylated, oleate conforms to the criteria that identify a low-risk polymer, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable. The Agency has determined that a tolerance is not necessary to protect the public health.

V. Cumulative Effects From Substances With a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found castor oil, ethoxylated, oleate to share a common mechanism of toxicity with any other substances, and castor oil, ethoxylated oleate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that castor oil, ethoxylated, oleate does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

VI. Additional Safety Factor for the Protection of Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA concludes that a different margin of safety will be safe for infants and children. Due to the expected low toxicity of castor oil, ethoxylated oleate, EPA has not used a safety factor analysis to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

VII. Determination of Safety

Based on the conformance to the criteria used to identify a low-risk polymer, EPA concludes that there is a reasonable certainty of no harm to the U.S. population, including infants and children, from aggregate exposure to residues of castor oil, ethoxylated, oleate.

VIII. Other Considerations

A. Existing Exemptions from the Requirement of a Tolerance

Castor oil, ethoxylated, oleate, minimum number average molecular weight (in amu) 2,000, (CAS Reg. No. 220037–02–5) is exempted from the requirement of a tolerance under 40 CFR 180.960 when used as an inert ingredient in pesticide chemical formulations.

B. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for castor oil, ethoxylated, oleate.

IX. Conclusion

Accordingly, EPA finds that exempting residues of castor oil, ethoxylated, oleate from the requirement of a tolerance will be safe.

X. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these rules from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes, or otherwise have any unique impacts on local governments. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

Although this action does not require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. As such, to the extent that information is publicly available or was submitted in comments to EPA, the Agency considered whether groups or segments of the population, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide discussed in this document, compared to the general population.

XI. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 7, 2010.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.960, the table is amended by revising the following polymer to read as follows:

§ 180.960 Polymers; exemptions from the requirement of a tolerance.

* * * * *

Polymer	CAS No.
* * * * *	
Castor oil, ethoxylated, oleate, minimum number average molecular weight (in amu), 1,600	220037–02–5
* * * * *	

* * * * *

[FR Doc. 2010–17153 Filed 7–13–10; 8:45 am]

BILLING CODE 6560–50–S

NATIONAL SCIENCE FOUNDATION

45 CFR Part 614

RIN 3145–AA53

Government in the Sunshine Act Regulations of the National Science Board

AGENCY: National Science Board (NSB), National Science Foundation (NSF).

ACTION: Direct final rule.

SUMMARY: The National Science Board (NSB) National Science Foundation (NSF) is amending part 614 of the Government in the Sunshine Act Regulations of the National Science Board. This document contains minor amendments to the Government in the Sunshine Act Regulations of the National Science Board. These technical amendments clarify that the NSB Office will maintain the General Counsel's certificate, the presiding officer's statement, and the transcript or recording of the closed meeting for at least three years (vice two years) and to clarify that announcements required by section 552b(e) of the Sunshine Act will occur via the NSF Web site (vice posting on public notice boards or to journals of general scientific interest, neither of which is required by law). This final rule is an administrative simplification that makes no substantive or major change in NSF or NSB policy or procedures for maintaining official records and information, and informing the public of closed meetings in accordance with the Sunshine Act.

DATES: This final rule is effective July 14, 2010.

FOR FURTHER INFORMATION CONTACT: Daniel A. Lauretano, Counsel to the National Science Board at 703–292–2648 (not a toll-free call) and e-mail *dlaureta@nsf.gov*.

SUPPLEMENTARY INFORMATION:

Background

The current National Science Board's Government in the Sunshine Act regulations require the National Science Board Office (NSBO) to maintain the General Counsel's certificate, the presiding officer's statement, and the transcript or recording of the closed meeting for at least two years, consistent with section 552b(f)(2) of the Government in the Sunshine Act, 5 USC 552b. The current regulation should be revised to reflect the three-year retention period required by amendments to the National Science Foundation Act at 42 USC 1862n–5(a)(5). Additionally, the regulations, which date to the 1970s, require the NSBO to post meeting announcements on public notice boards at the National Science Foundation and make them available to journals of general scientific interest. The current regulation is being revised to delete the words, "public notice boards at" and "and make them available to journals of general scientific interest" (which is not required by law) and make clear that the public announcement required by section 552b(e) of the Sunshine Act will occur via the NSF Web site.

Executive Order 12866

The change in this rule is nonsignificant.

Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b))

This proposed regulatory action will not have a significant adverse impact on a substantial number of small entities.

Unfunded Mandates Act of 1995 (Sec. 202, Pub. L. 104–4)

This proposed regulatory action does not contain a Federal mandate that will result in the expenditure by State, local, and tribal governments, in aggregate, or by the private sector of $100 million or more in any one year.

Paperwork Reduction Act of 1995 (44 U.S.C., Chapter 35)

This regulatory action will not impose any additional reporting or recordkeeping requirements under the Paperwork Reduction Act.

Federalism (Executive Order 13132)

This proposed regulatory action does not have Federalism implications, as set forth in Executive Order 13132. It will not have 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.

List of Subjects in 45 CFR Part 614

Materials relating to closed portions of meetings; Public announcement.

■ Accordingly, under the authority of 42 U.S.C. 1870, NSF amends the Code of Federal Regulations, Title 45, Chapter VI, as follows:

Title 45—Public Welfare—Chapter VI—National Science Foundation

PART 614—GOVERNMENT IN THE SUNSHINE ACT REGULATIONS OF THE NATIONAL SCIENCE BOARD [AMENDED]

■ 1. The authority citation for part 614 continues to read as follows:

Authority: 42 U.S.C. 1870(a).

§ 614.3 [Amended]

■ 2. Paragraph (d) of § 614.3 is amended by removing the word "two" and by adding the word "three" in its place.

§ 614.5 [Amended]

■ 3. Section 614.5 amended by revising paragraph (b) to read as follows:

§ 614.5 Public announcement.

* * * * *

(b) Each such announcement will be promptly posted on the National Science Foundation's Web site at *http://www.nsf.gov/nsb/notices/*. Immediately following the issuance of such an announcement, it will be submitted for publication in the **Federal Register.**

* * * * *

Dated: July 9, 2010.

Daniel A. Lauretano,

Counsel to the National Science Board.

[FR Doc. 2010–17120 Filed 7–13–10; 8:45 am]

BILLING CODE 7555–01–P

Proposed Rules

Federal Register
Vol. 75, No. 134
Wednesday, July 14, 2010

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.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 37

[NRC–2010–0194]

RIN 3150–AI12

Implementation Guidance for Physical Protection of Byproduct Material; Category 1 and Category 2 Quantities of Radioactive Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability of draft guidance for public comment.

SUMMARY: The U. S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to establish security requirements for the use and transport of category 1 and category 2 quantities of radioactive material. The NRC has prepared draft guidance to address implementation of the proposed regulations. This notice is announcing the availability of the draft implementation guidance document for public comment.

DATES: Submit comments by November 12, 2010. Comments received after this date will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date.

ADDRESSES: Please include Docket ID NRC–2010–0194 in the subject line of your comments. For instructions on accessing documents related to this action, see Section I, "Submitting Comments and Accessing Information" in the **SUPPLEMENTARY INFORMATION** section of this document. You may submit comments by any one of the following methods.

Federal Rulemaking Web Site: Go to *http://www.regulations.gov* and search for documents filed under Docket ID NRC–2010–0194. Address questions about NRC dockets to Carol Gallagher, telephone (301) 492–3668; e-mail *Carol.Gallagher@nrc.gov*.

Mail comments to: Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of Administration, Mail Stop: TWB–05–B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Fax comments to: RADB at (301) 492–3446.

FOR FURTHER INFORMATION CONTACT: Paul Goldberg, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–7842, e-mail *Paul.Goldberg@nrc.gov*.

SUPPLEMENTARY INFORMATION:

Submitting Comments and Accessing Information

Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal rulemaking Web site *http://www.regulations.gov*. 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. The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed.

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, Room O–1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

NRC's Agencywide Documents Access and Management System (ADAMS): Publicly available documents created or received at the NRC are available electronically at the NRC's Electronic Reading Room 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 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, or 301–415–4737, or by e-mail to *PDR.Resource@nrc.gov*. The draft Part 37 implementation guidance is available electronically under ADAMS Accession Number ML101470684.

Federal Rulemaking Web Site: Public comments and supporting materials related to the implementation guidance, including the draft implementation guidance, can be found at *http://www.regulations.gov* by searching on Docket ID NRC–2010–0194. Documents related to the proposed rule can be found by searching on Docket ID NRC–2008–0120.

Discussion

The NRC has recently published a proposed rule that would place the security requirements for use of category 1 and category 2 quantities of radioactive material into a new part 37 of title 10 of the Code of Federal Regulations. The proposed rule was published on June 15, 2010 (75 FR 33902), and the public comment period runs through October 13, 2010. Documents related to the proposed rule can be found at *http://www.regulations.gov* by searching on Docket ID NRC–2008–0120.

In conjunction with the proposed rule, the NRC has developed implementation guidance. The implementation document provides guidance to a licensee or applicant for implementation of proposed 10 CFR part 37, "Physical Protection of Byproduct Material," specifically category 1 and category 2 quantities of radioactive material. It is intended for use by applicants, licensees, Agreement States, and NRC staff. The document describes methods acceptable to the NRC staff for implementing proposed 10 CFR part 37. The approaches and methods described in the document are provided for information only. Methods and solutions different from those described in the document are acceptable if they meet the requirements in proposed 10 CFR part 37. The guidance is provided in the form of questions and answers on the provisions of the proposed rule. The draft implementation guidance document for proposed 10 CFR part 37 is available electronically under ADAMS Accession Number ML101470684, and can also be found at *http://www.regulations.gov* by searching on Docket ID: NRC–2010–0194.

At this time, the NRC is announcing the availability for public comment of "Implementation Guidance for 10 CFR part 37 Physical Protection of Byproduct Material, Category 1 and Category 2 Quantities of Radioactive Material." The document provides guidance on implementing the provisions of proposed 10 CFR part 37, "Physical Protection of Byproduct Material." The NRC is planning to hold two public meetings to obtain public input on the draft implementation guidance in September 2010. Information on these meetings will be posted on *http://www.regulations.gov* under Docket ID NRC–2010–0194.

Dated at Rockville, Maryland, this 30th day of June 2010.

For the Nuclear Regulatory Commission.

Andrew Mauer,

Chief, Source Management and Protection Branch, Division of Materials Safety and State Agreements, Office of Federal and State Materials and Environmental Management Programs.

[FR Doc. 2010–17126 Filed 7–13–10; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2010–0596; Directorate Identifier 2010–NE–22–AD]

RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney PW4000 Series Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Pratt & Whitney PW4000 series turbofan engines. This proposed AD would require initial and repetitive borescope inspections (BSI) or fluorescent penetrant inspections (FPI) for cracks in the anti-vortex tube (AVT) shelf slots on the 10th stage disk of the high-pressure compressor (HPC) drum rotor disk assembly. This proposed AD results from 47 reports received since 2007 of HPC 10th stage disks found cracked in the AVT shelf slots during shop visit inspections. We are proposing this AD to prevent failure of the HPC 10th stage disk, uncontained engine failure, and damage to the airplane.

DATES: We must receive any comments on this proposed AD by September 13, 2010.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* (202) 493–2251.

Contact Pratt & Whitney, 400 Main St., East Hartford, CT 06108; telephone (860) 565–8770; fax (860) 565–4503, for a copy of the service information identified in this proposed AD.

FOR FURTHER INFORMATION CONTACT: James Gray, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; e-mail: *james.e.gray@faa.gov;* telephone (781) 238–7742; fax (781) 238–7199.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send us any written relevant data, views, or arguments regarding this proposal. Send your comments to an address listed under **ADDRESSES**. Include "Docket No. FAA–2010–0596; Directorate Identifier 2010–NE–22–AD" in the subject line of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments received by the closing date and may amend the proposed 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 proposed AD. Using the search function of the Web site, anyone can find and read the comments in any of our dockets, including, if provided, the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

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 this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is the same as the Mail address provided in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

Discussion

Since 2007, we have received 47 reports of HPC 10th stage disks found cracked in the AVT shelf slots during shop visit inspections. Investigation has revealed the root cause of the cracks to be the slot configuration in the 9th stage compressor stator inner shroud. The number of slots matches the number of anti-vortex tubes and causes an aerodynamic interaction during engine operation. This interaction results in high-cycle-fatigue cracks in the AVT shelf slots on the 10th stage disk of the HPC drum rotor disk assembly. This condition, if not corrected, could result in failure of the HPC 10th stage disk, uncontained engine failure, and damage to the airplane.

Relevant Service Information

We have reviewed and approved the technical contents of Pratt & Whitney Service Bulletin (SB) No. PW4ENG 72–799, dated January 22, 2010, and SB No. PW4G–100–72–226, dated April 22, 2010, that describe procedures for inspecting for cracks in the AVT shelf slots on the 10th stage disk of the HPC drum rotor disk assembly.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other products of this same type design. We are proposing this AD, which would require initial and repetitive BSI or FPI for cracks in the AVT shelf on the 10th stage disk of the HPC drum rotor disk assembly. The proposed AD would require you to use the service information described previously to perform these actions.

Interim Actions

These actions are interim actions and we may take further rulemaking actions in the future.

Costs of Compliance

We estimate that this proposed AD would affect 869 engines installed on airplanes of U.S. registry. We also estimate that it would take about one work-hour per engine to perform a proposed inspection, and that the average labor rate is $85 per work-hour. Required parts would cost about $303,010 per HPC drum rotor disk assembly. About 61 HPC drum rotor disk assemblies would need replacement due to cracks. Based on these figures, we estimate the cost of the AD on U.S. operators to be $18,557,475.

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 proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would 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 proposed 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. Would 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 proposed AD. You may get a copy of this summary at the address listed under **ADDRESSES**.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

Under the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 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:

Pratt & Whitney: Docket No. FAA–2010–0596; Directorate Identifier 2010–NE–22–AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this airworthiness directive (AD) action by September 13, 2010.

Affected ADs

(b) None.

Applicability

(c) This AD applies to the following Pratt & Whitney turbofan engines with a ring case configuration rear high-pressure compressor (HPC) installed. These engines are installed on, but not limited to, Boeing 747–200, 767–200/–300, and MD–11 airplanes, and Airbus A300–600, A310–300, A330–300, and A330–200 airplanes.

PW4000–94" Engines

(1) PW4000–94" series engine models PW4050, PW4052, PW4056, PW4060, PW4060A, PW4060C, PW4062, PW4062A, PW4152, PW4156, PW4156A, PW4158, PW4160, PW4460, PW4462, and PW4650, including all models with a dash number suffix.

PW4000–100" Engines

(2) PW4000–100" series engine models PW4168A–1D and PW4170 with serial numbers P735001 through P735039; and

(3) All engines converted to PW4164–1D, PW4168–1D, PW4168A–1D, or PW4170 model engines.

Unsafe Condition

(d) This AD results from 47 reports received since 2007 of HPC 10th stage disks found cracked in the AVT shelf slots during shop visit inspections. We are issuing this AD to prevent failure of the HPC 10th stage disk, uncontained engine failure, and damage to the airplane.

Compliance

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

Initial Inspection of the AVT Shelf Slots

(f) For engines listed in paragraphs (c)(1) and (c)(3) of this AD, do the following:

(1) Remove the low-pressure turbine (LPT) shaft and borescope-inspect (BSI) for cracks in the AVT shelf slots on the 10th stage disk of the HPC drum rotor disk assembly; or

(2) Remove the HPC drum rotor disk assembly and fluorescent-penetrant inspect (FPI) for cracks in the AVT shelf slots on the 10th stage disk of the HPC drum rotor disk assembly.

(3) Perform the inspection:

(i) Within 7,200 cycles-in-service (CIS) since incorporation of any of the following Pratt & Whitney Service Bulletins: (SB) No. PW4ENG 72–755, SB No. PW4ENG 72–756, SB No. PW4ENG 72–757, SB No. PW4ENG 72–759, or SB No. PW4G–100–72–220; or

(ii) Within 1,000 CIS after the effective date of this AD, whichever occurs later.

(4) If a crack is found, remove the HPC drum rotor disk assembly from service.

(g) For engines listed in paragraph (c)(2) of this AD, do the following:

(1) Remove the LPT shaft and BSI for cracks in the AVT shelf slots on the 10th stage disk of the HPC drum rotor disk assembly; or

(2) Remove the HPC drum rotor disk assembly and FPI for cracks in the AVT shelf slots on the 10th stage disk of the HPC drum rotor disk assembly.

(3) Perform the inspection:

(i) Within 7,200 cycles-since-new; or

(ii) Within 1,000 CIS after the effective date of this AD, whichever occurs later.

(4) If a crack is found, remove the HPC drum rotor disk assembly from service.

Repetitive Inspections of the AVT Shelf Slots

(h) Thereafter, perform a BSI or FPI for cracks in the AVT shelf slots on the 10th stage HPC disk of the HPC drum rotor disk assembly within every 7,200 cycles-since-last-inspection.

(i) If a crack is found, remove the HPC drum rotor disk assembly from service.

Relevant Service Bulletins

(j) Use paragraphs 3.A through 3.H of the Accomplishment Instructions of Pratt & Whitney SB No. PW4ENG 72–799, dated January 22, 2010, to perform the BSIs for engines listed in paragraph (c)(1) of this AD.

(k) Use paragraphs 3.A through 3.H of the Accomplishment Instructions of Pratt & Whitney SB No. PW4G–100–72–226, dated April 22, 2010, to perform the BSIs for engines listed in paragraphs (c)(2) and (c)(3) of this AD.

Alternative Methods of Compliance

(l) The Manager, Engine Certification Office, has the authority to approve alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

Interim Actions

(m) These actions are interim actions and we may take further rulemaking actions in the future.

Related Information

(n) Contact James Gray, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; e-mail: *james.e.gray@faa.gov;* telephone (781) 238–7742; fax (781) 238–7199, for more information about this AD.

(o) Pratt & Whitney SB No. PW4ENG 72–799, dated January 22, 2010, and SB No. PW4G–100–72–226, dated April 22, 2010, pertain to the subject of this AD. Contact Pratt & Whitney, 400 Main St., East Hartford, CT 06108; telephone (860) 565–8770; fax (860) 565–4503, for a copy of this service information.

Issued in Burlington, Massachusetts, on July 8, 2010.

Peter A. White,

Assistant Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2010–17145 Filed 7–13–10; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 922

Initiation of Review of Management Plan/Regulations of the Hawaiian Islands Humpback Whale National Marine Sanctuary; Intent To Prepare Draft Environmental Impact Statement and Management Plan; Scoping Meetings

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of Intent to Initiate Review of Management Plan/Regulations; Intent to Prepare Environmental Impact Statement; Scoping Meetings.

SUMMARY: In accordance with section 304(e) of the National Marine Sanctuaries Act, as amended, (NMSA) (16 U.S.C. 1431 *et seq.*), the Office of National Marine Sanctuaries (ONMS) of the National Oceanic and Atmospheric Administration (NOAA) has initiated a review of the Hawaiian Islands Humpback Whale National Marine Sanctuary (HIHWNMS or sanctuary) management plan, to evaluate substantive progress toward implementing the goals for the sanctuary, and to make revisions to its management plan and regulations as necessary to fulfill the purposes and policies of the NMSA and the Hawaiian Islands National Marine Sanctuary Act (HINMSA; Title II, Subtitle C, Pub. L. 102–587). The present management plan was written as part of the sanctuary's management plan review process in 2002 and did not contain any regulatory or boundary changes from the implementing regulations that became effective December 29, 1999 (64 FR 63262). NOAA anticipates completion of the revised management plan and concomitant documents will require approximately thirty-six months from the date of publication of this Notice of Intent. The management plan review process occurs concurrently with a public process under the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*). This notice also confirms that NOAA will coordinate its responsibilities under section 106 of the National Historic Preservation Act (NHPA, 16 U.S.C. 470) with its ongoing NEPA process, pursuant to 36 CFR 800.8(a)—coordination with NEPA—including the use of NEPA documents and public and stakeholder meetings to also meet the section 106 requirements.

DATES: All comments on issues related to the continued management of the Hawaiian Islands Humpback Whale National Marine Sanctuary will be considered if received on or before October 16, 2010. *See* **SUPPLEMENTARY INFORMATION** section below for the dates, times, and locations of the public scoping meetings.

ADDRESSES: All written inquiries and comments may be sent to: Management Plan Review Coordinator, Hawaiian Islands Humpback Whale National Marine Sanctuary, 6600 Kalaniana'ole Highway, Suite 301, Honolulu, Hawai'i 96825 or faxed to (808) 397–2650.

Electronic comments may be sent to: *hihwmanagementplan@noaa.gov.*

All comments received are a part of the public record. 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. NOAA will accept anonymous comments. Attachments to electronic comments will be accepted in Microsoft Word, Excel, Wordperfect, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Malia Chow, Policy Advisor, Telephone: (808) 397–2651.

SUPPLEMENTARY INFORMATION:

Background Information

The Hawaiian Islands Humpback Whale National Marine Sanctuary (sanctuary) was designated by Congress in 1992 as the 12th national marine sanctuary in the U.S. Its primary mission is to protect humpback whales (Megaptera novaeangliae) and their habitat in Hawai'i. The sanctuary enables citizens and government to work collectively on safeguarding humpback whale breeding and calving range in waters around the main Hawaiian Islands, an area that supports over half the North Pacific humpback whale population and constitutes one of the world's most important humpback whale habitats. Encompassing 3,548 square kilometers (1,370 square miles) of federal and state waters surrounding the main Hawaiian Islands, the sanctuary extends from the shoreline to the 100-fathom isobath (183-meter or 600 foot depth) and is composed of five separate marine protected areas (MPAs) accessible from six of the eight main Hawaiian Islands. The sanctuary's configuration presents unique challenges and opportunities for protecting sanctuary resources, developing programs, and increasing public awareness of humpback whales throughout the state.

In accordance with Section 304(e) of the National Marine Sanctuaries Act, as amended (NMSA), 16 U.S.C. 1431 *et seq.,* the Office of National Marine Sanctuaries (ONMS) of the National Oceanic and Atmospheric Administration (NOAA) is initiating a review of the current management plan to evaluate the substantive progress made toward implementing the goals for the sanctuary, and to make revisions to the plan and regulations as necessary to fulfill the purposes and policies of the NMSA. The proposed revised management plan may involve changes to existing policies and regulations of the sanctuary, as well as address current and emerging topics, challenges, and opportunities to better protect and manage the sanctuary's resources and qualities. The review process is composed of four primary stages:

(1) Information collection and characterization, including public scoping meetings;

(2) Preparation and release of a revised draft management plan/environmental evaluation that includes any proposed new regulations or amendments to current regulations;

(3) Public review and comment on the draft plan; and

(4) Preparation and release of a final management plan/environmental evaluation that could also include new regulations to fully implement the revised management plan.

NOAA anticipates that the completion of the revised management plan and concomitant documents will require approximately twenty-four to thirty-six months.

NOAA is opening a public comment period to:

1. Solicit public comments and identify issues on the continued management of the Hawaiian Islands Humpback Whale National Marine Sanctuary; and

2. Help determine the scope of issues to be addressed in the preparation of a management plan and an environmental impact statement (EIS) pursuant to the National Environmental Policy Act (NEPA), if warranted; and

3. Conduct a series of statewide scoping meetings across the State of Hawai'i to collect public comment. The intent of the scoping meetings is to gather information and other comments from individuals, organizations, and government agencies on the scope, types, and significance of issues related to the sanctuary's management plan and regulations. These scoping meetings will also help determine the scope of issues to be addressed in the preparation of an EIS pursuant to the NEPA, 43 U.S.C. 4321 *et seq.,* if warranted. The public scoping meeting schedule is presented below.

This notice confirms that NOAA will coordinate its responsibilities under section 106 of the National Historic Preservation Act (NHPA, 16 U.S.C. 470) with its ongoing NEPA process, pursuant to 36 CFR 800.8(a)—coordination with NEPA—including the use of NEPA documents and public and stakeholder meetings to also meet the section 106 requirements. The NHPA specifically applies to any agency undertaking that has an adverse effect on historic properties. Pursuant to 36 CFR 800.16(1)(1), historic properties includes: "any prehistoric or historic district, site, building, structure or object included in, or eligible for inclusion in, the National Register of Historic Places maintained by the Secretary of the Interior. The term includes artifacts, records, and remains that are related to and located within such properties. The term includes properties of traditional religious and cultural importance to an Indian tribe or Native Hawaiian organization and that meet the National Register criteria."

In coordinating its responsibilities under the NHPA and NEPA, NOAA intends to identify consulting parties; identify historic properties and assess the effects of the undertaking on such properties; initiate formal consultation with the Hawaii State Historic Preservation Officer, the Advisory Council of Historic Preservation, and other consulting parties; involve the public in accordance with NOAA's NEPA procedures, and develop in consultation with identified consulting parties alternatives and proposed measures that might avoid, minimize or mitigate any adverse effects on historic properties and describe them in any Environmental Assessment or Draft Environmental Impact Statement.

Public Scoping Meetings: The public scoping meetings will be held on the following dates and at the following locations beginning at 6 p.m. unless otherwise noted:

1. Hilo, Hawai'I, Tuesday, August 10, Mokupāpapa Discovery Center, 308 Kamehameha Avenue, Suite 109, Hilo, HI 96720.
2. Kailua-Kona, Hawai'I, Wednesday, August 11, Outrigger Keauhou Beach Resort, 78–6740 Ali'i Drive, Kailua-Kona, HI 96740.
3. Honolulu, O'ahu, Thursday, August 12, 5:30 p.m. to 8:30 p.m., Central Union Church, 1660 South Beretania Street, Honolulu, HI 96826.
4. Līhu'e, Kaua'I, Saturday, August 14, 9 a.m. to 12 p.m., Chiefess Kamakahelei Middle School Cafeteria, 4431 Nuhou Street, Līhu'e, HI 96766.
5. Kilauea, Kaua'I, Saturday, August 14, 4 p.m. to 7 p.m., Kaua'i Christian Academy Library, 4000 Kilauea Road, Kilauea, HI 96754.
6. Kīhei, Maui, Monday, August 16, Lokilani Middle School, 1401 Liloa Drive, Kīhei, HI 96753.
7. Lahaina, Maui, Tuesday, August 17, Lahaina Civic Center, 1840 Honoapi'ilani Highway, Lahaina, HI 96761.
8. Kaunakakai, Moloka'I, Wednesday, August 18, Mitchell Pauole Center, 90 Ainoa Street, Kaunakakai, HI 96748.
9. Hale'iwa, O'ahu, Monday, August 23, Sunset Beach Elementary School, 59–360 Kamehameha Highway, Hale'iwa, HI 96712.
10. Lana'i City, Lana'I, Wednesday, August 26, Lana'i High and Elementary School, 555 Fraser Avenue, Lana'i City, HI 96763.

Condition Report

In preparation for management plan review, NOAA has produced a Hawaiian Islands Humpback Whale National Marine Sanctuary 2010 Condition Report. The Condition Report provides a summary of resources, with a specific focus on humpback whales in the sanctuary, pressures on those resources, the current condition and trends, and management responses to the pressures that threaten the integrity of the marine environment. Specifically, the Condition Report includes information on the status and trends of water quality, habitat, living resources and maritime archaeological resources and the human activities that affect them. The report serves as a supporting document for the Management Plan Review Process, to inform constituents of the current status of humpback whales in the sanctuary.

An electronic copy of the final Hawaiian Islands Humpback Whale National Marine Sanctuary 2010 Condition Report is available to the public on the Internet at: *http://sanctuaries.noaa.gov/science/condition/welcome.html* or it can be accessed from the HIHWNMS Web site at: *http://hawaiihumpbackwhale.noaa.gov/*.

Scoping Comments

Scoping meetings provide an opportunity to make direct comments to NOAA on the management of the sanctuary's natural and cultural resources, including administrative programs. We encourage the public to participate and welcome any comments related to the sanctuary. In particular, we are interested in hearing about the public's view on the sanctuary's potential management priorities for the next ten to fifteen years. Specifically, the sanctuary is seeking input on a proposal to expand its scope and direction to protect and conserve other living marine resources, in addition to humpback whales and submerged cultural heritage resources within the sanctuary. This proposal is detailed in the State of the Sanctuary Report Special Management Plan Review Edition and is available to the public on the Internet at: *http://hawaiihumpbackwhale.noaa.gov/management/management_plan_review.html*.

Authority: 16 U.S.C. 1431 *et seq;* 16 U.S.C. 470.

(Federal Domestic Assistance Catalog Number 11.429 Marine Sanctuary Program)

Dated: July 7, 2010.

Daniel J. Basta,

Director for the Office of National Marine Sanctuaries.

[FR Doc. 2010–17083 Filed 7–13–10; 8:45 am]

BILLING CODE 3510–NK–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2009–0665; FRL–9175–3]

Approval and Promulgation of Air Quality Implementation Plans; Illinois; Volatile Organic Compound Site-Specific State Implementation Plan for Abbott Laboratories

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve Illinois' amendments to its manufacturing rules into the Illinois State Implementation Plan (SIP). On July 17, 2009, the Illinois Environmental Protection Agency (Illinois EPA) submitted amendments to its pharmaceutical manufacturing rules for approval into its SIP. These amendments consist of a site-specific rulemaking for certain of Abbott Laboratories' (Abbott) tunnel dryers and fluid bed dryers. This site-specific rule revision is approvable because it lowers the allowable emissions from these dryers and it is consistent with the Clean Air Act (CAA) and EPA regulations.

DATES: Comments must be received on or before August 13, 2010.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2009–0665, by one of the following methods:

1. *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *E-mail: bortzer.jay@epa.gov.*
3. *Fax:* (312) 692–2054.
4. *Mail:* Jay Bortzer, Chief, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.
5. *Hand Delivery:* Jay Bortzer, Chief, 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–2009–0665. 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 and 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 Steven Rosenthal at (312) 886–6052 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Steven Rosenthal, Environmental Engineer, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6052.

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. What action is EPA proposing to take?

EPA is proposing to approve revisions to Illinois' pharmaceutical manufacturing rule for three of Abbott's fluid bed dryers and four of its tunnel dryers. Each of the three fluid bed dryers previously had a five tons volatile organic compound (VOC) per year applicability cutoff and each of the four tunnel dryers had a 7.5 tons VOC per year applicability cutoff. This rule revision replaces these individual cutoffs with an overall combined cutoff for all seven dryers of 20.6 tons VOC per year.

III. What is the background for this action?

This rule revision was requested by Abbott to provide it with more manufacturing flexibility. Abbott owns a pharmaceutical manufacturing facility located in Lake County, Illinois. Abbott's operations are subject to the emission standards for VOCs at 35 Ill. Adm. Code, Subpart T—Pharmaceutical Manufacturing (Subpart T rules). Section 218.480(b) contains certain exemptions that are only applicable to Abbott's air suspension coater/dryer, fluid bed dryers, tunnel dryers, and Accelacotas. This rule revision amends these site-specific exemptions by capping and lowering the overall

emissions allowable under the exemptions from its tunnel dryers numbered #1, #2, #3, and #4, and fluid bed dryers numbered #1, #2, and #3. This amendment reduces combined cutoffs for these seven dryers while increasing Abbott's operational flexibility, by allowing it to make preferential use of the more efficient fluid bed dryers.

IV. What is EPA's analysis of Illinois' revised pharmaceutical manufacturing rule?

The revisions to Illinois' pharmaceutical manufacturing rule are approvable because it lowers the total allowable emissions from seven dryers and is consistent with the CAA, EPA regulations, and relevant policy.

More specifically, the individual applicability cutoffs for the seven affected dryers results in a combined allowable emission total of 45 tons of VOC per year. The 45 tons VOC per year is based on a 5 tons VOC cutoff (in prior subsection 218.480(b)(2)) for each of the three fluid bed dryers and a 7.5 tons VOC per year cutoff (in prior subsection 218.480 (b)(3) for each of the four tunnel dryers. This compares with a 20.6 tons VOC per year total in new subsection 218.480(b)(4) for tunnel dryers numbered #1, #2, #3, and #4, and fluid bed dryers numbered #1, #2, and #3. Subsection 218.480(b)(4) replaces subsections 218.480(b)(2) and 218.480(b)(3) for these seven dryers.

The main basis for evaluating this proposal is EPA's January 2001 policy on Economic Incentive Programs (EIP), which is EPA's applicable policy for evaluating emission averaging plans, also referred to as "bubbles." Under the EIP policy, a combined emission limit is based on the lower of actual or allowable emissions. Actual emissions are based on the highest consecutive two-year period during the preceding ten-year period, which in this case is 1999–2000. The average annual actual emissions for the seven dryers during this two-year period was calculated to be 22.9 tons VOC per year. The EIP policy also requires reducing this annual emission average by ten percent to establish an environmental benefit. This results in a combined emission limit of 20.6 tons VOC per year, which is the value in the new subsection 218.480(b)(4).

Illinois amended its July 17, 2009, SIP submittal in a May 12, 2010, letter and attachments from Laurel L. Kroack, Chief, Bureau of Air, Illinois Environmental Protection Agency, to EPA. This letter establishes how compliance with Abbott's 20.6 tons VOC per year limit is determined as well as Abbott's recordkeeping requirements. Specifically, this letter states:

> It is the Illinois EPA's interpretation that compliance with Abbott's 20.6 tons VOC per year limit shall be determined on a monthly basis from the sum of the data for the current month plus the preceding 11 months (running 12 month total) consistent with Condition 7.1.6(i) of Abbott's current Title V permit #96010010, issued on September 26, 2007. Compliance will be demonstrated according to the compliance calculation methodology and corresponding recordkeeping procedures in Katherine Hodge's April 23, 2008 email to EPA, including both the body of the email and its attachments, as well as the compliance procedures in Condition 7.1.12(e) of Abbott's current Title V permit. Also, Abbott's recordkeeping requirements should also be consistent with the recordkeeping requirements reflected in Katherine Hodge's April 23, 2008 email, including both the body of the e-mail and its attachments. These records would need to be maintained for five years.

V. 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, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: June 30, 2010.

Walter W. Kovalick Jr.,

Acting Regional Administrator, Region 5.

[FR Doc. 2010–17139 Filed 7–13–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2010–0514; FRL–9172–2]

Revisions to the California State Implementation Plan, Sacramento Metropolitan Air Quality Management District and South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve revisions to the Sacramento Metropolitan Air Quality Management District (SMAQMD) and South Coast Air Quality Management District (SCAQMD) portions of the California State Implementation Plan (SIP). These revisions concern volatile organic compound (VOC) emissions from vanishing oils, rust inhibitors, plastic coatings, rubber coatings, glass coatings, and aerospace operations. We are proposing to approve these local rules to

regulate these emission sources under the Clean Air Act as amended in 1990 (CAA or the Act).

DATES: Any comments on this proposal must arrive by August 13, 2010.

ADDRESSES: Submit comments, identified by docket number [EPA–R09–OAR–2010–0514], by one of the following methods:

1. *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions.

2. *E-mail: steckel.andrew@epa.gov.*

3. *Mail or deliver:* Andrew Steckel (Air-4), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Instructions: All comments 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 Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *http://www.regulations.gov* or e-mail. *http://www.regulations.gov* is an "anonymous access" system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send e-mail directly to EPA, your e-mail address will be automatically captured and included as part of the public comment. 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: The index to the docket for this action is available electronically at *http://www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material), and some may not be publicly available in either location (*e.g.,* CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Nicole Law, EPA Region IX, (415) 947–4126, *law.nicole@epa.gov.*

SUPPLEMENTARY INFORMATION: This proposal addresses the following local rules: SCAQMD 1144, SCAQMD 1145, and SMAQMD 456. In the Rules and Regulations section of this **Federal Register**, we are approving these local rules in a direct final action without prior proposal because we believe these SIP revisions are not controversial. If we receive adverse comments, however, we will publish a timely withdrawal of the direct final rule and address the comments in subsequent action based on this proposed rule. Please note that if we receive adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of an adverse comment.

We do not plan to open a second comment period, so anyone interested in commenting should do so at this time. If we do not receive adverse comments, no further activity is planned. For further information, please see the direct final action.

Dated: June 18, 2010.

Jared Blumenfeld,

Regional Administrator, Region IX.

[FR Doc. 2010–17074 Filed 7–13–10; 8:45 am]

BILLING CODE 6560–50–P

GENERAL SERVICES ADMINISTRATION

41 CFR Part 102–38

[FMR Case 2010–102–3; Docket 2010–0014; Sequence 1]

RIN 3090–AJ04

Federal Management Regulation; Sale of Personal Property

AGENCY: Office of Governmentwide Policy, General Services Administration (GSA).

ACTION: Proposed rule.

SUMMARY: The General Services Administration is amending the Federal Management Regulation (FMR) by amending the provisions for the sale of personal property through Federal Asset Sales (FAS) Sales Centers.

DATES: Interested parties should submit comments in writing on or before August 13, 2010 to be considered in the formulation of a final rule.

ADDRESSES: Submit comments identified by FMR case 2010–102–3 by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Agency Web Site: http://www.gsa.gov/fmr.* Click on FMR Proposed Rules, and the FMR case number to submit comments.
- *E-mail: fmrcase.2010–102–3@gsa.gov.* Include FMR case 2010–102–3 in the subject line of the message.
- *Fax:* 202–501–4067.
- *Mail:* General Services Administration, Regulatory Secretariat (MVCB), 1800 F Street, NW., Room 4041, ATTN: Hada Flowers, Washington, DC 20405.

Instructions: Please submit comments only and cite FMR case 2010–102–3 in all correspondence related to this case. All comments received will be posted without change to *http://www.gsa.gov/fmr,* including any personal information provided. Click on FMR Public Comments.

FOR FURTHER INFORMATION CONTACT: The Regulatory Secretariat, Room 4041, GS Building, Washington, DC 20405, at (202) 501–4755 for information pertaining to status or publication schedules. For clarification of content, contact Mr. Robert Holcombe, Office of Governmentwide Policy, Personal Property Management Policy, at (202) 501–3828, or e-mail at *robert.holcombe@gsa.gov.* Please cite FMR case 2010–102–3.

SUPPLEMENTARY INFORMATION:

A. Background

This proposed amendment to part 102–38 of the Federal Management Regulation (41 CFR part 102–38) updates policy pursuant to the transfer of the oversight of the Federal Asset Sales program from GSA's Office of Governmentwide Policy to GSA's Federal Acquisition Service. Due to this transfer, and the incorporation of these practices into the way the Government sells its property, references to the Executive Steering Committee, Planning Office and the eFAS acronym are proposed to be removed.

This proposed amendment also—

1. Adds the definition for contractor inventory and revises the definitions for Federal Asset Sales and Sales Center (section 102–38.35);

2. Clarifies that contractor inventory may be disposed of by the contractor when required by the Federal contract (section 102–38.40);

3. Clarifies the reporting requirement for negotiated sales (section 102–38.115(a));

4. Removes reference to Standard Form (SF) 97A, as this form is no longer available from GSA. (Section 102.38.285.);

5. Clarifies the policy on antitrust requirements (section 102–38.325); and

6. Makes minor edits, updates organizational designations, and makes non-substantive changes to improve the readability and ease of use of this policy.

B. Executive Order 12866

It has been determined that this proposed rule is not a significant regulatory action for the purposes of Executive Order 12866.

C. Regulatory Flexibility Act

This proposed rule is not required to be published in the **Federal Register** for comment. Therefore, the Regulatory Flexibility Act does not apply. However, this proposed rule is being published to provide transparency in the promulgation of Federal policies.

D. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the proposed changes to the FMR do not impose information collection requirements that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

E. Small Business Regulatory Enforcement Fairness Act

This proposed rule is exempt from Congressional review under 5 U.S.C. 801 since it relates solely to agency management and personnel.

List of Subjects in 41 CFR Part 102–38

Government property management, Surplus Government property.

Dated: May 17, 2010.

Kathleen M. Turco,

Associate Administrator, Office of Governmentwide Policy.

For the reasons set forth in the preamble, GSA amends 41 CFR part 102–38 as set forth below:

PART 102–38—SALE OF PERSONAL PROPERTY

1. The authority citation for part 102–38 continues to read as follows:

Authority: 40 U.S.C. 545 and 40 U.S.C. 121(c).

2. Amend § 102–38.15 by designating the existing paragraph as paragraph (a) and adding a new paragraph (b) to read as follows:

§ 102–38.15 Who must comply with these sales provisions?

* * * * *

(b) Sales of contractor inventory are not required to follow policy regarding the Federal Asset Sales program contained in Subpart H of this part. However, such sales must follow the policy contained in Subparts A through G of this part in addition to the terms of the Federal contract.

§ 102–38.30 [Amended]

3. Amend § 102–38.30 in the second sentence by removing "(eFAS)", "initiative", and "milestones".

4. Amend § 102–38.35 by—

a. Adding the definition for "Contractor Inventory";

b. Removing the definition for "Federal Asset Sales (eFAS)";

c. Adding the definition for "*Federal Asset Sales*";

d. Removing the definition for "Federal Asset Sales Planning Office (eFAS Planning Office)";

e. Removing the definition for "Migration Plan"; and

f. Revising the definition for "Sales Center (SC)".

The added and revised definitions read as follows:

§ 102–38.35 What definitions apply to this part?

* * * * *

Contractor Inventory means—

(1) Any property acquired by and in the possession of a contractor or subcontractor under a contract for which title is vested in the Government and which exceeds the amounts needed to complete full performance under the entire contract;

(2) Any property that the Government is obligated or has the option to take over under any type of contract, *e.g.,* as a result either of any changes in the specifications or plans thereunder or of the termination of the contract (or subcontract thereunder), before completion of the work, for the convenience or at the option of the Government; and

(3) Government-furnished property that exceeds the amounts needed to complete full performance under the entire contract.

* * * * *

Federal Asset Sales refers to the program which seeks to improve the way the Federal Government manages and sells its real and personal property assets. Under this program, only an agency designated as a Sales Center (SC) may sell Federal personal property, unless a waiver has been granted in accordance with § 102–38.360.

* * * * *

Sales Center (SC) means an agency that has been nominated, designated, and approved by GSA's Personal Property Management Policy Division (MTA) as an official sales solution for Federal property. The criteria for becoming an *SC,* the selection process, and the ongoing *SC* requirements for posting property for sale to the Federal Asset Sales portal and reporting sales activity and performance data were established in collaboration with agency working groups, and may be obtained from GSA, Personal Property Management Policy Division (MTA), 1800 F Street, NW., Suite 1221, Washington, DC 20405. *SCs* may utilize (and should consider) private sector entities as well as Government activities and are expected to provide exemplary asset management solutions in one or more of the following areas: Online sales; off-line sales; and sales-related value added services. *SCs* will enter into agreements with holding agencies to sell property belonging to these holding agencies. A holding agency may employ the services of multiple *SCs* to maximize efficiencies.

* * * * *

5. Revise § 102–38.40 to read as follows:

§ 102–38.40 Who may sell personal property?

(a) An executive agency may sell personal property (including on behalf of another agency when so requested) only if—

(1) The agency is a designated SC; or

(2) The agency has received a waiver from GSA's Personal Property Management Policy Division.

(b) A contractor selling contractor inventory under terms of a Federal contract.

(c) SCs or agencies selling under the authority of a waiver may elect to engage contractor support in the sales process.

(d) Only a duly authorized agency official may execute the sale award documents and bind the United States.

§ 102–38.50 [Amended]

6. Amend § 102–38.50, paragraph (b)—

a. In the first sentence by removing "Property Management Division (FBP), 1800 F Street, NW., Washington, DC 20406" and adding "Office of Personal Property Management (QSC), 2200 Crystal Drive, Suite 706, Arlington, VA 22202" in its place; and

b. In the third sentence by removing "MTP" and adding "(MTA)" in its place; and adding ", Suite 1221," after "1800 F Street, NW.".

§ 102–38.115 [Amended]

7. Amend § 102–38.115—

a. In paragraph (a) by removing "the General Services Administration (GSA)" and adding "your agency" in its place; and

b. In paragraph (b) by—

1. Removing "(MTP)" and adding "(MTA)" in its place;

2. Adding "Suite 1221," after "1800 F Street, NW."; and

3. Removing "or manually (see § 102.38–330)" and adding "to *https://GSA.INL.gov/Property*" in its place.

8. Amend § 102–38.130 by adding a second sentence to read as follows:

§ 102–38.130 Must we publicly advertise sales of Federal personal property?

* * * Listing of available items for sale via internet (online) auctions for the general public constitutes "public notice."

§ 102.38–175 [Amended]

9. Amend § 102.38–175 by—

a. Removing the phrase "through subscription from the U.S. Government Printing Office, or";

b. Removing the phrase "on the Internet"; and

c. Removing "*http//epls.arnet.gov*" and adding "*https://www.epls.gov*" in its place.

10. Amend § 102.38–285 by revising paragraph (b) to read as follows:

§ 102.38–285 How do we transfer title from the Government to the buyer for personal property sold?

* * * * *

(b) For sales of vehicles, you must issue to the purchaser a Standard Form (SF) 97, the United States Government Certificate to Obtain Title to a Vehicle, as evidence of transfer of title. For information on how to obtain this form, see § 102–2.135 of this chapter.

§ 102.38–295 [Amended]

11. Amend § 102.38–295 by removing from paragraph (a) "(including your share of the Governmentwide costs to support the eFAS Internet portal and Governmentwide reporting requirements)".

12. Revise § 102–38.325 to read as follows:

§ 102–38.325 What are the requirements pertaining to antitrust laws?

(a) When the sale of personal property has an estimated fair market value of $3 million or more, or the sale involves a patent, process, technique, or invention, you must post a notice in the sales offering advising potential buyers of the applicable antitrust laws contained in 40 U.S.C. 559, whereby the Attorney General of the Department of Justice must review the proposed sale and determine, prior to the finalization of award, whether the disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust laws.

(b) When the sale closes, you will:

(1) Notify the winning bidder advising them of their high bid and that you are awaiting clearance from the Attorney General before final award.

(2) Notify the Attorney General by providing the winning bid information, listed below, for his or her review and concurrence on sale.

(i) Item name;

(ii) Location of property;

(iii) Method of sale;

(iv) Location of sale, if different than location of property;

(v) Date and time of sale close;

(vi) Appraisal value;

(vii) Reserve amount, if different than appraised value;

(viii) Reference to the Sale Terms and Conditions; and

(ix) Listing of bidders, addresses and telephone numbers, as well as winning bidder's bid information.

(c) Once you are notified by the Attorney General, you will—

(1) Notify the high bidder via contract award if the Attorney General determines that the sale does not violate any antitrust laws; or

(2) Notify the high bidder and cancel potential award if the Attorney General determines that the sale violates any antitrust laws.

13. Amend § 102–38.330 introductory paragraph by removing "(MTP)" and adding "(MTA)" in its place, and adding paragraph (c) to read as follows:

§ 102–38.330 Are there any reports that we must submit to the General Services Administration?

* * * * *

(c) Beginning with FY 2010 reports, agencies will be required to report this information using the automated tool at *https://gsa.inl.gov/property.*

14. Revise § 102–38.335 to read as follows:

§ 102–38.335 Is there any additional personal property sales information that we must submit to the General Services Administration?

Yes, all SCs, agencies selling property under a Federal Asset Sales program waiver, and agencies selling property under §§ 102–38.365 and 102–38.370 must report quarterly sales performance measures to the GSA Electronic Federal Asset Sales reporting tool at *https://gsa.inl.gov/efas.* In addition, GSA may require additional sales data and information on an ad-hoc basis.

15. Revise § 102–38.360 to read as follows:

§ 102–38.360 What must an executive agency do to implement the Federal Asset Sales program?

(a) Unless a waiver has been granted, an executive agency must sell its personal property assets through an agency designated by GSA as an SC. To select a sales solution, an executive agency must review the effectiveness of all sales solutions, and compare them to the effectiveness (*e.g.,* cost, level of service, and value added services) of the SCs. Agencies should give full consideration to sales solutions utilizing private sector entities, including small businesses, that are more effective than the solutions provided by any approved SC. If the agency decides that there are more effective sales solutions than those offered by the SCs, the agency must request a waiver. Waivers will be approved upon presentation of a business case showing that complying with the prescribed requirements is either impracticable or inefficient. Waiver approval will be coordinated with GSA's Office of Travel, Transportation, and Asset Management. Contact the Personal Property Management Policy Division (MTA) (*see* address at § 102–38.115(b)) to obtain these procedures and forms.

(b) An approved waiver only relieves the agency of the requirements specified in the waiver request and its approval. Waiver to the Federal Asset Sales program policies will not be permanent. See the definition of a "Sales Center" at § 102–38.35 for an overview of how agency sales solutions become SCs.

(c) An agency which receives a waiver from the Federal Asset Sales process must still comply with Subparts A through G of this part as if it were an SC.

(d) An executive agency must comply with all Federal Asset Sales program processes promulgated by GSA, including those regarding the reporting of pre- and post-sales data.

§ 102–38.370 [Amended]

16. Amend § 102–38.370—

a. In the heading by adding "selected" after "its"; and

b. In the last sentence by removing "in accordance with eFAS ESC-approved format and content." and adding "using the reporting tool specified in § 102–38.335." in its place.

[FR Doc. 2010–17176 Filed 7–13–10; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Part 395

[Docket No. FMCSA–2010–0230]

Hours of Service; Limited Exemption for the Distribution of Anhydrous Ammonia in Agricultural Operations

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Proposed exemption; request for public comment.

SUMMARY: FMCSA announces its proposal to grant a 2-year, limited exemption from the Federal hours-of-service regulations for the transportation of anhydrous ammonia from any distribution point to a local farm retailer or to the ultimate consumer, and from a local farm retailer to the ultimate consumer, as long as the transportation takes place within a 100 air-mile radius of the retail or wholesale distribution point. This exemption would extend the agricultural operations exemption established by section 345 of the National Highway System Designation Act of 1995, as amended, by the sections 4115 and 4130 of the Safe, Accountable, Flexible, Efficient Transportation Equity: A Legacy for Users (SAFETEA–LU) to certain drivers and motor carriers engaged in the distribution of anhydrous ammonia during the planting and harvesting seasons, as defined by the States in which the carriers and drivers operate. The Agency believes that the exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption, based on the terms and conditions imposed. This exemption would preempt inconsistent State and local requirements applicable to interstate commerce.

DATES: Comments must be received on or before August 13, 2010.

ADDRESSES: You may submit comments identified by Federal Docket Management System Number FMCSA–2010–0230 by any of the following methods

- *Web site: http://www.regulations.gov.* Follow the instructions for submitting comments on the Federal electronic docket site.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, Room W–12–140, 1200 New Jersey Avenue, SE., 20590–0001.
- *Hand Delivery:* Ground Floor, Room W12–140, DOT Building, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m. e.t., Monday through Friday, except Federal Holidays.

Instructions: All submissions must include the Agency name and docket number. For detailed instructions on submitting comments and additional information on the exemption process, see the "Public Participation" heading below. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the "Privacy Act" heading below.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* at any time or to the ground floor, room W12–140, DOT Building, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the Federal Docket Management System published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8–785.pdf.*

Public Participation: The *www.regulations.gov* Web site is generally available 24 hours each day, 365 days each year. You can obtain electronic submission and retrieval help and guidelines under the "help" section of the *http://www.regulations.gov* Web site and also at the DOT's *http://docketsinfo.dot.gov* Web site. If you want us to notify you that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments online.

DATES: Comments must be received on or before August 13, 2010.

FOR FURTHER INFORMATION CONTACT: Thomas L. Yager, Chief, Driver and Carrier Operations Division, Office of Bus and Truck Standards and Operations, Federal Motor Carrier Safety Administration, 1200 New Jersey Ave., SE., Washington, DC 20590.

E-mail: *MCPSD@dot.gov.* Phone (202) 366–4325.

SUPPLEMENTARY INFORMATION:

Legal Basis

Section 4007(a) of the Transportation Equity Act for the 21st Century (Pub. L. 105–178, 112 Stat. 107, 401, June 9, 1998) provided the Secretary of Transportation (the Secretary) the authority to grant exemptions from any of the Federal Motor Carrier Safety Regulations (FMCSRs) issued under chapter 313 of title 49 of the United States Code or 49 U.S.C. 31136, to a person(s) seeking regulatory relief (49 U.S.C. 31136, 31315(b)). Prior to granting an exemption, the Secretary must request public comment and make a determination that the exemption is likely to achieve a level of safety that is equivalent to, or greater than, the level of safety that would be obtained in the absence of the exemption. Exemptions may be granted for a period of up to two years and may be renewed.

The FMCSA Administrator has been delegated authority under 49 CFR 1.73(e)(1) and (g) to carry out the functions vested in the Secretary by 49 U.S.C. chapter 313 and subchapters I and III of chapter 311, relating, respectively, to the commercial driver's license program and to commercial motor vehicle (CMV) programs and safety regulation.

Background

On March 22, 2010, FMCSA published a notice in the **Federal Register** announcing a limited 90-day waiver from the Federal hours-of-service (HOS) regulations for the transportation of anhydrous ammonia from any distribution point to a local farm retailer or to the ultimate consumer, and from a local farm retailer to the ultimate consumer, as long as the transportation takes place within a 100 air-mile radius of the retail or wholesale distribution point (54 FR 13441). The waiver extended the agricultural operations exemption established by section 345(a) of the National Highway System Designation Act of 1995 (NHS Act) (Pub. L. 104–59, November 28, 1995, 109 Stat. 568, 613, 49 U.S.C. 31136 note, as amended by section 4130, redesignated by section 4115(a)(2) of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU) (Pub. L. 109–59, August 10, 2005, 119 Stat. 1144, 1726) and implemented by 49 CFR 395.1(k)) to certain drivers and motor carriers engaged in the distribution of anhydrous ammonia during the 2010 spring planting season.

The FMCSA's notice indicated that the Agency had been contacted by members of Congress concerning the Agency's interpretation of the agricultural exemption provided in section 345(a) of the NHS. Constituents engaged in the transportation of farm supplies—particularly anhydrous ammonia—contacted the members to express concerns that the Agency's interpretation of the agricultural exemption results in the exclusion of certain distribution activities from the regulatory relief intended by Congress.

As amended by section 4130(a) of SAFETEA–LU, the agricultural provision reads as follows:

Transportation of agricultural commodities and farm supplies.—Regulations prescribed by the Secretary under sections 31136 and

31502 regarding maximum driving and on-duty time for drivers used by motor carriers shall not apply during planting and harvest periods, as determined by each State, to drivers transporting agricultural commodities or farm supplies for agricultural purposes in a State if such transportation is limited to an area within a 100 air mile radius from the source of the commodities or the distribution point for the farm supplies (119 Stat. 1743).

In its Notice, the Agency indicated that it has long understood that limited farm storage capacity necessitates a "just in time" delivery system from retail distributors of certain farm supplies to farms (or other locations where the farm supply product will be used) during the busy planting and harvesting seasons. Longstanding FMCSA guidance on its HOS regulations has consistently held that the agricultural operations exemption applies to the transportation of farm supplies from the local farm retailer to the ultimate consumer within a 100 air-mile radius. FMCSA's interpretation, however, has not extended the HOS exemption to deliveries from wholesalers to either local farm retailers or farms. (*See* Question 33, 49 CFR 395.1 on the Agency's Web site: *http://www.fmcsa.dot.gov.*) Question 33 reads as follows:

Question 33: How is "point of origin" defined for the purpose of § 395.1(k)?

Guidance: The term "point of origin" is not used in the NHS Designation Act; the statutory term is "source of the [agricultural] commodities." The exemption created by the Act applies to two types of transportation. The first type is transportation from the source of the agricultural commodity -where the product is grown or raised—to a location within a 100 air-mile radius of the source. The second type is transportation from a retail distribution point of the farm supply to a location (farm or other location where the farm supply product would be used) within a 100 air-mile radius of the retail distribution point.

The legislative history of the agricultural exemption indicates it was intended to only apply to retail store deliveries. Thus, it is clear Congress intended to limit this exemption to retail distributors of farm supplies.

Second-stage movements, such as grain hauled from an elevator (or sugar beets from a cold storage facility) to a processing plant, are more likely to fall outside the exempt radius. Similarly, the exemption does not apply to a wholesaler's transportation of an agricultural chemical to a local cooperative because this is not a retail delivery to an ultimate consumer, even if it is within the100 air-mile radius.

The Agency believes that the exclusive emphasis of its regulatory guidance on deliveries from local retailers to the ultimate farm consumer may not reflect today's economic reality as it pertains to the transportation of anhydrous ammonia during planting and harvesting seasons. Like farms, local retailers have limited storage capacity and therefore must constantly replenish certain supplies during the planting and harvesting seasons. They are part of the "just in time" distribution system that extends from a wholesaler to the ultimate consumer of the supplies.

Because of storage and time constraints on the demand for the transportation of anhydrous ammonia to support agricultural operations, and the likelihood that such constraints will continue for some time, FMCSA is proposing a two-year, limited exemption to provide regulatory relief for the transportation of anhydrous ammonia during the planting and harvesting seasons, as defined by the States in which the anhydrous ammonia transporters operate. This action would provide limited regulatory relief to facilitate planting activities that will ultimately result in the production of agricultural commodities at prices to which consumers have become accustomed, with no foreseeable degradation of safety.

The exemption would extend the agricultural operations exemption from the Federal HOS regulations to motor carriers in the distribution system, provided that: (1) The driver is delivering anhydrous ammonia; (2) none of the transportation movements within the distribution chain exceeds a 100 air-mile radius—whether from the retail or wholesale distribution point; and (3) the driver is employed by a motor carrier that has a "satisfactory" safety rating or is unrated; drivers for motor carriers with "conditional" or "unsatisfactory" safety ratings are prohibited from taking advantage of the exemption. Therefore, the exemption would allow drivers for motor carriers with a satisfactory safety rating or unrated motor carriers to use the HOS exemption when delivering anhydrous ammonia from any distribution point to a local farm retailer or to the ultimate consumer, and from a local farm retailer to the ultimate consumer, as long as the transportation takes place within a 100 air-mile radius of the retail or wholesale distribution point. This exemption would take effect on the date of publication of a final decision.

Safety Determination

FMCSA is committed to ensuring high standards of motor carrier safety. The Agency has considered the available data concerning the safety performance of agricultural operations in general, and the safety performance of anhydrous ammonia transporters during the 90-day, limited waiver granted earlier this year.

FMCSA compared safety performance data for agricultural carriers currently operating under the statutory HOS exemption provided by the NHS Act, as amended, with non-agricultural carriers that are not exempt from HOS regulations to determine whether the exemption would be likely to achieve a level of safety that is equivalent to, or greater than, the level of safety that would be obtained in the absence of the exemption. The data were collected as part of a study, "Agricultural Commodity and Utility Carriers Hours of Service Exemption Analysis," May 2010, FMCSA–RRA–10–448 A copy of the report has been placed in the public docket identified at the beginning of this notice.

The study was conducted in two phases. Phase 1 compares the safety performance of agricultural and non-agricultural carriers for the period 2005 through 2008, and also examines two additional industries, livestock and utility carriers, whose operations were not exempt from HOS regulations prior to the passage of SAFETEA–LU.[1] The Phase 1 analysis used carrier registration, inspection and crash data from FMCSA's Motor Carrier Management Information System (MCMIS). The study used cargo classification information on the FMCSA Motor Carrier Identification Report (Form MCS–150) in MCMIS to identify the carrier's industry group (agricultural, livestock, or utility carrier), and used MCS–150 information to identify carriers operating within and beyond a 100-air-mile radius. The operating radius information was used to create two agricultural carrier subgroups: (1) Agricultural carriers with 100 percent of drivers operating within a 100-air-mile radius; and (2) agricultural carriers with 100 percent of drivers operating beyond a 100-air-mile radius. The analysis used the first subgroup as representative of agricultural carriers exempt from the HOS requirements, and the second subgroup as representative of agricultural carriers not exempt from the HOS requirements.

For the Phase 2 analysis, inspection data of agricultural commodity and utility carriers (which are also exempt from HOS regulations) was collected during an FMCSA special study of a sample of States. These data included only those inspections occurring during the States' planting and harvesting seasons and indicated both the commodity being transported and

[1] Section 4130(a).

whether the driver was operating within or beyond the 100-air-mile radius exempt from HOS regulations. The Phase 2 analysis assessed the safety performance of the HOS exempt agricultural commodity and utility service carriers identified in the survey in comparison with non-HOS-exempt carriers based on their out of service (OOS) violation rates and crash rates.

The Agency did not place as much of an emphasis on the OOS rates because there were no HOS violation data to consider, given that the agricultural carriers for which data were available were operating under a statutory exemption from the HOS rule. Differences between the OOS rates for other issues such as driver qualifications and vehicle defects and deficiencies, while important in considering overall safety management controls of the carriers, were not necessarily related to the potential safety impact of the exemption.

The Phase 1 analysis indicates that nationally, agricultural carriers operating within a 100-air-mile radius had lower crash rates per 100 power units than those operating beyond this radius, except for in 2008, when there was no difference in the crash rates.

To provide additional validation of the crash analysis, which uses power unit data reported on the Form MCS–150, a separate analysis was performed using data only for carriers domiciled in States participating in the Performance and Registration Information Systems Management (PRISM) program that enforces MCS–150 updating.[2] PRISM links State motor vehicle registration systems with carrier safety data in order to identify unsafe commercial motor carriers. The PRISM State carriers are required to update their MCS–150 annually. By contrast, non-PRISM State carriers are required by FMCSA to update their MCS–150 biennially. As a result, the PRISM State data are considered more current and reliable than non-PRISM State data where there are no direct consequences for not updating the data. Data from PRISM States that enforce MCS–150 updating show that agricultural carriers operating within a 100-air-mile radius had more varied results, with crash rates higher than carriers operating beyond a 100-air-mile radius in 2008, lower in 2006 and 2007, and nearly the same in 2005.

[2] Current PRISM States that enforce the MCS–150 updating requirement are Alabama, Arizona, Arkansas, Connecticut, Georgia, Iowa, Kentucky, Louisiana, Maine, Minnesota, Missouri, Nebraska, New Hampshire, New Mexico, North Carolina, Ohio, South Carolina, South Dakota, Tennessee, Utah, Vermont, Washington, and West Virginia.

The Phase 2 analysis indicates that in the four States participating in the survey (Idaho, Kansas, Maryland, Michigan), agricultural carriers that were subject to the HOS requirements had higher crash rates per 100 power units than agricultural carriers exempt from the HOS requirements.

In addition to the study, the Agency considered information from the Pipeline and Hazardous Materials Safety Administration's (PHMSA) Hazardous Materials Incident Reporting Systems and from FMCSA field offices concerning the safety performance of anhydrous ammonia transporters during the limited 90-day waiver mentioned above. With respect to information from PHMSA, the Agency received information about five anhydrous ammonia incidents. Only one of the five involved a crash and that crash involved a driver who had been on duty only two hours after having two consecutive days off duty. Copies of all five incident reports are included in the docket referenced at the beginning of this notice.

With regard to information from FMCSA's field offices, the Agency did not receive any information about accidents, as defined in 49 CFR 390.5, involving motor carriers transporting anhydrous ammonia using drivers operating under the limited 90-day waiver. The Agency acknowledges that there is a gap between the date that a crash occurs and the date the States would typically submit crash reports. However, because FMCSA sought information through its field offices rather than relying solely on routine crash reporting by State enforcement agencies, it is unlikely that there have been any crashes resulting in fatalities or injuries, involving a driver operating under the limited 90-day waiver. The Agency requests comments from all interested parties that may have information concerning any crashes involving drivers operating under the limited 90-day waiver.

In the absence of any data or information to the contrary, the Agency believes the real-world experience of anhydrous ammonia transporters during the 90-day limited waiver suggests that the level of safety under an exemption would be equivalent to, or greater than, the level that would be achieved absent such exemption.

FMCSA Proposal

In light of the information described above, FMCSA is proposing a two-year limited exemption from the Federal HOS regulations for interstate motor carriers engaged in the distribution of anhydrous ammonia during the planting and harvesting seasons as defined by the States. A review of the available crash data comparing exempt and non-exempt motor carriers, and a review of crash data from anhydrous ammonia transporters operating during the limited 90-day waiver provide a reasonable basis to believe that a limited exemption would achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption, based on the terms and conditions that would be imposed.

Proposed Terms and Conditions of the Exemption

The FMCSA would provide a two-year, limited exemption from the requirements of 49 CFR part 395 concerning the HOS requirements for drivers of property-carrying vehicles engaged in the distribution of anhydrous ammonia during the relevant planting and harvesting seasons. This limited exemption would extend the agricultural operations exemption from the Federal HOS regulations to drivers used by motor carriers in the distribution system, provided that: (1) The driver is delivering anhydrous ammonia; (2) none of the transportation movements within the distribution chain exceeds a 100 air-mile radius—whether from the retail or wholesale distribution point; and (3) the motor carrier using the driver has a "satisfactory" safety rating or is "unrated;" drivers for motor carriers with "conditional" or "unsatisfactory" safety ratings are prohibited from taking advantage of the exemption.

The exemption would allow drivers for "unrated" motor carriers and those with a satisfactory safety rating to use the HOS exemption when the drivers are delivering anhydrous ammonia from any distribution point to a local farm retailer or to the ultimate consumer, and from a local farm retailer to the ultimate consumer, as long as the transportation takes place within a 100 air-mile radius of the retail or wholesale distribution point.

Safety Rating

Motor carriers that have received compliance reviews and want their drivers to be exempt from the HOS regulations are required to have a "satisfactory" rating. The compliance review is an on-site examination of a motor carrier's operations, including records on drivers' hours of service, maintenance and inspection, driver qualification, commercial driver's license requirements, financial responsibility, accidents, hazardous materials, and other safety and

transportation records to determine whether a motor carrier meets the safety fitness standard. The assignment of a "satisfactory" rating means the motor carrier has in place adequate safety management controls to comply with the Federal safety regulations, and that the safety management controls are appropriate for the size and type of operation of the motor carrier.

FMCSA would also allow drivers for "unrated" carriers to take advantage of the exemption. Unrated motor carriers are those that have not received a compliance review. FMCSA is allowing drivers for unrated motor carriers to participate because it would be unfair to exclude them simply because these carriers were not selected by the Agency for a compliance review. The absence of a compliance review is in no way an indication that the carrier has done anything wrong or has safety problems.

The Agency would not allow drivers for motor carriers with conditional or unsatisfactory ratings to participate because both of those ratings indicate that the carrier has safety management control problems. There is little reason to believe that carriers rated either unsatisfactory or conditional could be relied upon to comply with the terms and conditions of the exemption.

Accident and Hazardous Materials Reporting Requirement

Within 10 business days following an accident (as defined in 49 CFR 390.5) or any unintentional discharge of anhydrous ammonia that requires the submission of the Department of Transportation Hazardous Materials Incident Report (DOT Form F 5800.1) (*see* 49 CFR 171.16) involving any of the CMVs operated by a motor carrier whose drivers are using the exemption, irrespective of whether the CMV involved in the accident or discharge was being operated by a driver using the exemption, the motor carrier must submit the following information:

(a) Date of the accident;

(b) City or town in which the accident occurred, or city or town closest to the scene of the accident;

(c) Driver's name and license number;

(d) Vehicle number and State license number;

(e) Number of injuries;

(f) Number of fatalities;

(g) Whether hazardous materials, other than fuel spilled from the fuel tanks of the motor vehicles involved in the accident, were released;

(h) The police-reported cause of the accident;

(i) Whether the driver was cited for violating any traffic laws, motor carrier safety regulations, or hazardous materials discharge; and

(j) Whether the driver was operating under the exemption, and if so, an estimate of the total driving time, on-duty time for the day of the accident and each of the seven calendar days prior to the accident.

Duration of the Exemption

The exemption would be effective upon publication in the **Federal Register** and would be valid for up to two years unless revoked earlier by FMCSA. The exemption may be renewed by the Agency; the Agency would provide notice and an opportunity for public comment prior to renewing the exemption. The exemption would preempt inconsistent State or local requirements applicable to interstate commerce.

Safety Oversight of Carriers Operating Under the Exemption

FMCSA expects that any drivers and their employing motor carrier operating under the terms and conditions of the exemption will maintain their safety record. Should any deterioration occur, however, FMCSA would, consistent with the statutory requirements of TEA–21, take all steps necessary to protect the public interest. Use of the exemption would be voluntary, and FMCSA will immediately revoke the exemption for any interstate driver or motor carrier for failure to comply with the terms and conditions exemption.

Request for Comments

In accordance with 49 U.S.C. 31315(b)(4) and 31136(e), FMCSA requests public comment on the proposed exemption from the HOS requirements of 49 CFR part 395 for drivers and their employing motor carriers transporting anhydrous ammonia. The Agency will consider all comments received by close of business on August 13, 2010. Comments will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. The Agency will consider to the extent practicable comments received in the public docket after the closing date of the comment period.

Issued on: July 8, 2010.

Anne S. Ferro,

Administrator.

[FR Doc. 2010–17138 Filed 7–13–10; 8:45 am]

BILLING CODE 4910–EX–P

Notices

Federal Register
Vol. 75, No. 134
Wednesday, July 14, 2010

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.

DEPARTMENT OF AGRICULTURE

Creation of a New Computer Matching Program That Will Expire on December 31, 2013

AGENCY: USDA; Office of the Chief Financial Officer, National Finance Center.

ACTION: Notice.

SUMMARY: In accordance with the provisions of the Privacy Act, as amended, this notice announces the creation of a new computer matching program that we will conduct with the U.S. Office of Personnel Management (OPM), The Social Security Administration (SSA), and the Department of Agriculture's National Finance Center (NFC). Privacy Act of 1974, as Amended; Computer Matching Program (SSA/U.S. Office of Personnel Management (OPM)/U.S. Department of Agriculture's National Finance Center (NFC))—Match Number SSA# 1011.

DATES: The effective date of this matching program is August 13, 2010, provided that the following notice periods have lapsed: 30 days after publication of this notice in the **Federal Register** and 40 days after notice of the matching program is sent to Congress and OMB.

ADDRESSES: Interested parties may comment on this notice by either telefaxing to (202)–720–3445 or writing to the Chief Privacy Officer, Ravoyne Payton, Office of the Chief Information Officer, 1400 Independence Avenue, SW., Room 224–W, Washington, DC 20250.

All comments received will be available for public inspection at this address.

FOR FURTHER INFORMATION CONTACT: Chief Privacy Officer, Ravoyne Payton, Office of the Chief Information Officer, 1400 Independence Avenue, SW., Room 224–W, Washington, DC 20250.

SUPPLEMENTARY INFORMATION: We will file a report of the subject matching program with the Committee on Homeland Security and Governmental Affairs of the Senate; the Committee on Oversight and Government Reform of the House of Representatives, and the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). The matching program will be effective as indicated below.

A. General

The Computer Matching and Privacy Protection Act of 1988 (Pub. L. 100–503), amended the Privacy Act (5 U.S.C. 552a) by describing the conditions under which computer matching involving the Federal government could be performed and adding certain protections for persons applying for, and receiving, Federal benefits. Section 7201 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508) further amended the Privacy Act regarding protections for such persons.

The Privacy Act, as amended, regulates the use of computer matching by Federal agencies when records in a system of records are matched with other Federal, State, or local government records. It requires Federal agencies involved in computer matching programs to:

(1) Negotiate written agreements with the other agency or agencies participating in the matching programs;

(2) Obtain the approval of the matching agreement by the Data Integrity Boards (DIB) of the participating Federal agencies;

(3) Publish notice of the computer matching program in the **Federal Register**;

(4) Furnish detailed reports about matching programs to Congress and OMB;

(5) Notify applicants and beneficiaries that their records are subject to matching; and

(6) Verify match findings before reducing, suspending, terminating, or denying a person's benefits or payments.

B. SSA Computer Matches Subject to the Privacy Act

We have taken action to ensure that all of our computer matching programs comply with the requirements of the Privacy Act, as amended.

Notice of Computer Matching Program, SSA With the United States Department of Agriculture (USDA), National Finance Center (NFC)

A. Participating Agencies

SSA, OPM, and USDA–NFC.

B. Purpose of the Matching Program

The purpose of this matching program is to ensure that individuals eligible for the Pre-Existing Condition Insurance Plan (PCIP) are citizens or nationals of the United States or lawfully present in the United States. We will confirm the consistency of the information of the applicant against other federal records or systems.

C. Authority for Conducting the Matching Program

The legal authority for conducting the matching program is section 1411(c)(2)(A)(i) and (ii) of the PPACA, section 1106 of the Social Security Act (42 U.S.C. 1306(b)), section 1101 of the Affordable Care Act, 5 U.S.C. 552a(b)(3) of the Privacy Act, and the regulations and guidance promulgated thereunder.

D. Categories of Records and Persons Covered by the Matching Program

We will use the following categories of records to perform the matching program:

- Name
- Address
- Date of Birth
- Social Security Number, and
- Tax Identification Number

E. Inclusive Dates of the Matching Program

The effective date of this matching program is August 15, 2010, provided that the following notice periods have lapsed: 30 days after publication of this notice in the **Federal Register** and 40 days after notice of the matching program is sent to Congress and OMB. The matching program will continue for 18 months from the effective date and may be extended for an additional 12 months thereafter, if certain conditions are met.

Dated: July 12, 2010.

Karen Ross,

Chief of Staff, Office of the Secretary, Department of Agriculture.

[FR Doc. 2010–17284 Filed 7–12–10; 4:15 pm]

BILLING CODE 3410–90–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Proposed Collection; Comment Request—Supplemental Nutrition Assistance Program Forms: Applications, Periodic Reporting and Notices

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on the proposed collection. This collection is a revision of the currently approved burden for the applications, periodic reporting, and notices burden calculations for the Supplemental Nutrition Assistance Program (SNAP), formerly known as the Food Stamp Program, which also reflects corrections resulting from the changes in recently published SNAP regulations.

DATES: Written comments must be received on or before September 13, 2010.

ADDRESSES: 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 of the proposed collection of information including the validity of the methodology and assumptions used; (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 those who respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to Angela Kline, Chief, Certification Policy Branch, Program Development Division, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 812, Alexandria, VA 22302. Comments may also be faxed to the attention of Ms. Kline at (703) 305–2486.

Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov* and follow the online instructions for submitting comments electronically.

All written comments will be open for public inspection at the office of the Food and Nutrition Service during regular business hours (8:30 am to 5 pm, Monday through Friday) at 3101 Park Center Drive, Alexandria, Virginia, 22302, Room 800.

All responses to this notice will be summarized and included in the request for the Office of Management and Budget (OMB) approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Ms. Kline at (703) 305–2495.

SUPPLEMENTARY INFORMATION:

Title: Supplemental Nutrition Assistance Program Forms: Applications, Periodic Reporting and Notices.

OMB Number: 0584–0064.

Form Number: N/A.

Expiration Date: 12/31/2010.

Type of Request: Revision of the currently approved burden hours totaling 24,893,623 hours.

Abstract: This notice extends the applications, periodic reporting, and notices burden calculations for the Supplemental Nutrition Assistance Program (SNAP), which were recently revised and approved by the Office of Management and Budget (OMB) on March 26, 2010, and also reflects corrections resulting from changes in the Farm Security and Rural Investment Act of 2002 (FSRIA) final rule, published on January 29, 2010 (75 FR 4912). The SNAP regulations at 7 CFR Part 273 contain the requirements for the application, certification and continued eligibility of SNAP benefits.

The correction referenced in the above paragraph pertains to the simplified reporting component under the previously approved collection. The simplified reporting burden estimate approved under OMB clearance number 0584–0064, Food Stamp Forms: Applications, Periodic Reporting, Notices, expiring on December 31, 2010, was improperly calculated. In analyzing the data used to determine the burden estimate, we noted that the number of households under a simplified reporting system was overestimated. As a result of this overestimation, the burden for simplified reporting was miscalculated. Based on this, we estimate that the total burden for this collection will decrease from 24,893,623 hours to 23,609,236 hours.

Additionally, Section 4001(b) of Public Law 110–246, Food, Conservation, and Energy Act of 2008 (FCEA), renamed the Food Stamp Program to the Supplemental Nutrition Assistance Program or SNAP. The new program name reflects the fact that participants no longer receive stamps or coupons to make food purchases and emphasizes the nutritional aspect of the program. To comply with current law, FNS is using the new program name SNAP in this extension of information collection for OMB No. 0584–0064. It should be noted, however, that the program regulations at 7 CFR Parts 271–285 have not yet been revised to reflect the new name.

Reporting Burden

Initial Application for SNAP. Section 273.2 of the SNAP regulations requires that each applicant household complete and file an application, either in paper or electronic form. The application contains detailed information about each household member, income, and resources that is necessary to determine if the applicant household is entitled to assistance and, if so, the benefit amount. According to information reported by SNAP State agencies to FNS and compiled in the May 2009 National Data Bank Survey (NDB), there were 15,235,501 households certified with initial applications in SNAP. FNS estimates a total household burden of 4,834,224 hours (15,235,501 initial certifications × .3173 hours (19 minutes) to complete application = 4,834,224 burden hours). FNS estimates the State agency burden to be 4,834,224 hours (15,235,501 initial certification applications × .3173 hours to review applications = 4,834,224 burden hours).

Application for SNAP Recertification. Section 273.14 of the SNAP regulations indicates that in order to continue participating in SNAP, ongoing households must apply for recertification prior to the end of their current certification periods. According to the May 2009 NDB report, there were 12,252,802 recertification applications in SNAP. FNS estimates a total household burden of 3,887,814 hours (12,252,802 recertification applications × .3173 hours (or 19 minutes) to complete application = 3,887,814 burden hours). FNS estimates a burden of 3,887,814 hours (12,252,802 recertification applications × .3173 hours (or 19 minutes) to review applications = 3,887,814 burden hours) for the State agency review process.

Monthly Report. Under § 273.21 of the SNAP regulations, households subject to monthly reporting are required to submit reports of their circumstances on a monthly basis. According to FNS 2008 Quality Control data, a total of 86,142 households in two States (Minnesota and South Dakota) are subject to change reporting, resulting in a household burden of 110,770 hours (86,142 households × 11 reports per year × .1169 hours (or 7 minutes) to complete a

report = 110,770 burden hours). FNS estimates these State agencies will incur a burden of 174,067 hours (86,142 households × 11 reports per year × 0.1837 hours (or 11 minutes) to review each report = 174,067 burden hours).

Quarterly Report. Under § 273.12(a)(4) of the SNAP regulations, State agencies may require households to report changes on a quarterly basis. Currently, California is the only state that requires households to report changes in circumstances on a quarterly basis. The May 2009 NDB report indicates that 83 percent of California's caseload is under quarterly reporting, which results in 1,101,891 households. FNS estimates a household burden of 441,638 hours (1,101,891 household under quarterly reporting × 3 reports per year × .1336 hours (or 8 minutes) to complete a report = 441,638 burden hours) for quarterly reporting. The State agency burden is estimated at 662,457 hours (1,101,891 household under quarterly reporting × 3 reports per year × .2004 hours (or 12 minutes) to review each report = 662,457 burden hours).

Simplified Report. Section 273.12(a)(5) of the SNAP regulations allows State agencies to establish a simplified reporting system in which households certified for longer than 6 months must submit a periodic report that is due no later than the 6th month of their certification period. According to the FNS Office of Research and Analysis' 2008 data on SNAP reporting systems, a total of 6,238,761 households are currently subject to simplified reporting. FNS estimates a household burden of 833,498 hours (6,238,761 reports × .1336 hours (or 8 minutes) to complete each periodic report = 833,498 burden hours). FNS estimates a burden of 1,146,060 hours (6,238,761 reports × .1837 hours (or 11 minutes) to review each report = 1,146,060 burden hours) for State agencies.

Change Report. Under § 273.12(a)(1) of the SNAP regulations, households not subject to monthly, quarterly reporting or simplified reporting must report most changes in household circumstances within 10 days from the date that the change becomes known to the household. Based on information provided by State agencies in 2008 and compiled by FNS in the 2008 State Options Report, (dated June 2008) FNS estimates that 844,245 households assigned to change reporting each submit 2.5 reports each year, resulting in a total of 176,236 burden hours per year (844,245 households × 2.5 reports × .0835 hours (or 5 minutes) per report = 176,236 burden hours) for households. FNS estimates a State agency burden total of 387,720 hours (844,245 households × 2.5 reports × .1837 hours (or 11 minutes) to review each report = 387,720 burden hours).

Notice of Eligibility or Denial. According to § 273.10(g)(1) of the SNAP regulations, State agencies provide these notices to advise households of the disposition of their application for initial certification or recertification. Based on the May 2009 NDB data, an estimated 32,600,716 eligibility and denial notices are issued annually by all 53 State agencies. This leads to an estimated burden of 1,088,864 hours (32,600,716 notices × .0334 hours (or 2 minutes) per notice = 1,088,864 burden hours), for all 53 State agencies to generate and issue notices of approvals and denials of applications.

Other Notices

Notice of Missing or Incomplete Report. The SNAP regulations require that State agencies advise ongoing households when they have failed to submit complete or timely periodic reports under monthly, quarterly or simplified reporting systems.

Request for Contact (RFC). The RFC notice, as indicated in § 273.12(a)(3)(i) of the SNAP regulations, is used to contact the household when the State agency receives information regarding a potential change in a household's eligibility or benefits and such information is not sufficient for the State agency to determine exactly how the household's status would be affected.

Notice of Missed Interview (NOMI). Per § 273.14(b)(3)(ii) of the SNAP regulations, NOMIs are issued by State agencies to households that fail to appear for their scheduled initial or recertification interview, or in the case of households subject to telephone interviews, fail to contact the State agency or receive telephone calls initiated by the local office.

Notice of Expiration (NOE). As indicated in § 273.14(b)(1)(i) of the SNAP regulations, State agencies are required to mail an NOE to currently participating households at least 30 days prior to the expiration of their current certification period.

Notice of Adverse Action (NOAA). The NOAA, as indicated in § 273.13(a) of the SNAP regulations, is issued by State agencies to participating households whose benefits will be reduced or terminated as the result of a change in household circumstances.

Adequate Notice. As indicated in § 273.13(a) of the SNAP regulations, an adequate notice is sent to households by the State agency when the household's benefits are reduced or terminated based on information reported by the household.

Transitional Benefits Notice (TN). According to § 273.26 of the SNAP regulations, States have the option to provide transitional benefits to families leaving the Temporary Assistance for Needy Families program (TANF).

FNS estimates that a total of 21,089,658 notices (described as Other Notices) are issued annually by all 53 State agencies, with an average burden of 3 minutes or .0501 hours per notice. Based on this information, we estimate a total annual burden of 1,056,592 hours (21,089,658 notices × .0501 hours = 1,056,592 burden hours) for State agencies to generate and issue notices.

Recordkeeping Burden

State agencies are required to maintain client case records for 3 years and to perform duplicate participation checks on individual household members to ensure the member is not participating in more than one household.

(A) *Case Files:* The caseload to be maintained is equal to the number of participating households and their subsequent files, including documentation (*i.e.,* electronic files, caseworker written entries into the files, or hard copies of the documents) for notices which were sent to the households. FNS estimates that 253,862 documents will be sent to households in addition to the number of documents estimated and approved under the previous collection. The increase in recordkeeping burden associated with this revision is estimated to be 8,479 hours (253,862 documents × .0334 hours = 8,479 burden hours).

(B) *Monitoring Duplicate Participation:* The recordkeeping burden for maintaining this automated system is determined by multiplying the number of total applications expected to be received, the average number of persons (2.3) in each household, and the processing time per response (15 seconds or 0.0042 hours). Due to the rapid increase in caseload, 8,155,221 more applications than in the previously approved collection of 20,250,469 applications are expected to be received, thus increasing the estimated burden hours to 78,779 hours over the previously approved burden (8,155,221 applications × 2.3 average # of persons × .0042 hours = 78,779 burden hours).

(C) The total recordkeeping burden estimated under this revision is 87,258 hours.

The following tables illustrate all of the components of the reporting and

recordkeeping burdens associated with this information collection.

REPORTING

Section of regulation	Title	Form Number (if any)	Estimated Number of respondents	Report filed annually	Total annual responses/ records	Estimated avg. Number of man-hours per response	Estimated total man-hours
A	B	C	D	E	F	G	H (Col. F×G)
State Agency Level							
273.2(b)	Initial Application for SNAP		53	287,462.30	15,235,501	.3173	4,834,224
273.10(g)(2) & 273.14(b)	SNAP Recertification Applications		53	231,184.94	12,252,802	.3173	3,887,814
273.21(a)	Monthly Reports		2				
	Households		86,142	11.00	947,562	.1837	174,067
273.12(a)(4)	Quarterly Reports		1	3,305,673.00	3,305,673	.2004	662,457
273.12(a)(5)	Simplified Reporting—# HH on SR		50	124,775.22	6,238,761	.1837	1,146,060
273.12(a)(1)(i)(A)	Change Report—# HH on CR		32	65,956.65	2,110,612.80	.1837	387,720
273.10(g)(1)(i) & (ii)	Notice of Eligibility/Denial		53	615,107.85	32,600,716	.0334	1,088,864
	Other Notices (not captured individually and included below).		53	397,918.08	21,089,658	.0501	1,056,592
273.12(a)(4)(iii); 273.12(a)(5)(iii)(D); 273.12(a)(6)(i); 273.21(j)(2)(i).	Notice of Missing/Incomplete Report.						
273.12(c)(3)(i)	Request for Contact						
273.10(b)(3)(iii)	Notice of Missed Interview						
273.2(i)(4)(iii)(A) & (B), 273.2(k)(1)(iii)(B)(2) & (E)(2).	Notice of Expiration						
273.13(a)	Notice of Adverse Action						
273.13(b)(3) & 273.13(c)	Adequate Notice						
273.29	Transitional Benefits Notice		53	0	0	0	0
State Agency Level Totals			53	5,028,089	93,781,286		13,237,798
Household Level							
273.2(b)	Initial Application for SNAP		15,235,501	1.00	15,235,501	.3173	4,834,224
273.10(g)(2) & 273.14(b)	SNAP Recertification Applications		12,252,802	1.00	12,252,802	.3173	3,887,814
273.21(a)	Monthly Report		86,142	11.00	947,562	.1169	110,770
273.12(a)(4)	Quarterly Report		1,101,891	3.00	3,305,673	.1336	441,638
273.12(a)(5)	Simplified Report		6,238,761	1.00	6,238,761	.1336	833,498
273.12(a)(1)(i)(A)	Change Report		844,245	2.50	2,110,613	.0835	176,236
273.10(g)(1)(i) & (ii)	Notice of Eligibility/Denial		0	0	0	0	0
	Other Notices (not captured individually and included below).		0	0	0	0	0
273.12(a)(4)(iii); 273.12(a)(5)(iii)(D); 273.12(a)(6)(i); 273.21(j)(2)(i).	Notice of Missing/Incomplete Report.						
273.12(c)(3)(i)	Request for Contact						
273.10(b)(3)(iii)	Notice of Missed Interview						
273.2(i)(4)(iii)(A) & (B), 273.2(k)(1)(iii)(B)(2) & (E)(2).	Notice of Expiration						
273.13(a)	Notice of Adverse Action						
273.13(b)(3) & 273.13(c)	Adequate Notice						
273.29	Transitional Benefits Notice		0	0	0	0	0
Household Level Totals			35,759,342	19.5	40,090,912		10,284,180

RECORDKEEPING

Section of regulation	Title	Form Number (if any)	Estimated Number of respondents	Report filed annually	Total annual responses	Estimated avg. no. of man-hours per response	Estimated total man-hours
A	B	C	D	E	F (Col. D×E)	G	H (Col. F×G)
State Agency Level							
Part 273	Maintenance of Case Files		53	4,789.85	253,862	0.0334	8,479
272.4	Monitoring of Duplicate Participation		53	353,905.81	18,757,008	0.0042	78,779
State Agency Level Totals			53	358,695.66	19,010,870		87,258

Summary of Reporting Burden Hours

Affected Public: State and local government agencies administering SNAP and Individuals/Households.

Estimated Number of Respondents: 35,759,342: (State Agencies: 53 and Households: 35,759,342).

Estimated Number of Reports Filed Annually: State Agency: 5,028,089 Households: 19.50.

Estimated Number of Responses: 133,872,198: (State Agencies: 93,781,286 and Households: 40,090,912).

Estimated Total Annual Burden for Respondents: 23,521,978: (State Agencies: 13,237,798 and Households: 10,284,180).

Estimated Total Reporting and Recordkeeping Burden Hours: 23,521,978 + 87,258 = 23,609,236.

Dated: July 7, 2010.

Audrey Rowe,

Acting Administrator, Food and Nutrition Service.

[FR Doc. 2010–17183 Filed 7–13–10; 8:45 am]

BILLING CODE 3410–30–P

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Determination Under the African Growth and Opportunity Act

AGENCY: Committee for the Implementation of Textile Agreements.

ACTION: Directive to the Commissioner of U.S. Customs and Border Protection.

SUMMARY: The Committee for the Implementation of Textile Agreements (CITA) has determined that certain textile and apparel goods from Burkina Faso shall be treated as "folklore articles" and "ethnic printed fabrics" and qualify for preferential treatment under the African Growth and Opportunity Act. Imports of eligible products from Burkina Faso with an appropriate visa will qualify for duty-free treatment.

DATES: *Effective Date:* July 14, 2010.

FOR FURTHER INFORMATION CONTACT: Don Niewiaroski, Jr., International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–2496.

SUPPLEMENTARY INFORMATION:

Authority: Sections 112(a) and 112(b)(6) of the African Growth and Opportunity Act (Title I of the Trade and Development Act of 2000, Pub. L. No. 106–200) ("AGOA") as amended by Section 7(c) of the AGOA Acceleration Act of 2004 (Pub. L. 108–274) ("AGOA Acceleration Act") (19 U.S.C. §§ 3721(a) and (b)(6)); Sections 2 and 5 of Executive Order No. 13191 of January 17, 2001; Sections 25–27 and Paras. 13–14 of Presidential Proclamation 7912 of June 29, 2005.

AGOA provides preferential tariff treatment for imports of certain textile and apparel products of beneficiary sub-Saharan African countries, including handloomed, handmade, or folklore articles of a beneficiary country that are certified as such by the competent authority in the beneficiary country. The AGOA Acceleration Act further expanded AGOA by adding ethnic printed fabrics to the list of textile and apparel products made in the beneficiary sub-Saharan African countries that may be eligible for the preferential treatment described in section 112(a) of the AGOA. In Executive Order 13191 (January 17, 2001) and Presidential Proclamation 7912 (June 29, 2005), the President authorized CITA to consult with beneficiary sub-Saharan African countries and to determine which, if any, particular textile and apparel goods shall be treated as being handloomed, handmade, folklore articles, or ethnic printed fabrics. *See* 66 FR 7271, 7271–72 (January 22, 2001) and 70 FR 37959, 37961 & 63 (June 30, 2005).

In a letter to the Commissioner of Customs dated January 18, 2001, the United States Trade Representative directed Customs to require that importers provide an appropriate export visa from a beneficiary sub-Saharan African country to obtain preferential treatment under section 112(a) of the AGOA. *See* 66 FR 7837 (January 25, 2001). The first digit of the visa number corresponds to one of the groupings of textile and apparel products that are eligible for preferential tariff treatment. Grouping "9" is reserved for handmade, handloomed, folklore articles, or ethnic printed fabrics.

CITA consulted with Burkina Faso authorities on June 8, 2010 and has determined that folklore articles described in Annex A and ethnic printed fabrics described in Annex B, if produced in and exported from Burkina Faso, are eligible for preferential tariff treatment under section 112(a) of the AGOA, as amended. After further consultations with Burkina Faso authorities, CITA may determine that additional textile and apparel goods shall be treated as handloomed, handmade, folklore articles or ethnic printed fabrics. In the letter published below, CITA directs the Commissioner of U.S. Customs and Border Protection to allow duty-free entry of such products under U.S. Harmonized Tariff Schedule subheading 9819.11.27 if accompanied by an appropriate AGOA visa in grouping "9".

Kim Glas,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

July 7, 2010.

Commissioner, U.S. Customs and Border Protection, Department of Homeland Security, Washington, DC 20229

Dear Commissioner:

The Committee for the Implementation of Textiles Agreements ("CITA"), pursuant to Sections 112(a) and (b)(6) of the African Growth and Opportunity Act (Title I of the Trade and Development Act of 2000, Pub. L. No. 106–200) ("AGOA"), as amended by Section 7(c) of the AGOA Acceleration Act of 2004, (Pub. L. 108–274) ("AGOA Acceleration Act") (19 U.S.C. §§ 3721(a) and (b)(6)), Executive Order No. 13191 of January 17, 2001, and Presidential Proclamation 7912 of June 29, 2005, has determined, effective on July 14, 2010, that the following articles shall be treated as handloomed, handmade, folklore articles, or ethnic printed fabrics under the AGOA: (a) folklore articles described in Annex A to this letter and (b) ethnic printed fabrics described in Annex B, if made in Burkina Faso. Such articles are eligible for duty-free treatment only if entered under subheading 9819.11.27 and accompanied by a properly completed visa for product grouping "9", in accordance with the provisions of the Visa Arrangement between the Government of Burkina Faso and the Government of the United States Concerning Textile and Apparel Articles Claiming Preferential Tariff Treatment under Section 112 of the Trade and Development Act of 2000. After further consultations with Burkina Faso authorities, CITA may determine that additional textile and apparel goods shall be treated as for handmade, handloomed, folklore articles, or ethnic printed fabrics.

Sincerely,

Kim Glas,
Chairman, Committee for the Implementation of Textile Agreements.

ANNEX A: Burkina Faso Folklore Products

CITA has determined that the following textile and apparel goods shall be treated as folklore articles for purposes of the AGOA if such goods are made in Burkina Faso. Articles must be ornamented in characteristic Burkina

Faso or regional folk style. An article may not include modern features such as zippers, elastic, elasticized fabrics, snaps, or hook-and-pile fasteners (such as velcro© or similar holding fabric). An article may not incorporate patterns that are not traditional or historical to Burkina Faso, such as airplanes, buses, cowboys, or cartoon characters and may not incorporate designs referencing holidays or festivals not common to traditional Burkina Faso culture, such as Halloween and Thanksgiving.

Eligible folklore articles:

(a) Bala: Made of cotton fabric strips woven and assembled by hand; embroidered by machine. The colors vary but embroidery is usually white. It is a loose fitting garment for men, consisting of a tunic, which is three-quarters length, embroidered with sleeves, the neckline is a slit down the center, surrounded by embroidery; and a cap, which is cylindrical and fitted.

(b) Djiwa: Made of cotton fabric strips woven by hand with embroidery cotton floss. Patterns and colors of the fabrics vary as well as the embroidery. This men's garment is loose-fitting and consists of four pieces: 1) an inner tunic gown, three-quarter length, usually with intricate embroidery around the neckline, chest, pockets and end of sleeves; 2) trousers, loose fitting and secured at the waist by a drawstring, embroidery at the end of the trousers; 3) an outer gown, loose fitting, embroidery along the neckline, chest, waist and on the back; and 4) a matching cap which is cylindrical and fitted.

(c) Dozo Fani: Made of cotton fabric strips woven by hand, dyed with natural dyes (bogolan) and assembled by hand. The patterns consist of animals, dogon ideograms, or diverse geometrical forms. The colors are brown, black, yellow and red exclusively. This is a loose fitting, one-piece garment for men, open on both sides with no sleeves.

(d) Bougouni: Made of cotton fabric strips woven and assembled by hand. This is a loose fitting garment for men and women, open on both sides, with or without straps attaching the sides. It is white, black or indigo and patterned in strips of cloth with a hound's-tooth pattern in the middle.

ANNEX B: Burkina Faso Ethnic Printed Fabrics

Each ethnic print must meet all of the criteria listed below:

(A) Selvedge on both edges.

(B) Width of less than 50 inches.

(C) Classifiable under subheading 5208.52.30[1] or 5208.52.40[2] of the Harmonized Tariff Schedule of the United States.

(D) Contains designs, symbols, and other characteristics of African prints normally produced for and sold in Africa by the piece.

(E) Made from fabric woven in the U.S. using U.S. yarn or woven in one or more eligible sub-Saharan beneficiary countries using U.S or African yarn.

(F) Printed, including waxed, in one or more eligible sub-Saharan beneficiary countries.

[FR Doc. 2010–17179 Filed 7–13–10; 8:45 am]

BILLING CODE 3510–DS–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Illinois Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a fact finding meeting of the Illinois Advisory Committee to the Commission will convene at 9 a.m. and adjourn at 4:30 p.m. on August 11, 2010, at the National Museum of Mexican Art, 1852 W. 19th St., Chicago, IL 60608. The purpose of the meeting is to hear testimony regarding recommendations for addressing two health disparities topics: language barriers and food desserts. The meeting will consist of approximately six panels of local health disparities experts, community activists, health providers, and government officials providing their recommendations to these problems.

Members of the public are entitled to submit written comments; the comments must be received in the regional office by September 11, 2010. The address is 55 W. Monroe St., Suite 410, Chicago, IL 60603. Persons wishing to e-mail their comments, or to present their comments verbally at the meeting, or who desire additional information should contact Carolyn Allen, Administrative Assistant, 312–353–8311, TDD/TTY 312–353–8324], or by e-mail: *callen@usccr.gov.*

Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least ten (10) working days before the scheduled date of the meeting.

Records generated from this meeting may be inspected and reproduced at the Midwestern Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's Web site, *http://www.usccr.gov,* or to contact the Midwestern Regional Office at the above e-mail or street address.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission and FACA.

Dated in Washington, DC on July 9, 2010.

Peter Minarik, Acting Chief,

Regional Programs Coordination Unit.

[FR Doc. 2010–17127 Filed 7–13–10; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

International Trade Administration

Application(s) for Duty–Free Entry of Scientific Instruments

Pursuant to Section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, as amended by Pub. L. 106–36; 80 Stat. 897; 15 CFR part 301), we invite comments on the question of whether instruments of equivalent scientific value, for the purposes for which the instruments shown below are intended to be used, are being manufactured in the United States. Comments must comply with 15 CFR 301.5(a)(3) and (4) of the regulations and be postmarked on or before August 3, 2010. Address written comments to Statutory Import Programs Staff, Room 3720, U.S. Department of Commerce, Washington, D.C. 20230. Applications may be examined between 8:30 A.M. and 5:00 P.M. at the U.S. Department of Commerce in Room 3720.

Docket Number: 10–043. Applicant: National Superconducting Cyclotron Laboratory of Michigan State University, 1 Cyclotron Laboratory, South Shaw Lane, East Lansing, MI 48824–1321. Instrument: Radio Frequency Quadropole Accelerator (RFQ). Manufacturer: Institut fur Angewandte Physik, Germany. Intended Use: The instrument will be a component of a larger linear accelerator system to accelerate isotopes for nuclear structure and nuclear astrophysics studies. The characteristics of the 4–rod RFQ pertinent for the intended purpose are the reachable power and electrode voltage level, simple tuning of rod–voltage flatness, and simple resonance

[1] Printed plain weave fabrics of cotton, 85% or more cotton by weight, weighing over 100g/m2 but not more than 200g/m2, of yarn number 42 or lower.

[2] Printed plain weave fabrics of cotton, 85% or more cotton by weight, weighing over 100g/m2 but not more than 200g/m2, of yarn numbers 43–68.

frequency tuning in order to guarantee the required ion beam properties. No other RFQ structure can deliver these features in the according frequency range of 80.5 MHz. As the experimental program conducted with reaccelerated beams spans the entire range of the periodic table of elements, the structure must ensure stable operation at low and high power.
No degradation of the beam quality due to thermal stress can be tolerated. No shortfall of the experimental program due to multi–factoring of the RFQ can be accepted. Therefore a simple and reliable structure like the 4–rod RFQ is the best choice for the required task of reliable beam delivery. Justification for Duty–Free Entry: There are no similar instruments of the same general category as the foreign instrument being manufactured domestically. Application accepted by Commissioner of Customs: June 16, 2010.

Dated: July 7, 2010.

Christopher Cassel,

Director, IA Subsidies Enforcement Office.

[FR Doc. 2010–17167 Filed 7–13–10; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–520–803]

Polyethylene Terephthalate Film, Sheet and Strip From the United Arab Emirates: Extension of Time Limit for Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* July 14, 2010.

FOR FURTHER INFORMATION CONTACT: Andrew Huston or Jun Jack Zhao, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; *telephone:* (202) 482–4261 and (202) 482–1396, respectively.

Background

On December 23, 2009, the Department of Commerce (the Department) published the initiation of the administrative review of the antidumping duty order on polyethylene terephthalate film, sheet and strip from the United Arab Emirates (UAE) for the period November 06, 2008 through October 31, 2009. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocation in Part,* 74 FR 68229 (December 23, 2009). This review covers two producers and/or exporters of the subject merchandise to the United States: FLEX Middle East FZE (FLEX) and, JBF RAK LLC (JBF).

Extension of Time Limit for the Preliminary Results

Section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), and section 351.213(h)(1) of the Department's regulations require the Department to issue the preliminary results of a review within 245 days after the last day of the anniversary month of the order or suspension agreement for which the administrative review was requested, and final results of the review within 120 days after the date on which the notice of the preliminary results is published in the **Federal Register**. However, if the Department determines that it is not practicable to complete the review within the aforementioned specified time limits, section 751(a)(3)(A) of the Act and section 351.213(h)(2) of the Department's regulations allow the Department to extend the 245-day period to 365 days and to extend the 120-day period to 180 days.

The Department requires additional time to evaluate the questionnaire responses from FLEX and JBF in order to conduct a thorough analysis of all information on the record, specifically considering the cost and affiliation issues in this case. Therefore, the Department finds that it is not practicable to complete the preliminary results of this review within the original time limit and is extending the deadline for completion of the preliminary results of this administrative review by 120 days.

Additionally, on February 12, 2010, the Department issued a memorandum revising all case deadlines. As explained in the memorandum from the Deputy Assistant Secretary for Import Administration, the Department has exercised its discretion to toll deadlines for the duration of the closure of the Federal Government from February 5 through February 12, 2010. Thus, all deadlines in this segment of the proceeding have been extended by seven days. *See* Memorandum to the Record from Ronald Lorentzen, DAS for Import Administration, regarding "Tolling of Administrative Deadlines As a Result of the Government Closure During the Recent Snowstorm," dated February 12, 2010. Therefore, we are hereby extending the deadline for the preliminary results by a total of 127 days; the revised deadline for the preliminary results of this administrative review is now December 07, 2010.

This notice is issued and published pursuant to sections 751(a)(3)(A) and 777(i)(1) of the Act.

Dated: July 7, 2010.

Edward C. Yang,

Acting Deputy Assistant Secretary for Antidumping/Countervailing Duty Operations.

[FR Doc. 2010–17169 Filed 7–13–10; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XX47

Marine Mammals; File No. 14097

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of permit.

SUMMARY: Notice is hereby given that National Marine Fisheries Service, Southwest Fisheries Science Center (SWFSC) (Jeremy Rusin, Principal Investigator), Protected Resources Division, 3333 N. Torrey Pines Ct., La Jolla, CA 92037, has been issued a permit to conduct scientific research on five pinniped species, 57 cetacean species, and five sea turtle species in the Pacific, Southern, Indian, and Arctic Oceans.

ADDRESSES: The permit and related documents are available for review upon written request or by appointment in the following offices: See **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Kristy Beard or Amy Hapeman, (301) 713–2289.

SUPPLEMENTARY INFORMATION: On July 27, 2009, notice was published in the **Federal Register** (74 FR 37015) that a request for a permit to conduct scientific research on five pinniped species, 57 cetacean species, and five sea turtle species in the Pacific, Southern, Indian, and Arctic Oceans 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.*), 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 permit authorizes three projects. Under Project I (Pinnipeds) population assessments will be conducted of northern elephant seals (*Mirounga angustirostris*), California sea lions (*Zalophus californianus*), Steller sea lions (*Eumetopias jubatus*), and harbor seals (*Phoca vitulina*) via aerial photography, ground or vessel surveys, and photogrammetry to determine abundance, distribution patterns, length frequencies, and breeding densities. Scats and spewings will be collected from California sea lions to determine their diet. Under Project II (Cetaceans) surveys will be conducted to determine the abundance, distribution, movement patterns, and stock structure of cetaceans in U.S. territorial and international waters. These studies will be conducted through vessel surveys, aerial surveys, small plane photogrammetry, photo-identification (from vessels and small boats), biological sampling, radio tagging, and satellite tagging. Under Project III (Sea Turtles) surveys will be conducted to determine the abundance, distribution, movement patterns, stock structure, and diet of sea turtles in U.S. territorial and international waters. Sea turtles will be opportunistically captured during Project II surveys for collection of blood samples, stomach contents, and tissue biopsy and to attach satellite tags. Cetacean, pinniped, and sea turtle parts, specimens, and biological samples collected during these projects will also be salvaged and imported/exported.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an environmental assessment (EA) was prepared analyzing the effects of the permitted activities on the human environment. Based on the analyses in the EA, NMFS determined that issuance of the permit would not significantly impact the quality of the human environment and that preparation of an environmental impact statement was not required. That determination is documented in a Finding of No Significant Impact (FONSI), signed on July 1, 2010.

Issuance of this permit, as required by the ESA, 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.

Documents may be reviewed in the following locations:

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;

Northwest Region, NMFS, 7600 Sand Point Way NE, BIN C15700, Bldg. 1, Seattle, WA 98115–0700; phone (206) 526–6150; fax (206) 526–6426;

Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802–1668; phone (907) 586–7221; fax (907) 586–7249;

Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213; phone (562) 980–4001; fax (562) 980–4018; and

Pacific Islands Region, NMFS, 1601 Kapiolani Blvd., Rm 1110, Honolulu, HI 96814–4700; phone (808) 944–2200; fax (808) 973–2941.

Dated: July 7, 2010.

Tammy C. Adams,

Acting Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2010–17164 Filed 7–13–10; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–905]

Certain Polyester Staple Fiber From the People's Republic of China: Notice of Preliminary Results and Preliminary Rescission, in Part, of the Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce ("Department") is conducting the second administrative review of the antidumping duty order on certain polyester staple fiber ("PSF") from the People's Republic of China ("PRC") for the period of review ("POR") June 1, 2008, through May 31, 2009. The Department has preliminarily determined that sales have not been made below normal value ("NV") with respect to certain exporters who participated fully and are entitled to a separate rate in this administrative review. If these preliminary results are adopted in our final results of review, we will instruct U.S. Customs and Border Protection ("CBP") to assess antidumping duties on entries of subject merchandise during the POR for which the importer-specific assessment rates are above *de minimis.*

DATES: *Effective Date:* July 14, 2010.

FOR FURTHER INFORMATION CONTACT: Jerry Huang or Steven Hampton, AD/CVD Operations, Office 9, Import Administration, International Trade Administration, Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–4047 or (202) 482–0116, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 1, 2007, the Department published in the **Federal Register** an antidumping duty order on certain polyester staple fiber from the PRC. *See Notice of Antidumping Duty Order: Certain Polyester Staple Fiber from the People's Republic of China,* 72 FR 30545 (June 1, 2007) ("Order"). On July 29, 2009, the Department published a notice of initiation of an administrative review of certain polyester staple fiber from the People's Republic of China covering the period June 1, 2008, through May 31, 2009, for 27 companies.[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Deferral of Administrative Review,* 74 FR 37690 (July 29, 2009) ("Initiation Notice"). On February 9, 2010, the Department published in the **Federal Register** a notice extending the time period for issuing the preliminary results by 101 days. *See Certain Polyester Staple Fiber from the People's Republic of China: Extension of Time Limits for Preliminary Results of the Antidumping Duty Administrative Review,* 75 FR 6352 (February 9, 2010). On February 16, 2010, the Department issued a memorandum that tolled the deadlines for all Import Administration cases by seven calendar days due to the recent Federal Government closure. *See* Memorandum for the Record from Ronald Lorentzen, DAS for Import Administration, regarding Tolling of Administrative Deadlines as a Result of the Government Closure During the Recent Snowstorm, dated February 12, 2010. On June 1, 2010, the Department published in the **Federal Register** a second notice extending the time period for issuing the preliminary results by 19

[1] Those companies are: Far Eastern Industries, Ltd., (Shanghai) and Far Eastern Polychem Industries; Ningbo Dafa Chemical Fiber Co., Ltd.; Cixi Sansheng Chemical Fiber Co., Ltd.; Cixi Santai Chemical Fiber Co., Ltd.; Cixi Waysun Chemical Fiber Co., Ltd.; Hangzhou Best Chemical Fibre Co., Ltd.; Hangzhou Hanbang Chemical Fibre Co., Ltd.; Hangzhou Huachuang Co., Ltd.; Hangzhou Sanxin Paper Co., Ltd.; Hangzhou Taifu Textile Fiber Co., Ltd.; Jiaxang Fuda Chemical Fibre Factory; Nantong Loulai Chemical Fiber Co., Ltd.; Nan Yang Textile Co., Ltd.; Suzhou PolyFiber Co., Ltd.; Xiamen Xianglu Chemical Fiber Co.; Zhaoqing Tifo New Fiber Co., Ltd.; Zhejiang Anshun Pettechs Fibre Co., Ltd.; Zhejiang Waysun Chemical Fiber Co., Ltd.; Dragon Max Trading Development; Xiake Color Spinning Co., Ltd.; Jiangyin Hailun Chemical Fiber Co., Ltd.; Hyosung Singapore PTE Ltd.; Jiangyin Changlong Chemical Fiber Co., Ltd.; Ma Ha Company, Ltd.; Jiangyin Huahong Chemical Fiber Co., Ltd.; Jiangyin Mighty Chemical Fiber Co., Ltd.; and Huvis Sichuan.

days. *See Certain Polyester Staple Fiber from the People's Republic of China: Extension of Preliminary Results of the Antidumping Duty Administrative Review,* 75 FR 30373 (June 1, 2010).

Preliminary Partial Rescission of Administrative Review

Pursuant to 19 CFR 351.213(d)(3), we have preliminarily determined that Hangzhou Best Chemical Fibre Co., Ltd. ("Hangzhou Best") and Xiamen Xianglu Chemical Fiber Co. ("Xiamen Xianglu") made no shipments of subject merchandise during the POR of this administrative review. The Department received no-shipment certifications from Hangzhou Best and Xiamen Xianglu on August 24, 2009, and August 28, 2009, respectively. The Department also issued no-shipment inquiries to CBP in September 2009, asking CBP to provide any information contrary to our findings of no entries of subject merchandise for merchandise manufactured and shipped by Hangzhou Best and Xiamen Xianglu during the POR. We did not receive any response from CBP, thus indicating that there were no entries of subject merchandise into the United States exported by these companies. Consequently, as neither company made exports of subject merchandise during the POR, we are preliminarily rescinding the review, in part, with respect to Hangzhou Best and Xiamen Xianglu.

Respondent Selection

Section 777A(c)(1) of the Tariff Act of 1930, as amended ("the Act") directs the Department to calculate individual dumping margins for each known exporter or producer of the subject merchandise. However, section 777A(c)(2) of the Act gives the Department discretion to limit its examination to a reasonable number of exporters or producers if it is not practicable to examine all exporters or producers involved in the review.

On July 31, 2009, the Department released CBP data for entries of the subject merchandise during the POR under administrative protective order ("APO") to all interested parties having an APO, inviting comments regarding the CBP data and respondent selection. The Department received comments and rebuttal comments on August 10, 2009, and August 17, 2009, respectively.

On September 18, 2009, the Department issued its respondent selection memorandum after assessing its resources and determining that it could reasonably examine two exporters subject to this review. Pursuant to section 777A(c)(2)(B) of the Act, the Department selected Ningbo Dafa Chemical Fiber Co., Ltd. ("Ningbo Dafa") and Cixi Santai Chemical Fiber Co. ("Cixi Santai") as mandatory respondents.[2] The Department sent antidumping duty questionnaires to Ningbo Dafa and Cixi Santai on September 25, 2009.

Ningbo Dafa and Cixi Santai submitted the Section A Questionnaire Responses on November 2, 2009, the Section C & D Questionnaire Responses on November 16, 2009. Petitioners submitted deficiency comments regarding respondents' questionnaire responses between January and April 2010. The Department issued supplemental questionnaires to Ningbo Dafa and Cixi Santai between March 2010 and May 2010 to which both companies responded.

Surrogate Country and Surrogate Value Data

On February 18, 2010, the Department sent interested parties a letter inviting comments on surrogate country selection and surrogate value data.[3] No parties provided comments with respect to selection of a surrogate country. On April 16, 2009, the Department received information to value factors of production ("FOP") from Ningbo Dafa, Cixi Santai, and Petitioners. All the surrogate values placed on the record were obtained from sources in India.

Scope of the Order

The merchandise subject to this proceeding is synthetic staple fibers, not carded, combed or otherwise processed for spinning, of polyesters measuring 3.3 decitex (3 denier, inclusive) or more in diameter. This merchandise is cut to lengths varying from one inch (25 mm) to five inches (127 mm). The subject merchandise may be coated, usually with a silicon or other finish, or not coated. PSF is generally used as stuffing in sleeping bags, mattresses, ski jackets, comforters, cushions, pillows, and furniture.

The following products are excluded from the scope: (1) PSF of less than 3.3 decitex (less than 3 denier) currently classifiable in the Harmonized Tariff Schedule of the United States ("HTSUS") at subheading 5503.20.0025 and known to the industry as PSF for spinning and generally used in woven and knit applications to produce textile and apparel products; (2) PSF of 10 to 18 denier that are cut to lengths of 6 to 8 inches and that are generally used in the manufacture of carpeting; and (3) low-melt PSF defined as a bi-component fiber with an outer, non-polyester sheath that melts at a significantly lower temperature than its inner polyester core (classified at HTSUS 5503.20.0015).

Certain PSF is classifiable under the HTSUS subheadings 5503.20.0045 and 5503.20.0065. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise under the orders is dispositive.

Non-Market Economy ("NME") Country Status

In every case conducted by the Department involving the PRC, the PRC has been treated as an NME country. In accordance with section 771(18)(C)(i) of the Act, any determination that a foreign country is an NME country shall remain in effect until revoked by the administering authority. *See, e.g., Brake Rotors from the People's Republic of China: Final Results and Partial Rescission of the 2004/2005 Administrative Review and Notice of Rescission of 2004/2005 New Shipper Review,* 71 FR 66304 (November 14, 2006). None of the parties to this proceeding have contested such treatment. Accordingly, the Department calculated NV in accordance with section 773(c) of the Act, which applies to NME countries.

Surrogate Country

When the Department investigates imports from an NME country and available information does not permit the Department to determine NV pursuant to section 773(a) of the Act, then, pursuant to section 773(c)(4) of the Act, the Department bases NV on an NME producer's FOPs, to the extent possible, in one or more market-economy countries that (1) are at a level of economic development comparable to that of the NME country, and (2) are significant producers of comparable merchandise. The Department determined India, Philippines, Indonesia, Colombia, Thailand, and Peru are countries comparable to the PRC in terms of economic development.[4]

[2] *See* Memorandum to James Dole, Director, AD/CVD Operations, Office 9, from Emeka Chukwudebe and Tim Lord, Analysts, AD/CVD Operations, Office 9, regarding Second Antidumping Duty Administrative Review of Certain Polyester Staple Fiber from the PRC: Selection of Respondents for Individual Review, dated September 18, 2009 ("Respondent Selection Memo").

[3] *See* the Department's Letter to All Interested Parties; Antidumping Administrative Review of Certain Polyester Staple Fiber ("PSF") from the People's Republic of China ("PRC"): Surrogate Country List, dated February 18, 2010 ("Surrogate Country List").

[4] *See* Surrogate Country List.

Based on publicly available information placed on the record (*e.g.,* production data), the Department determines India to be a reliable source for surrogate values because India is at a comparable level of economic development pursuant to section 773(c)(4) of the Act, is a significant producer of subject merchandise, and has publicly available and reliable data. Accordingly, the Department has selected India as the surrogate country for purposes of valuing the FOPs because it meets the Department's criteria for surrogate country selection.

Separate Rates

In 2005, the Department notified parties of a new application and certification process by which exporters and producers may obtain separate rate status in an NME review. The process requires exporters and producers to submit a separate rate status certification and/or application. *See also Policy Bulletin 05.1: Separate-Rates Practice and Application of Combination Rates in Antidumping Investigations involving Non-Market Economy Countries,* (April 5, 2005) ("*Policy Bulletin 05.1*"), available at: *http://www.trade.gov/ia.* However, the standard for eligibility for a separate rate, which is whether a firm can demonstrate an absence of both *de jure* and *de facto* government control over its export activities, has not changed.

A designation of a country as an NME remains in effect until it is revoked by the Department. *See* section 771(18)(c)(i) of the Act. In proceedings involving NME countries, it is the Department's practice to begin with a rebuttable presumption that all companies within the country are subject to government control and thus should be assessed a single antidumping duty rate. *See, e.g., Policy Bulletin 05.1; see also Notice of Final Determination of Sales at Less Than Fair Value, and Affirmative Critical Circumstances, In Part: Certain Lined Paper Products from the People's Republic of China,* 71 FR 53079, 53082 (September 8, 2006); *Final Determination of Sales at Less Than Fair Value and Final Partial Affirmative Determination of Critical Circumstances: Diamond Sawblades and Parts Thereof from the People's Republic of China,* 71 FR 29303, 29307 (May 22, 2006) ("*Diamond Sawblades*"). It is the Department's policy to assign all exporters of merchandise subject to investigation in an NME country this single rate unless an exporter can affirmatively demonstrate that it is sufficiently independent so as to be entitled to a separate rate. *See, e.g., Diamond Sawblades,* 71 FR at 29307. Exporters can demonstrate this independence through the absence of both *de jure* and *de facto* government control over export activities. *Id.* The Department analyzes each entity exporting the subject merchandise under a test arising from the *Notice of Final Determination of Sales at Less Than Fair Value: Sparklers from the People's Republic of China,* 56 FR 20588, 20589 (May 6, 1991) ("*Sparklers*"), as further developed in *Notice of Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the People's Republic of China,* 59 FR 22585, 22586–87 (May 2, 1994) ("*Silicon Carbide*"). However, if the Department determines that a company is wholly foreign-owned or located in a market economy, then a separate rate analysis is not necessary to determine whether it is independent from government control. *See, e.g., Final Results of Antidumping Duty Administrative Review: Petroleum Wax Candles from the People's Republic of China,* 72 FR 52355, 52356 (September 13, 2007).

In addition to the two mandatory respondents, Ningbo Dafa and Cixi Santai, the Department received separate rate applications or certifications from the following 13 companies ("Separate-Rate Applicants"): Far Eastern Industries, Ltd., (Shanghai) and Far Eastern Polychem Industries; Cixi Sansheng Chemical Fiber Co., Ltd.; Cixi Waysun Chemical Fiber Co. Ltd.; Hangzhou Hanbang Chemical Fibre Co., Ltd.; Hangzhou Huachuang Co., Ltd.; Hangzhou Sanxin Paper Co., Ltd.; Hangzhou Taifu Textile Fiber Co., Ltd.; Jiaxang Fuda Chemical Fibre Factory; Nantong Loulai Chemical Fiber Co., Ltd.; Nanyang Textile Co., Ltd.; Zhaoqing Tifo New Fiber Co., Ltd.; Zhejiang Anshun Pettechs Fibre Co., Ltd.; and Zhejiang Waysun Chemical Fiber Co., Ltd.

However, the following 10 companies did not submit either a separate-rate application or certification: Dragon Max Trading Development; Xiake Color Spinning Co., Ltd.; Jiangyin Hailun Chemical Fiber Co., Ltd.; Hyosung Singapore PTE Ltd.; Jiangyin Changlong Chemical Fiber Co., Ltd.; Ma Ha Company, Ltd.; Jiangyin Huahong Chemical Fiber Co., Ltd.; Jiangyin Mighty Chemical Fiber Co., Ltd.; Huvis Sichuan; and Suzhou PolyFiber Co., Ltd. Therefore, because these companies did not demonstrate their eligibility for separate rate status, they have now been included as part of the PRC-wide entity.

a. Absence of De Jure Control

The Department considers the following *de jure* criteria in determining whether an individual company may be granted a separate rate: (1) An absence of restrictive stipulations associated with an individual exporter's business and export licenses; (2) any legislative enactments decentralizing control of companies; and (3) any other formal measures by the government decentralizing control of companies. *See Sparklers,* 56 FR at 20589. The evidence provided by Ningbo Dafa, Cixi Santai, and the Separate-Rate Applicants supports a preliminary finding of *de jure* absence of government control based on the following: (1) An absence of restrictive stipulations associated with the individual exporter's business and export licenses; (2) there are applicable legislative enactments decentralizing control of the companies; and (3) there are formal measures by the government decentralizing control of companies. *See, e.g.,* Ningbo Dafa's Section A Supplemental Questionnaire Response, dated March 16, 2010, at Exhibit 1SA–1; and Cixi Santai's Section A Questionnaire Response, dated November 2, 2009, at A2–12.

b. Absence of De Facto Control

Typically the Department considers four factors in evaluating whether each respondent is subject to *de facto* government control of its export functions: (1) Whether the export prices are set by or are subject to the approval of a government agency; (2) whether the respondent has authority to negotiate and sign contracts and other agreements; (3) whether the respondent has autonomy from the government in making decisions regarding the selection of management; and (4) whether the respondent retains the proceeds of its export sales and makes independent decisions regarding disposition of profits or financing of losses. *See Silicon Carbide,* 59 FR at 22586–87; *see also Notice of Final Determination of Sales at Less Than Fair Value: Furfuryl Alcohol From the People's Republic of China,* 60 FR 22544, 22545 (May 8, 1995). The Department has determined that an analysis of *de facto* control is critical in determining whether respondents are, in fact, subject to a degree of government control which would preclude the Department from assigning separate rates. The evidence provided by Ningbo Dafa, Cixi Santai, and the Separate-Rate Applicants supports a preliminary finding of *de facto* absence of government control based on the following: (1) The companies set their own export prices independent of the government and without the approval of a government authority; (2) the companies have authority to negotiate

and sign contracts and other agreements; (3) the companies have autonomy from the government in making decisions regarding the selection of management; and (4) there is no restriction on any of the companies' use of export revenue. *See, e.g.,* Ningbo Dafa's Section A Supplemental Questionnaire Response at Exhibit 1SA–1; and Cixi Santai's Section A Questionnaire Response at A2–12. Therefore, the Department preliminarily finds that Ningbo Dafa and Cixi Santai have established that they qualify for a separate rate under the criteria established by *Silicon Carbide* and *Sparklers.*

Separate Rate Calculation

As stated previously, this administrative review covers 25 exporters. Of those, the Department selected two exporters, Ningbo Dafa and Cixi Santai, as mandatory respondents in this review. As stated above, 10 companies are part of the PRC–Wide entity and thus are not entitled to a separate rate.[5] The remaining 13 companies submitted timely information as requested by the Department and thus, the Department has preliminary determined to treat these companies as cooperative Separate-Rate Applicants.

The statute and the Department's regulations do not address the establishment of a rate to be applied to individual companies not selected for examination where the Department limited its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally we have looked to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when calculating the rate for respondents we did not examine in an administrative review. Section 735(c)(5)(A) of the Act instructs that we are not to calculate an all-others rate using any zero or *de minimis* margins or any margins based entirely on facts available. Accordingly, the Department's practice in this regard, in reviews involving limited respondent selection based on exporters accounting for the largest volumes of trade, has been to average the rates for the selected companies, excluding zero and *de minimis* rates and rates based entirely on facts available. Section 735(c)(5)(B) of the Act also provides that, where all margins are zero, *de minimis,* or based entirely on facts available, we may use "any reasonable method" for assigning the rate to non-selected respondents, including "averaging the estimated weighted average dumping margins determined for the exporters and producers individually investigated."

The Department has available in administrative reviews information that would not be available in an investigation, namely rates from prior administrative and new shipper reviews. Accordingly, since the determination in the investigation in this proceeding, the Department has determined that in cases where we have found dumping margins in previous segments of a proceeding, a reasonable method for determining the rate for non-selected companies is to use the most recent rate calculated for the non-selected company in question, unless we calculated in a more recent review a rate for any company that was not zero, *de minimis* or based entirely on facts available. *See Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews and Rescission of Review in Part,* 73 FR 52823, 52824 (September 11, 2008) and accompanying Issues and Decision Memorandum at Comment 16; *see also Certain Fish Fillets from the Socialist Republic of Vietnam: Notice of Preliminary Results of the New Shipper Review and Fourth Antidumping Duty Administrative Review and Partial Rescission of the Fourth Administrative Review,* 73 FR 52015 (September 8, 2008) (changed in final results as final calculated rate for mandatory respondent was above *de minimis,* which remained unchanged in the amended final results).[6]

In this case, all the Separate-Rate Applicants received a separate rate in the original investigation. Therefore, for the preliminary results, we are assigning all the Separate-Rate Applicants a separate rate of 4.44%, which is the separate rate from the original investigation. Entities receiving this rate are identified by name in the "Preliminary Results of Review" section of this notice.

Date of Sale

Ningbo Dafa and Cixi Santai reported the invoice date as the date of sale because they claim that, for their U.S. sales of subject merchandise made during the POR, the material terms of sale were established on the invoice date. The Department preliminarily determines that the invoice date is the most appropriate date to use as Ningbo Dafa's and Cixi Santai's date of sale is in accordance with 19 CFR 351.401(i) and the Department's long-standing practice of determining the date of sale.[7]

Fair Value Comparisons

To determine whether sales of certain polyester staple fiber to the United States by Ningbo Dafa and Cixi Santai were made at less-than-fair-value, the Department compared the export price ("EP") to NV, as described in the "U.S. Price," and "Normal Value" sections below.

U.S. Price

Export Price

In accordance with section 772(a) of the Act, the Department calculated the EP for the sales to the United States from Ningbo Dafa and Cixi Santai because the first sale to an unaffiliated party was made before the date of importation and the use of constructed EP ("CEP") was not otherwise warranted. The Department calculated EP based on the price to unaffiliated purchasers in the United States. In accordance with section 772(c) of the Act, as appropriate, the Department deducted from the starting price to unaffiliated purchasers foreign inland freight and brokerage and handling. Each of these services was either provided by an NME vendor or paid for using an NME currency. Thus, the Department based the deduction of these movement charges on surrogate values.

Normal Value

Section 773(c)(1) of the Act provides that the Department shall determine the NV using a FOPs methodology if the merchandise is exported from an NME and the information does not permit the calculation of NV using home-market prices, third-country prices, or constructed value under section 773(a) of the Act. The Department bases NV on the FOPs because the presence of

[5] Those companies are: Dragon Max Trading Development; Xiake Color Spinning Co., Ltd.; Jiangyin Hailun Chemical Fiber Co., Ltd.; Hyosung Singapore PTE Ltd.; Jiangyin Changlong Chemical Fiber Co., Ltd.; Ma Ha Company, Ltd.; Jiangyin Huahong Chemical Fiber Co., Ltd.; Jiangyin Mighty Chemical Fiber Co., Ltd.; Huvis Sichuan; and Suzhou PolyFiber Co., Ltd.

[6] *See Notice of Final Results of the Antidumping Duty Administrative Review and New Shipper Reviews: Certain Frozen Fish Fillets from the Socialist Republic of Vietnam,* 74 FR 11349 (March 17, 2009) and accompanying Issues and Decision Memorandum at Comment 6; *Notice of Amended Final Results of the Fourth Antidumping Duty Administrative Review: Certain Frozen Fish Fillets from the Socialist Republic of Vietnam,* 74 FR 17816 (April 17, 2009).

[7] *See, e.g., 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.

government controls on various aspects of NMEs renders price comparisons and the calculation of production costs invalid under the Department's normal methodologies.

Factor Valuations

In accordance with 19 CFR 351.408(c)(1), the Department will normally use publicly available information to value the FOPs, but when a producer sources an input from a market economy ("ME") country and pays for it in a ME currency, the Department may value the factor using the actual price paid for the input. During the POR, both Ningbo Dafa and Cixi Santai reported that they purchased certain inputs from a ME supplier and paid for the inputs in a ME currency. *See* Ningbo Dafa Section D Questionnaire Response, dated November 16, 2009, at D–5–6 and Exhibit D–3; and Cixi Santai's Section D Questionnaire Response, dated November 16, 2009, at D–5–6 and Exhibit D–2.b. The Department has a rebuttable presumption that ME input prices are the best available information for valuing an input when the total volume of the input purchased from all ME sources during the period of investigation or review exceeds 33 percent of the total volume of the input purchased from all sources during the period. *See Antidumping Methodologies: Market Economy Inputs, Expected Non-Market Economy Wages, Duty Drawback; and Request for Comments,* 71 FR 61716, 61717–18 (October 19, 2006) ("*Antidumping Methodologies*").

In these cases, unless case-specific facts provide adequate grounds to rebut the Department's presumption, the Department will use the weighted-average ME purchase price to value the input. Alternatively, when the volume of an NME firm's purchases of an input from ME suppliers during the period is below 33 percent of its total volume of purchases of the input during the period, but where these purchases are otherwise valid and there is no reason to disregard the prices, the Department will weight-average the ME purchase price with an appropriate surrogate value according to their respective shares of the total volume of purchases, unless case-specific facts provide adequate grounds to rebut the presumption. *See Antidumping Methodologies.* When a firm has made ME input purchases that may have been dumped or subsidized, are not *bona fide,* or are otherwise not acceptable for use in a dumping calculation, the Department will exclude them from the numerator of the ratio to ensure a fair determination of whether valid ME purchases meet the 33-percent threshold. *See Antidumping Methodologies.* Cixi Santai reported as ME purchases certain input purchases from a NME supplier that were sourced from a ME country. *See* Cixi Santai's Section D Questionnaire Response at Exhibit D–2.b. Consistent with the Department's regulations at 19 CFR 351.408 (c)(1), the Department has preliminarily determined that such purchases from a NME supplier, even if the material was originally sourced from a ME country, should not be considered as ME purchases for the purposes of antidumping margin calculations, given that the sale price for the input was set by an NME vendor.

In accordance with section 773(c) of the Act, for subject merchandise produced by Ningbo Dafa and Cixi Santai, the Department calculated NV based on the FOPs reported by Ningbo Dafa and Cixi Santai for the POR. The Department used Indian import data and other publicly available Indian sources in order to calculate surrogate values for Ningbo Dafa and Cixi Santai's FOPs. To calculate NV, the Department multiplied the reported per-unit factor quantities by publicly available Indian surrogate values. The Department's practice when selecting the best available information for valuing FOPs is to select, to the extent practicable, surrogate values which are product-specific, representative of a broad market average, publicly available, contemporaneous with the POR and exclusive of taxes and duties. *See, e.g., Electrolytic Manganese Dioxide From the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 73 FR 48195 (August 18, 2008) and accompanying Issues and Decision Memorandum at Comment 2.

As appropriate, the Department adjusted input prices by including freight costs to render them delivered prices. Specifically, the Department added to Indian import surrogate values a surrogate freight cost using the shorter of the reported distance from the domestic supplier to the factory or the distance from the nearest seaport to the factory where we relied on an import value. This adjustment is in accordance with the decision of the *Federal Circuit in Sigma Corp. v. United States,* 117 F. 3d 1401, 1408 (Fed. Cir. 1997). Additionally, Ningbo Dafa and Cixi Santai both reported that they incurred brokerage and handling fees and import duties for some or all of their ME input purchases. *See* Ningbo Dafa's Second Section A, C and D Supplemental Questionnaire Response, dated May 20, 2010, at 2–3; and Cixi Santai's Second Section A, C&D Questionnaire Response, dated May 18, 2010, at 3. The Department adjusted the appropriate input prices to include the brokerage and handling fees based on a surrogate value. However, the Department made no adjustment for the import duties, as NME producers are not expected to pay import duties on products used in the manufacture of finished goods for export. *See Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From the People's Republic of China; Final Results of 1998–1999 Administrative Review, Partial Rescission of Review, and Determination Not To Revoke Order in Part,* 66 FR 1953 (January 10, 2001) and accompanying Issues and Decision Memorandum at Comment 12. Furthermore, these duties are assessed and collected by the PRC government, and the Department explained recently that the tax payments by NME respondents to NME governments are intra-NME transfers that do not provide a basis for the Department to adjust U.S. price. *See Silicon Metal from the People's Republic of China: Final Results and Partial Rescission of Antidumping Duty Administrative Review,* 75 FR 1592 (January 12, 2010) and accompanying Issues and Decision Memorandum at Comment 1.

In those instances where the Department could not obtain publicly available information contemporaneous to the POR with which to value factors, the Department adjusted the surrogate values using, where appropriate, the Indian Wholesale Price Index ("WPI") as published in the International Financial Statistics of the International Monetary Fund, a printout of which is attached to the Prelim Surrogate Value Memo at Attachment 2. Where necessary, the Department adjusted surrogate values for inflation and exchange rates, taxes, and the Department converted all applicable items to a per-kilogram basis.

The Department used Indian import data from the Global Trade Atlas ("GTA") published by Global Trade Information Services, Inc. ("GTIS"), which is sourced from the Directorate General of Commercial Intelligence & Statistics, Indian Ministry of Commerce, to determine the surrogate values for certain raw materials, by-products, and packing material inputs. The Department has disregarded statistics from NMEs, countries with generally available export subsidies, and undetermined countries, in calculating the average value. In accordance with the *OTCA 1988* legislative history, the Department continues to apply its long-standing practice of disregarding surrogate values if it has a reason to

believe or suspect the source data may be subsidized.[8] In this regard, the Department has previously found that it is appropriate to disregard such prices from India, Indonesia, South Korea and Thailand because we have determined that these countries maintain broadly available, non-industry specific export subsidies.[9] Based on the existence of these subsidy programs that were generally available to all exporters and producers in these countries at the time of the POR, the Department finds that it is reasonable to infer that all exporters from India, Indonesia, South Korea and Thailand may have benefitted from these subsidies. For a detailed description of all surrogate values used for Ningbo Dafa and Cixi Santai, *see* Memorandum to the File through Scot T. Fullerton, Program Manager, Office 9 from Jerry Huang, International Trade Analyst: Antidumping Duty Administrative Review of Certain Polyester Staple Fiber from the People's Republic of China ("PRC"): Surrogate Values for the Preliminary Results ("Prelim Surrogate Value Memo") dated July 7, 2010.

In past cases, it has been the Department's practice to value various FOPs using import statistics of the primary selected surrogate country from World Trade Atlas ("WTA"), as published by GTIS. *See Certain Preserved Mushrooms from the People's Republic of China: Preliminary Results of Antidumping Duty New Shipper Review,* 74 FR 50946, 50950 (October 2, 2009). However, in October 2009, the Department learned that Indian import data obtained from the WTA, as published by GTIS, began identifying the original reporting currency for India as the U.S. Dollar. The Department then contacted GTIS about the change in the original reporting currency for India from the Indian Rupee to the U.S. Dollar. Officials at GTIS explained that while GTIS obtains data on imports into India directly from the Ministry of Commerce, Government of India, as denominated and published in Indian Rupees, the WTA software is limited with regard to the number of significant digits it can manage. Therefore, GTIS made a decision to change the original reporting currency for Indian data from the Indian Rupee to the U.S. Dollar in order to reduce the loss of significant digits when obtaining data through the WTA software. GTIS explained that it converts the Indian Rupee to the U.S. Dollar using the monthly Federal Reserve exchange rate applicable to the relevant month of the data being downloaded and converted. *See Certain Oil Country Tubular Goods from the People's Republic of China: Final Determination of Sales at Less Than Fair Value, Affirmative Final Determination of Critical Circumstances, and Final Determination of Targeted Dumping,* 75 FR 20335 (April 19, 2010) and accompanying Issues and Decision Memorandum at Comment 4.

However, the data reported in the GTA software, published by GTIS, reports import statistics, such as from India, in the original reporting currency and thus this data corresponds to the original currency value reported by each country. Additionally, the data reported in the GTA software is reported to the nearest digit and thus there is not a loss of data by rounding, as there is with the data reported by the WTA software. Consequently, the Department will now obtain import statistics from GTA for valuing various FOPs because the GTA import statistics are in the original reporting currency of the country from which the data are obtained and have the same level of accuracy as the original data released.

The Department valued electricity using the updated electricity price data for small, medium, and large industries, as published by the Central Electricity Authority, an administrative body of the Government of India, in its publication titled *Electricity Tariff & Duty and Average Rates of Electricity Supply in India,* dated March 2008. These electricity rates represent actual country-wide, publicly-available information on tax-exclusive electricity rates charged to small, medium, and large industries in India. We did not inflate this value because utility rates represent current rates, as indicated by the effective dates listed for each of the rates provided.

The Department valued water using data from the Maharashtra Industrial Development Corporation ("MIDC") as it includes a wide range of industrial water tariffs. To value water, we used the average rate for industrial use from MIDC water rates at *http://www.midcindia.org. See* Prelim Surrogate Value Memo.

For direct, indirect, and packing labor, pursuant to a recent decision by the Court of Appeals for the Federal Circuit, we have calculated an hourly wage rate to use in valuing each respondent's reported labor input by averaging earnings and/or wages in countries that are economically comparable to the PRC and that are significant producers of comparable merchandise.[10] Because this wage rate does not separate the labor rates into different skill levels or types of labor, the Department has applied the same wage rate to all skill levels and types of labor reported by the respondents. *See* Prelim Surrogate Value Memo.

The Department valued truck freight expenses using a per-unit average rate calculated from data on the Infobanc Web site: *http://www.infobanc.com/logistics/logtruck.htm.* The logistics section of this Web site contains inland freight truck rates between many large Indian cities. Since this value is not contemporaneous with the POR, the Department deflated the rate using WPI. *See* Prelim Surrogate Value Memo.

The Department valued brokerage and handling using a price list of export procedures necessary to export a standardized cargo of goods in India. The price list is compiled based on a survey case study of the procedural requirements for trading a standard shipment of goods by ocean transport in India that is published in *Doing Business 2010: India,* by the World Bank. *See* Prelim Surrogate Value Memo.

To value factory overhead, selling, general, and administrative ("SG&A") expenses, and profit, the Department used the audited financial statements of Ganesh Polytex Limited.

We are preliminarily granting a by-product offset to Ningbo Dafa for waste paper and waste bottle hood. We are also preliminarily granting a by-product offset to Ningbo Dafa for waste fiber based on its production of waste fiber, as opposed to its POR reintroduction of waste fiber. *See* Ningbo Dafa's Third Section D Supplemental Questionnaire Response, dated May 27, 2010, at 3. Similarly, we are preliminarily granting a by-product offset to Cixi Santai for polypropylene ("PP") waste and polyethylene terephthalate ("PET") waste. Cixi Santai stated that it sells at the end of each month the scrap generated in the month. *See* Cixi Santai's Second Section A, C and D

[8] Omnibus Trade and Competitiveness Act of 1988, Conf. Report to Accompany H.R. 3, H.R. Rep. No. 576, 100th Cong., 2nd Sess. (1988) ("*OTCA 1988*") at 590.

[9] *See e.g., Expedited Sunset Review of the Countervailing Duty Order on Carbazole Violet Pigment 23 from India,* 75 FR 13257 (March 19, 2010) and accompanying Issues and Decision Memorandum at pages 4–5; *Expedited Sunset Review of the Countervailing Duty Order on Certain Cut-to-Length Carbon Quality Steel Plate from Indonesia,* 70 FR 45692 (August 8, 2005) and accompanying Issues and Decision Memorandum at page 4; *See Certain Hot-Rolled Carbon Steel Flat Products from Thailand: Final Results of Countervailing Duty Determination,* 66 FR 50410 (October 3, 2001) and accompanying Issues and Decision Memorandum at page 23.

[10] *See Dorbest Ltd.* v. *United States,* 2009–1257 at 20 (CAFC 2010).

Supplemental Questionnaire Response at 6.

Currency Conversion

Where necessary, the Department made currency conversions into U.S. dollars, in accordance with section 773A(a) of the Act, based on the exchange rates in effect on the dates of the U.S. sales, as certified by the Federal Reserve Bank.

Preliminary Results of Review

The Department preliminarily determines that the following weighted-average dumping margins exist:

CERTAIN POLYESTER STAPLE FIBER FROM THE PEOPLE'S REPUBLIC OF CHINA

Manufacturer/exporter	Weighted average margin (percent)
Ningbo Dafa Chemical Fiber Co., Ltd	* 0.02
Cixi Santai Chemical Fiber Co	* 0.48
Far Eastern Polychem Industries	4.44
Cixi Sansheng Chemical Fiber Co., Ltd	4.44
Cixi Waysun Chemical Fiber Co. Ltd	4.44
Hangzhou Hanbang Chemical Fibre Co., Ltd	4.44
Hangzhou Huachuang Co., Ltd	4.44
Hangzhou Sanxin Paper Co., Ltd	4.44
Hangzhou Taifu Textile Fiber Co., Ltd	4.44
Jiaxang Fuda Chemical Fibre Factory	4.44
Nantong Loulai Chemical Fiber Co., Ltd	4.44
Nanyang Textile Co., Ltd	4.44
Zhaoqing Tifo New Fiber Co., Ltd	4.44
Zhejiang Anshun Pettechs Fibre Co., Ltd	4.44
Zhejiang Waysun Chemical Fiber Co., Ltd	4.44
PRC-Wide Rate	44.30

* *De minimis*.

The Department will disclose to parties the calculations performed in connection with these preliminary results within five days of the date of publication of this notice. *See* 19 CFR 351.224(b). In accordance with 19 CFR 351.301(c)(3)(ii), for the final results of this administrative review, interested parties may submit publicly available information to value the factors of production within 20 days after the date of publication of these preliminary results. Interested parties must provide the Department with supporting documentation for the publicly available information to value each FOP. Additionally, in accordance with 19 CFR 351.301(c)(1), for the final results of this administrative review, interested parties may submit factual information to rebut, clarify, or correct factual information submitted by an interested party less than ten days before, on, or after, the applicable deadline for submission of such factual information. However, the Department notes that 19 CFR 351.301(c)(1) permits new information only insofar as it rebuts, clarifies, or corrects information recently placed on the record. The Department generally cannot accept the submission of additional, previously absent-from-the-record alternative surrogate value information pursuant to 19 CFR 351.301(c)(1). *See Glycine from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Rescission, in Part,* 72 FR 58809 (October 17, 2007) and accompanying Issues and Decision Memorandum at Comment 2.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, Room 1117, within 30 days of the date of publication of this notice. Requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. *Id.* Issues raised in the hearing will be limited to those raised in the respective case briefs. Case briefs from interested parties may be submitted not later than 30 days of the date of publication of this notice, pursuant to 19 CFR 351.309(c). Rebuttal briefs, limited to issues raised in the case briefs, will be due five days later, pursuant to 19 CFR 351.309(d). Parties who submit case briefs or rebuttal briefs in this proceeding are requested to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities. *See* 19 CFR 351.309(c) and (d).

The Department will issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon issuance of the final results, the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by these reviews. The Department intends to issue assessment instructions to CBP 15 days after the publication date of the final results of this review. In accordance with 19 CFR 351.212(b)(1), we calculated exporter/importer (or customer)-specific assessment rates for the merchandise subject to this review. Where the respondent has reported reliable entered values, we calculated importer (or customer)-specific ad valorem rates by aggregating the dumping margins calculated for all U.S. sales to each importer (or customer) and dividing this amount by the total entered value of the sales to each importer (or customer). *See* 19 CFR 351.212(b)(1). Where an importer (or customer)-specific ad valorem rate is greater than *de minimis,* we will apply the assessment rate to the entered value of the importers'/customers' entries during the POR. *See* 19 CFR 351.212(b)(1).

Where we do not have entered values for all U.S. sales, we calculated a per-unit assessment rate by aggregating the antidumping duties due for all U.S. sales to each importer (or customer) and dividing this amount by the total quantity sold to that importer (or customer). *See* 19 CFR 351.212(b)(1). To determine whether the duty assessment

rates are *de minimis,* in accordance with the requirement set forth in 19 CFR 351.106(c)(2), we calculated importer (or customer)-specific *ad valorem* ratios based on the estimated entered value. Where an importer (or customer)-specific *ad valorem* rate is zero or *de minimis,* we will instruct CBP to liquidate appropriate entries without regard to antidumping duties. *See* 19 CFR 351.106(c)(2).

For the companies receiving a separate rate that were not selected for individual review, the assessment rate will be based on the rate from the investigation or, if appropriate, a simple average of the cash deposit rates calculated for the companies selected for individual review pursuant to section 735(c)(5)(B) of the Act.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For the exporters listed above, the cash deposit rate will be established in the final results of this review (except, if the rate is zero or *de minimis, i.e.,* less than 0.5 percent, no cash deposit will be required for that company); (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (3) for all PRC exporters of subject merchandise which have not been found to be entitled to a separate rate, the cash deposit rate will be the PRC-wide rate of 44.3 percent; and (4) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporters that supplied that non-PRC exporter. These 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.

This determination is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

Dated: July 7, 2010.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 2010–17180 Filed 7–13–10; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–807]

Polyethylene Terephthalate Film, Sheet, and Strip from the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce is conducting an administrative review of the antidumping duty order on polyethylene terephthalate film, sheet and strip (PET film) from the Republic of Korea (Korea). This review covers one company, Kolon Industries Inc. (Kolon) and the period June 1, 2008, through May 31, 2009. We preliminarily determine that Kolon has not made sales below normal value (NV). The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.

Interested parties are invited to comment on these preliminary results. We will issue the final results no later than 120 days from the date of publication of this notice.

DATES: *Effective Date:* July 14, 2010.

FOR FURTHER INFORMATION CONTACT: Maryanne Burke or Robert James, AD/CVD Operations, Office 7, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–5604 or (202) 482–0649, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 1, 2009, the Department published in the **Federal Register** a notice of "Opportunity to Request Administrative Review" of the antidumping duty order on PET film from Korea. *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review*, 74 FR 26202 (June 1, 2009).

In accordance with Section 751(a)(1) of the Tariff Act, as amended (the Act) and 19 CFR 351.213(b)(2), on June 30, 2009, Kolon requested an administrative review of the antidumping duty order on PET film from Korea. On June 30, 2009, DuPont Teijin Films (DuPont), Mitsubishi Polyester Film, Inc. (Mitsubishi), and Toray Plastics America Inc. (Toray) (collectively "Petitioners"), also requested a review of Kolon.

On July 29, 2009, the Department initiated an administrative review for Kolon covering the period June 1, 2008, through May 31, 2009. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Deferral of Administrative Review*, 74 FR 37690 (July 29, 2009).

On August 6, 2009, we issued our antidumping questionnaire to Kolon. We received Kolon's response to our questionnaire on September 16, 2009 (Section A) and October 13, 2009 (Sections B, C, and D). On February 1, 2010, we issued a supplemental questionnaire to Kolon which covered sections A through D. Kolon responded to this supplemental questionnaire on March 1, 2010. Then, on June 15, 2010 we issued a second supplemental questionnaire to Kolon which covered sections B through D. Kolon filed its response to this questionnaire on June 29, 2010.

On March 3, 2010, we extended the deadline for the preliminary results of this review until no later than July 7, 2010. *See Polyethylene Terephthalate Film, Sheet and Strip from the Republic of Korea: Extension of Time Limit for Preliminary Results of the Antidumping Duty Administrative Review*, 75 FR 9579 (March 3, 2010).

Scope of the Order

Imports covered by this order are shipments of all gauges of raw, pretreated, or primed polyethylene terephthalate film, sheet, and strip, whether extruded or coextruded. The films excluded from this review are metallized films and other finished films that have had at least one of their surfaces modified by the application of a performance–enhancing resinous or inorganic layer more than 0.00001 inches (0.254 micrometers) thick.

PET film is currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheading 3920.62.00. The HTSUS subheading is provided for convenience and for

customs purposes. The written description remains dispositive as to the scope of the product coverage.

Period of Review

The period of review (POR) is June 1, 2008, to May 31, 2009.

Comparisons to Normal Value

To determine whether sales of PET film from Korea to the United States were made at less than normal value (NV), we compared Kolon's constructed export price (CEP) or export price (EP) sales made in the United States to unaffiliated purchasers to NV, as described in the "United States Price" and "Normal Value" sections of this notice, below. In accordance with section 777A(d)(2) of the Act, we compared the CEP and EP of individual transactions to monthly weighted–average NVs.

Product Comparisons

In accordance with section 771(16) of the Act we considered all products produced by Kolon covered by the description in the "Scope of the Order" section, above, and sold in the home market during the POR, to be foreign like products for purposes of determining appropriate product comparisons to U.S. sales. We first attempted to compare contemporaneous U.S. and comparison–market sales of products that are identical with respect to the following characteristics: 1) specification; 2) thickness; 3) surface treatment; and 4) grade. Consistent with the methodology employed in the 2007–2008 administrative review of this order, and in the less than fair value (LTFV) investigation of PET film from Thailand, we used the actual thicknesses of the film rather than a range of thicknesses for product comparison purposes. *See Polyethylene Terephthalate Film, Sheet, and Strip from the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review*, 74 FR 31922, 31923 (July 6, 2009) (unchanged in final results.) *See also, Notice of Preliminary Determination of Sales at Not Less Than Fair Value: Polyethylene Terephthalate Film, Sheet, and Strip from Thailand*, 73 FR 24565, 24567 (May 5, 2008) (unchanged in final determination). Where we were unable to compare sales of identical merchandise, we compared U.S. sales to home market sales of the most similar merchandise based on the above characteristics. Where there were no sales of the foreign like product of the identical merchandise in the ordinary course of trade in the home market to compare to a U.S. sale, we compared the price of the U.S. sale to constructed value (CV).

Level of Trade

In accordance with section 773(a)(1)(B) of the Act, to the extent practicable, we base NV on sales made in the home market at the same level of trade (LOT) as the CEP or EP sales in the U.S. market. The NV LOT is defined as the starting–price sales in the home market or, when NV is based on CV, as the sales from which selling, general, and administrative (SG&A) expenses and profit are derived. *See* 19 CFR 351.412(c)(1). The EP LOT is defined as the starting price in the United States to the unaffiliated U.S. customer. With respect to CEP transactions in the U.S. market, the CEP LOT is defined as the level of the constructed sale from the exporter to the importer. *See* 19 CFR 351.412(c)(1)(ii) of the Act.

To determine whether NV sales are at a different LOT than CEP sales, we examine stages in the marketing process and selling functions along the chain of distribution between the producer and the unaffiliated customer. *See* 19 CFR 351.412(c)(2). If the home–market sales are at different LOTs, and the difference affects price comparability, as manifested in a pattern of consistent price differences between the sales on which NV is based and comparison–market sales at the LOT of the export transaction, we make a LOT adjustment under section 773(a)(7)(A) of the Act. For CEP sales, if the NV level is more remote from the factory than the CEP level and there is no basis for determining whether the difference in the levels between NV and CEP affects price comparability, we adjust NV under section 773(a)(7)(B) of the Act (the CEP offset provision). *See, e.g., Certain Hot–Rolled Flat–Rolled Carbon Quality Steel Products from Brazil; Preliminary Results of Antidumping Duty Administrative Review*, 70 FR 17406, 17410 (April 6, 2005); unchanged in *Notice of Final Results of Antidumping Duty Administrative Review: Certain Hot–Rolled Flat–Rolled Carbon Quality Steel Products from Brazil*, 70 FR 58683 (October 7, 2005). For CEP sales, we consider only the selling activities reflected in the price after the deduction of expenses and CEP profit under section 772(d) of the Act. *See Micron Technology, Inc. v. United States*, 243 F.3d 1301, 1314–1315 (Fed. Cir. 2001). We expect that if the LOTs claimed by the respondent are the same, the functions and activities of the seller should be similar. Conversely, if a party claims that the LOTs are different for different groups of sales, the functions and activities of the seller should be dissimilar. *See Porcelain–on-Steel Cookware from Mexico: Final Results of Administrative Review*, 65 FR 30068 (May 10, 2000) and accompanying Issues and Decisions Memorandum at Comment 6.

We obtained information from Kolon regarding the marketing stages involved in making its reported foreign market and U.S. sales to unaffiliated customers. Kolon provided a description of all selling activities performed, along with a flowchart and tables comparing the LOTs among each channel of distribution and customer category for both markets. *See* Kolon's September 16, 2009, questionnaire response at Exhibit A–12.

For the home market, Kolon identified two channels of distribution described as follows: 1) direct shipments (*i.e.*, products produced to order); and 2) warehouse shipments from inventory. *Id.* Within each of these two channels of distribution, Kolon made sales to unaffiliated customers. *Id.* We reviewed the level at which Kolon performed each of these selling functions with respect to each claimed channel of distribution and customer category. For all of the activities listed (which included sales forecasting, strategic and economic planning, sales promotion, order processing, and technical assistance), the level of performance for both direct shipments and warehouse shipments was identical across all types of customers. Based on our analysis of all of Kolon's home market selling functions, we find all home market sales were made at a single LOT, the NV LOT. We also found that Kolon provided a similar level of selling functions on all of its EP sales, and that the level of these EP selling functions was comparable to the level of selling functions Kolon performed on its home market sales. Based on the foregoing, we determine there is one level of trade for Kolon's EP sales and that the EP LOT is comparable to the home market LOT.

Kolon also indicated it made CEP sales through its U.S. affiliate, Kolon USA. Id. We then compared the CEP LOT to the NV LOT. The CEP LOT is based on the selling activities associated with the transaction between Kolon and its affiliated importer, Kolon USA, whereas the NV LOT is based on the selling activities associated with the transactions between Kolon and unaffiliated customers in the home market. Our analysis indicates the selling functions performed for sales to unaffiliated home market customers are either performed at a higher degree of intensity or are greater in number than the selling functions performed for sales to Kolon USA. For example, in

comparing Kolon's selling activities, we find there are more functions performed in the home market which are not a part of CEP transactions (*e.g.*, sales promotion, inventory maintenance, sales and marketing support). For selling activities performed for both home market sales and CEP sales (*e.g.*, processing customer orders, freight and delivery arrangements), we find Kolon actually performed each activity at a higher level of intensity in the home market.

We note that CEP sales from Kolon to Kolon USA generally occur at the beginning of the distribution chain, representing essentially a logistical transfer of inventory that resembles ex–factory sales. In contrast, all sales in the home market occur closer to the end of the distribution chain and involve smaller volumes and more customer interaction which, in turn, require the performance of more selling functions. *Id*. Based on the foregoing, we conclude that the NV LOT is at a more advanced stage than the CEP LOT. Because we found the home market and U.S. sales were made at different LOTs, we examined whether a LOT adjustment or a CEP offset may be appropriate in this review. As we found only one LOT in the home market, it was not possible to make a LOT adjustment to home market prices, because such an adjustment is dependent on our ability to identify a pattern of consistent price differences between the home market sales on which NV is based and home market sales at the LOT of the export transaction. *See* 19 CFR 351.412(d)(1). Furthermore, we have no other information that provides an appropriate basis for determining a LOT adjustment. Because the data available do not form an appropriate basis for making a LOT adjustment, and because the NV LOT is at a more advanced stage of distribution than the CEP LOT, we have made a CEP offset to NV in accordance with section 773(a)(7)(B) of the Act.

United States Price

Section 772(a) of the Act defines EP as "the price at which the subject merchandise is first sold (or agreed to be sold) before the date of importation by the producer or exporter of the subject merchandise outside of the United States to an unaffiliated purchaser in the United States or to an unaffiliated purchaser for exportation to the United States, as adjusted under subsection (c) of this section." Section 772(b) of the Act defines CEP as "the price at which the subject merchandise is first sold (or agreed to be sold) in the United States before or after the date of importation by or for the account of the producer or exporter of the subject merchandise or by a seller affiliated with the producer or exporter, to a purchaser not affiliated with the producer or exporter, as adjusted under subsections (c) and (d)." For purposes of this administrative review, Kolon classified all of its U.S. sales shipped directly from Korea to the United States as EP sales. Kolon reported all sales that were invoiced through its U.S. subsidiary Kolon USA as CEP transactions. For these preliminary results, we have accepted these classifications. The merchandise shipped directly to unaffiliated customers in the U.S. market was not sold through an affiliated U.S. importer, and we find no other grounds for treating these transactions as CEP sales. We, therefore, preliminarily determine that these transactions were EP sales. We have classified as CEP transactions the merchandise invoiced through Kolon USA because these sales were "sold in the United States" within the meaning of 772(b) of the Act.

Export Price

We calculated EP in accordance with section 772(a) of the Act. We based EP on packed prices to customers in the United States. We made adjustments for the following movement expenses in accordance with section 772(c)(2)(A) of the Act: foreign inland freight, foreign brokerage and handling charges, bank charges and ocean freight. Finally, we made an addition to U.S. price for duty drawback in accordance with section 772(c)(1)(B) of the Act based upon Kolon's demonstration that it received duty drawback on imported materials used in the production of PET film. *See* Kolon's October 13, 2009, Section C response at C–34 to C–35 and Exhibit C–16.

Constructed Export Price

In accordance with section 772(b) of the Act, for those sales to the first unaffiliated purchaser that took place after importation into the United States, we calculated CEP. We based CEP on packed prices to unaffiliated purchasers in the United States. We made adjustments for billing adjustments and early payment discounts. We made deductions for movement expenses in accordance with section 772(c)(2)(A) of the Act; these included foreign inland freight, foreign brokerage and handling charges, U.S. brokerage and handling, ocean freight, marine insurance, U.S. inland freight, and U.S. customs duties. As further directed by section 772(d)(1) of the Act, we deducted those selling expenses associated with economic activity in the United States including direct selling expenses (*i.e.*, commissions, warehousing, and U.S. credit expenses), inventory carrying costs, and other U.S. indirect selling expenses. We also made an adjustment for profit in accordance with section 772(d)(3) of the Act. Finally, we made an addition to U.S. price for duty drawback in accordance with section 772(c)(1)(B) of the Act based upon Kolon's demonstration that it received duty drawback on imported materials used in the production of PET film. *See* Kolon's October 13, 2009, Section C response at C–34 to C–35 and Exhibit C–16.

Normal Value

A. Selection of Comparison Market

To determine whether there is a sufficient volume of sales in the home market to serve as a viable basis for calculating NV (*i.e.*, the aggregate volume of home market sales of the foreign like product is greater than five percent of the aggregate volume of U.S. sales), we compared Kolon's volume of home market sales of the foreign like product to the volume of its U.S. sales of the subject merchandise, in accordance with section 773(a)(1)(B) of the Act. Because Kolon's aggregate volume of home market sales of the foreign like product was greater than five percent of its aggregate volume of U.S. sales for subject merchandise, we determined the home market was viable. See Kolon's September 16, 2009, questionnaire response at Exhibit A–1.

B. Cost of Production Analysis

Pursuant to 773(b)(2)(A)(ii) of the Act, because the Department had disregarded certain of Kolon's sales in the *Polyethlylene Terephthalate Film, Sheet, and Strip from the Republic of Korea: Final Results of Antidumping Duty Changed Circumstances Review and Reinstatement of the Antidumping Duty Order* 73 FR 18259 (April 3, 2008) (the most recently completed review in which Kolon participated), the Department had reasonable grounds to believe or suspect that Kolon made home market sales at prices below Kolon's costs of production (COP) in this review. As a result, the Department was directed under section 773(b) of the Act to determine whether Kolon made home market sales during the POR at prices below its COP.

In accordance with section 773(b)(3) of the Act, we calculated COP based on the sum of Kolon's cost of materials and fabrication for the foreign like product, plus amounts for selling, general, and administrative expenses (SG&A), interest expenses, and home market

packing costs. We relied on the COP information provided by Kolon.

To determine whether Kolon's home market sales had been made at prices below the COP, we computed weighted–average COPs during the POR, and compared the weighted–average COP figures to home market sales prices of the foreign like product as required under section 773(b) of the Act. On a product–specific basis, we compared the COP to the home market prices net of billing adjustments, discounts and rebates, any applicable movement charges, selling expenses, and packing expenses.

In determining whether to disregard home market sales made at prices below the COP, we examined, in accordance with sections 773(b)(1)(A) and (B) of the Act, whether, within an extended period of time, such sales were made in substantial quantities, and whether such sales were made at prices which did not permit the recovery of all costs within a reasonable period of time in the normal course of trade. Where less than 20 percent of the respondent's home market sales of a given model were at prices below the COP, we did not disregard any below–cost sales of that model because we determined that the below–cost sales were not made within an extended period of time and in "substantial quantities." *See* section 773(b)(2)(C) of the Act. Where 20 percent or more of the respondent's home market sales of a given model were at prices less than the COP, we normally disregard the below–cost sales because: (1) they were made within an extended period of time in "substantial quantities," in accordance with sections 773(b)(2)(B) and (C) of the Act; and (2) based on our comparison of prices to the weighted–average COPs for the POR, they were at prices which would not permit the recovery of all costs within a reasonable period of time, in accordance with section 773(b)(2)(D) of the Act.

Our cost test for Kolon revealed that, for home market sales of certain models, less than 20 percent of the sales of those models were at prices below the COP. We therefore retained all such sales in our analysis and used them as the basis for determining NV. Our cost test also indicated that for home market sales of other models, more than 20 percent were sold at prices below the COP within an extended period of time and were at prices which would not permit the recovery of all costs within a reasonable period of time. Thus, in accordance with section 773(b)(1) of the Act, we excluded these below–cost sales from our analysis and used the remaining above–cost sales as the basis for determining NV.

C. Constructed Value

In accordance with section 773(e) of the Act, we calculated CV based on the sum of Kolon's material and fabrication costs, SG&A expenses, profit, and U.S. packing costs. We calculated the cost of materials for CV as described above in the "Cost of Production Analysis" section of this notice. In accordance with section 773(e)(2)(A) of the Act, we based SG&A expenses and profit on the amounts incurred and realized by the respondent in connection with the production and sale of the foreign like product in the ordinary course of trade, for consumption in the foreign country.

D. Price-to-Price Comparisons

We calculated NV based on prices to unaffiliated customers in Korea. We used Kolon's adjustments and deductions as reported. We made deductions, where appropriate, for foreign inland freight pursuant to section 773(a)(6)(B) of the Act. In addition, for comparisons involving similar merchandise, we made adjustments for differences in cost attributable to differences in physical characteristics of the merchandise compared pursuant to section 773(a)(6)(C)(ii) of the Act and 19 CFR 351.411. We also made adjustments for differences in circumstances of sale (COS) in accordance with section 773(a)(6)(C)(iii) of the Act and 19 CFR 351.410. We made COS adjustments for imputed credit expenses. As noted above in the "Level of Trade" section of this notice, we also made an adjustment for the CEP offset in accordance with section 773(a)(7)(B) of the Act. Finally, we deducted home market packing costs and added U.S. packing costs in accordance with sections 773(a)(6)(A) and (B) of the Act.

E. Price-to-CV Comparisons

If we were unable to find a home market match of such or similar merchandise, in accordance with section 773(a)(4) of the Act, we based NV on CV. Where appropriate, we made adjustments to CV in accordance with section 773(a)(8) of the Act.

Currency Conversion

We made currency conversions into U.S. dollars based on the exchange rates in effect on the dates of the U.S. sales, as certified by the Federal Reserve Bank, in accordance with section 773A(a) of the Act.

Preliminary Results of Review

We preliminarily determine the following weighted–average dumping margin exists for the period June 1, 2008 through May 31, 2009:

Manufacturer / Exporter	Weighted Average Margin (percentage)
Kolon Industries, Inc	0.30% *(de minimis)*

The Department will disclose to parties the calculations performed in connection with these preliminary results within five days of the date of publication of this notice. *See* 19 CFR 351.224(b). Pursuant to 19 CFR 351.309, interested parties may submit case briefs not later than 30 days after the publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than 35 days after the date of publication of this notice. Parties who submit case briefs or rebuttal briefs in this proceeding are requested to submit with each argument: (1) a statement of the issue, (2) a brief summary of the argument; and (3) a table of authorities.

Interested parties who wish to request a hearing or to participate if one is requested must submit a written request to the Assistant Secretary for Import Administration, Room 1870, within 30 days of the date of publication of this notice. Requests should contain: (1) the party's name, address and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. *See* 19 CFR 351.310(c). Issues raised in the hearing will be limited to those raised in the case briefs.

The Department will issue the final results of this administrative review, including the results of its analysis of issues raised in any written briefs, not later than 120 days after the publication of this notice, pursuant to section 751(a)(3)(A) of the Act.

Assessment

Pursuant to 19 CFR 351.212(b), the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries. The Department will issue appropriate assessment instructions directly to CBP 15 days after the date of publication of the final results of this review. For assessment purposes, where possible, we calculated importer–specific (or customer–specific) *ad valorem* assessment rates for PET film from Korea based on the ratio of the total amount of the dumping duties calculated for the examined sales to the total entered value of those same sales. *See* 19 CFR 351.212(b). However, where Kolon did not report the entered value

for its sales, we will calculate importer–specific (or customer–specific) per unit duty assessment rates. We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review if any assessment rate calculated in the final results of this review is above *de minimis*.

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided for by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for Kolon will be the rate established in the final results of review (except, if the rate is zero or *de minimis, i.e.*, less than 0.5 percent, no cash deposit will be required for Kolon); (2) if the exporter is not a firm covered in this review or the LTFV 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; and (3) if neither the exporter nor the manufacturer is a firm covered in this or any previous review, the cash deposit rate will be the all–others rate of 21.50 percent from the LTFV investigation. *See Polyethylene Terephthalate Film, Sheet, and Strip From the Republic of Korea; Notice of Final Court Decision and Amended Final Determination of Antidumping Duty Investigation*, 62 FR 50557 (September 26, 1997).

Notification to Importers

This notice also serves as a preliminary 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 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.

These preliminary results of administrative review are issued and this notice is published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: July 7, 2010.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 2010–17170 Filed 7–13–10; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–868]

Folding Metal Tables and Chairs From the People's Republic of China: 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 folding metal tables and chairs ("FMTCs") from the People's Republic of China ("PRC") covering the period June 1, 2008, through May 31, 2009, and a deferred administrative review for Feili Group (Fujian) Co., Ltd. and Feili Furniture Development Limited Quanzhou City (collectively, "Feili") [1] covering the period June 1, 2007, through May 31, 2008. The 2008–2009 administrative review covers Feili and New-Tec Integration (Xiamen) Co., Ltd. ("New-Tec") and the 2007–2008 deferred administrative review covers Feili. We have preliminarily determined that Feili and New-Tec did not make sales in the United States at prices below normal value ("NV") during the periods of review ("POR") pertinent to each company. If these preliminary results are adopted in our final results of these reviews, we will instruct U.S. Customs and Border Protection ("CBP") to liquidate entries of merchandise exported by Feili and New-Tec during the PORs without regard to antidumping duties.

We invite interested parties to comment on these preliminary results. We intend to issue the final results no later than 120 days from the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Tariff Act of 1930, as amended ("the Act").

DATES: Effective Date: July 14, 2010.

FOR FURTHER INFORMATION CONTACT: Lilit Astvatsatrian or Charles Riggle, AD/CVD Operations, Office 8, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; *telephone:* (202) 482–6412 and (202) 482–0650, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 27, 2002, the Department published the antidumping duty order on FMTCs from the PRC. *See Antidumping Duty Order: Folding Metal Tables and Chairs From the People's Republic of China,* 67 FR 43277 (June 27, 2002). On July 30, 2008, the Department granted Feili's request for deferral of the June 1, 2007, through May 31, 2008 review, to which no parties objected.[2] On June 1, 2009, the Department published a notice of opportunity to request an administrative review of this order for the June 1, 2008, through, May 31, 2009 POR. *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative* Review, 74 FR 26202 (June 1, 2009). In accordance with 19 CFR 351.213(b), interested parties made the following requests for review: (1) On June 23, 2009, New-Tec, a producer and exporter of subject merchandise to the United States, requested that the Department conduct an administrative review of its sales; (2) on June 25, 2009, Cosco Home & Office Products ("Cosco"), a U.S. importer of subject merchandise, requested that the Department conduct administrative reviews of Feili and New-Tec for the 2008–2009 POR . On July 29, 2009, the Department initiated the 2007–2008 and 2008–2009 reviews for Feili, and the 2008–2009 review for New-Tec.[3] The Department issued an antidumping duty questionnaire to Feili and New-Tec on August 7, 2009. On September 1, 2009 and September 10, 2009, New-Tec and Feili, respectively, submitted a section A questionnaire response ("AQR"), and on September 15, 2009 and September 25, 2009, New-Tec and Feili, respectively, submitted section C and D questionnaire responses ("CQR" and "DQR," respectively). On January 5, 2010, the Department requested the Office of Policy to provide a list of surrogate countries for this review. See Memorandum to Carole Showers, Director, Office of Policy, "2007–2008 Administrative Review of the Antidumping Duty Order on Folding Metal Tables and Chairs from the People's Republic of China: Request for Surrogate Country Selection" (January 5, 2010) and Memorandum to Carole

[1] The Department initiated both reviews for Feili using the following names: Feili Furniture Development Ltd. Quanzhou City, Feili Furniture Development Co., Ltd., Feili Group (Fujian) Co., Ltd., and Feili (Fujian) Co., Ltd. However, Feili has informed the Department that its name includes only Feili Group (Fujian) Co., Ltd. and Feili Furniture Development Limited Quanzhou City.

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews, Request for Revocation in Part, and Deferral of Administrative Review,* 73 FR 44220 (July 30, 2008).

[3] *See* Initiation of Antidumping and Countervailing Duty Administrative Reviews and Deferral of Administrative Review, 74 FR 37690 (July 29, 2009).

Showers, Executive Director, Office of Policy, "2008–2009 Administrative Review of the Antidumping Duty Order on Folding Metal Tables and Chairs from the People's Republic of China: Request for Surrogate Country Selection" (January 5, 2010). On January 25, 2010, the Office of Policy issued its list of surrogate countries. *See* Memoranda from Kelly Parkhill, Acting Director, Office of Policy, "Request for a List of Surrogate Countries for an Administrative Review of Folding Metal Tables and Chairs ("FMTC") from the People's Republic of China (PRC)" (January 25, 2010) ("Surrogate Country Memoranda").

On February 4, 2010, the Department requested interested parties to submit surrogate value information and to provide surrogate country selection comments. On February 2, 2010 and March 5, 2010 respectively, New-Tec and Meco Corporation ("Meco"), a domestic producer of the like product, Meco provided comments on publicly available information to value the factors of production ("FOP"). On February 24, 2010 and April 8, 2010, Feili submitted supplemental questionnaire responses. On February 16, 2010 and April 20, 2010, New-Tec submitted supplemental questionnaire responses.

On March 10, 2010, the Department published a notice in the **Federal Register** partially extending the time limit for the preliminary results of both reviews until no later than May 8, 2010.[4] On April 22, 2010, the Department published a notice in the **Federal Register** fully extending the time limit further for the preliminary results of both reviews until July 7, 2010.[5] From April 27, 2010, through April 30, 2010, the Department conducted sales and FOP verification of New-Tec.[6] In accordance with 19 CFR 351.301(c)(3)(ii), for the final results in an antidumping administrative review, interested parties may submit publicly available information to value FOPs within 20 days after the date of publication of these preliminary results of review.

Periods of Review

The PORs are June 1, 2007, through May 31, 2008, covering Feili and June 1, 2008, through May 31, 2009, covering both Feili and New-Tec.

Scope of Order

The products covered by this order consist of assembled and unassembled folding tables and folding chairs made primarily or exclusively from steel or other metal, as described below:

(1) Assembled and unassembled folding tables made primarily or exclusively from steel or other metal (folding metal tables). Folding metal tables include square, round, rectangular, and any other shapes with legs affixed with rivets, welds, or any other type of fastener, and which are made most commonly, but not exclusively, with a hardboard top covered with vinyl or fabric. Folding metal tables have legs that mechanically fold independently of one another, and not as a set. The subject merchandise is commonly, but not exclusively, packed singly, in multiple packs of the same item, or in five piece sets consisting of four chairs and one table. Specifically excluded from the scope of the order regarding folding metal tables are the following: Lawn furniture; Trays commonly referred to as "TV trays;" Side tables; Child-sized tables; Portable counter sets consisting of rectangular tables 36" high and matching stools; and, Banquet tables. A banquet table is a rectangular table with a plastic or laminated wood table top approximately 28″ to 36″ wide by 48″ to 96″ long and with a set of folding legs at each end of the table. One set of legs is composed of two individual legs that are affixed together by one or more cross-braces using welds or fastening hardware. In contrast, folding metal tables have legs that mechanically fold independently of one another, and not as a set.

(2) Assembled and unassembled folding chairs made primarily or exclusively from steel or other metal (folding metal chairs). Folding metal chairs include chairs with one or more cross-braces, regardless of shape or size, affixed to the front and/or rear legs with rivets, welds or any other type of fastener. Folding metal chairs include: those that are made solely of steel or other metal; those that have a back pad, a seat pad, or both a back pad and a seat pad; and those that have seats or backs made of plastic or other materials. The subject merchandise is commonly, but not exclusively, packed singly, in multiple packs of the same item, or in five piece sets consisting of four chairs and one table. Specifically excluded from the scope of the order regarding folding metal chairs are the following: Folding metal chairs with a wooden back or seat, or both; Lawn furniture; Stools; Chairs with arms; and Child-sized chairs.

The subject merchandise is currently classifiable under subheadings 9401.71.0010, 9401.71.0030, 9401.79.0045, 9401.79.0050, 9403.20.015, 9403.20.0030, 9403.70.8010, 9403.70.8020, and 9403.70.8030 of the Harmonized Tariff Schedule of the United States ("HTSUS"). Although the HTSUS subheadings are provided for convenience and customs purposes, the Department's written description of the merchandise is dispositive.

Based on a request by RPA International Pty., Ltd. and RPS, LLC (collectively, "RPA"), the Department ruled on January 13, 2003, that RPA's poly-fold metal folding chairs are within the scope of the order because they are identical in all material respects to the merchandise described in the petition, the initial investigation, and the determinations of the Secretary.

On May 5, 2003, in response to a request by Staples, the Office Superstore Inc. ("Staples"), the Department issued a scope ruling that the chair component of Staples' "Complete Office-To-Go," a folding chair with a tubular steel frame and a seat and back of plastic, with measurements of: height: 32.5 inches; width: 18.5 inches; and depth: 21.5 inches, is covered by the scope of the order because it is identical in all material respects to the scope description in the order, but that the table component, with measurements of: width (table top): 43 inches; depth (table top): 27.375 inches; and height: 34.875 inches, has legs that fold as a unit and meets the requirements for an exemption from the scope of the order.

On September 7, 2004, the Department found that table styles 4600 and 4606 produced by Lifetime Plastic Products Ltd. are within the scope of the order because these products have all of the components that constitute a folding metal table as described in the scope.

On July 13, 2005, the Department issued a scope ruling determining that "butterfly" chairs are not within the scope of the antidumping duty order because they do not meet the physical description of merchandise covered by the scope of the order as they do not have cross braces affixed to the front and/or rear legs, and the seat and back is one piece of cloth that is not affixed to the frame with screws, rivets, welds, or any other type of fastener.

[4] *See Folding Metal Tables and Chairs from the People's Republic of China: Notice of Extension of Time Limit for the Preliminary Results of the Antidumping Duty Administrative Reviews,* 75 FR 11120 (May 10, 2010).

[5] *See Folding Metal Tables and Chairs from the People's Republic of China: Extension of Time Limit for the Preliminary Results of the Antidumping Duty Administrative Review,* 75 FR 20983 (April 22, 2010).

[6] *See* Memorandum to the File from Charles Riggle, Program Manager and Giselle Cubillos, Case Analyst re: "Verification of the Sales and Factors Response of New-Tec Integration (Xiamen) Co., Ltd. in the Antidumping Review of Folding Metal Tables and Chairs from the Peoples Republic of China," dated July 7, 2010.

On July 13, 2005, the Department issued a scope ruling determining that folding metal chairs imported by Korhani of America Inc. are within the scope of the antidumping duty order because the imported chair has a wooden seat, which is padded with foam and covered with fabric or polyvinyl chloride, attached to the tubular steel seat frame with screws, and has cross braces affixed to its legs.

On May 1, 2006, the Department issued a scope ruling determining that "moon chairs" are not included within the scope of the antidumping duty order because moon chairs have different physical characteristics, different uses, and are advertised differently than chairs covered by the scope of the order.

On October 4, 2007, the Department issued a scope ruling determining that International E-Z Up Inc.'s ("E-Z Up") Instant Work Bench is not included within the scope of the antidumping duty order because its legs and weight do not match the description of the folding metal tables in the scope of the order.

On April 18, 2008, the Department issued a scope ruling determining that the VIKA Twofold 2-in-1 Workbench/Scaffold ("Twofold Workbench/Scaffold") imported by Ignite USA, LLC from the PRC is not included within the scope of the antidumping duty order because its rotating leg mechanism differs from the folding metal tables subject to the order, and its weight is twice as much as the expected maximum weight for folding metal tables within the scope of the order.

On May 6, 2009, the Department issued a final determination of circumvention, determining that imports from the PRC of folding metal tables with legs connected by cross–bars, so that the legs fold in sets, and otherwise meeting the description of in–scope merchandise, are circumventing the order and are properly considered to be within the class or kind of merchandise subject to the order on FMTCs from the PRC.

On May 22, 2009, the Department issued a scope ruling determining that folding metal chairs that have legs that are not connected with cross-bars are within the scope of the antidumping duty order on folding metal tables and chairs from the PRC.

On October 27, 2009, the Department issued a scope ruling determining that Lifetime Products Inc.'s ("Lifetime") fold-in-half adjustable height tables do not meet the description of merchandise within the scope of the antidumping duty order on folding metal tables and chairs from the PRC because Lifetime's tables essentially share the physical characteristics of banquet tables, which are expressly excluded from the scope of the order and, therefore, are outside the scope of the order.

Non-Market Economy Country Status

No party contested the Department's treatment of the PRC as a non-market economy ("NME") country, and the Department has treated the PRC as an NME country in all past antidumping duty investigations and administrative reviews.[7] No interested party in this case has argued that we should do otherwise. Designation as an NME country remains in effect until it is revoked by the Department. *See* section 771(18)(C)(i) of the Act. As such, we continue to treat the PRC as a NME in this proceeding.

Surrogate Country

Section 773(c)(1) of the Act directs the Department to base NV on the NME producer's FOPs, valued in a surrogate market economy country or countries considered to be appropriate by the Department. In accordance with section 773(c)(4) of the Act, in valuing the FOPs, the Department shall use, to the extent possible, the prices or costs of the FOPs in one or more market economy countries that are: (1) At a level of economic development comparable to that of the NME country; and (2) significant producers of comparable merchandise. The sources of the surrogate factor values are discussed under the "Normal Value" section below. See Memorandum to The File, "Preliminary Results of the 2007–2008 Administrative Review of Folding Metal Tables and Chairs from the People's Republic of China: Surrogate Value Memorandum," dated concurrently with this notice ("Surrogate Value Memorandum 07–08"), and Memorandum to The File, "Preliminary Results of the 2008–2009 Administrative Review of Folding Metal Tables and Chairs from the People's Republic of China: Surrogate Value Memorandum" ("Surrogate Value Memorandum 08–09"), dated concurrently with this notice.

The Department determined that Colombia, India, Indonesia, Peru, the Philippines and Thailand are countries comparable to the PRC in terms of economic development. See Surrogate Country Memoranda. Once we have identified the countries that are economically comparable to the PRC, we select an appropriate surrogate country by determining whether an economically comparable country is a significant producer of comparable merchandise and whether the data for valuing FOPs are both available and reliable.

The Department has determined that India is the appropriate surrogate country for use in these reviews. The Department based its decision on the following facts: (1) India is at a level of economic development comparable to that of the PRC; (2) India is a significant producer of comparable merchandise; and (3) India provides the best opportunity to use quality, publicly available data to value the FOPs. On the record of these reviews, we have usable surrogate financial data from India, and no party has submitted surrogate financial data from any other potential surrogate country. Additionally, the data submitted by Meco and New-Tec for our consideration as potential surrogate values are sourced from India.

Therefore, because India best represents the experience of producers of comparable merchandise operating in a market country, we have selected India as the surrogate country and, accordingly, have calculated NV using Indian prices to value the respondents' FOPs, when available and appropriate. See Surrogate Value Memoranda 07–08 and 08–09. We have obtained and relied upon publicly available information wherever possible.

Separate Rates

In proceedings involving NME countries, the Department has a rebuttable presumption that all companies within the country are subject to government control and, thus, should be assessed a single antidumping duty rate.[8] It is the Department's policy to assign all exporters of merchandise subject to review in an NME country this single rate unless an exporter can demonstrate that it is sufficiently independent so as to be entitled to a separate rate. *Id.* Exporters can demonstrate this independence through the absence of both *de jure* and *de facto* government control over export activities. The Department analyzes each entity exporting the subject merchandise under a test arising from the *Notice of Final Determination of Sales at Less Than Fair Value: Sparklers*

[7] *See, e.g., Chlorinated Isocyanurates from the People's Republic of China: Final Results of Antidumping Duty Administrative Review,* 73 FR 52645 (September 10, 2008); *see also Folding Metal Tables and Chairs from the People's Republic of China: Final Results of Antidumping Duty Administrative Review,* 74 FR 3560 (January 21, 2009).

[8] *See, e.g., Certain Coated Paper Suitable for High-Quality Print Graphics Using Sheet-Fed Presses From the People's Republic of China: Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination,* 75 FR at 24899 (May 6, 2010).

from the People's Republic of China, 56 FR 20588, at Comment 1 (May 6, 1991) ("*Sparklers*"), as further developed in *Notice of Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the People's Republic of China,* 59 FR 22585, 22587 (May 2, 1994) ("*Silicon Carbide*"). However, if the Department determines that a company is wholly foreign-owned or located in a market economy, then a separate-rate analysis is not necessary to determine whether it is independent from government control.[9]

1. Wholly Foreign-Owned

Feili reported that it is wholly owned by market-economy entities. Therefore, consistent with the Department's practice, a separate-rates analysis is not necessary to determine whether Feili's export activities are independent from government control, and we have preliminarily granted a separate rate to Feili.

2. Joint Ventures Between Chinese and Foreign Companies or Wholly Chinese-Owned Companies

New-Tec stated that it is a joint venture between Chinese and foreign companies. Therefore, the Department must analyze whether New-Tec can demonstrate the absence of both *de jure* and *de facto* government control over export activities.

A. Absence of De Jure Control

The Department considers the following de jure criteria in determining whether an individual company may be granted a separate rate: (1) An absence of restrictive stipulations associated with an individual exporter's business and export licenses; (2) any legislative enactments decentralizing control of companies; and (3) other formal measures by the government decentralizing control of companies. *See Sparklers,* 56 FR at 20589.

New-Tec has placed documents on the record to demonstrate the absence of *de jure* control including its list of shareholders, business license, and the Company Law of the PRC ("Company Law"). Other than limiting New-Tec to activities referenced in the business license, we found no restrictive stipulations associated with the license. In addition, in previous cases the Department has analyzed the Company Law and found that it establishes an absence of *de jure* control, lacking record evidence to the contrary.[10] We have no information in this segment of the proceeding that would cause us to reconsider this determination. Therefore, based on the foregoing, we have preliminarily found an absence of *de jure* control for New-Tec.

B. Absence of De Facto Control

Typically the Department considers four factors in evaluating whether each respondent is subject to *de facto* government control of its export functions: (1) Whether the export prices are set by or are subject to the approval of a government agency; (2) whether the respondent has authority to negotiate and sign contracts and other agreements; (3) whether the respondent has autonomy from the government in making decisions regarding the selection of management; and (4) whether the respondent retains the proceeds of its export sales and makes independent decisions regarding disposition of profits or financing of losses. The Department has determined that an analysis of *de facto* control is critical in determining whether respondents are, in fact, subject to a degree of government control that would preclude the Department from assigning separate rates.[11]

With regard to *de facto* control, New-Tec reported that: (1) It independently set prices for sales to the United States through negotiations with customers and these prices are not subject to review by any government organization; (2) it did not coordinate with other exporters or producers to set the price or to determine to which market the companies will sell subject merchandise; (3) the PRC Chamber of Commerce did not coordinate the export activities of New-Tec; (4) its general manager has the authority to contractually bind it to sell subject merchandise; (5) its board of directors appoints its general manager; (6) there is no restriction on its use of export revenues; (7) its shareholders ultimately determine the disposition of respective profits, and New-Tec has not had a loss in the last two years; and (8) none of New-Tec's board members or managers is a government official. Furthermore, our analysis of New-Tec's questionnaire responses reveals no information indicating government control of its export activities. Therefore, based on the information on the record, we preliminarily determine that there is an absence of *de facto* government control with respect to New-Tec's export functions and that New-Tec has met the criteria for the application of a separate rate.

The evidence placed on the record of this review by New-Tec demonstrates an absence of *de jure* and *de facto* government control with respect to its exports of subject merchandise, in accordance with the criteria identified in *Sparklers,* 56 FR at 20589; and *Silicon Carbide,* 59 FR at 22587. Accordingly, we have preliminarily granted a separate rate to New-Tec.

Date of Sale

19 CFR 351.401(i) states that:

> In identifying the date of sale of the subject merchandise or foreign-like product, the Secretary normally will use the date of invoice, as recorded in the exporter or producer's records kept in the ordinary course of business. However, the Secretary may use a date other than the date of invoice if the Secretary is satisfied that a different date better reflects the date on which the exporter or producer establishes the material terms of sale.

See also Allied Tube and Conduit Corp. v. *United States,* 132 F. Supp. 2d 1087, 1090–1092 (CIT 2001) (upholding the Department's rebuttable presumption that invoice date is the appropriate date of sale). After examining the questionnaire responses and the sales documentation placed on the record by Feili and New-Tec, we preliminarily determine that invoice date is the most appropriate date of sale for Feili and New-Tec. Nothing on the record rebuts the presumption that invoice date should be the date of sale.

Normal Value Comparisons

To determine whether sales of FMTCs to the United States by Feili and New-Tec were made at less than NV, we compared export price ("EP") to NV, as described in the "Export Price," and "Normal Value" sections of this notice, pursuant to section 771(35) of the Act.

Export Price

Because Feili and New-Tec sold subject merchandise to unaffiliated purchasers in the United States prior to importation into the United States or to unaffiliated resellers outside the United States with knowledge that the merchandise was destined for the United States, and use of a constructed export price methodology is not otherwise indicated, we have used EP for both Feili and New-Tec in

[9] *See, e.g., Final Results of Antidumping Duty Administrative Review: Petroleum Wax Candles From the People's Republic of China,* 72 FR 52355, 52356 (September 13, 2007).

[10] *See, e.g., Certain Non-Frozen Apple Juice Concentrate from the People's Republic of China: Final Results, Partial Rescission and Termination of a Partial Deferral of the 2002–2003 Administrative Review,* 69 FR 65148, 65150 (November 10, 2004).

[11] See Silicon Carbide, 59 FR at 22586–87; see also Notice of Final Determination of Sales at Less Than Fair Value: Furfuryl Alcohol From the People's Republic of China, 60 FR 22544, 22545 (May 8, 1995).

accordance with section 772(a) of the Act.

We calculated EP based on the free-on-board or delivered price to unaffiliated purchasers for Feili and New-Tec. From this price, we deducted amounts for foreign inland freight, international movement expenses, air freight, and brokerage and handling, as applicable, pursuant to section 772(c)(2)(A) of the Act.[12]

The Department valued brokerage and handling using a price list of export procedures necessary to export a standardized cargo of goods in India. The price list is compiled based on a survey case study of the procedural requirements for trading a standard shipment of goods by ocean transport in India that is published in Doing Business 2010: India, published by the World Bank. The Department adjusted the average brokerage and handling rate for deflation. See Surrogate Value Memoranda 07–08 and 08–09, New-Tec Preliminary Analysis Memorandum, Feili Deferred Preliminary Analysis Memorandum and Feili 2008–2009 Preliminary Analysis Memorandum.

Zero-Priced Transactions

In the final results of previous administrative reviews of FMTCs, we included New-Tec's and Feili's zero-priced transactions in the margin calculation because the record demonstrated that respondents provided the same merchandise in significant quantities, indicating that these "samples" did not primarily serve for evaluation or testing of the merchandise.[13] Additionally, respondents provided "samples" to the same customers to whom it was selling the same products in commercial quantities.[14] As a result, we concluded that these transactions were not what we consider to be samples because respondents were providing these products to strengthen their customer relationships and to promote future sales.

The U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") has not required the Department to exclude zero-priced or *de minimis* sales from its analysis but, rather, has defined a sale, as used in section 772 of the Act, as requiring "both a transfer of ownership to an unrelated party and consideration."[15] The Court of International Trade ("CIT") in *NSK Ltd.* v. *United States* stated that it saw "little reason in supplying and re-supplying and yet re-supplying the same product to the same customer in order to solicit sales if the supplies are made in reasonably short periods of time," and that "it would be even less logical to supply a sample to a client that has made a recent bulk purchase of the very item being sampled by the client."[16] Furthermore, the Courts have consistently ruled that the burden rests with a respondent to demonstrate that it received no consideration in return for its provision of purported samples.[17] Moreover, even where the Department does not ask a respondent for specific information to demonstrate that a transaction is a sample, the respondent has the burden of presenting the information in the first place to demonstrate that its transactions qualify for exclusion as a sample.[18]

An analysis of Feili's and New-Tec's section C computer sales listings reveals that they provided zero-priced merchandise to customers to whom they already are selling the same products in commercial quantities, indicating that Feili and New-Tec were not providing this zero-priced merchandise for a customer's evaluation and testing, with the hope of future sales. Consequently, based on the facts cited above, the guidance of past court decisions, and our previous decisions, for the preliminary results of this review, we have not excluded these zero-priced transactions from the margin calculations for Feili and New-Tec.

Billing Adjustments

We have not adjusted Feili's U.S. sales price with its reported billing adjustments for brokerage and handling charges incurred in China and reimbursed by its U.S. customers in U.S. dollars. After careful examination of this issue, we have preliminarily determined that these charges are not included within the Department's surrogate value for brokerage and handling and, therefore, do not warrant an offset to the brokerage and handling expense. See Feili Deferred Preliminary Analysis Memorandum and Feili 2008–2009 Preliminary Analysis Memorandum.

Normal Value

Section 773(c)(1) of the Act provides that, in the case of an NME, the Department shall determine NV using an FOP methodology if the merchandise is exported from an NME and the information does not permit the calculation of NV using home-market prices, third-country prices, or constructed value under section 773(a) of the Act.

The Department bases NV on FOPs because the presence of government controls on various aspects of NME economies renders price comparisons and the calculation of production costs invalid under our normal methodologies. Therefore, in these preliminary results, we have calculated NV based on FOPs in accordance with sections 773(c)(3) and (4) of the Act and 19 CFR 351.408(c). The FOPs include: (1) Hours of labor required; (2) quantities of raw materials employed; (3) amounts of energy and other utilities consumed; and (4) representative capital costs. In accordance with 19 CFR 351.408(c)(1), the Department normally uses publicly available information to value the FOPs. However, when a producer sources a meaningful amount of an input from a market-economy country and pays for it in market-economy currency, the Department may value the factor using the actual price paid for the input.[19] Further, the Department disregards prices it has reason to suspect may be subsidized.[20]

[12] See Memorandum to The File, "Analysis for the Preliminary Results of the 2008–2009 Administrative Review of Folding Metal Tables and Chairs from the People's Republic of China: New-Tec Integration (Xiamen) Co. Ltd. ("New-Tec")" (July 7, 2010) ("New-Tec Preliminary Analysis Memorandum"), Memorandum to The File), "Analysis for the Preliminary Results of the 2007–2008 Administrative Review of Folding Metal Tables and Chairs from the People's Republic of China: Feili" (July 7, 2010) ("Feili 2007–2008 Preliminary Analysis Memorandum"), and Memorandum to The File, "Analysis for the Preliminary Results of the 2008–2009 Administrative Review of Folding Metal Tables and Chairs from the People's Republic of China: Feili" (July 7, 2010) ("Feili 2008–2009 Preliminary Analysis Memorandum").

[13] *See Folding Metal Tables and Chairs from the People's Republic of China; Final Results of Antidumping Duty Administrative Review,* 71 FR 2905 (January 18, 2006), and accompanying Issues and Decision Memorandum at Comment 4; *Folding Metal Tables and Chairs from the People's Republic of China: Final Results of Antidumping Duty Administrative Review,* 71 FR 71509 (December 11, 2006), and accompanying Issues and Decision Memorandum at Comment 4; and *Folding Metal Tables and Chairs from the People's Republic of China: Final Results of Antidumping Duty Administrative Review,* 72 FR 71355 (December 17, 2007), and accompanying Issues and Decision Memorandum at Comments 10 and 11.

[14] *Id.*

[15] *See NSK Ltd.* v. *United States,* 115 F.3d 965, 975 (Fed. Cir. 1997).

[16] *See NSK Ltd.* v. *United States,* 217 F. Supp. 2d 1291, 1311–1312 (CIT 2002).

[17] *See, e.g., Zenith Electronics Corp.* v. *United States,* 988 F.2d 1573, 1583 (Fed. Cir. 1993) (explaining that the burden of evidentiary production belongs "to the party in possession of the necessary information"). *See also Tianjin Machinery Import & Export Corp.* v. *United States,* 806 F. Supp. 1008, 1015 (CIT 1992) ("The burden of creating an adequate record lies with respondents and not with {the Department}.") (citation omitted).

[18] *See NTN Bearing Corp. of America.* v. *United States,* 997 F.2d 1453, 1458 (Fed. Cir. 1993).

[19] *See* 19 CFR 351.408(c)(1); *see also Lasko Metal Products* v. *United States,* 43 F.3d 1442, 1445–1446 (Fed. Cir. 1994) (affirming the Department's use of market-based prices to value certain FOPs).

[20] *See, e.g., China National Machinery Import & Export Corp.* v. *United States,* 293 F. Supp. 2d 1334, 1339 (CIT 2003) (aff'd, 104 Fed. Appx. 183 (Fed.

In accordance with the *OTCA 1988* legislative history, the Department continues to apply its long-standing practice of disregarding surrogate values if it has a reason to believe or suspect the source data may be subsidized.[21] In this regard, the Department has previously found that it is appropriate to disregard such prices from India, Indonesia, South Korea and Thailand because we have determined that these countries maintain broadly available, non-industry specific export subsidies.[22] Based on the existence of these subsidy programs that were generally available to all exporters and producers in these countries at the time of the POR, the Department finds that it is reasonable to infer that all exporters from India, Indonesia, South Korea and Thailand may have benefitted from these subsidies.

Factor Valuations

In accordance with section 773(c) of the Act, we calculated NV based on the FOPs reported by Feili and New-Tec for the PORs. To calculate NV, we multiplied the reported per-unit factor quantities by publicly available Indian surrogate values (except as noted below). In selecting the surrogate values, we considered the quality, specificity, public availability, and contemporaneity of the data. As appropriate, we adjusted input prices by including freight costs to render them delivered prices. Specifically, we added to Indian import surrogate values a surrogate freight cost using the shorter of the reported distance from the domestic supplier to the factory or the distance from the nearest seaport to the factory where appropriate (*i.e.,* where the sales terms for the market-economy inputs were not delivered to the factory). This adjustment is in accordance with the decision of the Federal Circuit in *Sigma Corp.* v. *United States,* 117 F. 3d 1401, 1408 (Fed. Cir. 1997). For a detailed description of all surrogate values used for Feili and New-Tec, *see* the Surrogate Value Memoranda 07–08 and 08–09.

In past cases, it has been the Department's practice to value various FOPs using import statistics of the primary selected surrogate country from World Trade Atlas ("WTA"), as published by Global Trade Information Services ("GTIS").[23] However, in October 2009, the Department learned that Indian import data obtained from the WTA, as published by GTIS, began identifying the original reporting currency for India as the U.S. Dollar. The Department then contacted GTIS about the change in the original reporting currency for India from the Indian Rupee to the U.S. Dollar. Officials at GTIS explained that while GTIS obtains data on imports into India directly from the Ministry of Commerce, Government of India, as denominated and published in Indian Rupees, the WTA software is limited with regard to the number of significant digits it can manage. Therefore, GTIS made a decision to change the original reporting currency for Indian data from the Indian Rupee to the U.S. Dollar in order to reduce the loss of significant digits when obtaining data through the WTA software. GTIS explained that it converts the Indian Rupee to the U.S. Dollar using the monthly Federal Reserve exchange rate applicable to the relevant month of the data being downloaded and converted.[24]

However, the data reported in the Global Trade Atlas ("GTA") software, published by GTIS, reports import statistics, such as from India, in the original reporting currency and thus this data corresponds to the original currency value reported by each country. Additionally, the data reported in the GTA software is reported to the nearest digit and thus there is not a loss of data by rounding, as there is with the data reported by the WTA software. Consequently, the Department will now obtain import statistics from GTA for valuing various FOPs because the GTA import statistics are in the original reporting currency of the country from which the data are obtained and have the same level of accuracy as the original data released.

We further adjusted material input values to account for freight costs incurred between the supplier and respondent. We used the freight rates published by *http://www.infobanc.com,* "The Great Indian Bazaar, Gateway to Overseas Markets." The logistics section of the Web site contains inland freight truck rates between many large Indian cities. The truck freight rates are for the period August 2008 through July 2009. Since these dates are not contemporaneous with the 2007–2008 POR, we deflated the rates using Indian WPI. *See* Surrogate Value Memoranda 07–08 and 08–09.

Feili and New-Tec made raw materials purchases from market-economy suppliers. Therefore, in accordance with our practice outlined in *Antidumping Methodologies: Market Economy Inputs,*[25] where at least 33 percent of an input is sourced from market-economy suppliers and purchased in a market-economy currency, the Department will use actual weighted-average purchase prices to value these inputs.[26] Where the quantity of the input purchased from market-economy suppliers during the period is below 33 percent of its total volume of purchases of the input during the period, the Department will weight-average the weighted average market-economy purchase price with an appropriate surrogate value. *See Antidumping Methodologies: Market Economy Inputs.* For a complete description of the factor values we used, *see* Surrogate Value Memoranda 07–08 and 08–09 and Feili and New-Tec Preliminary Analysis Memoranda.

To value liquid petroleum gas, we used per-kilogram values obtained from Bharat Petroleum, published June 4, 2009. We made adjustments to account for inflation and freight costs incurred between the supplier and New-Tec. *See*

Cir. 2004)) ("*China National Machinery*"), and *see Frontseating Service Valves from the People's Republic of China; Preliminary Determination of Sales at Less Than Fair Value, Preliminary Negative Determination of Critical Circumstances, and Postponement of Final Determination,* 73 FR 62952 (October 22, 2008) (unchanged in *Frontseating Service Valves from the People's Republic of China: Final Determination of Sales at Less Than Fair Value and Final Negative Determination of Critical Circumstances,* 74 FR 10886 (March 13, 2009) ("*Frontseating Service Valves*").

[21] Omnibus Trade and Competitiveness Act of 1988, Conf. Report to Accompany H.R. 3, H.R. Rep. No. 576, 100th Cong., 2nd Sess. (1988) ("*OTCA 1988*") at 590.

[22] *See, e.g.,* Expedited Sunset Review of the Countervailing Duty Order on Carbazole Violet Pigment 23 from India, 75 FR 13257 (March 19, 2010) and accompanying Issues and Decision Memorandum at pages 4–5; Expedited Sunset Review of the Countervailing Duty Order on Certain Cut-to-Length Carbon Quality Steel Plate from Indonesia, 70 FR 45692 (August 8, 2005) and accompanying Issues and Decision Memorandum at page 4; *See* Corrosion-Resistant Carbon Steel Flat Products from the Republic of Korea: Final Results of Countervailing Duty Administrative Review, 74 FR 2512 (January 15, 2009) and accompanying Issues and Decision Memorandum at pages 17, 19–20; *See* Certain Hot-Rolled Carbon Steel Flat Products from Thailand: Final Results of Countervailing Duty Determination, 66 FR 50410 (October 3, 2001), and accompanying Issues and Decision Memorandum at page 23.

[23] *See Certain Preserved Mushrooms from the People's Republic of China: Preliminary Results of Antidumping Duty New Shipper Review,* 74 FR 50946, 50950 (October 2, 2009).

[24] *See Certain Oil Country Tubular Goods from the People's Republic of China: Final Determination of Sales at Less Than Fair Value, Affirmative Final Determination of Critical Circumstances,* and Final Determination of Targeted Dumping, 75 FR 20335 (April 19, 2010), and accompanying Issues and Decision Memorandum at Comment 4.

[25] *See Antidumping Methodologies: Market Economy Inputs, Expected Non-Market Economy Wages, Duty Drawback; and Request for Comments,* 71 FR 61716, 61717–19 (October 19, 2006) ("*Antidumping Methodologies: Market Economy Inputs*").

[26] For a detailed description of all actual values used for market-economy inputs, *see* New-Tec Preliminary Analysis Memorandum dated concurrently with this notice.

Surrogate Value Memoranda 07–08 and 08–09. To value diesel, we used per-kilogram values obtained from Bharat Petroleum, published December 2, 2008. We made adjustments to account for deflation for Feili's 2007–2008 administrative review, whereas the source is contemporaneous with the 2008–2009 POR. *See* Surrogate Value Memoranda 07–08 and 08–09.

To value electricity, we used price data for small, medium, and large industries, as published by the Central Electricity Authority of the Government of India in its publication entitled "Electricity Tariff & Duty and Average Rates of Electricity Supply in India," dated March 2008. These electricity rates represent actual country-wide, publicly-available information on tax-exclusive electricity rates charged to industries in India. We did not inflate this value because utility rates represent current rates, as indicated by the effective dates listed for each of the rates provided. *See* Surrogate Value Memoranda 07–08 and 08–09.

To value water, we used the revised Maharashtra Industrial Development Corporation ("MIDC") water rates available at *http://www.midcindia.com/water-supply,* which we deflated using Indian WPI. *See* Surrogate Value Memoranda 07–08 and 08–09.

For direct, indirect, and packing labor, pursuant to a recent decision by the Court of Appeals for the Federal Circuit, we have calculated an hourly wage rate to use in valuing each respondent's reported labor input by averaging earnings and/or wages in countries that are economically comparable to the PRC and that are significant producers of comparable merchandise.[27] Because this wage rate does not separate the labor rates into different skill levels or types of labor, the Department has applied the same wage rate to all skill levels and types of labor reported by the respondents. *See* Surrogate Value Memoranda 07–08 and 08–09.

For factory overhead, selling, general, and administrative expenses ("SG&A"), and profit values, both New-Tec and Meco submitted identical financial statements to those that were submitted and considered by the Department for use as surrogate financial statements in the preceding administrative review, none of which is contemporaneous with the current POR.[28] The Department examined these financial statements in the 2007–2008 review of New-Tec, and found that Maximaa Systems Limited ("Maximaa") produced a greater proportion of comparable merchandise than the other companies (Infiniti Modules PVT Ltd., Godrej & Boyce Manufacturing Company Limited, and Tube Investments of India, Ltd.) and, therefore, best met the Department's criteria for surrogate financial ratios.[29] Because parties have submitted for the instant review the same surrogate financial statements as those from the 2007–2008 review of New-Tec, and the record indicates that Maximaa produced a greater proportion of comparable merchandise than other surrogate companies whose financial statements were placed on the record, we find that Maximaa continues to be the best available information with which to determine factory overhead as a percentage of the total raw materials, labor and energy ("ML&E") costs; SG&A as a percentage of ML&E plus overhead (*i.e.,* cost of manufacture); and the profit rate as a percentage of the cost of manufacture plus SG&A. *See* Surrogate Value Memoranda 07–08 and 08–09 for a full discussion of the calculation of these ratios.

For packing materials, we used the per-kilogram values obtained from the GTA and made adjustments to account for freight costs incurred between the PRC supplier and New-Tec's and Feili's plants. *See* Surrogate Value Memoranda 07–08 and 08–09.

Currency Conversion

We made currency conversions into U.S. dollars, where appropriate, in accordance with section 773A(a) of the Act, based on the exchange rates in effect on the dates of the U.S. sales, as certified by the Federal Reserve Bank.

Preliminary Results of Review

We preliminarily determine that the following weighted-average dumping margins exist:

Manufacturer/exporter	Margin (percent)
New-Tec (6/1/2008–5/31/2009)	* 0.00
Feili (6/1/2008–5/31/2009)	* 0.00
Feili (6/1/2007–5/31/2008)	* 0.04

* *De minimis.*

Disclosure

We will disclose the calculations used in our analysis to parties to this proceeding within five days of the publication date of this notice. *See* 19 CFR 351.224(b). Interested parties are invited to comment on the preliminary results and may submit case briefs and/or written comments within 30 days of the date of publication of this notice. *See* 19 CFR 351.309(c). Interested parties may file rebuttal briefs and rebuttals to written comments, limited to issues raised in such briefs or comments, no later than five days after the date on which the case briefs are due. *See* 19 CFR 351.309(d). The Department requests that parties submitting written comments provide an executive summary and a table of authorities as well as an additional copy of those comments electronically.

Any interested party may request a hearing within 30 days of publication of this notice. *See* 19 CFR 351.310(c). If a request for a hearing is made, parties will be notified of the time and date for the hearing to be held at the U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230. *See* 19 CFR 351.310(d). The Department will issue the final results of this administrative review, which will include the results of its analysis of issues raised in any such comments, within 120 days of publication of these preliminary results, pursuant to section 751(a)(3)(A) of the Act.

Deadline for Submission of Publicly Available Surrogate Value Information

In accordance with 19 CFR 351.301(c)(3)(ii), the deadline for submission of publicly available information to value FOPs under 19 CFR 351.408(c) is 20 days after the date of publication of the preliminary results. In accordance with 19 CFR 351.301(c)(1), if an interested party submits factual information less than ten days before, on, or after (if the Department has extended the deadline), the applicable deadline for submission of such factual information, an interested party has ten days to submit factual information to rebut, clarify, or correct the factual information no later than ten days after such factual information is served on the interested party. However, the Department generally will not accept in the rebuttal submission additional or alternative surrogate value information not previously on the record, if the deadline for submission of surrogate value information has passed.[30] Furthermore,

[27] *See Dorbest Ltd.* v. *United States,* 2009–1257 at 20 (CAFC 2010) ("*Dorbest*").

[28] *See* New-Tec's January 21, 2009, Surrogate Value Comments at Exhibit 1, and Meco's January 21, 2009, Surrogate Value Comments at Exhibit 7.

[29] See *Folding Metal Tables and Chairs from the People's Republic of China: Final Results of Antidumping Duty Administrative Review,* 74 FR 68568 (December 28, 2009), and accompanying Issues and Decision Memorandum at Comment 1.

[30] *See, e.g., Glycine from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Rescission, in Part,* 72 FR 58809 (October 17, 2007), and accompanying Issues and Decision Memorandum at Comment 2.

the Department generally will not accept business proprietary information in either the surrogate value submissions or the rebuttals thereto, as the regulation regarding the submission of surrogate values allows only for the submission of publicly available information. *See* 19 CFR 351.301(c)(3).

Assessment Rates

Upon issuance of the final results, the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by these reviews. The Department intends to issue assessment instructions to CBP 15 days after the publication date of the final results of these reviews. In accordance with 19 CFR 351.212(b)(1), we calculated exporter/importer (or customer)-specific assessment rates for the merchandise subject to these reviews.

Where the respondent reports reliable entered values, we calculate importer (or customer)-specific *ad valorem* rates by aggregating the dumping margins calculated for all U.S. sales to each importer (or customer) and dividing this amount by the total entered value of the sales to each importer (or customer). *See* 19 CFR 351.212(b)(1). Where an importer (or customer)-specific *ad valorem* rate is greater than *de minimis,* we will apply the assessment rate to the entered value of the importers'/customers' entries during the POR. *See* 19 CFR 351.212(b)(1). Where we do not have entered values for all U.S. sales, we calculate a per-unit assessment rate by aggregating the antidumping duties due for all U.S. sales to each importer (or customer) and dividing this amount by the total quantity sold to that importer (or customer).

To determine whether the duty assessment rates are *de minimis,* in accordance with the requirement set forth in 19 CFR 351.106(c)(2), we calculated importer (or customer)-specific *ad valorem* ratios based on the estimated entered value. Where an importer (or customer)-specific *ad valorem* rate is zero or *de minimis,* we will instruct CBP to liquidate appropriate entries without regard to antidumping duties. *See* 19 CFR 351.106(c)(2).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of these administrative reviews for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For New-Tec and Feili, the cash deposit rate will be the company-specific rate established in the final results of the 2008–2009 review (except, if the rate is zero or *de minimis,* no cash deposit will be required); (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (3) for all PRC exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the PRC-wide rate of 70.71 percent; and (4) for all non-PRC exporters of subject merchandise that have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporters that supplied that non-PRC exporter. These 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) 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.

This determination is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: July 7, 2010.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 2010–17172 Filed 7–13–10; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 44–2010]

Review of Sourcing Change, Foreign–Trade Subzone 61H, Baxter Healthcare of Puerto Rico (Inhalation Anesthetics Manufacturing), Guayama, Puerto Rico

Pursuant to the regulations of the Foreign–Trade Zones (FTZ) Board (the Board), a review has been initiated (under 15 CFR Sec. 400.28(a)(3)(iii)(A)) of changes in sourcing related to inhalation anesthetics at Foreign–Trade Subzone 61H, at the facility of Baxter Healthcare of Puerto Rico (Baxter).

Subzone 61H was approved by the FTZ Board on February 25, 1997 (Board Order 875, 62 FR 10521, 3/7/1997) at the Baxter Healthcare of Puerto Rico (Baxter) (formerly Ohmeda Caribe Inc./Ohmeda Pharmaceutical Manufacturing Inc.) facility in Guayama, Puerto Rico, for the manufacturing and distribution of pharmaceutical products, primarily inhalation anesthetics for hospital and critical care therapy. The subzone was initially approved for a period of five years. On August 25, 2003 (Board Order 1293, 68 FR 53346, 9/10/2003), the subzone was extended indefinitely and the scope of approved authority was expanded.

On products shipped to the U.S. market, the company is able to choose the duty rate during customs entry procedures that applies to the finished products (duty–free) for the otherwise dutiable foreign components (duty rates range from duty–free to 20%).

Baxter has now notified the Board of additional sourcing of two chemical inputs. The new foreign–sourced chemical ingredients are sevomethylether (HTSUS 2909.19.1800 5.5%) and N,N–diisopropylethylamine (HTSUS 2921.19.6090 - 6.5%). The use of zone procedures for the additional inputs could exempt Baxter from customs duty payments on the foreign components used in export production. The company estimates that some 40 percent of the plant's shipments are exported. On the domestic sales, Baxter would be able to choose the duty rate during customs entry procedures that applies to the finished inhalation anesthetics (duty–free) for the foreign inputs noted above. The finished products remain unchanged and were included in the scope of manufacturing authority approved by the Board.

In accordance with the Board's regulations, Diane Finver of the FTZ Staff is designated examiner to investigate the sourcing change, including its potential to cause "significant adverse effects" (15 CFR 400.28(a)(3)(iii)(A)), and report to the Board. Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is August 13, 2010. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to August 30, 2010.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign–Trade Zones Board, Room 2111, U.S. Department of Commerce, 1401 Constitution Avenue, NW, Washington, DC 20230–0002, and in the

"Reading Room" section of the Board's website, which is accessible via www.trade.gov/ftz.

For further information, contact Diane Finver at Diane.Finver@trade.gov or 482–1367.

Dated: July 2, 2010.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2010–17173 Filed 7–13–10; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF DEFENSE

Office of the Secretary

Federal Advisory Committee; Department of Defense Wage Committee

AGENCY: Department of Defense (DoD).

ACTION: Notice of closed meeting.

SUMMARY: Pursuant to the provisions of section 10 of Public Law 92–463, the Federal Advisory Committee Act, notice is hereby given that a closed meeting of the Department of Defense Wage Committee will be held on August 10, 2010, in Rosslyn, VA.

DATES: The meeting will be held on Tuesday, August 10, 2010, at 10 a.m.

ADDRESSES: The meeting will be held at 1400 Key Boulevard, Level A, Room A101, Rosslyn, VA 22209.

FOR FURTHER INFORMATION CONTACT: Additional information concerning the meetings may be obtained by writing to the Chairman, Department of Defense Wage Committee, 4000 Defense Pentagon, Washington, DC 20301–4000.

SUPPLEMENTARY INFORMATION: Under the provisions of section 10(d) of Public Law 92–463, the Department of Defense has determined that the meeting meets the criteria to close meetings to the public because the matters to be considered are related to internal rules and practices of the Department of Defense and the detailed wage data to be considered were obtained from officials of private establishments with a guarantee that the data will be held in confidence.

However, members of the public who may wish to do so are invited to submit material in writing to the chairman (*see* **FOR FURTHER INFORMATION CONTACT**) concerning matters believed to be deserving of the Committee's attention.

Dated: July 9, 2010.

Mitchell S. Bryman,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2010–17165 Filed 7–13–10; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before September 13, 2010.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, *e.g.* new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: July 9, 2010.

Darrin A. King,

Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management.

Office of Innovation and Improvement

Type of Review: Extension.

Title: Credit Enhancement for Charter School Facilities Program Performance Report.

OMB #: 1855–0010.

Form #: N/A.

Frequency: Annually.

Affected Public: Businesses or other for-profit; Not-for-profit institutions; State, Local, or Tribal Government, Secondary educational agencies (SEAs) or Local Educational Agencies (LEAs).

Reporting and Recordkeeping Hour Burden:

Responses: 30.

Burden Hours: 750.

Abstract: Department of Education (ED) will use the information through this report to monitor and evaluate competitive grants. These grants are made to private, non-profits; governmental entities; and consortia of these entities. These organizations will use the funds to leverage private capital to help charter schools construct, acquire, and renovate charter schools.

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov,* by selecting the "Browse Pending Collections" link and by clicking on link number 4357. When you access the information collection, click on "Download Attachments" to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 2010–17144 Filed 7–13–10; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Proposed Agency Information Collection

AGENCY: U.S. Department of Energy.

ACTION: Notice and request for comments.

SUMMARY: The Department of Energy (DOE) invites public comment on a proposed collection of information that DOE is developing for submission to the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act of 1995. 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 of the proposed collection of information, including 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 respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Comments regarding this proposed information collection must be received on or before September 13, 2010. If you anticipate difficulty in submitting comments within that period, contact the person listed in **ADDRESSES** as soon as possible.

ADDRESSES: Written comments may be sent to: Frank Norcross, EE–2K, U.S. Department of Energy, 1000 Independence Ave., SW., Washington, D.C. 20585–1290, *Fax#:* (202) 586–1233, *frank.norcross@ee.doe.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to: Frank Norcross, EE–2K, U.S. Department of Energy, 1000 Independence Ave., SW., Washington, D.C. 20585–1290, *Fax#:* (202) 586–1233, *frank.norcross@ee.doe.gov.*

Reporting guidance concerning the Energy Efficiency and Conservation Block Grant (EECBG) Program is available for review at the following Web site: *http://www1.eere.energy.gov/wip/recovery_act_guidance.html.*

SUPPLEMENTARY INFORMATION: This information collection request contains: (1) OMB No. 1910–5150; (2) Information Collection Request Title: "Energy Efficiency and Conservation Block Grant (EECBG) Program Status Report"; (3) Type of Review: Regular; (4) Purpose: To collect information on the status of grantee activities, expenditures, and results, to ensure that program funds are being used appropriately, effectively and expeditiously (especially important for Recovery Act funds); (5) Annual *Estimated Number of Respondents:* 2,359; (6) Annual Estimated Number: 128,688; (7) Annual Estimated Reporting and Recordkeeping Cost Burden: $377,000.

Authority: Title V, Subtitle E of the Energy Independence and Security Act (EISA), Pub. L. 110–140.

Issued in Washington, DC on July 8, 2010.

Tobias Russell,

Acting Program Manager, Office of Weatherization and Intergovernmental Program, Energy Efficiency and Renewable Energy.

[FR Doc. 2010–17142 Filed 7–13–10; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 10855–177]

Upper Peninsula Power Company; Notice of Application for Temporary Amendment of License and Soliciting Comments, Motions To Intervene, and Protests

July 7, 2010.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Request for drought-based temporary variance of the reservoir elevations and minimum flow releases at the Dead River Project.

b. *Project No.:* 10855–177.

c. *Date Filed:* June 28, 2010.

d. *Applicant:* Upper Peninsula Power Company.

e. *Name of Project:* Dead River Hydroelectric Project (P–10855).

f. *Location:* The Dead River Project is located on the Dead River in Marquette County, Michigan and consists of three separate developments: the Silver Lake, Dead River (Hoist), and McClure Developments.

g. *Filed Pursuant to:* Federal Power Act, 16 USC 791a–825r.

h. *Applicant Contact:* Mr. Shawn Puzen, Upper Peninsula Power Company, 700 North Adams Street, P.O. Box 19001, Green Bay, WI 54307–9001, Tel: (920) 433–1094.

i. *FERC Contact:* Ms. Rachel Price, (202) 502–8907; e-mail: *rachel.price@ferc.gov.*

j. *Deadline for filing comments, motions to intervene and protests:* July 26, 2010.

Please include the project number (P–10855–177) on any comments or motions filed. All documents should be filed with: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. Comments, protests, and interventions may be filed electronically via the Internet, *see* 18 CFR 385.2001 (a)(1)(iii) and the instructions on the Commission's Web site under the "e-filing" link. The Commission strongly encourages electronic filings. In lieu of electronic filing, an original and eight copies of all documents may be mailed to the Secretary at the address above.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

k. *Description of Request:* Upper Peninsula Power Company (UPPCO) is requesting a drought-based temporary variance to the reservoir elevation and minimum flow requirements at the Hoist Development. The variance would be in effect from the date of Commission approval to November 15, 2010, and would include: (1) Releasing a minimum flow of 75 cubic feet per second (cfs) from the Hoist Reservoir, instead of 100 cfs required by the project license; and (2) operating the Hoist Development to maintain a target elevation of 1339.5 feet and a minimum of 1338.5 feet, instead of a target of 1341 and a minimum of 1339.5 feet as required by the license. Under the variance, UPPCO would hold the Silver Lake Reservoir at its current elevation (1,469.087 feet) in order to release all inflow to the downstream Hoist Reservoir. In addition, the 75 cfs minimum flow from the Hoist Reservoir would be maintained regardless of the Hoist Reservoir elevation. If conditions change such that the Hoist Reservoir revised target elevation could be maintained for at least 30 days, UPPCO would return to operation requirements of the project license.

l. *Location of the Application:* The filing is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426 or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://ferc.gov*

using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docsfiling/esubscription.asp* to be notified vial e-mail or new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or e-mail *ferconlinesupport@ferc.gov,* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, and 385.214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. Any filing must bear in all capital letters the title "COMMENTS", "PROTEST", or 'MOTION TO INTERVENE", as applicable, and the Project Number of the particular application to which the filing refers.

p. *Agency Comments:* Federal, State, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

q. Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper. *See,* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov* under the "e-Filing" link.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–17102 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2144–038]

City of Seattle; Notice of Application Ready for Environmental Analysis and Soliciting Comments, Recommendations, Preliminary Terms and Conditions, and Preliminary Fishway Prescriptions

July 6, 2010.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New Major License.

b. *Project No.:* 2144–038.

c. *Date Filed:* September 29, 2009.

d. *Applicant:* City of Seattle.

e. *Name of Project:* Boundary Hydroelectric Project.

f. *Location:* The existing project is located on the Pend Oreille River in Pend Oreille County, Washington. The project currently occupies 920.87 acres of Federal land managed by the U.S. Forest Service and U.S. Bureau of Land Management.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791 (a)–825(r).

h. *Agent Contact:* Jorge Carrasco, Superintendent, Seattle City Light, 700 Fifth Avenue, Suite 3200, Seattle, WA 98124–4023; (206) 615–1091.

i. *FERC Contact:* David Turner (202) 502–6091.

j. Deadline for filing comments, recommendations, terms and conditions, and prescriptions is 60 days from the issuance of this notice; reply comments are due 105 days from the issuance date of this notice.

All documents may be filed electronically via the Internet. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov/docs-filing/ferconline.asp*) under the "eFiling" link. For a simpler method of submitting text only comments, click on "Quick Comment." For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov;* call toll-free at (866) 208–3676; or, for TTY, contact (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and eight copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted and is now ready for environmental analysis.

l. *Project Description:* The existing project consists of: (1) A concrete arch dam with a crest elevation of 2,004 feet NGVD (North American Vertical Datum), a structural height of 340 feet, a thickness ranging from 8 feet at the crest to 32 feet at the base, and a crest length of 508 feet, with a total length, including the spillways, of 740 feet; (2) two 50-feet-wide spillways fitted with 45-feet-high radial gates, one on each abutment, which have a combined maximum capacity of 108,000 cubic feet per second (cfs) at a forebay water surface elevation of 1994 feet NGVD; (3) seven 21-foot-high by 17-foot-wide, low-level vertical fixed-wheel sluice gates that provide an additional discharge capacity of 252,000 cfs, for a total discharge capacity at the dam of 360,000 cfs; (4) a 17.5-mile-long, 1,794-acre reservoir at a normal full pool elevation of 1,994 feet NGVD with 87,913 acre-feet of gross storage; (5) power intake facilities excavated on the left abutment area consisting of an approximately 300-foot-wide by 800-foot-long forebay, a trash rack structure across the entrance to the forebay, and the portal face with six 30-foot-wide by 34-foot-high horseshoe-shaped tunnels extending to intake gate chambers; (6) six 315-feet-long penstocks lead from each of the intake gates to one of the six turbine-generator units in the power plant; (7) an underground power plant comprised of a 76-feet wide by 172-feet-high by 477-feet-long machine hall; (8) two 204,506-horsepower (hp) Francis turbines, with 158.4-megawatt (MW) generators, two 204,506-hp Francis turbines, with 161.5-MW generators, and two 259,823-hp Francis turbines, with 200-MW generators for a total authorized generating capacity of 1,003 MW; (9) six draft tubes that discharge water into the tailrace immediately below the dam; (10) six horseshoe-shaped transformer bays; (11) six individual three-phase, 230-kilovolt (kV) transmission lines up the vertical face of the left abutment of the dam to six pairs of transmission towers on top of the abutment; and (12) appurtenant equipment. The applicant proposes to install new high efficiency turbines in Units 55 and 56, concurrently with

planned generator rewinds and step-up transformer replacements.

m. *Locations of the Application:* A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at 1–866–208–3676, or for TTY, (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

Register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. All filings must (1) Bear in all capital letters the title "COMMENTS," "REPLY COMMENTS," "RECOMMENDATIONS," "PRELIMINARY TERMS AND CONDITIONS," or "PRELIMINARY FISHWAY PRESCRIPTIONS;" (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person submitting the filing; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. Each filing must be accompanied by proof of service on all persons listed on the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b), and 385.2010.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

o. A license applicant must file no later than 60 days following the date of issuance of the notice of acceptance and ready for environmental analysis provided for in § 5.22: (1) A copy of the water quality certification; (2) a copy of the request for certification, including proof of the date on which the certifying agency received the request; or (3) evidence of waiver of water quality certification.

p. *Procedural Schedule:* The application will be processed according to the following Hydro Licensing Schedule. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Filing of Recommendations, Preliminary Terms and Conditions, and Fishway Prescriptions	September 6, 2010.
Reply Comments due	October 19, 2010.
Issue Draft EA	March 3, 2011.
Comments on Draft EA Due	April 4, 2011.
Filing of Modified Mandatory Terms and Conditions	June 3, 2011.
Issue Final EA	September 2, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–17111 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13597–000]

McGinnis, Inc.; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

July 6, 2010.

On September 29, 2009, McGinnis, Inc. filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act, proposing to study the feasibility of the Wilson Hydrokinetic Project, to be located on the Tennessee River downstream of the Tennessee Valley Authority (TVA) and the Corps of Engineers' (COE) existing Wilson Lock & Dam in Lauderdale and Colbert County, Alabama. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed Wilson Hydrokinetic Project consists of: (1) 10 proposed 35 kilowatt axial flow turbine generating units having a total installed capacity of 350 kilowatts; (2) a 700-foot-long, 13.2 kilovolt transmission line; and (3) appurtenant facilities. The proposed Wilson Hydrokinetic Project would have an average annual generation of 1.533 gigawatt-hours.

Applicant Contact: Bruce McGinnis, Sr., CEO, McGinnis, Inc., 502 Second Street Ext., South Point, OH 45680; phone: (740) 377–4391.

FERC Contact: Kim Carter, 202–502–6486.

Deadline for filing comments or motions to intervene: 60 days from the issuance of this notice. Comments and motions to intervene may be filed electronically via the internet. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov/docs-filing/ferconline.asp*) under the "eFiling" link. For a simpler method of submitting text only comments, click on "Quick Comment." For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov;* call toll-free at (866) 208–3676; or, for TTY, contact (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and eight copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

More information about this project, including a copy of the application, can be viewed or printed on the "eLibrary" link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–13597) in the docket number field to access the document. For assistance, contact FERC Online Support.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–17100 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2225–013]

Public Utility District No. 1 of Pend Orielle County; Notice of Application for Surrender of License Accepted for Filing, Soliciting Comments, Motions To Intervene and Protests, and Ready for Environmental Analysis

July 6, 2010.

Take notice that the following hydroelectric application has been with the Commission and is available for public inspection.

a. *Type of Application:* Surrender of License.

b. *Project No.:* Sullivan Creek: P–2225–013.

c. *Date Filed:* March 29, 2010.

d. *Applicant:* Public Utility District No. 1 of Pend Oreille County (Pend Oreille PUD).

e. *Location:* The existing project is located on Sullivan Creek and Outlet Creek, tributaries to the Pend Oreille River, in northeast Washington. The project occupies lands within the Colville National Forest.

f. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

g. *Applicant Contact:* Mark J Cauchy, Public Utility District No. 1 of Pend Oreille, County, Washington, PO Box 190, Newport, WA 99156–0190; 509 447 9331.

h. *FERC Contact:* David Turner (202) 502–6091 or via e-mail at *david.turner@ferc.gov.*

i. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item J below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See,* 94 FERC ¶ 1,076 (2001).

j. Deadline for filing comments, motions to intervene, protests, and requests for cooperating agency status is 60 days from the issuance date of this notice; reply comments are due 105 days from the issuance date of this notice.

All documents may be filed electronically via the Internet. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov/docs-filing/ferconline.asp*) under the "eFiling" link. For a simpler method of submitting text only comments, click on "Quick Comment." For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov;* call toll-free at (866) 208–3676; or, for TTY, contact (202) 502–8659.

Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and eight copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. All documents (original and eight copies) should be filed with: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's Rules of Practice require all interveners filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted for filing and is now ready for environmental analysis.

l. The Sullivan Creek Project works include: (1) A 172-foot-long, 34-foot-high concrete and earth-filed Sullivan Lake dam; (2) the 1,240-acre Sullivan Lake; (3) a 134-foot-long, 55-foot-high concrete, gravity Mill Pond dam; and (4) the 80.5-acre Mill Pond. Other abandoned project works include: (5) a 0.8-mile-long Sullivan Creek diversion conduit, (6) a 12,500-foot-long wooden flume, (7) a 2,200-foot-long earthen canal, (8) a 1,150-foot-long, 8-foot diameter horseshoe tunnel, and (9) a 100-foot by 8-foot masonry brick powerhouse. The turbines were removed from the powerhouse in 1958 and the turbine bays filled with rock and gravel.

The Pend Orielle PUD proposes to (1) retain and operate under a Forest Service Special Use Authorization the Sullivan Lake dam and lake; (2) install a new cold-water release facility at Sullivan Lake dam; and (3) remove Mill Pond dam and restore the site and downstream stream channel and conduct short-term monitoring and maintenance in accordance with its filed Mill Pond Decommissioning Plan. No action is proposed for the remaining abandoned project works.

m. A copy of the surrender application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's website at *http://www.ferc.gov,* using the "e-Library" link. Enter the docket number, excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at 1–866–208–3676, or for TTY, (202) 502–8659. A copy is also available for inspection and reproduction at the address in item h above. A copy of the application may be obtained by agencies directly from the applicant.

Register online at *http://www.ferc.gov/esubscribenow.htm* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date in item j.

All filings must (1) bear in all capital letters the title "COMMENTS", "PROTEST", "MOTION TO INTERVENE", or "REQUEST TO BE COOPERATING AGENCY"; as appropriate; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene or protests should relate to project works which are the subject of the license surrender. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

o. A copy of the application for water quality certification was filed on April 8, 2010.

p. Procedural schedule and final amendments: The application will be processed according to the following

schedule. Revisions to the schedule will be made if the Commission determines it necessary to do so:

Milestone	Target date
Filing of comments, motions to intervene, protests, and requests for cooperating agency status.	September 6, 2010.
Reply Comments due	October 19, 2010.
Issue Draft EA	March 3, 2011.
Comments on Draft EA Due	April 4, 2011.
Issue Final EA	September 2, 2011.

Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of this notice.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–17099 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12642–003]

Wilkesboro Hydropower, LLC; Notice of Application Accepted for Filing and Soliciting Motions To Intervene and Protests

July 6, 2010.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Original Major License.

b. *Project No.:* P–12642–003.

c. *Date filed:* September 29, 2009.

d. *Applicant:* Wilkesboro Hydroelectric Company, LLC.

e. *Name of Project:* W. Kerr Scott Hydropower Project.

f. *Location:* The proposed project would be located at the existing U.S. Army Corps of Engineers' (Corps) W. Kerr Scott dam on the Yadkin River, near Wilkesboro in Wilkes County, North Carolina. A total of 3.5 acres of federal lands, administered by the Corps, would be occupied by the proposed project.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contacts:* Mr. Kevin Edwards, P.O. Box 143, Mayodan, NC 27027; Mr. Dean Edwards, P.O. Box 1565, Dover, FL 33527;

i. *FERC Contact:* Jennifer Adams at (202) 502–8087, or *jennifer.adams@ferc.gov.*

j. Deadline for filing motions to intervene and protests: 60 days from the issuance date of this notice, or September 4, 2010.

All documents may be filed electronically via the Internet. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's website (*http://www.ferc.gov/docs-filing/ferconline.asp*) under the "eFiling" link. For a simpler method of submitting text only comments, click on "Quick Comment." For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov;* call toll-free at (866) 208–3676; or, for TTY, contact (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and eight copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's Rules of Practice and Procedure require all interveners filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted for filing, but is not ready for environmental analysis at this time.

l. The proposed project would use the existing Kerr Scott dam, which is federally owned and administered by the Corps. The proposed project would use releases from the reservoir, as directed by the Corps, which would normally be released directly to the Yadkin River downstream from the dam. All existing facilities would remain, but some features would be modified and new facilities would be constructed.

The proposed project would consist of: (1) Modifying the existing low-level intake tower to be a multilevel intake structure with trashracks; (2) placing a 580-foot-long, 11-foot-diameter steel liner in the downstream portion of the existing 749-foot-long reinforced concrete water conduit to enable pressurization of the conduit; (3) a penstock bifurcation and two 8-foot-diameter steel penstocks; (4) a gate at the end of the water conduit, with a Howell-Bunger-ring-jet-type fixed cone valve installed in the gate; (5) an 80-foot-long by 30-foot-wide powerhouse containing one 2.0–MW Kaplan unit and one 2.0–MW propeller-type unit; (6) an 80-foot-wide by 30-foot-long discharge channel that joins the Yadkin River at the downstream end of the existing stilling basin; (7) a substation; (8) a new underground 12.47-kilovolt (kV) transmission line that extends 150 feet from the proposed powerhouse to an existing utility pole to the south of the powerhouse, and an upgraded 3,600-foot-long, 12.47-kV three-phase line that connects the utility pole to a Duke Energy substation; and (9) appurtenant facilities. The Kerr Scott project would generate approximately 22,400 megawatt-hours of energy annually.

m. A copy of the application is available for review at the Commission in the Public Reference Room, or may be viewed on the Commission's website at *http://www.ferc.gov,* using the "eLibrary" link. Enter the docket number, excluding the last three digits in the docket number field, to access the document. For help, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h.

You may also register online at *http://www.ferc.gov/docs-filing/e-subscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. Any qualified applicant desiring to file a competing application must submit to the Commission, on or before the specified intervention deadline date, a competing development application no later than 120 days after the specified intervention deadline date. Applications for preliminary permits will not be accepted in response to this notice.

A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an

unequivocal statement of intent to submit a development application. A notice of intent must be served on the applicant(s) names in this public notice.

Anyone may submit a protest or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, and 385.214. In determining the appropriate action to take, the Commission will consider all protests filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any protests or motions to intervene must be received on, or before, the specified deadline date for the particular application.

When the application is ready for environmental analysis, the Commission will issue a public notice requesting comments, recommendations, terms and conditions, or prescriptions.

All filings must: (1) Bear in all capital letters the title "PROTEST" or "MOTION TO INTERVENE;" (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–17097 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP10–2–001]

Southern Star Central Gas Pipeline, Inc.; Notice of Application

July 8, 2010.

Take notice that on July 2, 2010, Southern Star Central Gas Pipeline, Inc. (Southern Star), 4700 Highway 56, Owensboro, Kentucky 42301, filed in Docket No. CP10–2–001, an application pursuant to section 7(c) of the Natural Gas Act (NGA) and Part 157 of the Commission's regulations, to amend its certificate issued on May 20, 2010 in docket number CP10–2–000. Specifically, Southern Star proposes to increase the working gas capacity and amend the operational plan of the Elk City Storage Field located in Elk, Chautauqua, and Montgomery Counties, Kansas. Specifically, Southern Star proposes to convert 1.4 Bcf of cushion gas to working gas, all as more fully set forth in the application which is on file with the Commission and open to public inspection. In addition, Southern Star seeks a determination that this additional 1.4 Bcf of firm storage service qualifies for market-based rates under Section 4(f) of the NGA. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, call (866) 208–3676 or TTY, (202) 502–8659.

Any questions regarding this application should be directed to David N. Roberts, Manager, Regulatory Affairs, Southern Star Central Gas Pipeline, Inc., 4700 Highway 56, Owensboro, Kentucky 42301, or by calling (270) 852–4654 (telephone) or (270) 852–5010 (fax).

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding, or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC. 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

Motions to intervene, protests and comments may be filed electronically via the internet in lieu of paper; see, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link. The Commission strongly encourages electronic filings.

Comment Date: July 29, 2010.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–17160 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13702–000]

FFP Missouri 2, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

July 7, 2010.

On April 5, 2010, FFP Missouri 2, LLC filed an application, pursuant to section 4(f) of the Federal Power Act, proposing to study the feasibility of the Grenada Lake Hydroelectric Project, to be located on the Yalobusha River, Grenada County, Mississippi. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed Grenada Lake Hydroelectric Project consists of: (1) An existing 13,900-foot-long dam and dike; (2) a control tower containing four vertical gates connected to a 400-foot-long outlet tunnel; (3) a proposed intake structure; (4) a proposed 600-foot-long, 14-foot diameter steel penstock; (5) a proposed reinforced concrete powerhouse containing a 5.0 megawatt turbine/generator; (6) a proposed 2,000-foot-long 12.5-kilovolt three-phase overhead transmission line; and (7) appurtenant facilities. The FFP Missouri 2, LLC, project would have an average annual generation of 25-gigawatt-hours.

Applicant Contact: Ms. Ramya Swaminathan, FFP Missouri 2, LLC, 33 Commercial Street, Gloucester, MA 01930, phone (978) 283–2822.

FERC Contact: Pennie Lewis-Partee, (202) 502–6018.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance date of this notice. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link. If unable to be filed electronically, documents may be paper-filed. To paper-file, an original and eight copies should be mailed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

For more information on how to submit these types of filings, please go to the Commission's Web site located at *http://www.ferc.gov/filing-comments.asp.* More information about this project can be viewed or printed on the "eLibrary" link of the Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–13702) in the docket number field to access the document. For assistance, call toll-free 1–866–208–3372.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–17110 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13703–000]

FFP Missouri 2, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

July 7, 2010.

On April 5, 2010, FFP Missouri 2, LLC filed an application, pursuant to section 4(f) of the Federal Power Act, proposing to study the feasibility of the Enid Lake Hydroelectric Project, to be located on the Yucoma River, Yalobusha County, Mississippi. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed Enid Lake Hydroelectric Project consists of: (1) An existing 8,400-foot-long dam and dike; (2) a control tower containing vertical gates connected to a 400-foot-long outlet tunnel; (3) a proposed 40-foot-wide intake structure; (4) a proposed 600-foot-long, 10-foot diameter steel penstock; (5) a proposed reinforced concrete powerhouse containing a 4-megawatt turbine/generator; (6) a proposed 0.5-mile-long 12.5-kilovolt three-phase overhead transmission line; and (7) appurtenant facilities. The FFP Missouri 2, LLC, project would have an average annual generation of 20-gigawatt-hours.

Applicant Contact: Ms. Ramya Swaminathan, FFP Missouri 2, LLC, 33 Commercial Street, Gloucester, MA 01930, phone (978) 283–2822.

FERC Contact: Pennie Lewis-Partee, (202) 502–6018.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance date of this notice. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link. If unable to be filed electronically, documents may be paper-filed. To paper-file, an original and eight copies should be mailed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

For more information on how to submit these types of filings, please go to the Commission's Web site located at *http://www.ferc.gov/filing-comments.asp.* More information about this project can be viewed or printed on the "eLibrary" link of the Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–13703) in the docket number field to access the document. For assistance, call toll-free 1–866–208–3372.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–17109 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13701–000]

FFP Missouri 2, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

July 7, 2010.

On April 5, 2010, FFP Missouri 2, LLC filed an application, pursuant to section 4(f) of the Federal Power Act, proposing to study the feasibility of the Sardis Lake Hydroelectric Project, to be located on the Little Tallahatchie River, Panola County, Mississippi. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands

or waters owned by others without the owners' express permission.

The proposed Sardis Lake Hydroelectric Project consists of: (1) An existing 15,300-foot-long dam and dike; (2) a control tower containing four vertical gates connected to a 550-foot-long outlet tunnel; (3) a proposed 75-foot-wide intake structure; (4) a proposed 800-foot-long, 16-foot diameter steel penstock; (5) a proposed reinforced concrete powerhouse containing a 8.0-megawatt turbine/generator; (6) a proposed 1 and 0.25-mile-long 138-kilovolt three-phase overhead transmission line; and (7) appurtenant facilities. The FFP Missouri 2, LLC, project would have an average annual generation of 40-gigawatt-hours.

Applicant Contact: Ms. Ramya Swaminathan, FFP Missouri 2, LLC, 33 Commercial Street, Gloucester, MA 01930, phone (978) 283–2822.

FERC Contact: Pennie Lewis-Partee, (202) 502–6018.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance date of this notice. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link. If unable to be filed electronically, documents may be paper-filed. To paper-file, an original and eight copies should be mailed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

For more information on how to submit these types of filings please go to the Commission's Web site located at *http://www.ferc.gov/filing-comments.asp.* More information about this project can be viewed or printed on the "eLibrary" link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–13701) in the docket number field to access the document. For assistance, call toll-free 1–866–208–3372.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–17106 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13704–000]

FFP Missouri 2, LLC; Notice of Preliminary Permit Applications Accepted for Filing and Soliciting Comment, Motions To Intervene, and Competing Applications

July 7, 2010.

On April 5, 2010, FFP Missouri 2, LLC filed an application, pursuant to section 4(f) of the Federal Power Act, proposing to study the feasibility of the Arkabutla Lake Hydroelectric Project, to be located on the Coldwater River, Tate and DeSoto Counties, Mississippi. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed Arkabutla Lake Hydroelectric Project consists of: (1) An existing 11,500-foot-long dam and dike; (2) a control tower containing four vertical gates connected to a 400-foot-long outlet tunnel; (3) a proposed 50-foot-wide intake structure; (4) a proposed 900-foot-long, 12-foot diameter steel penstock; (5) a proposed reinforced concrete powerhouse containing a 3.5-megawatt turbine/generator; (6) a proposed 0.5-mile-long, 12.5-kilovolt three-phase overhead transmission line; and (7) appurtenant facilities. The FFP Missouri 2, LLC, project would have an average annual generation of 17.5 gigawatt-hours.

Applicant Contact: Ms. Ramya Swaminathan, FFP Missouri 2, LLC, 33 Commercial Street, Gloucester, MA 01930, phone (978) 283–2822.

FERC Contact: Pennie Lewis-Partee, (202) 502–6018.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance date of this notice. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link. If unable to be filed electronically, documents may be paper-filed. To paper-file, an original and eight copies should be mailed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

For more information on how to submit these types of filings please go to the Commission's Web site located at *http://www.ferc.gov/filing-comments.asp.* More information about this project can be viewed or printed on the "eLibrary" link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–13704) in the docket number field to access the document. For assistance, call toll-free 1–866–208–3372.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–17092 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13591–000]

McGinnis, Inc.; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

July 6, 2010.

On September 29, 2009, McGinnis, Inc. filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act, proposing to study the feasibility of the Kentucky Hydrokinetic Project, to be located on the Tennessee River downstream of the Tennessee Valley Authority (TVA) and the Corps of Engineers' (COE) existing Kentucky Lock & Dam in Marshall and Livingston County, Kentucky. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed Kentucky Hydrokinetic Project consists of: (1) 10 proposed 35 kilowatt axial flow turbine generating units having a total installed capacity of 350 kilowatts; (2) a 700-foot-long, 13.2 kilovolt transmission line; and (3) appurtenant facilities. The proposed Kentucky Hydrokinetic Project would have an average annual generation of 1.533 gigawatt-hours.

Applicant Contact: Bruce McGinnis, Sr., CEO, McGinnis, Inc., 502 Second Street Ext., South Point, OH 45680; phone: (740) 377–4391.

FERC Contact: Kim Carter, 202–502–6486.

Deadline for filing comments or motions to intervene: 60 days from the issuance of this notice. Comments and motions to intervene may be filed electronically via the internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov/docs-filing/ferconline.asp*) under the "eFiling" link. For a simpler method of submitting text only comments, click on "Quick Comment." For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov;* call toll-free at (866) 208–3676; or, for TTY, contact (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and eight copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

More information about this project, including a copy of the application, can be viewed or printed on the "eLibrary" link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–13591) in the docket number field to access the document. For assistance, contact FERC Online Support.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–17096 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

McGinnis, Inc. Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

July 6, 2010.

On September 29, 2009, McGinnis, Inc. filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act, proposing to study the feasibility of the Pickwick Hydrokinetic Project, to be located on the Tennessee River downstream of the Tennessee Valley Authority (TVA) and the Corps of Engineers' (COE) existing Pickwick Lock & Dam in Harden County, Tennessee. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed Pickwick Hydrokinetic Project consists of: (1) 10 proposed 35 kilowatt axial flow turbine generating units having a total installed capacity of 350 kilowatts; (2) a 1,300-foot-long, 13.2 kilovolt transmission line; and (3) appurtenant facilities. The proposed Pickwick Hydrokinetic Project would have an average annual generation of 1.533 gigawatt-hours.

Applicant Contact: Bruce McGinnis, Sr., CEO, McGinnis, Inc., 502 Second Street Ext., South Point, OH 45680; *phone:* (740) 377–4391.

FERC Contact: Kim Carter, 202–502–6486.

Deadline for filing comments or motions to intervene: 60 days from the issuance of this notice. Comments and motions to intervene may be filed electronically via the Internet. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov/docs-filing/ferconline.asp*) under the "eFiling" link. For a simpler method of submitting text only comments, click on "Quick Comment." For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov;* call toll-free at (866) 208–3676; or, for TTY, contact (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and eight copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

More information about this project, including a copy of the application, can be viewed or printed on the "eLibrary" link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–13594) in the docket number field to access the document. For assistance, contact FERC Online Support.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–17095 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

July 2, 2010.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1649–000.

Applicants: Midwest Independent Transmission System Operator, Inc.

Description: Midwest Independent Transmission System Operator, Inc submits proposed revisions to the Coordination Agreement with Independent Electricity System Operator.

Filed Date: 06/30/2010.

Accession Number: 20100630–0234.

Comment Date: 5 p.m. Eastern Time on Wednesday, July 21, 2010.

Docket Numbers: ER10–1650–000.

Applicants: New England Power Pool Participants Committee.

Description: The New England Power Pool Participants Committee submits transmittal letter along with counterpart signature pages of the Agreement dated 9/1/71 *etc.*

Filed Date: 06/30/2010.

Accession Number: 20100630–0233.

Comment Date: 5 p.m. Eastern Time on Wednesday, July 21, 2010.

Docket Numbers: ER10–1653–000.

Applicants: ISO New England and NEPOOL.

Description: ISO New England Inc et al submits transmittal letter and Fourth Revised Sheet 7319B *et al* to FERC Electric Tariff 3- Section III- Market Rule 1- Standard Market Design *etc.*

Filed Date: 06/30/2010.

Accession Number: 20100630–0221.

Comment Date: 5 p.m. Eastern Time on Wednesday, July 21, 2010.

Docket Numbers: ER10–1654–000.

Applicants: Connecticut Light & Power Company.

Description: The Connecticut Light and Power Company submits Interconnection Agreement with Covanta Projects of Wallingford, LP *etc.*

Filed Date: 06/30/2010.

Accession Number: 20100630–0219.

Comment Date: 5 p.m. Eastern Time on Wednesday, July 21, 2010.

Docket Numbers: ER10–1655–000.

Applicants: MATEP, Inc.

Description: MATEP Limited Partnership submits Notice of Succession to New MATEP, Inc's market- based rate tariff.

Filed Date: 06/30/2010.

Accession Number: 20100630–0220.

Comment Date: 5 p.m. Eastern Time on Wednesday, July 21, 2010.

Docket Numbers: ER10–1659–000.

Applicants: PSEG Nuclear LLC.

Description: PSEG Nuclear LLC submits tariff filing per 35.12: Baseline Filing of Market-Based Rates Tariff Under Order No. 714 to be effective 7/1/2010.

Filed Date: 07/01/2010.

Accession Number: 20100701–5008.

Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1660–000.
Applicants: PSEG Fossil LLC.
Description: PSEG Fossil LLC submits tariff filing per 35.12: Baseline Filing of Market-Based Rate Tariff Under Order No. 714 to be effective 7/1/2010.
Filed Date: 07/01/2010.
Accession Number: 20100701–5011.
Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1661–000.
Applicants: PSEG Power Connecticut LLC.
Description: PSEG Power Connecticut LLC submits tariff filing per 35.12: Baseline Filing of Market-Based Rate Tariff under Order No. 714 to be effective 7/1/2010.
Filed Date: 07/01/2010.
Accession Number: 20100701–5012.
Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1662–000.
Applicants: PSEG Energy Resources & Trade LLC.
Description: PSEG Energy Resources & Trade LLC submits tariff filing per 35.12: Baseline Filing of Market-Based Rate Tariff under Order No. 714 to be effective 7/1/2010.
Filed Date: 07/01/2010.
Accession Number: 20100701–5013.
Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1663–000.
Applicants: PSEG Energy Resources & Trade LLC.
Description: PSEG Energy Resources & Trade LLC submits tariff filing per 35.12: Baseline Filing of Reactive Power Tariff Under No. 714 to be effective 7/1/2010.
Filed Date: 07/01/2010.
Accession Number: 20100701–5015.
Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1664–000.
Applicants: Southwest Power Pool, Inc.
Description: Southwest Power Pool, Inc. submits an executed Service Agreement for Network Integration Transmission Service.
Filed Date: 06/30/2010.
Accession Number: 20100701–0201.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 21, 2010.

Docket Numbers: ER10–1665–000.
Applicants: Xcel Energy Services Inc.
Description: Public Service Company of Colorado submits an informational filing re the Letter of Agreement.
Filed Date: 06/30/2010.
Accession Number: 20100701–0202.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 21, 2010.

Docket Numbers: ER10–1666–000.
Applicants: Midwest Independent Transmission System Operator, Inc.
Description: Midwest Independent Transmission System Operator, Inc. submits proposed revisions to its Open Access Transmission, Energy and Operating Reserve Markets Tariff to be effective 9/1/10.
Filed Date: 06/30/2010.
Accession Number: 20100701–0204.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 21, 2010.

Docket Numbers: ER10–1667–000.
Applicants: Southwest Power Pool, Inc.
Description: Southwest Power Pool, Inc. submits two executed service agreements for Firm Point-to-Point Transmission Service with Kansas City Power & Light Company *etc.*
Filed Date: 06/30/2010.
Accession Number: 20100701–0203.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 21, 2010.

Docket Numbers: ER10–1668–000.
Applicants: Midwest Independent Transmission System Operator, Inc.
Description: Midwest Independent Transmission System Operator, Inc submits proposed revisions to its Open Access Transmission, Energy and Operating Reserve Market Tariff *etc.*
Filed Date: 06/30/2010.
Accession Number: 20100701–0239.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 21, 2010.

Docket Numbers: ER10–1669–000.
Applicants: Cleco Power LLC.
Description: Cleco Power LLC submits a Service Agreement for Network Integration Transmission Service with Entergy Gulf States Louisiana LL *etc.*
Filed Date: 06/30/2010.
Accession Number: 20100701–0205.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 21, 2010.

Docket Numbers: ER10–1670–000.
Applicants: North Western Energy.
Description: North Western Corporation submits Clean and Redlined Version of Third Revised Sheet 25 *et al* to their Rate Schedule FERC 188 *etc.*
Filed Date: 06/30/2010.
Accession Number: 20100701–0206.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 21, 2010.

Docket Numbers: ER10–1671–000.
Applicants: RRI Energy Services, Inc.
Description: RRI Energy Services, Inc. submits tariff filing per 35.12: Baseline Filing to be effective 8/1/2010.
Filed Date: 07/01/2010.
Accession Number: 20100701–5045.
Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1672–000.
Applicants: Old Dominion Electric Cooperative.
Description: Old Dominion Electric Cooperative submits an executed Mutual Operating Agreement, designated as Original Service Agreement 2542.
Filed Date: 07/01/2010.
Accession Number: 20100701–0248.
Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1673–000.
Applicants: Synergics Roth Rock North Wind Energy, LLC.
Description: Synergics Roth Rock North Wind Energy, LLC submits an application for authorization to sell energy and capacity in wholesale transactions at negotiated, market-based rates.
Filed Date: 07/01/2010.
Accession Number: 20100701–0249.
Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1675–000.
Applicants: Wisconsin Electric Power Company.
Description: Wisconsin Electric Power Company submits Notice of Termination of FERC Electric Tariff, Original Volume 9, Service Agreement 1.
Filed Date: 07/01/2010.
Accession Number: 20100701–0275.
Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1676–000.
Applicants: Entergy Services, Inc.
Description: Entergy submits amendments to Service Schedule MSS–3 and Service Schedule MSS–4 of Entergy System Agreement.
Filed Date: 06/30/2010.
Accession Number: 20100701–0253.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 21, 2010.

Docket Numbers: ER10–1677–000.
Applicants: Midwest Independent Transmission System Operator, Inc.
Description: Midwest Independent Transmission System Operator, Inc. submits proposed amendments to its Open Access Transmission, Energy and Operating Reserve Markets Tariff.
Filed Date: 07/01/2010.
Accession Number: 20100701–0225.
Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1678–000.
Applicants: Berkshire Power Company, LLC.
Description: Berkshire Power Company, LLC submits Notice of Cancellation of its Rate Schedule FERC No 2.
Filed Date: 07/01/2010.
Accession Number: 20100701–0224.
Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1679–000.
Applicants: Allegheny Power.
Description: Allegheny Power *et al.* submits revised Interconnection Agreement dated as of 8/26/09 designated as First Revised Service Agreement 2149 to FERC Electric Tariff, 6R1.
Filed Date: 07/01/2010.
Accession Number: 20100701–0223.
Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1680–000.
Applicants: Ally Energy, LLC.
Description: Ally Energy, LLC submits Application for Market-Based Rate Authorization, Designation of Category 1 Status, and Request for Waivers and Blanket Approvals.
Filed Date: 07/01/2010.
Accession Number: 20100701–0222.
Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1681–000.
Applicants: Allegheny Energy Service Corporation.
Description: Allegheny Energy Service Corporation submits revised Borderline Interchange Agreement with Virginia Electric and Power Company *etc.*
Filed Date: 07/01/2010.
Accession Number: 20100701–0221.
Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1682–000.
Applicants: Virginia Electric and Power Company.
Description: Dominion Virginia Power submits revised and executed Mutual Operating Agreement with Old Dominion Electric Cooperative.
Filed Date: 07/01/2010.
Accession Number: 20100701–0220.
Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1683–000.
Applicants: Virginia Electric and Power Company.
Description: Virginia Electric and Power Company submits tariff filing per 35.13(a)(2)(iii): VEPCO—Third Revised Rate Schedule FERC No. 122 to be effective 6/30/2010.
Filed Date: 07/01/2010.
Accession Number: 20100701–5102.
Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1684–000.
Applicants: Southwest Power Pool, Inc.
Description: Southwest Power Pool, Inc. submits an executed Service Agreement for Network Integration Transmission Service with Kansas City Power *etc.*
Filed Date: 07/01/2010.
Accession Number: 20100701–0229.
Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1685–000.
Applicants: Southwest Power Pool, Inc.
Description: Southwest Power Pool, Inc. submits an executed Service Agreement for Network Integration Transmission Service with Grand River Dam Authority *etc.*
Filed Date: 07/01/2010.
Accession Number: 20100701–0228.
Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1686–000.
Applicants: Southwest Power Pool, Inc.
Description: Southwest Power Pool, Inc. submits an executed Service Agreement for Network Integration Transmission Service.
Filed Date: 07/01/2010.
Accession Number: 20100701–0230.
Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1687–000.
Applicants: Southwest Power Pool, Inc.
Description: Southwest Power Pool, Inc. submits notice of cancellation of the Meter Agent Services Agreement with Kansas Power Pool *etc.*
Filed Date: 07/01/2010.
Accession Number: 20100701–0227.
Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1688–000.
Applicants: Southwest Power Pool, Inc.
Description: Southwest Power Pool, Inc. submits First Revised Service Agreement 1822, First Revised Volume No. 1.
Filed Date: 07/01/2010.
Accession Number: 20100701–0265.
Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1689–000.
Applicants: Southwest Power Pool, Inc.
Description: Southwest Power Pool, Inc. submits Tenth Revised Service Agreement 1166, Fifth Revised Volume 1.
Filed Date: 07/01/2010.
Accession Number: 20100701–0264.
Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1690–000.
Applicants: ISO New England Inc.
Description: ISO New England submits FERC Electric Tariff No. 3, 2nd Revised Sheet 7303.
Filed Date: 07/01/2010.
Accession Number: 20100701–0263.
Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1691–000.
Applicants: Southwest Power Pool, Inc.
Description: Southwest Power Pool, Inc. submits First Revised Service Agreement 1534, Fifth Revised Volume No. 1.
Filed Date: 07/01/2010.
Accession Number: 20100701–0262.
Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Take notice that the Commission received the following public utility holding company filings:
Docket Numbers: PH10–7–001.
Applicants: BlackRock, Inc.
Description: Notification of Material Change in Facts of BlackRock, Inc.
Filed Date: 06/28/2010.
Accession Number: 20100628–5221.
Comment Date: 5 p.m. Eastern Time on Monday, July 19, 2010.

Take notice that the Commission received the following electric reliability filings:
Docket Numbers: RR06–1–024; RR07–8–004; RR07–8–005.
Applicants: North American Electric Reliability Corporation.
Description: North American Electric Reliability Corporation, on behalf of itself and FRCC, submits a compliance filing in response to Paragraphs 127 and 128 of the December 19, 2008 Order.
Filed Date: 06/30/2010.
Accession Number: 20100630–5113.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 21, 2010.

Docket Numbers: RR07–3–004; RR07–3–005; RR06–1–025.
Applicants: North American Electric Reliability Corporation.
Description: North American Electric Reliability Corporation, on behalf of itself and NPCC, submits a compliance filing in response to Paragraph 94 of the December 19, 2008 Order.
Filed Date: 06/30/2010.
Accession Number: 20100630–5111.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 21, 2010.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that

document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St. NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2010–17148 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

July 6, 2010.

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC10–78–000.

Applicants: Sierra Pacific Power Company, California Pacific Electric Company, LLC.

Description: California Pacific Electric Company, LLC submits joint application for authorization for disposition of jurisdictional assets under Section 203 of the Federal Power Act and Request for privileged treatment.

Filed Date: 07/02/2010.

Accession Number: 20100706–0205.

Comment Date: 5 p.m. Eastern Time on Friday, July 23, 2010.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER94–1384–039; ER00–1803–009; ER01–457–010; ER02–1485–012; ER03–1108–012; ER03–1109–012; ER04–733–008; ER08–1432–006; ER99–2329–010.

Applicants: Morgan Stanley Capitol Group Inc., Naniwa Energy LLC, Power Contract Finance, L.L.C., South Eastern Generating Corporation, South Eastern Electric Development Corp, Utility Contract Funding II, LLC, MS Solar Solutions Corp., Power Contract Financing II, L.L.C., Power Contract Financing II, Inc.;

Description: Morgan Stanley Capital Group Inc., et. al. Notice of Change in Status.

Filed Date: 07/01/2010.

Accession Number: 20100701–5183.

Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER96–780–029; ER00–3240–019; ER01–1633–016.

Applicants: Southern Company Services, Inc.; Oleander Power Project, L.P.; Southern Company—Florida LLC.

Description: Notification of Non-Material Change in Status re Market-Based Rate Tariff Authority of Southern Company Services, Inc.

Filed Date: 06/30/2010.

Accession Number: 20100630–5227.

Comment Date: 5 p.m. Eastern Time on Wednesday, July 21, 2010.

Docket Numbers: ER98–1643–018.

Applicants: Portland General Electric Company.

Description: Portland General Electric Company submits their triennial market power analysis.

Filed Date: 06/29/2010.

Accession Number: 20100630–0211.

Comment Date: 5 p.m. Eastern Time on Monday, August 30, 2010.

Docket Numbers: ER01–48–016.

Applicants: Powerex Corp.

Description: Powerex Corp submits an errata to its December 11, 2009 notice of change in status.

Filed Date: 06/24/2010.

Accession Number: 20100625–0205.

Comment Date: 5 p.m. Eastern Time on Thursday, July 15, 2010.

Docket Numbers: ER06–560–009.

Applicants: Credit Suisse Energy LLC.

Description: Credit Suisse Energy LLC Notice of Non-Material Change in Status.

Filed Date: 07/02/2010.

Accession Number: 20100702–5140.

Comment Date: 5 p.m. Eastern Time on Friday, July 23, 2010.

Docket Numbers: ER06–747–003.

Applicants: Equilon Enterprises LLC.

Description: Equilon Enterprises LLC US submits an updated market power analysis for the Southwest Region in compliance with the requirements of Section 205 of the FPA.

Filed Date: 06/29/2010.

Accession Number: 20100630–0201.

Comment Date: 5 p.m. Eastern Time on Monday, August 30, 2010.

Docket Numbers: ER07–1106–010; ER07–751–003; ER97–4084–012.

Applicants: ArcLight Energy Marketing, LLC, Denver City Energy Associates LP, Lea Power Partners, LLC.

Description: ArcLight Energy Marketing, LLC, *et al.,* Notice of Non-Material Change in Status.

Filed Date: 07/02/2010.

Accession Number: 20100702–5056.

Comment Date: 5 p.m. Eastern Time on Friday, July 23, 2010.

Docket Numbers: ER09–1196–002.

Applicants: Lost Creek Wind, LLC.

Description: Notice of Change in Status of Lost Creek Wind, LLC.

Filed Date: 06/29/2010.

Accession Number: 20100629–5202.

Comment Date: 5 p.m. Eastern Time on Tuesday, July 20, 2010.

Docket Numbers: ER10–1313–001.

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc submits an executed Meter Agent Services Agreement.

Filed Date: 07/01/2010.

Accession Number: 20100702–0206.

Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1357–001.

Applicants: Southern California Edison Company.

Description: Southern California Edison Company submits tariff filing per 35.17(b): TOT_Amendment_070110 to be effective 6/1/2010.

Filed Date: 07/02/2010.

Accession Number: 20100702–5058.

Comment Date: 5 p.m. Eastern Time on Friday, July 23, 2010.

Docket Numbers: ER10–1655–001; ER06–1143–005.

Applicants: MATEP LLC, MATEP Limited Partnership.

Description: Notice of Change in Status and Compliance Filing of MATEP LLC and MATEP LP.

Filed Date: 07/01/2010.

Accession Number: 20100701–5188.

Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1567–000.

Applicants: Consolidated Edison Company of New York,

Description: Consolidated Edison Company of New York, Inc. submits an

amendment to Con Edison's Delivery Service Rate Schedule 96.

Filed Date: 06/28/2010.

Accession Number: 20100628–0218.

Comment Date: 5 p.m. Eastern Time on Monday, July 19, 2010.

Docket Numbers: ER10–1638–000.

Applicants: Public Service Electric and Gas Company.

Description: Public Service Electric and Gas Company submits tariff filing per: Submittal of revised transmittal letter to be effective N/A.

Filed Date: 07/06/2010.

Accession Number: 20100706–5043.

Comment Date: 5 p.m. Eastern Time on Tuesday, July 27, 2010.

Docket Numbers: ER10–1693–000.

Applicants: New York State Electric & Gas Corp.

Description: New York State Electric & Gas Corporation submits filing to cancel its Open Access Transmission Tariff.

Filed Date: 07/01/2010.

Accession Number: 20100702–0208.

Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1694–000.

Applicants: Rochester Gas & Electric Corporation.

Description: Rochester Gas and Electric Corporation submits filing to cancel its Open Access Transmission Tariff.

Filed Date: 07/01/2010.

Accession Number: 20100702–0209.

Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1695–000.

Applicants: Entergy Services, Inc.

Description: Entergy Gulf States Louisiana, LLC submits an executed Amended and Restated Wholesale Power Sales Service Agreement with City of Jasper.

Filed Date: 07/01/2010.

Accession Number: 20100702–0210.

Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1696–000.

Applicants: Midwest Independent Transmission System Operator, Inc.

Description: Midwest Independent Transmission System Operator, Inc submits a proposed amendment to Module B of its Open Access Transmission, Energy and Operating Reserve Markets Tariff.

Filed Date: 07/01/2010.

Accession Number: 20100702–0211.

Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1697–000.

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc. submits an executed Service Agreement for Network Integration Transmission Service.

Filed Date: 07/01/2010.

Accession Number: 20100702–0212.

Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1698–000.

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc. submits an executed Service Agreement for Network Integration Transmission Service with City of Lindsborg etc.

Filed Date: 07/01/2010.

Accession Number: 20100702–0213.

Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1699–000.

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc. submits an executed Service Agreement for Network Integration Transmission Service with Westar Energy etc.

Filed Date: 07/01/2010.

Accession Number: 20100702–0214.

Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1700–000.

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc. submits an executed Service Agreement for network Integration Transmission Service.

Filed Date: 07/01/2010.

Accession Number: 20100702–0216.

Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1701–000.

Applicants: Ameren Services Company.

Description: Illinois Power Company *et al.* submits Transmission Upgrade Agreement with Exelon Generation Company, LLC etc.

Filed Date: 07/01/2010.

Accession Number: 20100702–0215.

Comment Date: 5 p.m. Eastern Time on Thursday, July 22, 2010.

Docket Numbers: ER10–1702–000.

Applicants: Orion Power Midwest, L.P.

Description: Orion Power Midwest, L.P. submits tariff filing per 35.12: Baseline Filing to be effective 8/1/2010.

Filed Date: 07/02/2010.

Accession Number: 20100702–5028.

Comment Date: 5 p.m. Eastern Time on Friday, July 23, 2010.

Docket Numbers: ER10–1703–000.

Applicants: California Pacific Electric Company, LLC.

Description: California Pacific Electric Company, LLC submits tariff filing per 35.12: Emergency Backup Service Agreement and Borderline Customer Agreement to be effective 12/31/1998.

Filed Date: 07/02/2010.

Accession Number: 20100702–5059.

Comment Date: 5 p.m. Eastern Time on Friday, July 23, 2010.

Docket Numbers: ER10–1704–000.

Applicants: Xcel Energy Services Inc.

Description: Public Service Company of Colorado submits proposed Engineering and Procurement Agreement with Tri-State Generation and Transmission Association, Inc.

Filed Date: 07/02/2010.

Accession Number: 20100702–0221.

Comment Date: 5 p.m. Eastern Time on Friday, July 23, 2010.

Docket Numbers: ER10–1705–000.

Applicants: Starion Energy NY, Inc.

Description: Starion Energy NY submits Petition for Acceptance of Initial Tariff, Waivers and Blanket Authorization.

Filed Date: 07/02/2010.

Accession Number: 20100702–0222.

Comment Date: 5 p.m. Eastern Time on Friday, July 23, 2010.

Docket Numbers: ER10–1706–000.

Applicants: California Independent System Operator Corporation.

Description: California Independent System Operator Corporation submits tariff filing per 35.13(a)(2)(iii): 2010–07–02—IRRP Amendment to be effective 7/3/2010.

Filed Date: 07/02/2010.

Accession Number: 20100702–5101.

Comment Date: 5 p.m. Eastern Time on Friday, July 23, 2010.

Docket Numbers: ER10–1707–000.

Applicants: Hess Corporation.

Description: Hess Corporation submits tariff filing per 35.12: Hess FERC Electric Rate Schedule No. 1 to be effective 7/2/2010.

Filed Date: 07/02/2010.

Accession Number: 20100702–5134.

Comment Date: 5 p.m. Eastern Time on Friday, July 23, 2010.

Docket Numbers: ER10–1708–000.

Applicants: Select Energy New York, Inc.

Description: Select Energy New York, Inc. submits tariff filing per 35.12: Select Energy FERC Electric Rate Schedule No. 1 to be effective 7/2/2010.

Filed Date: 07/02/2010.

Accession Number: 20100702–5135.

Comment Date: 5 p.m. Eastern Time on Friday, July 23, 2010.

Docket Numbers: ER10–1713–000.

Applicants: RRI Energy Mid-Atlantic Power Holdings,

Description: RRI Energy Mid-Atlantic Power Holdings, LLC submits tariff filing per 35.12: Baseline Filing to be effective 8/1/2010.

Filed Date: 07/06/2010.

Accession Number: 20100706–5055.

Comment Date: 5 p.m. Eastern Time on Tuesday, July 27, 2010.

Docket Numbers: ER10–1714–000.

Applicants: LG&E Energy Marketing Inc.

Description: LG&E Energy Marketing Inc. submits tariff filing per 35.12: LEM Energy Marketing Baseline to be effective 7/7/2010.

Filed Date: 07/06/2010.

Accession Number: 20100706–5061.

Comment Date: 5 p.m. Eastern Time on Tuesday, July 27, 2010.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES10–46–000.

Applicants: Golden Spread Electric Cooperative, Inc.

Description: Amendment to Application of Golden Spread Electric Cooperative, Inc.

Filed Date: 07/02/2010.

Accession Number: 20100702–5141.

Comment Date: 5 p.m. Eastern Time on Monday, July 12, 2010.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

As it relates to any qualifying facility filings, the notices of self-certification [or self-recertification] listed above, do not institute a proceeding regarding qualifying facility status. A notice of self-certification [or self-recertification] simply provides notification that the entity making the filing has determined the facility named in the notice meets the applicable criteria to be a qualifying facility. Intervention and/or protest do not lie in dockets that are qualifying facility self-certifications or self-recertifications. Any person seeking to challenge such qualifying facility status may do so by filing a motion pursuant to 18 CFR 292.207(d)(iii). Intervention and protests may be filed in response to notices of qualifying facility dockets other than self-certifications and self-recertifications.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2010–17147 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

July 7, 2010.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER04–1181–006; ER04–1182–006; ER04–1184–006; ER04–1186–007.

Applicants: KGen Hot Spring LLC, KGEN Sandersville LLC, KGen Hinds LLC, KGen Murray I and II LLC.

Description: Notice of Change in Status of KGen Hinds LLC, *et al.*

Filed Date: 07/06/2010.

Accession Number: 20100706–5208.

Comment Date: 5 p.m. Eastern Time on Tuesday, July 27, 2010.

Docket Numbers: ER10–1231–001.

Applicants: Detroit Edison Company.

Description: Detroit Edison Company submits revised unexecuted service agreement.

Filed Date: 07/06/2010.

Accession Number: 20100706–0216.

Comment Date: 5 p.m. Eastern Time on Tuesday, July 13, 2010.

Docket Numbers: ER10–1559–000.

Applicants: California Independent System Operator Corporation.

Description: The California Independent System Operator Corporation submits revisions to its tariff necessary to implement convergence bidding in the ISO's markets.

Filed Date: 06/25/2010.

Accession Number: 20100628–0212.

Comment Date: 5 p.m. Eastern Time on Friday, July 16, 2010.

Docket Numbers: ER10–1674–000.

Applicants: Deseret Generation & Transmission Co-operative, Inc.

Description: Deseret Generation & Transmission Co-operative, Inc. submits tariff filing per 35.37: Triennial Market Power Update to be effective 7/1/2010.

Filed Date: 07/01/2010.

Accession Number: 20100701–5072.

Comment Date: 5 p.m. Eastern Time on Monday, August 30, 2010.

Docket Numbers: ER10–1692–000.

Applicants: California Independent System Operator Corporation.

Description: California Independent System Operator Corporation submits tariff filing per 35.13(a)(2)(iii): 2010–07–02 CAISO CRR Credit Enhancement Amendment to be effective 9/1/2010.

Filed Date: 07/02/2010.

Accession Number: 20100702–5010.

Comment Date: 5 p.m. Eastern Time on Friday, July 23, 2010.

Docket Numbers: ER10–1709–000.

Applicants: Sierra Pacific Power Company.

Description: Sierra Pacific Power Company submits an executed Borderline Customer Agreement with California Pacific Electric Company, LLC dated 10/8/09.

Filed Date: 07/02/2010.

Accession Number: 20100706–0212.

Comment Date: 5 p.m. Eastern Time on Friday, July 23, 2010.

Docket Numbers: ER10–1710–000.

Applicants: Vista Energy Marketing, LP.

Description: Vista Energy Marketing submits Notice of Cancellation of its Rate Schedule FERC No. 1.

Filed Date: 07/02/2010.

Accession Number: 20100706–0210.

Comment Date: 5 p.m. Eastern Time on Friday, July 23, 2010.

Docket Numbers: ER10–1711–000.

Applicants: Duke Energy Carolinas, LLC.

Description: Duke Energy Carolinas, LLC submits Eleventh Amendment to the Revised and Restated Interconnection Agreement with North Carolina Electric Membership Corporation *et al.*

Filed Date: 07/02/2010.

Accession Number: 20100706–0209.

Comment Date: 5 p.m. Eastern Time on Friday, July 23, 2010.

Docket Numbers: ER10–1712–000.

Applicants: Sierra Pacific Power Company.

Description: Sierra Pacific Power Company submits an executed Interconnection Agreement with California Pacific Electric Company, LLC dated 10/8/09.

Filed Date: 07/02/2010.

Accession Number: 20100706–0211.

Comment Date: 5 p.m. Eastern Time on Friday, July 23, 2010.

Docket Numbers: ER10–1715–000.

Applicants: Wisconsin Public Service Corporation.

Description: Wisconsin Public Service Corporation submits revised page to Exhibit 2–H to its Agreement dated July 18, 2007 with the City of Marshfield.

Filed Date: 07/06/2010.

Accession Number: 20100706–0208.

Comment Date: 5 p.m. Eastern Time on Tuesday, July 27, 2010.

Docket Numbers: ER10–1716–000.

Applicants: East Coast Power & Gas, LLC.

Description: East Coast Power and Gas, LLC submits Petition for Acceptance of Initial Tariff, Waivers and Blanket Authorization.

Filed Date: 07/06/2010.

Accession Number: 20100706–0207.

Comment Date: 5 p.m. Eastern Time on Tuesday, July 27, 2010.

Docket Numbers: ER10–1717–000.

Applicants: PJM Interconnection, LLC.

Description: PJM Interconnection, LLC submits revisions to the Amended and Restated Operating Agreement of PJM's Schedule 1 and the Open Access Transmission Tariff Attachment K Appendix.

Filed Date: 07/06/2010.

Accession Number: 20100706–0213.

Comment Date: 5 p.m. Eastern Time on Tuesday, July 27, 2010.

Docket Numbers: ER10–1718–000.

Applicants: Northern States Power Company.

Description: Northern States Power Company submits an unexecuted version of a Transmission Capacity Exchange Agreement, FERC Electric Rate Schedule Original Volume 1.

Filed Date: 07/06/2010.

Accession Number: 20100706–0214.

Comment Date: 5 p.m. Eastern Time on Tuesday, July 27, 2010.

Docket Numbers: ER10–1719–000.

Applicants: Sierra Pacific Power Company.

Description: Sierra Pacific Power Company submits a Rate Schedule FERC 55, which is a consolidated version of an executed power service agreement.

Filed Date: 07/02/2010.

Accession Number: 20100706–0218.

Comment Date: 5 p.m. Eastern Time on Friday, July 23, 2010.

Docket Numbers: ER10–1720–000.

Applicants: Dry Lake Wind Power II LLC.

Description: Dry Lake Wind Power II LLC submits tariff filing per 35.12: 20100706_initial tariff to be effective 9/4/2010.

Filed Date: 07/06/2010.

Accession Number: 20100706–5093.

Comment Date: 5 p.m. Eastern Time on Tuesday, July 27, 2010.

Docket Numbers: ER10–1721–000.

Applicants: Wabash Valley Power Association, Inc.

Description: Wabash Valley Power Association, Inc. submits tariff filing per 35.12: WVPA Baseline Formulary Rate Tariff to be effective 7/6/2010.

Filed Date: 07/06/2010.

Accession Number: 20100706–5105.

Comment Date: 5 p.m. Eastern Time on Tuesday, July 27, 2010.

Docket Numbers: ER10–1722–000.

Applicants: New York Independent System Operator, Inc.

Description: New York Independent System Operator, Inc. submits tariff filing per to Order 719 Compliance Filing—Schnell (Hunton), to be effective 7/6/2010.

Filed Date: 07/07/2010.

Accession Number: 20100707–5000.

Comment Date: 5 p.m. Eastern Time on Wednesday, July 28, 2010.

Docket Numbers: ER10–1723–000.

Applicants: Wisconsin Electric Power Company.

Description: Wisconsin Electric Power Company submits tariff revisions to its Formula Rate Wholesale Sales Tariff, effective 9/1/10.

Filed Date: 07/06/2010.

Accession Number: 20100707–0201.

Comment Date: 5 p.m. Eastern Time on Tuesday, July 27, 2010.

Docket Numbers: ER10–1724–000.

Applicants: Wisconsin Electric Power Company.

Description: Wisconsin Electric Power Company submits tariff revisions to the Restated Power Service Agreement between WE and WPPI Energy, effective 9/1/10.

Filed Date: 07/06/2010.

Accession Number: 20100707–0202.

Comment Date: 5 p.m. Eastern Time on Tuesday, July 27, 2010.

Docket Numbers: ER10–1725–000.

Applicants: Hardscrabble Wind Power LLC.

Description: Hardscrabble Wind Power LLC submits tariff filing per 35.12: 20100707_initial tariff to be effective 9/5/2010.

Filed Date: 07/07/2010.

Accession Number: 20100707–5055.

Comment Date: 5 p.m. Eastern Time on Wednesday, July 28, 2010.

Docket Numbers: ER10–1726–000.

Applicants: RRI Energy Wholesale Generation, LLC.

Description: RRI Energy Wholesale Generation, LLC submits tariff filing per 35.12: Baseline Filing to be effective 8/1/2010.

Filed Date: 07/07/2010.

Accession Number: 20100707–5072.

Comment Date: 5 p.m. Eastern Time on Wednesday, July 28, 2010.

Take notice that the Commission received the following open access transmission tariff filings:

Docket Numbers: OA10–11–000.

Applicants: Avista Corporation.

Description: Avista Corporation submits revisions to its Open Access Transmission Tariff.

Filed Date: 07/06/2010.

Accession Number: 20100706–0217.

Comment Date: 5 p.m. Eastern Time on Tuesday, July 27, 2010.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

As it relates to any qualifying facility filings, the notices of self-certification [or self-recertification] listed above, do not institute a proceeding regarding qualifying facility status. A notice of self-certification [or self-recertification] simply provides notification that the entity making the filing has determined the facility named in the notice meets the applicable criteria to be a qualifying facility. Intervention and/or protest do

not lie in dockets that are qualifying facility self-certifications or self-recertifications. Any person seeking to challenge such qualifying facility status may do so by filing a motion pursuant to 18 CFR 292.207(d)(iii). Intervention and protests may be filed in response to notices of qualifying facility dockets other than self-certifications and self-recertifications.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St. NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2010–17149 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

July 2, 2010.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER98–1796–013; ER98–1127–014; ER97–4281–022; ER10–574–002; ER10–204–003; ER07–486–005; ER07–1406–005; ER07–649–004; ER99–1115–014; ER99–1116–014.

Applicants: EL Segundo Power II LLC, Long Beach Generation LLC, Long Beach Peakers LLC, NRG Power Marketing LLC, Cabrillo Power I LLC, Cabrillo Power II LLC, El Segundo Power LLC, NRG Solar Blythe LLC, Saguaro Power Company, A Limited Partner.

Description: Updated Market Power Analysis of NRG Southwest MBR Entities.

Filed Date: 06/30/2010.

Accession Number: 20100630–5219.

Comment Date: 5 p.m. e.t. on Monday, August 30, 2010.

Docket Numbers: ER98–2640–034; ER98–4590–032.

Applicants: Northern States Power Companies; Public Service Company of Colorado.

Description: Public Service Company of Colorado submits Triennial Market Power Analysis and change-in-status report.

Filed Date: *06/30/2010.*

Accession Number: 20100701–0208.

Comment Date: 5 p.m. e.t. on Monday, August 30, 2010.

Docket Numbers: ER98–3184–012; ER00–494–006.

Applicants: TransAlta Energy Marketing (U.S.) Inc.; TransAlta Centralia Generation LLC

Description: TransAlta Entities submits letter requesting that the Commission issue an order classifying as Category 1 Seller in all regions.

Filed Date: 06/30/2010.

Accession Number: 20100701–0246.

Comment Date: 5 p.m. e.t on Wednesday, July 21, 2010.

Docket Numbers: ER00–1814–012; ER98–4336–016; ER99–1435–024.

Applicants: Avista Corporation; Avista Turbine Power, Inc.; Spokane Energy, LLC.

Description: Avista Corporation *et al.* submits their triennial market power study.

Filed Date: 06/30/2010.

Accession Number: 20100701–0211.

Comment Date: 5 p.m. e.t. on Monday, August 30, 2010.

Docket Numbers: ER00–2469–006.

Applicants: Williams Flexible Generation, LLC.

Description: Application for Finding as a Category 1 Seller of Williams Flexible Generation, LLC.

Filed Date: 06/30/2010.

Accession Number: 20100630–5217.

Comment Date: 5 p.m. e.t. on Wednesday, July 21, 2010.

Docket Numbers: ER00–2815–002.

Applicants: Wheelabrator Shasta Energy Company Inc.

Description: Wheelabrator Shasta Energy Company Inc. submits request for Category 1 Seller Classification pursuant to the requirements of § 35.36 of the regulations of FERC.

Filed Date: 06/30/2010.

Accession Number: 20100630–0232.

Comment Date: 5 p.m. e.t. on Wednesday, July 21, 2010.

Docket Numbers: ER00–3614–014; ER00–443–002; ER08–337–007.

Applicants: BP Energy Company, BP West Coast Products LLC, Watson Cogeneration Company.

Description: Updated Market Power Analysis for Southwest Region of BP Energy Co., Watson Cogeneration Company, and BP West Coast Products, LLC.

Filed Date: 06/30/2010.

Accession Number: 20100630–5039.

Comment Date: 5 p.m. e.t. on Monday, August 30, 2010.

Docket Numbers: ER01–1270–014; ER01–1278–014; ER02–1213–012.

Applicants: Mirant Delta LLC; Mirant Potrero LLC; Mirant Energy Trading LLC;

Description: Mirant Entities submits their joint triennial market power filing.

Filed Date: 06/30/2010.

Accession Number: 20100701–0242.

Comment Date: 5 p.m. e.t. on Monday, August 30, 2010.

Docket Numbers: ER02–1695–008; ER02–2309–007.

Applicants: Cabazon Wind Partners, LLC; Whitewater Hill Wind Partners, LLC.

Description: Cabazon Wind Partners, LLC et al submits updated market power analysis and the revised regional review schedule set forth in Order No 697–C.

Filed Date: 06/30/2010.

Accession Number: 20100701–0207.

Comment Date: 5 p.m. e.t. on Monday, August 30, 2010.

Docket Numbers: ER03–155–012; ER03–179–011; ER04–947–011; ER04–127–010; ER05–222–009; ER02–2018–013; ER09–832–010; ER09–902–005; ER09–901–005; ER09–900–005.

Applicants: POSDEF Power Company, LP; FPL Energy Green Power Wind, LLC; Diablo Winds, LLC; High Winds, LLC; FPL Energy New Mexico Wind, LLC; Blythe Energy, LLC; NextEra Energy Power Marketing, LLC; FPL Energy Cabazon Wind, LLC; Sky River LLC; Victory Garden Phase IV, LLC.

Description: NextEra Companies Southwest Triennial Market Power Update and Request for Waiver.

Filed Date: 06/30/2010.

Accession Number: 20100630–5221.

Comment Date: 5 p.m. e.t. on Monday, August 30, 2010.

Docket Numbers: ER03–342–011; ER03–24–012; ER02–2227–013; ER02–2229–012; ER02–600–014; ER05–67–009; ER05–68–009; ER06–755–009; ER06–756–009; ER99–1983–012; ER01–2887–013; ER01–2688–016

Applicants: Calpine Power America—CA, LLC; Los Esteros Critical Energy Facility LLC; Creed Energy Center, LLC; Goose Haven Energy Center, LLC; Delta Energy Center, LLC; Metcalf Energy Center, LLC; Pastoria Energy Center, LLC; Calpine Gilroy Cogen, L.P.; Los Medanos Energy Center LLC; Geysers Power Company LLC; South Point Energy Center, LLC; Gilroy Energy Center, LLC.

Description: Order 697–A compliance filing re Calpine Applicants.

Filed Date: 06/30/2010.

Accession Number: 20100701–0241.

Comment Date: 5 p.m. e.t. on Wednesday, July 21, 2010.

Docket Numbers: ER05–1178–015; ER09–838–001.

Applicants: Gila River Power LP, Entegra Power Services LLC.

Description: Gila River Power, L.P. and Entegra Power Services, LLC submit Updated Market Power Analysis for Continued Market-Based Rate Authority.

Filed Date: 06/30/2010.

Accession Number: 20100630–5148.

Comment Date: 5 p.m. e.t. on Monday, August 30, 2010.

Docket Numbers: ER05–1232–027; ER07–1113–014; ER09–335–009.

Applicants: J.P. Morgan Ventures Energy Corporation, BE CA LLC.

Description: Updated Market Power Analysis of J.P. Morgan Ventures Energy Corporation and BE CA LLC.

Filed Date: 06/30/2010.

Accession Number: 20100630–5124.

Comment Date: 5 p.m. e.t. on Monday, August 30, 2010.

Docket Numbers: ER06–736–004.

Applicants: Midway Sunset Cogeneration Company.

Description: Updated Market Power Analysis for the Southwest Region of Midway Sunset Cogeneration Company.

Filed Date: 06/30/2010.

Accession Number: 20100630–5224.

Comment Date: 5 p.m. e.t. on Monday, August 30, 2010.

Docket Numbers: ER06–1331–006; ER01–2545–008; ER01–2544–008; ER01–2543–008; ER01–2546–008; ER01–2547–008; ER03–1182–009.

Applicants: CalPeak Power LLC, CalPeak Power—Panoche LLC, CalPeak Power—Vaca Dixon LLC, CalPeak Power—El Cajon LLC, CalPeak Power—Enterprise LLC, CalPeak Power—Border LLC, Tyr Energy LLC.

Description: Updated Market Power Analysis of CalPeak Entities and Tyr Energy, LLC.

Filed Date: 06/30/2010.

Accession Number: 20100630–5218.

Comment Date: 5 p.m. e.t. on Monday, August 30, 2010.

Docket Numbers: ER07–1000–007.

Applicants: Las Vegas Power Company, LLC.

Description: Order 697–A compliance filing re Las Vegas Power Company, LLC.

Filed Date: 06/30/2010.

Accession Number: 20100701–0247.

Comment Date: 5 p.m. e.t. on Wednesday, July 21, 2010.

Docket Numbers: ER07–1106–008.

Applicants: ArcLight Energy Marketing, LLC.

Description: Updated Market Power Analysis of ArcLight Energy Marketing, LLC.

Filed Date: 06/30/2010.

Accession Number: 20100630–5082.

Comment Date: 5 p.m. e.t. on Monday, August 30, 2010.

Docket Numbers: ER08–656–008.

Applicants: Shell Energy North America (US), L.P.

Description: Updated Market Power Analysis for the Southwest Region of Shell Energy North America (US), L.P.

Filed Date: 06/30/2010.

Accession Number: 20100630–5222.

Comment Date: 5 p.m. e.t. on Monday, August 30, 2010.

Docket Numbers: ER08–110–000.

Applicants: Starwood Power-Midway, LLC.

Description: Updated Market Power Analysis of Starwood Power-Midway, LLC.

Filed Date: 06/30/2010.

Accession Number: 20100630–5174.

Comment Date: 5 p.m. e.t. on Monday, August 30, 2010.

Docket Numbers: ER08–912–012; ER09–1723–008; ER05–1146–024; ER07–460–014; ER04–94–024.

Applicants: Iberdrola Renewables; Dry Lake Wind Power, LLC; Shiloh I Wind Project LLC; Dillon Wind LLC; Mountain View Power Partners III. LLC.

Description: Iberdrola Renewables, Inc. *et al.* submits notifications of and requests for Category 1 Seller classification.

Filed Date: 06/30/2010.

Accession Number: 20100701–0240.

Comment Date: 5 p.m. e.t. on Wednesday, July 21, 2010.

Docket Numbers: ER09–1388–001.

Applicants: Vermont Transco, LLC.

Description: Vermont Transco, LLC submits updated Exhibit A to its FERC Rate Schedule No 1, effective 7/1/2010.

Filed Date: 06/30/2010.

Accession Number: 20100630–0240.

Comment Date: 5 p.m. e.t. on Wednesday, July 21, 2010.

Docket Numbers: ER10–566–001; ER08–1255–003.

Applicants: oso Geothermal Power Holdings, LLC; Oak Creek Wind Power, LLC.

Description: Coso Geothermal Power Holdings, LLC et al submits updated market power analysis in compliance with the requirements of section 35.37 of the regulations of the FERC etc.

Filed Date: 06/30/2010.

Accession Number: 20100630–0239.

Comment Date: 5 p.m. e.t. on Monday, August 30, 2010.

Docket Numbers: ER10–713–002.

Applicants: PJM Interconnection, L.L.C., Carolina Power & Light Company.

Description: Supplemental Information of PJM Interconnection, L.L.C. and Carolina Power and Light Company.

Filed Date: 06/28/2010.

Accession Number: 20100628–5230.

Comment Date: 5 p.m. e.t. on Monday, July 19, 2010.

Docket Numbers: ER10–1310–001.

Applicants: Southwest Power Pool Inc.

Description: Southwest Power Pool, Inc. submits Ninth Revised Service Agreement 607, Fifth Revised Volume No. 1.

Filed Date: 07/01/2010.

Accession Number: 20100701–0257.

Comment Date: 5 p.m. e.t. on Thursday, July 22, 2010.

Docket Numbers: ER10–1319–002.

Applicants: CMS Generation Michigan Power, LLC.

Description: CMS Generation Michigan Power, LLC submits tariff filing per 35: Baseline Cost-Based Tariff to be effective 7/1/2010.

Filed Date: 06/30/2010.

Accession Number: 20100630–5096.

Comment Date: 5 p.m. e.t. on Wednesday, July 21, 2010.

Docket Numbers: ER10–1323–003.

Applicants: RRI Energy West, Inc.

Description: RRI Energy West, Inc. submits an amendment to their Notice of Succession to the tariff.

Filed Date: 06/30/2010.

Accession Number: 20100630–0210.

Comment Date: 5 p.m. e.t. on Wednesday, July 21, 2010.

Docket Numbers: ER10–1353–002.

Applicants: Dearborn Industrial Generation, L.L.C.

Description: Dearborn Industrial Generation, L.L.C. submits tariff filing per 35: Baseline Reactive Supply and Voltage Control Service Tariff No. 1 to be effective 7/1/2010.

Filed Date: 06/30/2010.

Accession Number: 20100630–5112.

Comment Date: 5 p.m. e.t. on Wednesday, July 21, 2010.

Docket Numbers: ER10–1647–000.

Applicants: MidAmerican Energy Company.

Description: MidAmerican Energy Company submits a Notice of Cancellation of the Partial Requirements Wholesale Service Agreement with City of Fonda.

Filed Date: 06/30/2010.

Accession Number: 20100630–0236.

Comment Date: 5 p.m. e.t. on Wednesday, July 21, 2010.

Docket Numbers: ER10–1648–000.

Applicants: Midwest Independent Transmission System Operator, Inc.

Description: Midwest Independent Transmission System Operator, Inc submit proposed revisions to its Open Access Transmission etc to be effective 9/1/10.

Filed Date: 06/30/2010.

Accession Number: 20100630–0235.

Comment Date: 5 p.m. e.t. on Wednesday, July 21, 2010.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. e.t. on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St. NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2010–17146 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP10–76–000]

Eastern Shore Natural Gas Company; Notice of Availability of the Environmental Assessment for the Proposed Mainline Extension Interconnect Project

July 6, 2010.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared an environmental assessment (EA) for the Mainline Extension Interconnect Project proposed by Eastern Shore Natural Gas Company (Eastern Shore) in the above referenced docket. Eastern Shore requests authorization to construct pipeline facilities in Lancaster and Chester Counties, Pennsylvania to provide firm transportation service for local distribution companies in Delaware, Maryland, and Pennsylvania.

The EA assesses the potential environmental effects of the construction and operation of the Mainline Extension Interconnect Project in accordance with the requirements of the National Environmental Policy Act. The FERC staff concludes that approval of the proposed project, with appropriate mitigating measures, would not constitute a major Federal action significantly affecting the quality of the human environment.

The proposed Mainline Extension Interconnect Project includes the following facilities:

- 8.3 miles of 16-inch-diameter natural gas pipeline;
- One meter station/pig [1] launcher at the interconnect with Texas Eastern Transmission, LP, near Honey Brook, Pennsylvania;
- One mainline valve; and
- One interconnect/pig receiver at the existing Eastern Shore meter station near Parkesburg, Pennsylvania.

The EA has been placed in the public files of the FERC and is available for public viewing on the FERC's Web site at *http://www.ferc.gov* using the eLibrary link. A limited number of copies of the EA are available for distribution and public inspection at: Federal Energy Regulatory Commission, Public Reference Room, 888 First Street, NE., Room 2A, Washington, DC 20426. (202) 502–8371.

Copies of the EA have been mailed to Federal, State, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; potentially affected landowners and other interested individuals and groups; newspapers and libraries in the project area; and parties to this proceeding.

Any person wishing to comment on the EA may do so. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that your comments are properly recorded and considered prior to a Commission decision on the proposal, it is important that the FERC receives your comments in Washington, DC on or before August 5, 2010.

For your convenience, there are three methods you can use to submit your comments to the Commission. In all instances, please reference the project docket number (CP10–76–000) with your submission. The Commission encourages electronic filing of comments and has dedicated eFiling expert staff available to assist you at (202) 502–8258 or *efiling@ferc.gov.*

(1) You may file your comments electronically by using the *Quick Comment* feature, which is located on the Commission's Web site at *http://www.ferc.gov* under the link to *Documents and Filings.* A Quick Comment is an easy method for interested persons to submit text-only comments on a project;

(2) You may file your comments electronically by using the *eFiling* feature, which is located on the Commission's Web site at *http://www.ferc.gov* under the link to *Documents and Filings.* eFiling involves preparing your submission in the same manner as you would if filing on paper, and then saving the file on your computer's hard drive. You will attach that file as your submission. New eFiling users must first create an account by clicking on "*Sign up*" or

[1] A "pig" is a tool that is inserted into and moves through the pipeline, and is used for cleaning the pipeline, internal inspections, or other purposes.

"*eRegister.*" You will be asked to select the type of filing you are making. A comment on a particular project is considered a "Comment on a Filing"; or

(3) You may file a paper copy of your comments at the following address:

Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Room 1A, Washington, DC 20426.

Although your comments will be considered by the Commission, simply filing comments will not serve to make the commentor a party to the proceeding. Any person seeking to become a party to the proceeding must file a motion to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (18 CFR 385.214).[2] Only intervenors have the right to seek rehearing of the Commission's decision.

Affected landowners and parties with environmental concerns may be granted intervenor status upon showing good cause by stating that they have a clear and direct interest in this proceeding which would not be adequately represented by any other parties. You do not need intervenor status to have your comments considered.

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC or on the FERC Web site (*http://www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on "General Search" and enter the docket number excluding the last three digits in the Docket Number field (*i.e.,* CP10–76). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *http://www.ferc.gov/esubscribenow.htm.*

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–17094 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

[2] Interventions may also be filed electronically via the Internet in lieu of paper. *See* the previous discussion on filing comments electronically.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL08–47–006]

PJM Interconnection, L.L.C.; Notice of Filing

July 7, 2010.

Take notice that on July 1, 2010, PJM Interconnection, L.L.C. (PJM) filed revised sheets to Schedule 1 of the Amended and Restated Operating Agreement of PJM Interconnection, L.L.C. (Operating Agreement) and the parallel provisions of Attachment K—Appendix of the PJM Open Access Transmission Tariff, and also revisions to Schedule 2 of PJM's Operating Agreement, pursuant to the Federal Energy Regulatory Commission's February 19, 2009 Initial Order on Market Power Mitigation Provisions and Establishing Procedures, *PJM Interconnection, L.L.C.,* 126 FERC ¶ 61,145 (2009) (February 19th Order), May 28, 2009 Order On Clarification, *PJM Interconnection, L.L.C.,* 127 FERC ¶ 61,188 (2009) (May 28th Order), and March 23, 2010 Order on Compliance Filing, *PJM Interconnection, L.L.C.,* 130 FERC ¶ 61,230 (2010) (March 30th Order).

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant and all the parties in this proceeding.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on July 22, 2010

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–17103 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL08–14–007]

Black Oak Energy, LLC, EPIC Merchant Energy, LP, SESCO Enterprises, LLC v. PJM Interconnection, LLC; Notice of Filing

July 8, 2010.

Take notice that on June 1, 2010, PJM Interconnection, LLC filed a report of refund pursuant to the Federal Energy Regulatory Commission's (Commission) April 15, 2010 Order Denying Rehearing and Accepting Compliance Filing issued in this proceeding, *Black Oak Energy, LLC, et al.* v. *PJM Interconnection, LLC,* 131 FERC ¶ 61,024 (2010) (April 15 Order).

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the "eLibrary" link and is available for

review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on July 22, 2010.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–17162 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12626–002; Project No. 12717–002]

Northern Illinois Hydropower, LLC; Notice of Meeting

July 7, 2010.

a. *Date and Time of Meeting:* Thursday, July 22, 2010 from 9 a.m. to 12 p.m. CDT.

b. *Place:* Illinois Historic Preservation Agency, Old State Capitol Building, Springfield, IL 62701.

c. *FERC Contact:* Janet Hutzel, (202) 502–8675 or *janet.hutzel@ferc.gov*.

d. *Purpose of Meeting:* Commission staff will be meeting with Illinois Historic Preservation Agency to discuss the effects that the Dresden Island (P–12626–002) and Brandon Road (P–12717–002) projects may have on cultural resources. Discussion topics will include the following: (1) Effects that project operations may have on properties listed on, or eligible for, the National Register of Historic Places (historic properties); (2) ways to lessen, avoid, or mitigate for adverse effects on historic properties; and (3) the Commission's standard programmatic agreement and guidelines for the development of Historic Properties Management Plans.

e. All local, state, and federal agencies, tribes, and interested parties are hereby invited to participate. The meeting location will be provided upon a request made by interested parties. Please make that request to Janet Hutzel via e-mail at *janet.hutzel@ferc.gov* by the close of business on Wednesday, July 14, 2010.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–17108 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13351–000]

Marseilles Land and Water Company; Notice of Meeting

July 7, 2010.

a. *Date and Time of Meeting:* Thursday, July 22, 2010 from 9 a.m. to 12 p.m. CDT.

b. *Place:* Illinois Historic Preservation Agency, Old State Capitol Building, Springfield, IL 62701.

c. *FERC Contact:* Janet Hutzel, (202) 502–8675 or *janet.hutzel@ferc.gov*.

d. *Purpose of Meeting:* Commission staff will be meeting with Illinois Historic Preservation Agency to discuss the effects that the Marseilles Lock and Dam Project (P–13351–000) may have on cultural resources. Discussion topics will include the following: (1) Effects that project operations may have on properties listed on, or eligible for, the National Register of Historic Places (historic properties); (2) ways to lessen, avoid, or mitigate for adverse effects on historic properties; and (3) the Commission's standard programmatic agreement and guidelines for the development of Historic Properties Management Plans.

e. All local, state, and federal agencies, tribes, and interested parties are hereby invited to participate. The meeting location will be provided upon a request made by interested parties. Please make that request to Janet Hutzel via e-mail at *janet.hutzel@ferc.gov* by the close of business on Wednesday, July 14, 2010.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–17107 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Sunshine Act Meeting Notice

July 8, 2010.

The following notice of meeting is published pursuant to section 3(a) of the government in the Sunshine Act (Pub. L. No. 94–409), 5 U.S.C. 552b:

AGENCY HOLDING MEETING: Federal Energy Regulatory Commission.

DATE AND TIME: July 15, 2010, 10 a.m.

PLACE: Room 2C, 888 First Street, NE., Washington, DC 20426.

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda*.

Note: Items listed on the agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION: Kimberly D. Bose, Secretary, Telephone (202) 502–8400. For a recorded message listing items struck from or added to the meeting, call (202) 502–8627.

This is a list of matters to be considered by the Commission. It does not include a listing of all documents relevant to the items on the agenda. All public documents, however, may be viewed on line at the Commission's Web site at *http://www.ferc.gov* using the eLibrary link, or may be examined in the Commission's Public Reference Room.

961ST—MEETING; REGULAR MEETING; JULY 15, 2010; 10 A.M.

Item No.	Docket No.	Company
	Administrative	
A–1	AD02–1–000	Agency Administrative Matters.
A–2	AD02–7–000	Customer Matters, Reliability, Security and Market Operations
A–3	AD10–15–000	Smart Grid Update.
	Electric	
E–1	EL10–64–000	California Public Utilities Commission.
	EL10–66–000	Southern California Edison Company, Pacific Gas and Electric Company and San Diego Gas & Electric Company.

961ST—MEETING; REGULAR MEETING; JULY 15, 2010; 10 A.M.—Continued

Item No.	Docket No.	Company
E–2	ER10–1269–000	Southwest Power Pool, Inc.
E–3	RD10–13–000	North American Electric Reliability Corporation.
E–4	RM08–19–003	Mandatory Reliability Standards for the Calculation of Available Transfer Capability, Capacity Benefit Margins, Transmission Reliability; Margins, Total Transfer Capability, and Existing Transmission Commitments; Mandatory Reliability Standards for the Bulk Power System.
	RM05–5–019	Standards for Business Practices and Communication Protocols for Public Utilities.
E–5	OA08–52–007	New York Independent System Operator, Inc. New York Transmission Owners.
E–6	ER10–1268–000 ER10–516–000. ER10–855–000.	South Carolina Electric & Gas Company.
E–7	OMITTED	
E–8	EG06–73–000	BG Dighton Power, LLC.
	EG98–79–000	MASSPOWER.
	EG99–220–000	Lake Road Generating Company, LP.
E–9	ER10–1185–000	ISO New England Inc.
E–10	ER10–765–000	California Independent System Operator Corporation.
E–11	ER10–942–000	ISO New England Inc. and New England Power Pool
E–12	ER07–521–009	New York Independent System Operator, Inc.
E–13	ER08–1281–004	New York Independent System Operator, Inc.
E–14	OMITTED	
E–15	EL10–69–000	Virginia Electric and Power Company v. PJM Interconnection, L.L.C.
	Gas	
G–1	RP09–2–002	Portland Natural Gas Transmission System.
G–2	RP01–245–031	Transcontinental Gas Pipe Line Corporation.
G–3	RP10–149–000	Great Lakes Gas Transmission Limited Partnership.
	Hydro	
H–1	P–1888–028	York Haven Power Company, LLC.
H–2	UL09–1–002	L.S. Starrett Company.
H–3	P–460–033 P–460–040 P–460–021	City of Tacoma, Washington.
H–4	EL10–53–000	FPL Energy Maine Hydro LLC v. Great Lakes Hydro America, LLC and Rumford Falls Hydro LLC.
H–5	P–2355–014	Exelon Generation Company, LLC.
	Certificates	
C–1	OMITTED	
C–2	CP10–73–000	TGGT Holdings, LLC.
C–3	CP09–455–000	Florida Gas Transmission Company, LLC.
	CP09–456–000	Transcontinental Gas Pipe Line Company, LLC. Florida Gas Transmission Company, LLC.

Kimberly D. Bose,

Secretary.

A free Web cast of this event is available through *http://www.ferc.gov*. Anyone with Internet access who desires to view this event can do so by navigating to *http://www.ferc.gov's* Calendar of Events and locating this event in the Calendar. The event will contain a link to its Web cast. The Capitol Connection provides technical support for the free Web casts. It also offers access to this event via television in the DC area and via phone bridge for a fee. If you have any questions, visit *http://www.CapitolConnection.org* or contact Danelle Springer or David Reininger at 703–993–3100.

Immediately following the conclusion of the Commission Meeting, a press briefing will be held in the Commission Meeting Room. Members of the public may view this briefing in the designated overflow room. This statement is intended to notify the public that the press briefings that follow Commission meetings may now be viewed remotely at Commission headquarters, but will not be telecast through the Capitol Connection service.

[FR Doc. 2010–17218 Filed 7–12–10; 11:15 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL10–77–000]

City of Pella, Iowa, v. Midwest Independent Transmission System Operator, Inc., MidAmerican Energy Company, Inc.; Notice of Petition for Declaratory Order and Complaint

July 8, 2010,

Take notice that on July 2, 2010, pursuant to Rules 206 and 207 of the Rules and Practice and Procedure, 18 CFR 385.206 and 385.207, Order No.

888[1], and sections 205, 206, 211, 212 and 309 of the Federal Power Act, 16 U.S.C. 824(e), 824(j), 824(k), and 825(h), City of Pella, Iowa (Complainant) filed (1) a petition for declaratory order requesting that the Commission confirm that Complainant's 69 kV facilities connecting and integrating the transmission of the Complainant, MidAmerican Energy Company, Central Iowa Power Cooperative and ITC Midwest are "transmission lines" under Order No. 888, and (2) a formal complaint against Midwest Independent System Operator, Inc. and MidAmerican Energy Company, Inc. (Respondents) alleging that the Respondents have improperly denied certain of the Complainant's 69 kV facilities reclassification as transmission and corresponding compensation.

The Complainant certifies that copies of the complaint were served on the contacts for the Respondents as listed on the Commission's list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 pm Eastern Time on August 2, 2010.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–17161 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

[1] *Promoting Wholesale Competition Through Open Access Non-Discriminatory Transmission Services by Public Utilities; Recovery of Stranded Costs by Public Utilities and Transmitting Utilities,* Order No. 888, FERC Stats. & Regs. ¶ 31,036 (1996), *order on reh'g,* Order No. 888–A, FERC Stats. & Regs. ¶ 31,048, *order on reh'g,* Order No. 888–B, 81 FERC ¶ 61,248 (1997), *order on reh'g,* Order No. 888–C, 82 FERC ¶ 61,046 (1998), *aff'd in relevant part sub nom. Transmission Access Policy Study Group* v. *FERC,* 225 F.3d 667 (D.C. Cir. 2000), *aff'd sub nom. New York* v. *FERC,* 535 U.S. 1 (2002).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL10–76–000]

Green Energy Express LLC; 21st Century Transmission Holdings, LLC; Notice of Petition for Declaratory Order

July 8, 2010.

Take notice that on July 2, 2010, Green Energy Express LLC and 21st Century Transmission Holdings, LLC, pursuant to Rule 207 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.207 (2010), filed a Petition for Declaratory Order requesting the Commission to clarify the appropriate interpretation of provisions in the California Independent System Operator Corp's (CAISO) Tariff, specifically provisions in the Larger Generator Interconnection Agreement in Appendix V to the Tariff and provisions in section 24 of the Tariff relating to Location Constrained Resource Interconnection facilities.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on July 23, 2010.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–17158 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL10–75–000]

California Pacific Electric Company, LLC; Notice of Petition for Declaratory Order

July 6, 2010.

Take notice that on July 2, 2010, pursuant to Rule 207 of the Rules of Practice and Procedure of the Federal Energy Regulatory Commission (Commission), 18 CFR 385.207 (2009), California Pacific Electric Company, LLC filed a Petition for Declaratory Order requesting that the Commission find that certain local distribution services and facilities are not subject to FERC's jurisdiction under the Federal Power Act.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to

serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on August 2, 2010.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–17091 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the-Record Communications; Public Notice

July 6, 2010.

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. The communications listed are grouped by docket numbers in ascending order. These filings are available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the eLibrary link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, please contact FERC, Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Exempt

Docket No.	File date	Presenter or requester
1. P–516–459 ..	6–24–10	Lee Emery.[1]
2. P–739–000 ..	6–15–10	Kristen Murphy.[2]
3. P–2621–009	6–24–10	Alicia M. Rowe.
4. P–2677–019	6–15–10	John Smith.[3]
5. P–2850–016	6–29–10	John Baummer.[4]

[1] E-mail (from Alan Stuart and Noah Silverman).

[2] Telephone record.

[3] E-mail exchange (with Arie DeWaal and Byron Dale Simon).

[4] Record of telephone call with Matt Maraglio of New York State Division of Coastal Resources regarding Natural Dam hydroelectric project.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–17098 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD10–14–000]

Reliability Standards Development and NERC and Regional Entity Enforcement; Notice Soliciting Comments

July 7, 2010.

Take notice that on July 6, 2010, the Federal Energy Regulatory Commission held a Commissioner-led technical conference to explore issues pertaining to the development of mandatory Reliability Standards for the Bulk-Power System by the North American Electric Reliability Corporation. As previously noticed,[1] and as stated at the technical conference, any person interested may submit written comments regarding the issues discussed at the conference. Comments should be filed with the Commission in this docket, AD10–14–000, no later than July 26, 2010.

Anyone with questions pertaining to the technical conference or this notice should contact either Karin Larson at 202–502–8236, *Karin.Larson@ferc.gov* or Christopher Young at 202–502–6403, *Christopher.Young@ferc.gov.*

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–17101 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP10–465–000]

Gulf South Pipeline Company, LP; Notice of Request Under Blanket Authorization

July 7, 2010.

Take notice that on June 23, 2010, Gulf South Pipeline Company, LP (Gulf), 9 Greenway Plaza, Suite 2800, Houston, Texas 77046, filed a prior notice request pursuant to sections 157.205, 157.208, and 157.210 of the Commission's regulations under the Natural Gas Act (NGA) for authorization to construct, own, operate, and maintain one new 10,311 horsepower (HP) compressor including appurtenant, auxiliary facilities at Gulf's existing Clarence Compressor Station located in Natchitoches Parish, Louisiana, all as more fully set forth in the application,

[1] *Supplemental Notice of Technical Conference,* 75 FR 36,385 (June 18, 2010).

which is on file with the Commission and open to public inspection. The filing may also be viewed on the Web at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or TTY, (202) 502–8659.

Specifically, South proposes to construct, own, and operate one new compressor unit at its existing compressor station near Clarence, Louisiana. This additional compression unit is designed to enhance Gulf South's capability in order to provide the firm transportation service which BG Energy Merchants, LLC has requested.

Any questions regarding the application should be directed to M.L. Gutierrez, Director of Regulatory Affairs, Boardwalk Pipeline Partners, LP, 9 Greenway Plaza, Suite 2800, Houston, Texas 77046, by telephone at (713) 479–8059, or by facsimile at (713) 479–1846, or by e-mail at *nell.gutierrez@bwpmlp.com.*

Any person may, within 60 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention. Any person filing to intervene or the Commission's staff may, pursuant to section 157.205 of the Commission's regulations under the NGA (18 CFR 157.205) file a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

The Commission strongly encourages electronic filings of comments, protests, and interventions via the internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov*) under the "e-Filing" link.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–17104 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL10–63–000]

EnerNOC, Inc. v. FirstEnergy Corp.; Notice Requiring Protective Order and Establishing Answer Date

July 8, 2010.

On April 30, 2010, EnerNOC, Inc. (EnerNOC) filed a Complaint in this proceeding naming FirstEnergy Corp. (FirstEnergy) as the respondent (April 30 Complaint). On May 11, 2010, EnerNOC, Inc. and FirstEnergy (collectively, the Parties) filed an expedited joint motion to suspend the answer date (Joint Motion), noting that the Parties were working on a solution that would permit use, in this proceeding, of certain materials subject to protection in an on-going proceeding before the Public Utilities Commission of Ohio.

On May 14, 2010, the Commission issued a notice suspending the answer date in this docket, as requested by the Parties (May 14 Notice). In addition, the Commission informed the Parties that the submission, treatment and/or exchange of privileged information in this proceeding would be subject to the requirements of 18 CFR 385.206(e) and would therefore require the submission of a proposed protective agreement.

On July 1, 2010, EnerNOC submitted a supplemental complaint filing (July 1 Supplemental Complaint Filing), under seal, along with a redacted version. EnerNOC requests that its submission, under seal, be accorded confidential treatment, pursuant to 18 CFR 388.112 (2010). EnerNOC further states that a portion of its confidential submittal (Attachment 2) is a data response subject to an existing protective agreement.

EnerNOC's July 1 Supplemental Complaint Filing does not include a proposed form of protective agreement applicable to this proceeding. As indicated by the May 14 Notice, this is required by 385.2069 (e) of the Commission's regulations. Nor does EnerNOC address the means by which the parties to this proceeding will be entitled to review material submitted under seal, or the extent to which the existing protective agreement addresses this matter. Accordingly, EnerNOC is hereby directed to provide to FirstEnegy and to any other entity (at its request) that has filed a motion to intervene, herein, a proposed form of protective agreement that can be used to obtain an unredacted version of EnerNOC's July 1, 2010 submittal and any other submittal filed under seal. The Commission will require EnerNOC to provide that protected agreement by July 15, 2010. The time period for filing answers, protests and/or comments on EnerNoc's April 30 Complaint and the July 1 Supplemental Complaint Filing will be extended to August 4, 2010.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–17159 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

City of Broken Bow, Oklahoma; Project No. 12470–001—Oklahoma Broken Bow Re-Regulation Dam Hydropower Project; Notice of Revised Restricted Service List for a Programmatic Agreement for Managing Properties Included in or Eligible for Inclusion in the National Register of Historic Places

July 8, 2010.

On June 8, 2010, the Federal Energy Regulatory Commission (Commission) issued notice of a proposed restricted service list for the preparation of a programmatic agreement for managing properties included in, or eligible for inclusion in, the National Register of Historic Places at the Broken Bow Re-Regulation Dam Hydroelectric Project No. 12470. Rule 2010(d)(1) of the Commission's Rules of Practice and Procedure, 18 CFR section 385.2010 (2009), provides for the establishment of such a list for a particular phase or issue in a proceeding to eliminate unnecessary expense or improve administrative efficiency. Under Rule 2010(d)(4), persons on the official service list are to be given notice of any proposal to establish a restricted service list and an opportunity to show why they should also be included on the restricted service list or why a restricted service list should not be established.

On June 23, 2010, Southwestern Power Administration filed a response to the notice requesting that it be included in the development of the programmatic agreement. On July 2, 2010, the Commission staff received a telephone request from the Oklahoma State Historic Preservation Office (Oklahoma SHPO) that the Caddo Nation be included in the development of the programmatic agreement.

Under Rule 2010(d)(2), any restricted service list will contain the names of each person on the official service list, or the person's representative, who, in the judgment of the decisional authority

establishing the list, is an active participant with respect to the phase or issue in the proceeding for which the list is established. Southwestern Power Administration and the Oklahoma SHPO on behalf of the Caddo Nation have identified an interest in issues relating to the management of historic properties at the project. Therefore, they and their representatives will be added to the restricted service list.

Accordingly, the restricted service list issued on June 8, 2010, for the Broken Bow Re-Regulation Dam Hydroelectric Project No. 12470 is revised to add the following persons:

Robert Cast, Tribal Historic Preservation Officer, Caddo Nation, P.O. Box 487, Binger, OK 73009.

Steven A. Porter, U.S. Department of Energy, 1000 Independence Avenue, SW., 6D–033/FORS, Washington, DC 20585.

James K. McDonald, Southwestern Power Administration, One West Third Street, Suite 1522, Tulsa, OK 74103–3539.

Laurence J. Yadon, II, Southwestern Power Administration, One West Third Street, Suite 1522, Tulsa, OK 74103–3539.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–17157 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2149–131]

Public Utility District No. 1 of Douglas County; Notice of Settlement Agreement and Soliciting Comments

July 7, 2010.

Take notice that the following Settlement Agreement (Settlement) has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Aquatic Settlement Agreement for the relicensing of the Wells Hydroelectric Project.

b. *Project No.:* P–2149–131.

c. *Date Filed:* May 27, 2010.

d. *Applicant:* Public Utility District No. 1 of Douglas County, Washington.

e. *Location:* The existing project is located at river mile 515.6 on the Columbia River in Chelan, Douglas, and Okanogan Counties in central Washington. The project occupies 15.15 acres of Federal land administered by the Department of the Interior and the U.S. Corps of Engineers.

g. Filed Pursuant to Rule 602 of the Commission's Rules of Practice and Procedure, 18 CFR 385.602 Federal Power Act 16 U.S.C. 791 (a)–825(r).

h. *Applicant Contact:* Shane Bickford, Natural Resources Supervisor, Public Utility District No. 1 of Douglas County, 1151 Valley Mall Parkway, East Wenatchee, WA 98802–4497; (509) 881–2208.

i. *FERC Contact:* Kim A. Nguyen (202) 502–6105 or e-mail at *kim.nguyen@ferc.gov.*

j. *Deadline for filing comments on the Settlement: July 27, 2010.* Reply comments due *August 6, 2010.* All comments should be filed electronically via the Internet. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov/docs-filing/ferconline.asp*) under the "eFiling" link. For a simpler method of submitting text only comments, click on "Quick Comment." For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov;* call toll-free at (866) 208–3676; or, for TTY, contact (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and eight copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC.

k. The Public Utility District No. 1 of Douglas County (Douglas PUD) filed an aquatic settlement agreement (Settlement) on behalf of Douglas PUD; U.S. Fish and Wildlife Service; U.S. Bureau of Land Management; Washington Department of Fish and Wildlife; Washington Department of Ecology; Confederated Tribes of the Colville Reservation; and Confederated Bands and Tribes of the Yakama Nation (collectively, the Parties). The Settlement resolves among the Parties all remaining aquatic resource issues and includes proposed license articles and six aquatic resource management plans for white sturgeon, bull trout, Pacific lamprey, resident fish, aquatic nuisance species and water quality. The Parties request that the Commission accept and incorporate, without material modification, all of the proposed license articles in Attachment A of the Settlement in the new project license for the Wells Project.

l. A copy of the Settlement is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov,* using the "e-Library" link. Enter the docket number, excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at 1–866–208–3676, or for TTY, (202) 502–8659. A copy is also available for inspection and reproduction at the address in item h above.

Register online at *http://www.ferc.gov/esubscribenow.htm* to be notified via e-mail of new filings and issuances related to this or other pending projects before the Commission. For assistance, contact FERC Online Support.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–17105 Filed 7–13–10; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2010–0398; FRL–8832–1]

Methyl Soyate; Receipt of Application for Emergency Exemption, Solicitation of Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received a specific exemption request from the Wyoming Department of Agriculture to use the pesticide methyl soyate (BIO-LARV) (CAS Reg. No. 67762–38–3) to treat aquatic vegetation to control mosquito larvae. The applicant proposes the use of a new chemical which has not been registered by EPA. EPA is soliciting public comment before making the decision whether or not to grant the exemption.

DATES: Comments must be received on or before July 29, 2010.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2010–0398, 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's telephone number is (703) 305–5805.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2010–0398. 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 website 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's telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Princess Campbell, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8033; fax number: (703) 605–0781; e-mail address: *campbell.princess @epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI*. Do not submit this information to EPA through www.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, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

3. *Environmental justice*. EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide discussed in this document, compared to the general population.

II. What Action is the Agency Taking?

Under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136p), at the discretion of the Administrator, a Federal or State agency may be exempted from any provision of FIFRA if the Administrator determines that emergency conditions exist which require the exemption. The Wyoming Department of Agriculture has requested the Administrator to issue a specific exemption for the use of methyl soyate on aquatic vegetation to control mosquito larvae. Information in accordance with 40 CFR part 166 was submitted as part of this request.

As part of this request, the applicant asserts that the use of methyl soyate on aquatic vegetation will control mosquito larvae, including those that transmit the West Nile virus, in ponds within the State of Wyoming. The applicant asserts

that other products can be harmful to the environment, but methyl soyate (BIO-LARV) has been shown to have little or no side effects on other aquatic species or mammal life in or near ponds. The applicant also cites statistics detailing the number of cases of West Nile virus infections during the period 2003–2008, and reports 14 deaths over the period.

Methyl soyate (BIO-LARV) will be applied at the rate of 3–5 gallons per acre depending on the density of the vegetation. Per the label the mixture will consist of 3–5 gallons of BIO-LARV to 100 gallons of water.

This notice does not constitute a decision by EPA on the application itself. The regulations governing section 18 of FIFRA require publication of a notice of receipt of an application for a specific exemption proposing use of a new chemical (i.e., an active ingredient) which has not been registered by EPA. This notice provides an opportunity for public comment on the application.

The Agency will review and consider all comments received during the comment period in determining whether to issue the specific exemption requested by the Wyoming Departmrnt of Agriculture.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: June 30, 2010.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2010–16923 Filed 7–13–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2005–0494; FRL–8827–9]

Rotenone; Cancellation Order for Amendments to Terminate Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's order for amendments to terminate uses, voluntarily requested by the registrants and accepted by the Agency, of products containing rotenone, pursuant to section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. This cancellation order follows a June 7, 2006 **Federal Register** Notice of Receipt of Requests from the registrants listed in Table 2 of Unit II. to voluntarily amend to terminate uses of these product registrations. These are not the last products containing this pesticide registered for use in the United States. In the June 7, 2006 notice, EPA indicated that it would issue an order implementing the amendments to terminate uses, unless the Agency received substantive comments within the 30 day comment period that would merit its further review of these requests, or unless the registrants withdrew their requests. The Agency received one comment on the notice but it did not merit further review of the requests. Further, the registrants did not withdraw their requests. Accordingly, EPA hereby issues in this notice a cancellation order granting the requested amendments to terminate uses. Any distribution, sale, or use of the products subject to this cancellation order is permitted only in accordance with the terms of this order, including any existing stocks provisions.

DATES: The amendments are effective July 14, 2010.

FOR FURTHER INFORMATION CONTACT: Katie Weyrauch, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–0166; fax number: (703) 308–8090; e-mail address: *weyrauch.katie@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Copies of this Document and Other Related Information?

EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2005–0494. 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 Office of Pesticide Programs (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.

II. What Action is the Agency Taking?

This notice announces the amendments to delete uses, as requested by registrants, of products registered under section 3 of FIFRA. These registrations are listed in sequence by registration number in Table 1 of this unit.

TABLE 1. – ROTENONE PRODUCT REGISTRATION AMENDMENTS TO DELETE USES

EPA Registration Number	Product Name	Uses Deleted
655-3	Prentox Cube Powder	Livestock, agriculture, residential and home owner, domestic pet uses, and all other uses EXCEPT for piscicide uses
655-69	Prentox Cube Resins	Do.
655-422	Prentox Prenfish Toxicant	Do.
655-691	Prentox Rotenone Fish Toxicant Powder	Do.
655-805	Noxfish Fish Toxicant Liquid-Emulsifiable	Do.
655-806	Cube Powder Fish Toxicant	Do.
655-807	Powdered Cube Root	Do.
655-808	Brittle Extract of Cube Root	Do.
6458-1	Cube Root Powder	Do.

TABLE 1. – ROTENONE PRODUCT REGISTRATION AMENDMENTS TO DELETE USES—Continued

EPA Registration Number	Product Name	Uses Deleted
6458-5	Rotenone Resin for Manufacturing Use Only	Do.
6458-6	Cube Powder	Do.
82397-1	Chem Fish Regular	Do.
82397-2	Chem Fish Synergized	Do.
82397-3	Powdered Cube Root	Do.
82397-4	Chem-Sect Brand Rotenone Resins	Do.
82397-5	Cube Powder Fish Toxicant	Do.

Table 2 of this unit includes the names and addresses of record for all registrants of the products in Table 1 of this unit, in sequence by EPA company number. This number corresponds to the first part of the EPA registration numbers of the products listed in Table 1.

TABLE 2. – REGISTRANTS OF AMENDED PRODUCTS

EPA Company Number	Company Name and Address
655	Prentiss, Inc., 3600 Mansell Road, Suite 350, Alpharetta, GA 30022
6458	Foreign Domestic Chemicals Corp., 3 Post Road, Oakland, NJ 07436
82397	Tifa International, LLC, 50 Division Avenue, Millington, NJ 07946

III. Summary of Public Comments Received and Agency Response to Comments

One comment was received during the 30–day public comment period. The commenter expressed her opinion that no living thing should be exposed to rotenone products. The commenter did not, however, provide any information or reason to not grant the request to terminate certain uses. Therefore, the Agency does not believe that the comment submitted during the comment period merits further review or a denial of the requests for voluntary use deletion.

IV. Cancellation Order

Pursuant to FIFRA section 6(f), EPA hereby approves the requested amendments to terminate uses of rotenone registrations identified in Table 1 of Unit II. Accordingly, the Agency hereby orders that the product registrations identified in Table 1 of Unit II. are amended to terminate the affected uses. The effective date of the cancellations that are subject of this notice is July 14, 2010. Any distribution, sale, or use of existing stocks of the products identified in Table 1 of Unit II. in a manner inconsistent with any of the provisions for disposition of existing stocks set forth in Unit VI. will be a violation of FIFRA.

V. What is the Agency's Authority for Taking this Action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled or amended to terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, following the public comment period, the EPA Administrator may approve such a request. The notice of receipt for this action was published for comment on June 7, 2006 (71 FR 32948) (FRL–8071–1). The comment period closed on July 7, 2006.

VI. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which were packaged, labeled, and released for shipment prior to the effective date of the action. The existing stocks provision for the products subject to this order is as follows.

For all products listed in Table 1 of Unit II, there is no provision for existing stocks of products with labels that include the deleted uses in the hands of technical registrants or any formulation of these products as of July 14, 2010. Thereafter, the registrants are prohibited from selling or distributing products listed in Table 1 of Unit II, except for export in accordance with FIFRA section 17 or for proper disposal.

Persons other than the registrant may not formulate but may sell, distribute, or use existing stocks of products whose labels include the deleted uses for July 14, 2011, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling that included the deleted uses.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: July 1, 2010.

Richard P. Keigwin, Jr.,

Director, Pesticide Re-evaluation Division, Office of Pesticide Programs.

[FR Doc. 2010–17015 Filed 7–13–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2009–0191; FRL–8828–5]

Monosodium methanearsonate (MSMA); Cancellation Order for Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's order for the cancellations, voluntarily requested by the registrants and accepted by the Agency, of products containing the organic arsenical monosodium methanearsonate (MSMA), pursuant to section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. This cancellation order follows an April 7, 2010 **Federal Register** Notice of Receipt of Requests from the registrants listed in Table 2 of Unit II. to voluntarily cancel these product registrations. These are not the last products containing this pesticide registered for use in the United States. In the April 7, 2010 notice, EPA indicated that it would issue an order implementing the cancellations, unless the Agency received substantive comments within the 30 day comment period that would merit its further review of these requests, or unless the registrants withdrew their requests. The Agency did not receive any comments on the notice. Further, the registrants did not withdraw their requests. Accordingly, EPA hereby issues in this notice a cancellation order granting the requested cancellations. Any distribution, sale, or use of the products subject to this cancellation order is permitted only in accordance with the terms of this order, including any existing stocks provisions.

DATES: The cancellations are effective July 14, 2010.

FOR FURTHER INFORMATION CONTACT: Tom Myers, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8589; fax number: (703) 308–8005; e-mail address: *myers.tom@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Copies of this Document and Other Related Information?

EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0191 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 Office of Pesticide Programs (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.

II. What Action is the Agency Taking?

This notice announces the cancellations, as requested by registrants, of products registered under section 3 of FIFRA. These registrations are listed in sequence by registration number in Table 1 of this unit.

TABLE 1.—MSMA PRODUCT CANCELLATIONS

Registration Number	Product Name	Chemical Name
42750–38	Weed Hoe 120	MSMA
42750–39	Weed Hoe 108	MSMA
61483–13	Daconate	MSMA
61483–14	Daconate 6	MSMA
61483–15	Bueno–6	MSMA
61483–17	Daconate Super Brand	MSMA
61483–18	Bueno	MSMA

Table 2 of this unit includes the names and addresses of record for all registrants of the products in Table 1 of this unit, in sequence by EPA company number. This number corresponds to the first part of the EPA registration numbers of the products listed above.

TABLE 2.—REGISTRANTS OF CANCELLED PRODUCTS

EPA Company Number	Company Name and Address
042750	Albaugh Inc. 1525 NE 36th Street Ankeny, IA 50021
061483	KMG-Bernuth, Inc. 9555 W. Sam Houston Pkwy South Suite 600 Houston, TX 77099

III. Summary of Public Comments Received and Agency Response to Comments

During the public comment period provided, EPA received no comments in response to the April 7, 2010 **Federal Register** notice (75 FR 17733; FRL–8819–2)announcing the Agency's receipt of the requests for voluntary cancellations of products listed in Table 1 of Unit II.

IV. Cancellation Order

Pursuant to FIFRA section 6(f), EPA hereby approves the requested cancellations of MSMA registrations identified in Table 1 of Unit II. Accordingly, the Agency hereby orders that the product registrations identified in Table 1 of Unit II. are canceled. The effective date of the cancellations that are subject of this notice is July 14, 2010. Any distribution, sale, or use of existing stocks of the products identified in Table 1 of Unit II. in a manner inconsistent with any of the provisions for disposition of existing stocks set forth in Unit VI. will be a violation of FIFRA.

V. What is the Agency's Authority for Taking this Action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled or amended to terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, following the public comment period, the EPA Administrator may approve such a request. The notice of receipt for this action was published for comment on April 7, 2010 (75 FR 17733) (FRL–8819–2). The comment period closed on May 7, 2010.

VI. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which were packaged, labeled, and released for shipment prior to the effective date of the action. The existing stocks provision for the products subject to this order is as follows.

1.After July 14, 2010, registrants are prohibited from selling or distributing existing stocks of products listed in Table 1.

2. After December 31, 2010, persons other than registrants are prohibited from selling or distributing existing stocks of products listed in Table 1.

3. After December 31, 2010, existing stocks of products listed in Table 1, already in the hands of users can be used legally until they are exhausted, provided that such use complies with the EPA-approved label and labeling of the affected product.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: July 6, 2010.

Richard P. Keigwin, Jr.,

Pesticide Re-evaluation Division, Office of Pesticide Programs.

[FR Doc. 2010–17155 Filed 7–13–10; 8:45 a.m.]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2009–0760; FRL–8833–4]

Clofencet; Cancellation Order for Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's order for the cancellations, voluntarily requested by the registrant and accepted by the Agency, of products containing clofencet, pursuant to section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. This cancellation order follows an April 28, 2010 **Federal Register** Notice of Receipt of Request from the registrant Monsanto Company to voluntarily cancel all these product registrations. These are the last products containing this pesticide registered for use in the United States. In the April 28, 2010 notice, EPA indicated that it would issue an order implementing the cancellations, unless the Agency received substantive comments within the 30–day comment period that would merit its further review of this request, or unless the registrant withdrew their request. The Agency did not receive any comments on the notice. Further, the registrant did not withdraw their request. Accordingly, EPA hereby issues in this notice a cancellation order granting the requested cancellations. Any distribution, sale, or use of the products subject to this cancellation order is permitted only in accordance with the terms of this order, including any existing stocks provisions.

DATES: The cancellations are effective July 14, 2010.

FOR FURTHER INFORMATION CONTACT: Wilhelmena Livingston, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8025; fax number: (703) 308–8005; e-mail address: *livingston.wilhelmena@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Copies of this Document and Other Related Information?

EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0760. 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 Office of Pesticide Programs (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.

II. What Action is the Agency Taking?

This notice announces the cancellations, as requested by registrant, of products registered under section 3 of FIFRA. These registrations are listed in sequence by registration number in Table 1 of this unit.

TABLE 1.—CLOFENCET PRODUCT CANCELLATIONS

EPA Registration Number	Product Name
524-479	Genesis Hybridizing Agent
524-481	Mon 21200 Technical Registration
524-482	Mon 21233 Manufacturing Use Product

Table 2 of this unit includes the name and address of record for the registrant of the products in Table 1 of this unit, by EPA company number. This number corresponds to the first part of the EPA registration numbers of the products listed above.

TABLE 2.—REGISTRANT OF CANCELLED PRODUCTS

EPA Company Number	Company Name and Address
524	Monsanto Company 1300 I Street N.W. Suite 450 Washington, DC 20005

III. Summary of Public Comments Received and Agency Response to Comments

During the public comment period provided, EPA received no comments in response to the April 28, 2010 **Federal Register** notice announcing the Agency's receipt of the request for voluntary cancellation of products listed in Table 1 of Unit II.

IV. Cancellation Order

Pursuant to FIFRA section 6(f), EPA hereby approves the requested cancellation of clofencet registrations identified in Table 1 of Unit II. Accordingly, the Agency hereby orders that the product registrations identified in Table 1 of Unit II. are canceled. The effective date of the cancellations that are subject of this notice is July 14, 2010. Any distribution, sale, or use of existing stocks of the products identified in Table 1 of Unit II. in a manner inconsistent with any of the provisions for disposition of existing stocks set forth in Unit VI. will be a violation of FIFRA.

V. What is the Agency's Authority for Taking this Action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled or amended to terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, following the public comment period, the EPA Administrator may approve such a request. The notice of receipt for this action was published for comment on April 28, 2010 (75 FR 22404) (FRL–8822–1). The comment period closed on May 28, 2010.

VI. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which were packaged, labeled, and released for shipment prior to the effective date of the action. The existing stocks provision for the products subject to this order is as follows.

For voluntary cancellations, the registrant may continue to sell and distribute existing stocks of product listed in Table 1 until July 14, 2011, which is 1 year after publication of this cancellation order in the **Federal Register**. Thereafter, the registrant is prohibited from selling or distributing products listed in Table 1 of Unit II. except for export in accordance with FIFRA section 17 or for proper disposal.

Persons other than the registrant may sell, distribute, or use existing stocks of canceled products until supplies are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled products.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: July 1, 2010.

Richard P. Keigwin, Jr.,

Director, Pesticide Re-evaluation Division, Office of Pesticide Programs.

[FR Doc. 2010–17020 Filed 7–13–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2009–1005; FRL–8836–6]

Petitions Concerning Whether Ammonia or Urea Sold or Distributed and Used for Certain Purposes Should Be Regulated as Pesticides; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; extension of comment period.

SUMMARY: EPA issued a notice in the **Federal Register** of May 19, 2010, concerning petitions concerning whether ammonia or urea sold or distributed and used for certain purposes should be regulated as pesticides. This document extends the comment period for 45 days, from July 19, 2010 to September 2, 2010.

DATES: Comments, identified by docket identification (ID) number EPA–HQ–OPP–2009–1005, must be received on or before September 2, 2010.

ADDRESSES: Follow the detailed instructions as provided under **ADDRESSES** in the **Federal Register** document of May 19, 2010.

FOR FURTHER INFORMATION CONTACT: Melba S. Morrow, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308-2716; e-mail address: *morrow.melba @epa.gov.*

SUPPLEMENTARY INFORMATION: This document extends the public comment period established in the **Federal Register** of May 19, 2010 (75 FR 28014) (FRL–8824–4). In that document, the Agency announced the availability of and sought public comment on petitions concerning whether ammonia or urea sold or distributed and used for certain purposes should be regulated as pesticides. EPA is hereby extending the comment period, which was set to end on July 19, 2010, to September 2, 2010.

To submit comments, or access the docket, please follow the detailed instructions as provided under **ADDRESSES** in the May 19, 2010 **Federal Register** document. If you have questions, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: July 7, 2010

Joan Harrigan-Farrelly,

Director, Antimicrobials Division, Office of Pesticide Programs.

[FR Doc. 2010–17152 Filed 7–13–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9175–5]

Proposed Consent Decree, Clean Air Act Citizen Suit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed consent decree; request for public comment.

SUMMARY: In accordance with section 113(g) of the Clean Air Act, as amended (“CAA” or the “Act”), 42 U.S.C. 7413(g), notice is hereby given of a proposed consent decree to address a lawsuit filed by Sierra Club in the United States District Court for the Northern District of California: *Sierra Club* v. *Jackson,* No. 09-cv-00152 SBA (N.D. Cal.). On January 13, 2009, Plaintiff filed a complaint alleging that EPA failed to meet its obligations under sections 112(d)(6) and 112(f)(2) of the CAA to take actions relative to the review/revision of the National Emission Standards for Hazardous Air Pollutants with respect to 28 source categories identified in the complaint. The proposed consent decree establishes deadlines for EPA’s proposed and final actions for meeting these obligations.

DATES: Written comments on the proposed consent decree must be received by August 13, 2010.

ADDRESSES: Submit your comments, identified by Docket ID number EPA–HQ–OGC–2010–0508, online at *http://www.regulations.gov* (EPA’s preferred method); by e-mail to *oei.docket@epa.gov;* by mail to EPA Docket Center, Environmental Protection Agency, *Mailcode:* 2822T, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; or by hand delivery or courier to EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC, between 8:30 a.m. and 4:30 p.m. Monday through Friday, excluding legal holidays. Comments on a disk or CD–ROM should be formatted in Word or ASCII file, avoiding the use of special characters and any form of encryption, and may be mailed to the mailing address above.

FOR FURTHER INFORMATION CONTACT: Amy Branning, Air and Radiation Law Office (2344A), Office of General Counsel, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; *telephone:* (202) 564–1744; *fax number:* (202) 564–5603; *e-mail address: branning.amy@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Additional Information About the Proposed Consent Decree

Under sections 112(d)(6) and 112(f)(2) of the CAA, EPA has a mandatory duty to take actions relative to the review/revision of national emission standards for hazardous air pollutants (“NESHAP”) within eight years of the issuance of such standards. The proposed consent decree would resolve a deadline suit filed by Plaintiff for EPA’s failure to take the above actions within eight years of issuing the NESHAP for the following 28 source categories:

(1) Marine Tank Vessel Loading Operations (40 CFR part 63, subpart Y);

(2) Pharmaceuticals Production (40 CFR part 63, subpart GGG);

(3) Printing and Publishing (40 CFR part 63, subpart KK);

(4) Hand and Decorative Chromium Electroplating and Chromium Anodizing Tanks (40 CFR part 63, subpart N);

(5) Steel Pickling-HCL Process Facilities and Hydrochloric Acid Regeneration Plants (40 CFR part 63, subpart CCC);

(6) Group I Polymers and Resins (40 CFR part 63, subpart U);

(7) Ship Building and Ship Repair (Surface Coating) Operations (40 CFR part 63, subpart II);

(8) Wood Furniture Manufacturing Operations (40 CFR part 63, subpart JJ);

(9) Primary Lead Smelting (40 CFR part 63, subpart TTT);

(10) Secondary Lead Smelting (40 CFR part 63, subpart X);

(11) Pulp and Paper Production (40 CFR part 63, subpart S);

(12) Aerospace Manufacturing and Rework Facilities (40 CFR part 63, subpart GG);

(13) Mineral Wool Production (40 CFR part 63, subpart DDD);

(14) Primary Aluminum Reduction Plants (40 CFR part 63, subpart LL);

(15) Ferroalloys Production: Ferromanganese and Silicomanganese (40 CFR part 63, subpart XXX);

(16) Wool Fiberglass Manufacturing (40 CFR part 63, subpart NNN);

(17) Secondary Aluminum Production (40 CFR part 63, subpart RRR);

(18) Pesticide Active Ingredient Production (40 CFR part 63, subpart MMM);

(19) Polyether Polyols Production (40 CFR part 63, subpart PPP);

(20) Group IV Polymers and Resins (40 CFR part 63, subpart JJJ);

(21) Flexible Polyurethane Foam Production (40 CFR part 63, subpart III);

(22) Acrylic and Modacrylic Fibers Production (40 CFR part 63, subpart YY);

(23) Polycarbonate Production (40 CFR part 63, subpart YY);

(24) Off-Site Waste Recovery operations (40 CFR part 63, subpart DD);

(25) Phosphoric Acid Manufacturing (40 CFR part 63, subpart AA);

(26) Phosphate Fertilizers Production Plants (40 CFR part 63, subpart BB);

(27) Group III Polymers and Resins—Manufacture of Amino/Phenolic Resins (40 CFR part 63, subpart OOO); and

(28) Portland Cement manufacturing (40 CFR part 63, subpart LLL).

The proposed Consent Decree establishes deadlines for EPA's proposed and final actions for meeting these obligations. The proposed Consent Decree further requires that, within 15 business days of signing a proposed or final action, EPA shall deliver a notice of such action to the Office of the Federal Register for prompt publication. The proposed consent decree states that, after EPA fulfills its obligations under the decree, EPA may move to have this Decree terminated.

For a period of thirty (30) days following the date of publication of this notice, the Agency will accept written comments relating to the proposed consent decree from persons who were not named as parties or intervenors to the litigation in question. EPA or the Department of Justice may withdraw or withhold consent to the proposed consent decree if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act. Unless EPA or the Department of Justice determines, based on any comment submitted, that consent to this consent decree should be withdrawn, the terms of the decree will be affirmed.

II. Additional Information About Commenting on the Proposed Consent Decree

A. How Can I Get a Copy of the Consent Decree?

The official public docket for this action (identified by Docket ID No. EPA–HQ–OGC–2010–0508) contains a copy of the proposed consent decree. The official public docket is available for public viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center 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, and the telephone number for the OEI Docket is (202) 566–1752.

An electronic version of the public docket is available through *http://www.regulations.gov.* You may use *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. Once in the system, key in the appropriate docket identification number then select "search".

It is important to note that EPA's policy is that public comments, whether submitted electronically or on paper, will be made available for public viewing online at *http://www.regulations.gov* without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. Information claimed as CBI and other information whose disclosure is restricted by statute is not included in the official public docket or in the electronic public docket. EPA's policy is that copyrighted material, including copyrighted material contained in a public comment, will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the EPA Docket Center.

B. How and to Whom Do I Submit Comments?

You may submit comments as provided in the **ADDRESSES** section. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment and with any disk or CD ROM you submit. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. 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.

Use of the *http://www.regulations.gov* Web site to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment. In contrast to EPA's electronic public docket, EPA's electronic mail (e-mail) system is not an "anonymous access" system. If you send an e-mail comment directly to the Docket without going through *http://www.regulations.gov,* your e-mail address is automatically captured and included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

Dated: July 8, 2010.

Richard B. Ossias,

Associate General Counsel.

[FR Doc. 2010–17136 Filed 7–13–10; 8:45 am]

BILLING CODE 6560–50–P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Agency Information Collection Activities: Existing Collection; Emergency Extension

AGENCY: Equal Employment Opportunity Commission.

ACTION: Notice of information collection—emergency extension without change: Elementary-Secondary Staff Information Report (EEO–5).

SUMMARY: In accordance with the Paperwork Reduction Act, the Equal Employment Opportunity Commission (EEOC or Commission) announces that it submitted to the Office of Management and Budget (OMB) a request for a 90-day emergency extension of the Elementary-Secondary Staff Information Report (EEO–5) to be effective after the current July 31, 2010 expiration date.

FOR FURTHER INFORMATION CONTACT: Ronald Edwards, Director, Program Research and Surveys Division, 131 M Street, NE, Room 4SW30F, Washington, DC 20507; (202) 663–4949 (voice) or (202) 663–7063 (TTY).

SUPPLEMENTARY INFORMATION: Elementary and secondary public school systems and districts have been required to submit EEO–5 reports to EEOC since 1974 (biennially in even-numbered years since 1982). Since 1996, each public school district or system has submitted all of the district data on a single form, EEOC Form 168A. The individual school form, EEOC Form 168B, was eliminated in 1996, reducing the respondent burden and cost.

Overview of Information Collection

Collection Title: Elementary-Secondary Staff Information Report (EEO–5).
OMB Number: 3046–0003.
Frequency of Report: Biennial.
Type of Respondent: Certain public elementary and secondary school districts.
Description of Affected Public: Certain public elementary and secondary school districts.
Number of Responses: 7,155.
Reporting Hours: 10,000.
Cost to the Respondents: $266,000.
Federal Cost: $160,000.
Number of Forms: 1.
Form Number: EEOC Form 168A.
Abstract: Section 709 (c) of Title VII of the Civil Rights Act of 1964, as amended, 42 U.S.C. 2000e-8(c), requires employers to make and keep records relevant to a determination of whether unlawful employment practices have been or are being committed, to preserve such records, and to produce reports as the Commission prescribes by regulation or order. Accordingly, the EEOC issued regulations prescribing the reporting requirements for elementary and secondary public school districts. The EEOC uses EEO–5 data to investigate charges of employment discrimination against elementary and secondary public school districts. The data also are used for research. The data are shared with the Department of Education (Office for Civil Rights) and the Department of Justice. Pursuant to Section 709(d) of Title VII of the Civil Rights Act of 1964, as amended, EEO–5 data also are shared with State and local Fair Employment Practices Agencies (FEPAs).

Burden Statement: The estimated number of respondents included in the biennial EEO–5 survey is 7,155 public elementary and secondary school districts. The form is estimated to impose 10,000 burden hours biennially.

Dated: July 2, 2010.
For the Commission.
Jacqueline A. Berrien,
Chair.

[FR Doc. 2010–17184 Filed 7–13–10; 8:45 am]
BILLING CODE 6570–01–P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Agency Information Collection Activities: Existing Collection; Emergency Extension

AGENCY: Equal Employment Opportunity Commission.

ACTION: Notice of information collection—emergency extension without change: State and Local Government Information Report (EEO–4).

SUMMARY: In accordance with the Paperwork Reduction Act, the Equal Employment Opportunity Commission (EEOC or Commission) announces that it submitted to the Office of Management and Budget (OMB) a request for a 90-day emergency extension of the State and Local Government Information Report (EEO–4), to be effective after the current July 31, 2010 expiration date.

FOR FURTHER INFORMATION CONTACT: Ronald Edwards, Director, Program Research and Surveys Division, 131 M Street, NE., Room 4SW30F, Washington, DC 20507; (202) 663–4958 (voice) or (202) 663–7063 (TTY).

SUPPLEMENTARY INFORMATION: The EEOC has collected information from State and local governments with 100 or more full-time employees since 1974 (biennially in odd-numbered years since 1993).

Overview of Information Collection

Collection Title: State and Local Government Information Report (EEO–4).
OMB Number: 3046–0008.
Frequency of Report: Biennial.
Type of Respondent: State and local government jurisdictions with 100 or more employees.
Description of Affected Public: State and local governments excluding elementary and secondary public school districts.
Number of Responses: 13,456.
Reporting Hours: 44,719.
Cost to Respondents: $1,045,000.
Number of Forms: 1.
Form Number: EEOC Form 164.
Federal Cost: $187,500.
Abstract: Section 709(c) of Title VII of the Civil Rights Act of 1964, as amended, 42 U.S.C. 2000e–8(c), requires employers to make and keep records relevant to a determination of whether unlawful employment practices have been or are being committed, to preserve such records, and to produce reports as the Commission prescribes by regulation or order. Accordingly, the EEOC issued regulations prescribing the reporting requirements for State and local governments. State and local governments with 100 or more employees have been required to submit EEO–4 reports since 1974 (biennially in odd-numbered years since 1993). The individual reports are confidential.

EEO–4 data are used by the EEOC to investigate charges of discrimination against State and local governments and to provide information on the employment status of minorities and women. The data are shared with several other Federal agencies. Pursuant to section 709(d) of Title VII of the Civil Rights Act of 1964, U.S.C. 2000e–8(d), as amended, EEO–4 data is shared with State and local Fair Employment Practices Agencies (FEPAs). Aggregated data are also used by researchers and the general public.

Burden Statement: The estimated number of respondents included in the EEO–4 survey is 9,000 state and local governments. These 9,000 jurisdictions file about 13,456 reports due to the requirement for some to file separate reports by function. The form is estimated to impose 44,719 burden hours biennially.

Dated: July 2, 2010.
For the Commission.
Jacqueline A. Berrien,
Chair.

[FR Doc. 2010–17187 Filed 7–13–10; 8:45 am]
BILLING CODE 6750–01–P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Agency Information Collection Activities: Existing Collection; Emergency Extension

AGENCY: Equal Employment Opportunity Commission.

ACTION: Notice of information collection—emergency extension without change: Local Union Report (EEO–3).

SUMMARY: In accordance with the Paperwork Reduction Act, the Equal Employment Opportunity Commission (EEOC or Commission) announces that it submitted to the Office of Management and Budget (OMB) a request for a 90-day emergency extension of the Local Union Report

(EEO–3), to be effective after the current July 31, 2010 expiration date.

FOR FURTHER INFORMATION CONTACT: Ronald Edwards, Director, Program Research and Surveys Division, 131 M Street, NE, Room 4SW30F, Washington, DC 20507; (202) 663–4949 (voice) or (202) 663–7063 (TTY).

SUPPLEMENTARY INFORMATION: The EEOC has collected information from local unions on the EEO–3 form since 1966 (biennially since 1985).

Overview of Information Collection

Collection Title: Local Union Report (EEO–3).

OMB Number: 3046–0006.

Frequency of Report: Biennial.

Type of Respondent: Referral local unions with 100 or more members.

Description of Affected Public: Referral local unions and independent or unaffiliated referral unions and similar labor organizations.

Responses: 1,399.

Reporting Hours: 4,500 (including recordkeeping).

Cost to Respondents: $85,000.

Federal Cost: $60,000.

Number of Forms: 1.

Form Number: EEOC Form 274.

Abstract: Section 709(c) of Title VII of the Civil Rights Act of 1964, as amended, 42 U.S.C. 2000e-8(c), requires labor organizations to make and keep records relevant to a determination of whether unlawful employment practices have been or are being committed, and to produce reports from the data. The EEOC issued regulations requiring referral local unions with 100 or more members to submit EEO–3 reports. The individual reports are confidential. The EEOC uses EEO–3 data to investigate charges of discrimination and for research.

Burden Statement: The estimated number of respondents included in the biennial EEO–3 survey is 1,399 referral unions. The form is estimated to impose 4,500 burden hours biennially. In order to help reduce survey burden, respondents are encouraged to report data electronically whenever possible.

Dated: *July 2, 2010.*

For the Commission.

Jacqueline A. Berrien,

Chair.

[FR Doc. 2010–17188 Filed 7–13–10; 8:45 am]

BILLING CODE 6570–01–P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Agency Information Collection Activities: Existing Collection; Emergency Extension

AGENCY: Equal Employment Opportunity Commission.

ACTION: Notice of information collection—emergency extension without change: Employer Information Report (EEO–1)

SUMMARY: In accordance with the Paperwork Reduction Act, the Equal Employment Opportunity Commission (EEOC or Commission) announces that it submitted to the Office of Management and Budget (OMB) a request for an emergency extension of the Employer Information Report (EEO–1) to be effective after the current July 31, 2010 expiration date.

FOR FURTHER INFORMATION CONTACT: Ronald Edwards, Director, Program Research and Surveys Division, 131 M Street, NE., Room 4SW30F, Washington, DC 20507; (202) 663–4949 (voice) or (202) 663–7063 (TTY).

SUPPLEMENTARY INFORMATION: The EEOC has collected information from certain private employers on the EEO–1 Report form since 1966.

Overview of Information Collection

Collection Title: Employer Information Report (EEO–1)

OMB Number: 3046–0007.

Frequency of Report: Annual.

Type of Respondent: Private employers with 100 or more employees and certain Federal Government contractors and first-tier subcontractors with 50 or more employees.

Description of Affected Public: Private employers with 100 or more employees and certain Federal Government contractors and first-tier subcontractors with 50 or more employees.

Reporting Hours: 599,000.

Respondent Cost: $11.4 million.

Federal Cost: $2.1 million.

Number of Forms: 1.

Form Number: Standard Form 100.

Abstract: Section 709(c) of Title VII of the Civil Rights Act of 1964, as amended, 42 U.S.C. 2000e–8(c), requires employers to make and keep records relevant to a determination of whether unlawful employment practices have been or are being committed, to preserve such records, and to produce reports as the Commission prescribes by regulation or order. Accordingly, the EEOC issued regulations prescribing the EEO–1 reporting requirement. Employers in the private sector with 100 or more employees and some Federal contractors with 50 or more employees have been required to submit EEO–1 reports annually since 1966. The individual reports are confidential. EEO–1 data is used by EEOC to investigate charges of employment discrimination against employers in private industry and to provide information about the employment status of minorities and women. The data is shared with the Office of Federal Contract Compliance Programs (OFCCP), U.S. Department of Labor, and several other Federal agencies. Pursuant to § 709(d) of Title VII of the Civil Rights Act of 1964, as amended, EEO–1 data is also shared with State and local Fair Employment Practices Agencies (FEPAs).

Burden Statement: The estimated number of respondents included in the annual EEO–1 survey is 80,000 private employers. The estimated number of establishment-based responses per reporting company is between three and four EEO–1 reports annually. The annual number of responses is approximately 170,000. The form is estimated to impose 599,000 burden hours annually. In order to help reduce survey burden, respondents are encouraged to report data electronically whenever possible.

Dated: *July 2, 2010.*

For the Commission.

Jacqueline A. Berrien,

Chair.

[FR Doc. 2010–17189 Filed 7–13–10; 8:45 am]

BILLING CODE 6570–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Submitted for Review and Approval to the Office of Management and Budget (OMB), Comments Requested

July 8, 2010.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, 44 U.S.C. 3501 – 3520. Comments are requested concerning: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways

to enhance the quality, utility, and clarity of the information collected; (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; and (e) ways to further reduce the information collection burden for small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a currently valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before August 13, 2010. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget, via fax at 202–395–5167 or via the Internet at Nicholas_A._Fraser@omb.eop.gov and to the Federal Communications Commission via email to PRA@fcc.gov. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the web page http://reginfo.gov/public/do/PRAMain, (2) look for the section of the web page called "Currently Under Review", (3) click on the downward–pointing arrow in the "Select Agency" box below the "Currently Under Review" heading, (4) select "Federal Communications Commission" from the list of agencies presented in the "Select Agency" box, (5) click the "Submit" button to the right of the "Select Agency" box, and (6) when the list of FCC ICRs currently under review appears, look for the title of this ICR (or its OMB Control Number, if there is one) and then click on the ICR Reference Number to view detailed information about this ICR.

FOR FURTHER INFORMATION CONTACT: Judith B. Herman, Office of Managing Director, (202) 418–0214. For additional information or copies of the information collection(s), contact Judith B. Herman, OMD, 202–418–0214 or email judith–b.herman@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0855.

Title: Telecommunications Reporting Worksheets and Related Collections.

Form Numbers: FCC Forms 499–A and 499–Q.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for–profit and not–for–profit institutions.

Number of Respondents and Responses: 9,672 respondents; 44,574 responses.

Estimated Time per Response: 13.5 – 25 hours.

Frequency of Response: On occasion, annual and quarterly reporting requirements.

Obligation to Respond: Mandatory. Statutory authority for this information collection is contained in 47 U.S.C. sections 151, 154(i), 154(j), 157, 201, 205, 214, 225, 254 and 303(r).

Total Annual Burden: 281,710 hours.

Total Annual Cost: N/A.

Privacy Act Impact Assessment: N/A.

Nature and Extent of Confidentiality: The Commission will allow respondents to certify that data contained in their submissions is privileged or confidential commercial or financial information and that disclosure of such information would likely cause substantial harm to the competitive position of the entity filing the FCC worksheets. If the Commission receives a request for or proposes to disclose the information, the respondent would be required to make the full showing pursuant to the Commission's rules for withholding from public inspection information submitted to the Commission.

Needs and Uses: The Commission will submit this expiring information collection to the Office of Management and Budget (OMB) after this comment period to obtain the full three year clearance from them. The Commission is reporting an extension (no change in the reporting requirements). The Commission is reporting a 8,581 hour adjustment increase. This adjustment to our burden estimates reflects a re–estimate of the number of responses for some requirements and correcting some errors in previous burden calculations.

The Commission uses the collected information to evaluate individual contributor's contributions to the universal service mechanisms, pursuant to section 254 of the Act. Consistent with the Commission's existing policy, contributors will file a FCC Form 499–Q on a quarterly basis and/or the FCC Form 499–A on an annual basis. The Commission continues to believe that its reporting requirements will not be burdensome for contributors, as they need to track such information for their own internal business purposes.

Federal Communications Commission.

Marlene H. Dortch,

Secretary,

Office of the Secretary,

Office of Managing Director.

[FR Doc. 2010–17090 Filed 7–13–10; 8:45 am]

BILLING CODE 6712–01–S

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

July 8, 2010.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, 44 U.S.C. 3501–3520. Comments are requested concerning: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; (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, and (e) ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a currently valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before September 13, 2010. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget, via fax at 202–395–5167 or via the Internet at Nicholas_A._Fraser@omb.eop.gov and

to the Federal Communications Commission via email to PRA@fcc.gov.

FOR FURTHER INFORMATION CONTACT: Judith B. Herman, Office of Managing Director, (202) 418–0214. For additional information, contact Judith B. Herman, OMD, 202–418–0214 or email judith–b.herman@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0779.

Title: Sections 90.20(a)(1)(iii), 90.769, 90.767, 90.763(b)(l)(i)(a), 90.763(b)(l)(i)(B), 90.771(b) and 90.743, Rules to Provide for Use of the 220 MHz Band by the Private Land Mobile Radio Service (PLMRS).

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for–profit, not–for–profit institutions and state, local or tribal government.

Number of Respondents and Responses: 2,313 respondents, 2,313 responses.

Estimated Time Per Response: 2 – 20 hours.

Frequency of Response: On occasion reporting requirement and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. sections 154(i), 303(g), 303(r), and 332(a).

Total Annual Burden: 23,433 hours.

Total Annual Cost: $657,500.

Privacy Act Impact Assessment: N/A.

Nature and Extent of Confidentiality: There is no need for confidentiality.

Needs and Uses: The Commission will submit this expiring information collection to the Office of Management and Budget (OMB) after this comment period to obtain the full three year clearance from them. The Commission is reporting an extension (no change in the reporting and/or third party disclosure requirements).

This collection includes rules to govern the future operation and licensing of the 220–222 MHz band (220 MHz service). In establishing this licensing plan, the FCC's goal is to establish a flexible regulator framework that allows for efficient licensing in the 220 MHz service, eliminates unnecessary regulatory burdens, and enhances the competitive potential of the 220 MHz service in the mobile service marketplace. However, as with any licensing and operational plan for a radio service, a certain number of regulatory and information collection requirements are necessary to verify licensee compliance with Part 90 and 97 rules.

Federal Communications Commission.

Marlene H. Dortch,

Secretary,

Office of the Secretary,

Office of Managing Director.

[FR Doc. 2010–17088 Filed 7–13–10 8:45 am]

BILLING CODE 6712–01–S

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Submitted for Review and Approval to the Office of Management and Budget (OMB), Comments Requested

July 8, 2010.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, 44 U.S.C. 3501 – 3520. Comments are requested concerning: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; (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; and (e) ways to further reduce the information collection burden for small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a currently valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before [August 13, 2010]. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget, via fax at 202–395–5167 or via the Internet at Nicholas_A._Fraser@omb.eop.gov and to the Federal Communications Commission via email to PRA@fcc.gov. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the web page http://reginfo.gov/public/do/PRAMain, (2) look for the section of the web page called "Currently Under Review", (3) click on the downward–pointing arrow in the "Select Agency" box below the "Currently Under Review" heading, (4) select "Federal Communications Commission" from the list of agencies presented in the "Select Agency" box, (5) click the "Submit" button to the right of the "Select Agency" box, and (6) when the list of FCC ICRs currently under review appears, look for the title of this ICR (or its OMB Control Number, if there is one) and then click on the ICR Reference Number to view detailed information about this ICR.

FOR FURTHER INFORMATION CONTACT: Judith B. Herman, Office of Managing Director, (202) 418–0214. For additional information or copies of the information collection(s), contact Judith B. Herman, OMD, 202–418–0214 or email judith–b.herman@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0865.

Title: Wireless Telecommunications Bureau Universal Licensing System (ULS) Recordkeeping and Third Party Disclosure Requirements.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Individuals or households, business or other for–profit, not–for–profit institutions and state, local or tribal government.

Number of Respondents and Responses: 62,677 respondents, 62,677 responses.

Estimated Time per Response: .166 hours to 4 hours.

Frequency of Response: On occasion reporting requirement and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. sections 154(i) and 309(j).

Total Annual Burden: 89,117 hours.

Total Annual Cost: N/A.

Privacy Act Impact Assessment: Yes.

Nature and Extent of Confidentiality: There is no need for confidentiality with respect to all Private Land Mobile Radio (PLMRS) service filers in this information collection. Information on the PLMRS licensees is maintained in the Commission's system of records, FCC/WTB–1, "Wireless Services Licensing Records".

Needs and Uses: The Commission will submit this expiring information collection to the Office of Management and Budget (OMB) during this comment period. There is no change to the reporting, recordkeeping and/or third party disclosure requirements. The Commission is reporting a 25,671 hour increase in the total annual burden. This increase adjustment is due to an adjustment in the number of responses by licensees who operate within the various service categories. The estimates were gathered from the Commission's Universal Licensing System (ULS) and the CORES databases.

The purpose of this information collection is to streamline the set of rules which minimize filing requirements via the Universal Licensing System (ULS); to eliminate redundant and unnecessary submission requirements; and to assure ongoing collection of reliable licensing and ownership data. The recordkeeping and third party disclosure requirements, along with certifications which are made via the FCC Form 601 are ways the Commission reduced the filing burdens on the industry. However, applicants must maintain records to document compliance with the requirements for which they provide certifications. In some instances third party coordination is required.

Federal Communications Commission.

Marlene H. Dortch,

Secretary,

Office of the Secretary,

Office of Managing Director.

[FR Doc. 2010–17087 Filed 7–13–10– 8:45 am]

BILLING CODE 6712–01–S

FEDERAL COMMUNICATIONS COMMISSION

Sunshine Act Meeting; Open Commission Meeting; Thursday, July 15, 2010

Date: July 8, 2010.

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Thursday July 15, 2010, which is scheduled to commence at 10:30 a.m. in Room TW–C305, at 445 12th Street, SW., Washington, DC.

ITEM NO.	BUREAU	SUBJECT
1	WIRELINE COMPETITION	TITLE: Rural Health Care Support Mechanism (WC Docket No. 02–60) SUMMARY: The Commission will consider a Notice of Proposed Rulemaking initiating reforms to the Universal Service Rural Health Care Fund to expand the reach and use of broadband connectivity by health care providers throughout the nation.
2	OFFICE OF ENGINEERING AND TECHNOLOGY, WIRELESS TELE–COMMUNICATIONS AND INTERNATIONAL.	TITLE: Fixed and Mobile services in the Mobile Satellite Service Bands at 1525–1559 MHz and 1626.5–1660.5 MHz, 1610–1626.5 MHz and 2483.5–2500 MHz, and 2000–2020 MHz and 2180–2200 MHz SUMMARY: The Commission will consider a Notice of Proposed Rulemaking and Notice of Inquiry to increase value, utilization, and investment in the 2 GHz, Big LEO, and L–bands of the Mobile Satellite Service.
3	WIRELINE COMPETITION	TITLE: Electronic Tariff Filing System (ETFS) SUMMARY: The Commission will consider a Notice of Proposed Rulemaking seeking comment on streamlining the tariff filing and formatting process by transitioning from paper to electronic filing to reduce industry burden and promote an open, transparent, and efficient flow of information.

The meeting site is fully accessible to people using wheelchairs or other mobility aids. Sign language interpreters, open captioning, and assistive listening devices will be provided on site. Other reasonable accommodations for people with disabilities are available upon request. In your request, include a description of the accommodation you will need and a way we can contact you if we need more information. Last minute requests will be accepted, but may be impossible to fill. Send an e–mail to: fcc504@fcc.gov or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

Additional information concerning this meeting may be obtained from Audrey Spivack or David Fiske, Office of Media Relations, (202) 418–0500; TTY 1–888–835–5322. Audio/Video coverage of the meeting will be broadcast live with open captioning over the Internet from the FCC Live web page at www.fcc.gov/live.

For a fee this meeting can be viewed live over George Mason University's Capitol Connection. The Capitol Connection also will carry the meeting live via the Internet. To purchase these services call (703) 993–3100 or go to www.capitolconnection.gmu.edu.

Copies of materials adopted at this meeting can be purchased from the FCC's duplicating contractor, Best Copy and Printing, Inc. (202) 488–5300; Fax (202) 488–5563; TTY (202) 488–5562. These copies are available in paper format and alternative media, including large print/type; digital disk; and audio and video tape. Best Copy and Printing, Inc. may be reached by e–mail at FCC@BCPIWEB.com.

Federal Communications Commission.

Marlene H. Dortch,

Secretary,

Office of the Secretary,

Office of Managing Director.

[FR Doc. 2010–17227 Filed 7–12–10; 11:15 am]

BILLING CODE 6712–01–S

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 11:10 a.m. on Monday, July 12, 2010, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters related to the Corporation's supervision and resolution activities.

In calling the meeting, the Board determined, on motion of Vice Chairman Martin J. Gruenberg, seconded by Director John E. Bowman (Acting Director, Office of Thrift Supervision), concurred in by Director Thomas J. Curry (Appointive), Director John C. Dugan (Comptroller of the Currency), and Chairman Sheila C. Bair, that Corporation business required its consideration of the matters which were to be the subject of this meeting on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10)).

The meeting was held in the Board Room of the FDIC Building located at 550 17th Street, NW., Washington, DC.

Dated: July 12, 2010.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2010–17303 Filed 7–12–10; 4:15 pm]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that the Federal Deposit Insurance Corporation's Board of Directors met in open session at 10:35 a.m. on Monday, July 12, 2010, to consider the following matters:

SUMMARY AGENDA: Disposition of minutes of previous Board of Directors' Meetings.

DISCUSSION AGENDA: Memorandum and resolution re: Information Sharing Memorandum of Understanding.

In calling the meeting, the Board determined, on motion of Vice Chairman Martin J. Gruenberg, seconded by Director Thomas J. Curry (Appointive), concurred in by Director John E. Bowman (Acting Director, Office of Thrift Supervision), Director John C. Dugan (Comptroller of the Currency), and Chairman Sheila C. Bair, that Corporation business required its consideration of the matters on less than seven days' notice to the public; and that no earlier notice of the meeting than that previously provided on July 6, 2010, was practicable.

The meeting was held in the Board Room on the sixth floor of the FDIC Building located at 550 17th Street, NW., Washington, DC.

Dated: July 12, 2010.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2010–17304 Filed 7–12–10; 4:15 pm]

BILLING P

FEDERAL ELECTION COMMISSION

Sunshine Act Notices

AGENCY: Federal Election Commission.

DATE AND TIME: Thursday, July 15, 2010, at 10 a.m.

PLACE: 999 E Street, NW., Washington, DC (Ninth Floor).

STATUS: This meeting will be open to the public.

The following item has been added to the agenda for the above-captioned open meeting:

Report of the Audit Division on Biden for President, Inc.

Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Darlene Harris, Deputy Commission Secretary, at (202) 694–1040, at least 72 hours prior to the hearing date.

PERSON TO CONTACT FOR INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Shawn Woodhead Werth,

Secretary and Clerk of the Commission.

[FR Doc. 2010–17079 Filed 7–13–10; 8:45 am]

BILLING CODE 6715–01–M

FEDERAL HOUSING FINANCE AGENCY

[No. 2010–N–08]

Proposed Collection; Comment Request

AGENCY: Federal Housing Finance Agency.

ACTION: 30-day Notice of Submission of Information Collection for Approval from the Office of Management and Budget.

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act of 1995, the Federal Housing Finance Agency (FHFA) is seeking public comments concerning the information collection known as "Capital Requirements for the Federal Home Loan Banks," which has been assigned control number 2590–0002 by the Office of Management and Budget (OMB). FHFA will submit the information collection to OMB for review and approval of a three-year extension of the control number, which is due to expire on July 31, 2010.

DATES: Interested persons may submit comments on or before August 13, 2010.

COMMENTS: Submit comments to the Office of Information and Regulatory Affairs of the Office of Management and Budget, Attention: Desk Officer for the Federal Housing Finance Agency, Washington, DC 20503, *Fax:* 202–395–6974, *E-mail: OIRA_Submission@omb.eop.gov.* Please also submit comments to FHFA using any one of the following methods:

- *E-mail: RegComments@fhfa.gov.* Please include Proposed Collection; Comment Request: "Capital Requirements for the Federal Home Loan Banks, (No. 2010–N–08)" in the subject line of the message.
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. If you submit your comment to the *Federal eRulemaking Portal,* please also send it by *e-mail* to FHFA at *RegComments@fhfa.gov* to ensure timely receipt by the agency. Please include Proposed Collection; Comment Request: "Capital Requirements for the Federal Home Loan Banks, (No. 2010–

N–08)" in the subject line of the message.

• *U.S Mail/Hand Delivery:* Federal Housing Finance Agency, Fourth Floor, 1700 G Street NW., Washington, DC 20552, ATTENTION: Proposed Collection Public Comment Request: "Capital Requirements for the Federal Home Loan Banks, (No. 2010–N–08)."

We will post all public comments we receive without change, including any personal information you provide, such as your name and address, on the FHFA Web site at *http://www.fhfa.gov.* In addition, copies of all comments received will be available for examination by the public on business days between the hours of 10 a.m. and 3 p.m., at the Federal Housing Finance Agency, Fourth Floor, 1700 G Street, NW., Washington, DC 20552. To make an appointment to inspect comments, please call the Office of General Counsel at 202–414–6924.

FOR FURTHER INFORMATION CONTACT: Jonathan F. Curtis, Financial Analyst, Division of Federal Home Loan Bank Regulation, by telephone at 202–408–2866 (not a toll free number), by e-mail at *jonathan.curtisj@fhfa.gov*, or by regular mail at the Federal Housing Finance Agency, 1625 Eye Street NW., Washington, DC 20006. The telephone number for the Telecommunications Device for the Deaf is 800–877–8339.

SUPPLEMENTARY INFORMATION:

A. Need For and Use of the Information Collection

Section 6 of the Federal Home Loan Bank Act (Bank Act) establishes the capital structure for the Federal Home Loan Banks (Banks) and requires FHFA to issue regulations prescribing uniform capital standards applicable to each Bank.[1] Parts 930, 931, 932, and 933 of title 12, Code of Federal Regulations implement the statutory capital structure for the Banks. Part 930 establishes definitions applicable to risk management and the capital regulations; part 931 concerns Bank capital stock; part 932 establishes Bank capital requirements; and part 933 sets forth the requirements for Bank capital structure plans. The provisions of part 931 provide that a Bank must require its members to maintain a minimum investment in the capital stock of the Bank as a condition to becoming and remaining a member of the Bank and as a condition to transacting business with the Bank or obtaining advances from the Bank. The amount of the required minimum investment is determined in accordance with the Bank's capital plan under part 933.

The Banks use the information collection to determine the amount of capital stock a member must purchase to maintain membership in and to obtain services from a Bank. More specifically, the provisions of §§ 931.3 and 933.2(a) authorize a Bank to offer its members several options to satisfy a membership investment in capital stock and an activity-based stock purchase requirement. The information collection is necessary to provide the Banks with the flexibility to meet the statutory and regulatory capital structure requirements while allowing Bank members to choose the option best suited to their business requirements.

The OMB control number for the information collection is 2590–0002. The OMB clearance for the information collection expires on July 31, 2010. The likely respondents include Banks and Bank members.

B. Burden Estimate

While the number of member respondents has remained essentially the same, the overall burden on members of the Banks has decreased because of more accurate calculations. The estimate for the total annual hour burden for all member respondents is 3,023 hours. The estimate for the total annual cost burden for member respondents is $123,943. These estimates are based on the following calculations:

FHFA estimates the total annual average number of activity-based stock purchase requirement for member respondents at 28,080 (108 daily borrowers x 260 working days, x 1 response per respondent). The estimate for the average hours per response is 0.05 hours. The estimate for the annual hour burden for activity-based stock purchase requirement member respondents is 1,404 hours (108 daily borrowers x 260 working days, x 1 response x 0.05 hours). The estimate for the annual cost burden for member respondents is $57,564 (1,404 hours x $41 hourly rate).

FHFA estimates the total annual average number of investment in capital stock membership maintenance respondents at 32,372 (8,093 with 4 responses per respondent). The estimate for the average hours per response is 0.05 hours. The estimate for the annual hour burden for membership maintenance investment in capital stock respondents is 1,619 hours (8,093 membership respondents x 4 responses per year x 0.05 hours per response). The estimate for the annual cost burden $66,379 (1,619 hours x $41 hourly rate).

C. Comment Request

In accordance with the requirements of 5 CFR 1320.8(d), FHFA published a request for public comments regarding this information collection in the **Federal Register** on March 29, 2010. *See* 75 FR 15431 (Mar. 29, 2010). The 60-day comment period closed on May 28, 2010. No public comments were received.

FHFA requests written comments on the following: (1) Whether the collection of information is necessary for the proper performance of FHFA functions, including whether the information has practical utility; (2) the accuracy of FHFA's estimates of the burdens of the collection of information; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) 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.

Dated: July 6, 2010.

Edward J. DeMarco,

Acting Director, Federal Housing Finance Agency.

[FR Doc. 2010–17121 Filed 7–13–10; 8:45 am]

BILLING CODE 8070–01–P

[1] 12 U.S.C. 1426.

FEDERAL HOUSING FINANCE AGENCY

[No. 2010–N–09]

Proposed Collection; Comment Request

AGENCY: Federal Housing Finance Agency.

ACTION: 30-day Notice of Submission of Information Collection for Approval from the Office of Management and Budget.

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act of 1995, the Federal Housing Finance Agency (FHFA) is seeking public comments concerning the information collection known as "Members of the Banks," which has been assigned control number 2590–0003 by the Office of Management and Budget (OMB). FHFA will submit the information collection to OMB for review and approval of a three-year extension of the control number, which is due to expire on July 31, 2010.

DATES: Interested persons may submit comments on or before August 13, 2010.

Comments: Submit comments to the Office of Information and Regulatory Affairs of the Office of Management and Budget, Attention: Desk Officer for the Federal Housing Finance Agency,

Washington, DC 20503, *Fax:* 202–395–6974, *E-mail: OIRA_Submission@omb.eop.gov.* Please also submit comments to FHFA using any one of the following methods:

- *E-mail: RegComments@fhfa.gov.* Please include Proposed Collection; Comment Request: "Members of the Banks, (No. 2010–N–09)" in the subject line of the message.
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. If you submit your comment to the *Federal eRulemaking Portal,* please also send it by e-mail to FHFA at *RegComments@fhfa.gov* to ensure timely receipt by the agency. Please include Proposed Collection; Comment Request: "Members of the Banks, (No. 2010–N–09)" in the subject line of the message.
- *U.S. Mail/Hand Delivery:* Federal Housing Finance Agency, Fourth Floor, 1700 G Street, NW., Washington, DC 20552, ATTENTION: Public Comments/Proposed Collection; Comment Request: "Members of the Banks, (No. 2010–N–09)."

We will post all public comments we receive without change, including any personal information you provide, such as your name and address, on the FHFA Web site at *http://www.fhfa.gov.* In addition, copies of all comments received will be available for examination by the public on business days between the hours of 10 a.m. and 3 p.m., at the Federal Housing Finance Agency, Fourth Floor, 1700 G Street, NW., Washington, DC 20552. To make an appointment to inspect comments, please call the Office of General Counsel at 202–414–6924.

FOR FURTHER INFORMATION CONTACT: Jonathan F. Curtis, Financial Analyst, Division of Federal Home Loan Bank Regulation, by telephone at 202–408–2866 (not a toll-free number), by e-mail at *jonathan.curtisj@fhfa.gov,* or by regular mail at the Federal Housing Finance Agency, 1625 Eye Street, NW., Washington, DC 20006. The telephone number for the Telecommunications Device for the Deaf is 800–877–8339.

SUPPLEMENTARY INFORMATION:

A. Need for and Use of the Information Collection

Section 4 of the Federal Home Loan Bank Act (Bank Act) establishes the eligibility requirements an institution must meet in order to become a member of a Federal Home Loan Bank (Bank).[1] The membership rule, which implements section 4 of the Bank Act, provides uniform requirements an applicant for Bank membership must meet and review criteria a Bank must apply to determine if an applicant satisfies the statutory and regulatory membership eligibility requirements.[2]

More specifically, the membership rule implements the statutory eligibility requirements and provides guidance on how an applicant may satisfy such requirements. The Banks, and where appropriate, FHFA, use the information collection to determine: (i) If an institution satisfies the statutory and regulatory membership requirements; (ii) a member's initial capital stock purchase in a Bank; (iii) member withdrawals; and (iv) where a member transfers to a different Bank district. The rule authorizes a Bank to approve or deny each membership application subject to the statutory and regulatory requirements, and permits an applicant to appeal to FHFA a Bank's decision to deny certification as a Bank member. The rule also imposes a continuing obligation on a current Bank member to provide information necessary to determine if it remains in compliance with applicable statutory and regulatory eligibility requirements.

The provisions governing this information collection are found in §§ 1263.2 through 1263.31 of the membership rule, 12 CFR 1263.2—1263.31. The information collection is necessary to enable a Bank to determine whether prospective and current Bank members satisfy the statutory and regulatory requirements to be certified initially and maintain their status as members eligible to obtain Bank advances. FHFA requires and uses the information collection to determine whether to uphold or overrule a Bank's decision to deny member certification to an applicant.

The OMB control number for the information collection is 2590–0003, which is due to expire on July 31, 2010. The likely respondents are institutions that want to be certified as or are members of a Bank seeking continued certification.

B. Burden Estimate

FHFA has analyzed the cost and hour burden for the four facets of the information collection: (1) Membership Application Process, (2) Minimum initial capital stock calculation for applicants, (3) Membership withdrawals, and (4) Transfer of membership to another Bank district. The estimate for the total annual hour burden for all respondents is 5,564 hours. The estimate for the total annual cost burden is $535,549. These estimates are based on the following calculations:

Membership Application and Appeal Process

FHFA estimates the total annual average number of member applicants at 283, with 1 response per applicant. Of those 283 applicants, FHFA estimates that 1 applicant will appeal a Bank's membership determination to FHFA. The estimate for the average hours per application is 19.25 hours. The estimate for the average hours per appeal is 10 hours. The estimate for the total annual hour burden to applicants for the membership application and appeal process is 5,458 hours (283 applicants x 1 response per applicant x 19.25 hours per response + 1 appellant x 1 appeal x 10 hours). The estimate for the total annual cost burden to applicants for the membership application and appeal process is $521,136.

Initial Capital Stock Calculation for Applicants

FHFA estimates the total annual average number of applicant initial capital stock subscription calculations at 283, with 1 response per applicant. The estimate for the average hours per application is 0.25 hours. The estimate for the annual hour burden for applicants' initial capital stock subscription calculations is 71 hours (283 applicants x 1 response per applicant x 0.25 hours per response). The estimate for the total annual cost burden to applicants of initial capital stock calculation is $9,727.

Membership Withdrawals

FHFA estimates the total annual average number of membership withdrawals at 8, with 1 response per withdrawing member. The estimate for the average hours per member withdrawal is 3.5 hours. The estimate for the annual hour burden for membership withdrawals is 28 hours (8 membership withdrawals x 1 response per member x 3.5 hours per response). The estimate for the total annual cost burden to members for withdrawals from membership is $3,836.

Transfers of Membership to Another Bank District

FHFA estimates the total annual average number of transfers of membership at 2, with 1 response per transferring member. The estimate for the average hours per member transfer is 3.5 hours. The estimate for the annual hour burden for membership transfers is 7 hours (2 membership transfers x 1

[1] 12 U.S.C. 1424.

[2] 12 CFR *part* 1263 (former part 925). *See* 75 FR 678, 690 (Jan. 5, 2010).

response per member x 3.5 hours per response). The estimate for the total annual cost burden to member respondents of the transfer of membership process is $850.

C. Comment Request

In accordance with the requirements of 5 CFR 1320.8(d), FHFA published a request for public comments regarding this information collection in the **Federal Register** on March 29, 2010. *See* 75 FR 15431 (Mar. 29, 2010). The 60-day comment period closed on May 28, 2010. FHFA received one public comment from a consumer that referred to another proposed collection of information that was not related to this collection.

FHFA requests written comments on the following: (1) Whether the collection of information is necessary for the proper performance of FHFA functions, including whether the information has practical utility; (2) the accuracy of FHFA's estimates of the burdens of the collection of information; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) 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.

Dated: July 6, 2010.

Edward J. DeMarco,

Acting Director, Federal Housing Finance Agency.

[FR Doc. 2010–17122 Filed 7–13–10; 8:45 am]

BILLING CODE 8070–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within ten days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (*http://www.fmc.gov*) or by contacting the Office of Agreements at (202)–523–5793 or *tradeanalysis@fmc.gov*.

Agreement No.: 011279–027.

Title: Latin America Agreement.

Parties: ABC Discussion Agreement; Caribbean Shipowners Association; Central America Discussion Agreement; Compania Libra de Navegacion Uruguay S.A.; Inland Shipping Services Association; Venezuelan Discussion Agreement; West Coast of South America Discussion Agreement; and Zim Integrated Shipping Services, Ltd.

Filing Party: Wayne R. Rohde, Esq.; Sher & Blackwell LLP; 1850 M Street, NW.; Suite 900; Washington, DC 20036.

Synopsis: The amendment deletes the Hispaniola Discussion Agreement as a party to the Agreement and updates the membership of various constituent agreements.

Agreement No.: 011794–012.

Title: COSCON/KL/YMUK/Hanjin Worldwide Slot Allocation & Sailing Agreement.

Parties: COSCO Container Lines Company, Limited; Kawasaki Kisen Kaisha, Ltd.; Yangming (UK) Ltd.; and Hanjin Shipping Co., Ltd.

Filing Party: Robert B. Yoshitomi, Esq.; Nixon Peabody LLP; 555 West Fifth Street, 46th Floor; Los Angeles, CA 90013.

Synopsis: The amendment authorizes communications within the Agreement regarding operational matters where parties to the Agreement share space with outside parties.

Agreement No.: 012104.

Title: Tropical Shipping & Construction Co., Ltd. and Discovery Sun Partnership Space Agreement.

Parties: Discovery Sun Partnership and Tropical Shipping & Construction Co., Ltd.

Filing Parties: Neal M. Mayer, Esq.; Hoppel, Mayer & Coleman; 1050 Connecticut Avenue, NW., 10th Floor; Washington, DC 20036.

Synopsis: The agreement authorizes Discovery Sun Partnership to provide space to Tropical Shipping & Construction Co., Ltd. in the trade between the U.S. East Coast and ports in the Bahamas.

Dated: July 9, 2010.

By Order of the Federal Maritime Commission.

Karen V. Gregory,

Secretary.

[FR Doc. 2010–17177 Filed 7–13–10; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission an application for a license as a Non-Vessel-Operating Common Carrier (NVO) and/or Ocean Freight Forwarder (OFF)—Ocean Transportation Intermediary (OTI) pursuant to section 19 of the Shipping Act of 1984 as amended (46 U.S.C. Chapter 409 and 46 CFR 515). Notice is also hereby given of the filing of applications to amend an existing OTI license or the Qualifying Individual (QI) for a license.

Interested persons may contact the Office of Transportation Intermediaries, Federal Maritime Commission, Washington, D.C. 20573.

A–1 Fargo Van and Storage, Inc. (OFF), 7700 S.W. 100th Street, Miami, FL 33156. Officers: Treva H. Ward, Vice President, (Qualifying Individual), Virgil Hale, President, Application Type: New OFF License.

AFL International Logistics Group LLC (NVO), 671 N.W. 4th Avenue, Fort Lauderdale, FL 33311. Officer: Gabriele U. Heinrichs, Managing Member, (Qualifying Individual), Application Type: New NVO License.

Air Tiger Express (USA), Inc. (NVO & OFF), 149–09 183rd Street, 2nd Floor, Springfield Gardens, NY 11413. Officers: Russell Lee, Vice President, (Qualifying Individual), Richard Chu, Director/Chief Executive Officer, Application Type: QI Change.

Allstate Int'l Freight USA, Inc. dba A.I.F. Company (NVO & OFF), 200 E. Stanley Street, Compton, CA 90220. Officer: Byung H. Kim, CEO/President/Secretary/CFO/Director, (Qualifying Individual), Application Type: QI Change.

Amarine USA, Inc. (NVO), 21 Langerfeld Road, Hillsdale, NJ 07642. Officers: Moon H. You, President/Secretary, (Qualifying Individual), Han J. Song, Treasurer, Application Type: Name Change.

Cargo Infinity USA, Inc. (OFF), 23322 Madero Road, Suite K, Mission Viejo, CA 92691. Officers: Jean L. Niu, President/CEO, (Qualifying Individual), Annie Lam, Director/Secretary/Treasurer/CFO, Ada Lai Y. Lee, Director, Application Type: New OFF License.

Direct Service Inc. dba Tiger Freight International, Corporation (NVO), 1209 John Reed Court, City of Industry, CA 91745. Officer: Chi (Steve) H. Hung, President, (Qualifying Individual), Application Type: Trade Name Change.

Eagle Maritime Private Limited dba Eagle Maritime USA Inc. (NVO), 17, Contractor Building, 1st Floor, 15, Vajukotak Marg, Fort, Mumbai 400001 India. Officer: Dasharath Y. Patade, Chairman/Director/Shareholder, (Qualifying Individual), Application Type: New NVO License.

Global Freight Services, Inc. (NVO & OFF), 32 Raymond Avenue, Chestnut Ridge, NY 10977. Officer: Rosario Vizzari, President/Secretary/Treasurer, (Qualifying Individual), Application Type: License Transfer.

Intership, Inc dba Helm Express (NVO & OFF), 2530 Knoblock, Houston, TX 77023. Officer: Yasser Shaikh, President, (Qualifying Individual), Application Type: Add NVO Service and Trade Name Change.

Jupiter Airline Services, Inc. dba Mercury Logistics (NVO), 5456 McConnell Avenue, Los Angeles, CA 90066. Officers: Zack Vernikovsky, Vice President/Director, (Qualifying Individual), Joseph A. Czyzyk, CEO/Director, Application Type: New NVO License.

Legend Express Co. (OFF), 1506 S. Paloma Street, Los Angeles, CA 90021. Officers: Gila Morad, Chief Executive Officer/Chief Financial Officer, (Qualifying Individual), Natali Morad, Secretary, Application Type: QI Change.

Linsan.Tex Investments, L.L.C. (OFF), 8404 Endicott Lane, Dallas, TX 75227. Officers: Franklin E. Aigbuza, Secretary/Member, (Qualifying Individual), Roseline A. Izedonmwen, CEO/Member, Application Type: New OFF License.

Ocean Air Land Freight, Corp. (OFF), 8600 NW 30th Terrace 2nd Floor, Miami, FL 33122. Officers: Martha Zuluaga, President, (Qualifying Individual), Maria J. Gori, Secretary/Treasurer, Application Type: Trade Name Change.

Ocean Channel Shipping Co., Ltd. (NVO), 13091 Nordland Drive, Corona, CA 92880. Officer: Xiaohua Huo, President, (Qualifying Individual), Application Type: New NVO License. Siman Logistics, Inc. (NVO & OFF), 765 N, IL Route 83, Suite 124, Bensenville, IL 60106. Officers: Wolfgang A. Ries, Senior Vice President, (Qualifying Individual), Christian Ludwig, President, Application Type: New NVO & OFF License.

Top Wise Logistics Inc. (NVO), 654 N. Spring Street, Los Angeles, CA 90012. Officer: George N. Lee, CEO/CFO/Secretary, (Qualifying Individual), Application Type: New NVO License.

Trinity Logistics USA, Inc. (NVO), 10 East Merrick Road, Suite 304, Valley Stream, NY 11580. Officers: Doris McGregory, Treasurer, (Qualifying Individual), David Pereira, President/Secretary, Application Type: New NVO License.

Twenty Two Global Transport, LP (NVO & OFF), 1911 Bagby Street, Houston, TX 77002. Officers: Kevin A. Smoot, Partner/Director, (Qualifying Individual), Robert Crossland, Vice President, Application Type: New NVO & OFF License.

United Marine Lines, L.L.C. (NVO), 201 Sevilla Avenue, Suite 309, Coral Gables, FL 33134. Officers: Eduardo Del Riego, President/Secretary, (Qualifying Individual), Robert Boucek, Vice President/Treasurer, Application Type: New NVO License.

Dated: July 9, 2010.

Karen V. Gregory,

Secretary.

[FR Doc. 2010–17175 Filed 7–13–10; 8:45 am]

BILLING CODE 6730–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Establishment of the Advisory Board on Elder Abuse, Neglect, and Exploitation

AGENCY: Department of Health and Human Services, Administration on Aging.

ACTION: Notice.

AUTHORITY: The Advisory Board on Elder Abuse, Neglect, and Exploitation is authorized under section 2021, Subtitle H—Elder Justice Act, of the Affordable Care Act, Public Law 111–148. The Advisory Board is governed by provisions of Public Law 92–463, as amended, (5 U.S.C. App. 2), which sets forth standards for the formation and use of advisory committees.

SUMMARY: The U.S. Department of Health and Human Services announces establishment of the Advisory Board on Elder Abuse, Neglect, and Exploitation, as directed by section 2022, Subtitle H—Elder Justice Act, of the Affordable Care Act, Public Law 111–148.

FOR FURTHER INFORMATION CONTACT: Edwin Walker, Deputy Assistant Secretary for Program Operations, Department of Health and Human Services, Administration on Aging, Washington, DC 20201, Telephone: 202–357–3557, Fax: 202–357–3549.

SUPPLEMENTARY INFORMATION: Subtitle H—Elder Justice Act of the Affordable Care Act, Public Law 111–148, establishes the Advisory Board within the Department of Health and Human Services (HHS). To comply with the authorizing directive and guidelines under the Federal Advisory Committee Act (FACA), a charter has been filed with the Committee Management Secretariat in the General Services Administration (GSA), the appropriate committees in the Senate and U.S. House of Representatives, and the Library of Congress to establish the Advisory Board as a non-discretionary Federal advisory committee. The charter was filed on July 8, 2010.

Objectives and Scope of Activities

The Advisory Board on Elder Abuse, Neglect, and Exploitation (Advisory Board) is the Department's statutory public advisory body in the Elder Justice Act on creating short- and long-term multidisciplinary strategic plans for the development of the field of elder justice in the U.S. The Advisory Board will examine relevant research and identify best practices and make recommendations to the Elder Justice Coordinating Council and Congress regarding improving and enhancing Federal, State, and local elder justice programs, research, training, and coordination.

Membership and Designation

The Secretary is soliciting nominations for appointment to the 27-member Advisory Board from among members of the general public who are individuals with experience and expertise in elder abuse, neglect, and exploitation prevention, detection, treatment, intervention, or prosecution. Each member of the Advisory Board shall be appointed for a term of 3 years except that, of the members first appointed, 9 shall be appointed for a term of 3 years; 9 shall be appointed for a term of 2 years; and 9 shall be appointed for a term of 1 year. Nominations shall be submitted to: Edwin Walker, Deputy Assistant Secretary for Program Operations, Department of Health and Human Services, Administration on Aging, Washington, DC 20201, no later than August 15, 2010. Any vacancy on the Advisory Board shall not affect its powers, but shall be filled in the same manner as the original appointment was made. An individual chosen to fill a vacancy shall be appointed for the unexpired term of the member replaced. The Advisory Board shall elect a Chair and Vice Chair from among its members.

Administrative Management and Support

HHS will provide funding and administrative support for the Advisory Board to the extent permitted by law within existing appropriations. Management and oversight for support services provided to the Advisory Board will be the responsibility of the Administration on Aging, which is an operating division within HHS. Staff will be assigned to support the activities of the Advisory Board. All executive departments and agencies shall provide information to the Advisory Board as the Chair may request for purposes of carrying out the Advisory Board's

functions, to the extent permitted by law. A copy of the Commission charter can be obtained from the designated contacts or by accessing the FACA database that is maintained by the GSA Committee Management Secretariat. The website for the FACA database is *http://fido.gov/facadatabase/*.

Dated: July 9, 2010.

Kathy Greenlee,

Assistant Secretary for Aging.

[FR Doc. 2010–17197 Filed 7–13–10; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0357]

Agency Information Collection Activities; Proposed Collection; Comment Request; Hazard Analysis and Critical Control Point Procedures for the Safe and Sanitary Processing and Importing of Juice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on recordkeeping requirements for applying hazard analysis and critical control point (HAACP) procedures for safe and sanitary processing for processors of fruit and vegetable juice.

DATES: Submit either electronic or written comments on the collection of information by September 13, 2010.

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: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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, including each proposed extension of an existing 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.

Hazard Analysis and Critical Control Point (HACCP) Procedures for the Safe and Sanitary Processing and Importing of Juice—21 CFR Part 120 (OMB Control Number 0910–0466)—Extension

FDA's regulations in part 120 (21 CFR part 120) mandate the application of HACCP procedures to fruit and vegetable juice processing. HACCP is a preventative system of hazard control that can be used by all food processors to ensure the safety of their products to consumers. A HACCP system of preventive controls is the most effective and efficient way to ensure that these food products are safe. FDA's mandate to ensure the safety of the Nation's food supply is derived principally from the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 *et seq.*). Under the act, FDA has authority to ensure that all foods in interstate commerce, or that have been shipped in interstate commerce, are not contaminated or otherwise adulterated, are produced and held under sanitary conditions, and are not misbranded or deceptively packaged; under section 701 (21 U.S.C. 371), the act authorizes the agency to issue regulations for its efficient enforcement. The agency also has authority under section 361 of the Public Health Service Act (42 U.S.C. 264) to issue and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases from one State to another other State. Information development and recordkeeping are essential parts of any HACCP system. The information collection requirements are narrowly tailored to focus on the development of appropriate controls and document those aspects of processing that are critical to food safety. Through these regulations, FDA is implementing its authority under section 402(a)(4) of the act (21 U.S.C. 342(a)(4)).

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours Per Record	Total Hours
120.6(c) and 120.12(a)(1) and (b)	1,875	365	684,375	0.1	68,437.5
120.7; 120.10(a); and 120.12(a)(2), (b), and (c)	2,300	1.1	2,530	20	50,600

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	No of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours Per Record	Total Hours
120.8(b)(7) and 120.12(a)(4)(i) and (b)	1,450	14,600	21,170,000	0.01	211,700
120.10(c) and 120.12(a)(4)(ii) and (b)	1,840	12	22,080	0.1	2,208
120.11(a)(1)(iv) and (a)(2) and 120.12(a)(5)	1,840	52	95,680	0.1	9,568
120.11(b) and 120.12(a)(5) and (b)	1,840	1	1,840	4	7,360
120.11(c) and 120.12(a)(5) and (b)	1,840	1	1,840	4	7,360
120.14(a)(2), (c), and (d)	308	1	308	4	1,232
Total					358,466

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 1 of this document provides a breakdown of the total estimated annual recordkeeping burden. FDA bases this hour burden estimate on its experience with the application of HACCP principles in food processing.

The burden estimates in table 1 of this document are based on an estimate of the total number of juice manufacturing plants (i.e., 2,300) affected by the regulations. Included in this total are 850 plants currently identified in FDA's official establishment inventory plus 1,220 very small apple juice manufacturers and 230 very small orange juice manufacturers. The total burden hours are derived by estimating the number of plants affected by each portion of this final rule and multiplying the corresponding number by the number of records required annually and the hours needed to complete the record. These numbers were obtained from the agency's final regulatory impact analysis prepared for these regulations.

Moreover, these estimates assume that every processor will prepare sanitary standard operating procedures and a HACCP plan and maintain the associated monitoring records and that every importer will require product safety specifications. In fact, there are likely to be some small number of juice processors that, based upon their hazard analysis, determine that they are not required to have a HACCP plan under these regulations.

Dated: July 9, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–17150 Filed 7–13–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0355]

Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA's regulations regarding current good manufacturing practice (CGMP) for dietary supplements.

DATES: Submit either electronic or written comments on the collection of information by September 13, 2010.

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: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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, including each proposed extension of an existing 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.

Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements—21 CFR Part 111 (OMB Control Number 0910–0606)—Extension

On October 25, 1994, the Dietary Supplement Health and Education Act (DSHEA) (Public Law 103–417) was signed into law. DSHEA, among other things, amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 402(g) of the act (21 U.S.C. 342(g)). Section 402(g)(2) of the act provides, in part, that the Secretary of Health and Human Services may, by regulation, prescribe good manufacturing practices for dietary supplements. Section 402(g) of the act also stipulates that such regulations shall be modeled after CGMP regulations for food and may not impose standards for which there are no current, and generally available, analytical methodology. Section 402(g)(1) of the act states that a dietary supplement is adulterated if "it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations." Under section 701(a) of the act (21 U.S.C. 371(a)), FDA may issue regulations necessary for the efficient enforcement of the act. In the **Federal Register** of June 25, 2007 (72 FR 34752) (the June 25, 2007, final rule) FDA published a final rule that established, in part 111 (21 CFR part 111), the minimum CGMP necessary for activities related to manufacturing, packaging, labeling, or holding dietary supplements to ensure the quality of the dietary supplement.

Records are an indispensable component of CGMP. The records required by FDA's regulations in part 111 provide the foundation for the planning, control, and improvement processes that constitute a quality control system. Implementation of these processes in a manufacturing operation serves as the backbone to CGMP. The records will show what is to be manufactured; what was, in fact, manufactured; and whether the controls that the manufacturer put in place to control the identity, purity, strength, and composition and limits on contaminants and to prevent adulteration were effective. Further, records will show whether and what deviations from control processes occurred, facilitate evaluation and corrective action concerning these deviations (including, where necessary, whether associated batches of product should be recalled from the marketplace), and enable a manufacturer to assure that the corrective action was effective. In addition, by requiring records, FDA will be able to ensure that industry follows CGMP during manufacturing, packaging, labeling, or holding operations. The regulations in part 111 establish the minimum manufacturing practices necessary to ensure that dietary supplements are manufactured, packaged, labeled, or held in a manner that will ensure the quality of the dietary supplements during manufacturing, packaging, labeling or holding operations.

The records requirements of the regulations include written procedures and records pertaining to: (1) Personnel; (2) sanitation; (3) calibration of instruments and controls; (4) calibration, inspection, or checks of automated, mechanical, or electronic equipment; (5) maintaining, cleaning, and sanitizing equipment and utensils and other contact surfaces; (6) water used that may become a component of the dietary supplement; (7) production and process controls; (8) quality control; (9) components, packaging, labels and product received for packaging and labeling; (10) master manufacturing and batch production; (11) laboratory operations; (12) manufacturing operations; (13) packaging and labeling operations; (14) holding and distributing operations; (15) returned dietary supplements; and (16) product complaints.

Description of Respondents: Manufacturers, dietary supplement manufacturers, packagers and repackagers, labelers and re-labelers, holders, distributors, warehousers, exporters, importers, large businesses, and small businesses.

The recordkeeping requirements of the regulations in part 111 are set forth in each subpart. In table 1 of this document we list the annual burdens associated with recordkeeping. In the table, where the same records are mentioned in more than one provision of a subpart, we list the burden under the provisions corresponding to the heading in the June 25, 2007, final rule, "Under this subpart, what records must you make and keep?" For some provisions listed in table 1, we did not estimate the annual frequency of recordkeeping because recordkeeping occasions consist of frequent brief entries of dates, temperatures, monitoring results, or documentation that specific actions were taken. Information might be recorded a few times a day, week, or month. When the records burden involves frequent brief entries, we entered one as the default for the annual frequency of recordkeeping. For example, many of the records listed under § 111.35 in table 1, such as § 111.35(b)(2) (documentation, in individual equipment logs, of the date of the use, maintenance, cleaning, and sanitizing of equipment), involve many short sporadic entries over the course of the year, varying across equipment and plants in the industry. We did not attempt to estimate the actual number of recordkeeping occasions for these provisions, but instead entered an estimate of the average number of hours per year. We entered the default value of 1 as the annual frequency of recordkeeping for these and similar provisions. For § 111.35, the entry for annual frequency is 1 as a default representing a large number of brief recordkeeping occasions.

In many rows of table 1 of this document, we list a burden under a single provision that covers the written procedures or records described in several provisions. For example, the burden of the batch production records listed in table 1 under § 111.260 includes the burden for records listed under § 111.255 because the batch production records must include those records.

The annual frequency for batch production records (and other records kept on a batch basis in table 1 of this document) equals the annual number of batches. The estimated burden for records kept by batch includes both records kept for every batch and records kept for some but not all batches. We use the annual number of batches as the frequency for records that will not necessarily be kept for every batch, such as test results or material review and disposition records, because such records are part of records, if they are necessary, that will be kept for every batch.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
111.14	15,000	4	60,000	1	60,000
111.23	15,000	1	15,000	0.2	3,000
111.35	400	1	400	12.5	5,000
111.95	250	1	250	45	11,250
111.140	240	1,163	279,120	1	279,120
111.180	240	1,163	279,120	1	279,120
111.210	240	1	240	2.5	600
111.260	145	1,408	204,160	1	204,160
111.325	120	1	120	15	1,800
111.375	260	1	260	2	520
111.430	50	1	50	12.6	630
111.475	15,000	1	15,000	0.4	6,000
111.535	110	4	440	13.5	5,940
111.570	240	600	144,000	0.5	72,000
Total					929,140

[1] There are no capital or operating and maintenance costs associated with this collection of information.

The burden estimates in table 1 of this document are based on those in the June 25, 2007, final rule, which were based on our institutional experience with other CGMP requirements and on data provided by Research Triangle Institute in the "Survey of Manufacturing Practices in the Dietary Supplement Industry" cited in that rule.

The estimates in table 1 of the number of firms affected by each provision of part 111 are based on the percentage of manufacturers, packagers, labelers, holders, distributors, and warehousers that reported in the survey that they have not established written SOPs or do not maintain records that were later required by the June 25, 2007, final rule. Because we do not have survey results for general warehouses, we entered the approximate number of facilities in that category for those provisions covering general facilities. For the dietary supplement industry, the survey estimated that 1,460 firms would be covered by the final rule, including manufacturers, packagers, labelers, holders, distributors, and warehousers. The time estimates include the burden involved in documenting that certain requirements are performed and in recordkeeping. We used an estimated annual batch production of 1,408 batches per year to estimate the burden of requirements that are related to the number of batches produced annually, such as § 111.260, "What must the batch production record include?" The estimate of 1,408 batches per year is near the midpoint of the number of annual batches reported by survey firms.

The length of time that CGMP records must be maintained is set forth in § 111.605. Table 1 of this document reflects the estimated burdens for written procedures, record maintenance, periodically reviewing records to determine if they may be discarded, and for any associated documentation for that activity for records that are required under part 111. We have not included a separate estimate of burden for those sections that require maintaining records in accordance with § 111.605, but have included those burdens under specific provisions for keeping records. For example, § 111.255(a) requires that the batch production records be prepared every time a batch is manufactured, and § 111.255(d) requires that batch production records be kept in accordance with § 111.605. The estimated burdens for both § 111.255(a) and (d) are included under § 111.260 (what the batch record must include).

Dated: July 8, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–17054 Filed 7–13–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Public Health Service Act (PHS), Delegation of Authority

Notice is hereby given that I have delegated to the Director, Centers for Disease Control and Prevention, with authority to redelegate, the authorities vested in the Secretary of Health and Human Services under the following section under Title XXVI of the Public Health Service Act, and the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Pub. L. 111–87), as amended hereafter, as it pertains to the functions assigned to the Centers for Disease Control and Prevention:

- Section 2695 (42 U.S.C. 300ff–131)—Infectious Diseases and Circumstances Relevant to Notification Requirements.

These authorities shall be exercised under the Department's policy on regulations and existing delegation of

authority to approve and issue regulations.

This delegation became effective upon date of signature. In addition, I affirm and ratifiy any actions taken by the Director, Centers for Disease Control and Prevention, or his/her subordinates which involved the exercise of authorities delegated herein prior to the effective date of the delegation.

Kathleen Sebelius,

Secretary.

[FR Doc. 2010–17196 Filed 7–13–10; 8:45 am]

BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0344]

International Conference on Harmonisation; Draft Guidance on Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 13 on Bulk Density and Tapped Density of Powders General Chapter; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 13: Bulk Density and Tapped Density of Powders General Chapter." The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance provides the results of the ICH Q4B evaluation of the Bulk Density and Tapped Density of Powders General Chapter harmonized text from each of the three pharmacopoeias (United States, European, and Japanese) represented by the Pharmacopoeial Discussion Group (PDG). The draft guidance conveys recognition of the three pharmacopoeial methods by the three ICH regulatory regions and provides specific information regarding the recognition. The draft guidance is intended to recognize the interchangeability between the local regional pharmacopoeias, thus avoiding redundant testing in favor of a common testing strategy in each regulatory region. This draft guidance is the thirteenth annex to the core Q4B guidance, which was made available in the **Federal Register** of February 21, 2008 (73 FR 9575).

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 September 13, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. 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:

Regarding the guidance: Robert H. King, Sr., Center for Drug Evaluation and Research (HFD–003), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4150, Silver Spring, MD 20993–0002, 301–796–1242; or Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–0373.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In June 2010, the ICH Steering Committee agreed that a draft guidance entitled "Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 13: Bulk Density and Tapped Density of Powders General Chapter" should be made available for public comment. The draft guidance is the product of the Q4B Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Q4B Expert Working Group.

The draft guidance provides the specific evaluation results from the ICH Q4B process for the Bulk Density and Tapped Density of Powders General Chapter harmonization proposal originating from the three-party PDG. This draft guidance is in the form of an annex to the core ICH Q4B guidance. Once finalized, the annex will provide guidance to assist industry and regulators in the implementation of the

specific topic evaluated by the ICH Q4B process.

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 this topic. 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. 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.regulations.gov*, *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm*.

Dated: July 8, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–17055 Filed 7–13–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 materials, 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 Mental Health Special Emphasis Panel, HIV/AIDS Intervention Development.

Date: July 22, 2010.

Time: 9 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call)

Contact Person: Enid Light, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6132, MSC 9608, Bethesda, MD 20892–9608. 301–443–0322. *elight@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: July 8, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–17129 Filed 7–13–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0321]

Town Hall Discussion With the Director of the Center for Devices and Radiological Health and Other Senior Center Management

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing a public meeting entitled: "Town Hall Discussion With the Director of the Center for Devices and Radiological Health and Other Senior Center Management." The purpose of this meeting is to present the Center for Devices and Radiological Health (CDRH) Fiscal Year (FY) 2010 Priorities. In addition, FDA is interested in engaging in discussions about issues that are of importance to the medical device industry.

Date and Time: The public meeting will be held on October 7, 2010, from 8 a.m. to 12 noon.

Location: The public meeting will be held at the Hilton Irvine/Orange County Airport Hotel, 18800 MacArthur Blvd., Irvine, CA 92612. The meeting will not be videotaped or webcast.

Contact: Heather Howell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 66, rm. 4320, Silver Spring, MD 20993, 301–796–5718, email: *heather.howell@fda.hhs.gov*.

Registration and Requests for Oral Presentations: If you wish to attend the public meeting, you must register online at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm215113.htm*. Those without Internet access may contact Heather Howell (see *Contact*).

Provide complete contact information for each attendee, including name, title, company or organization, address, email, telephone and fax number. Registration requests must be received by 5 p.m. on Wednesday, September 22, 2010.

If you wish to make an oral presentation during any of the discussions at the meeting (see section II of this document, Public Meeting), you must indicate this at the time of registration. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and to request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin.

Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the public meeting will be provided on a space-available basis beginning at 7 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan at 301–796–5661 or by email: *susan.monahan@fda.hhs.gov* at least 7 days in advance.

Comments: FDA is holding this public meeting to share information and discuss issues of importance to the medical device industry. CDRH is specifically interested in addressing the following question: What mechanism(s) would you prefer or suggest for FDA to

engage with industry? The deadline for responding to this question and for submitting other comments related to this public meeting is September 22, 2010.

Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments regarding this document. Submit electronic comments 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. 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.

SUPPLEMENTARY INFORMATION:

I. Background

CDRH has announced four priority areas of activity for FY 2010, each of which presents significant opportunities to improve the Center's effectiveness in fulfilling our public health mission. More information, including specific goals and actions associated with each priority, is available under "CDRH Strategic Planning" at *www.fda.gov/AboutFDA/CentersOffices/CDRH*.

II. Public Meeting

The objective of this public meeting is to present the CDRH FY 2010 priorities. In addition, FDA is interested in engaging in discussions about issues that are of importance to the medical device industry. CDRH wishes to obtain feedback/ideas for facilitating two-way communication between CDRH and the medical device industry.

The meeting will open with an introduction of CDRH Senior Staff in attendance. Following introductions, Dr. Jeffrey Shuren, the Director of CDRH, will present the FY 2010 CDRH priorities. Industry representatives and other members of the public will then be given the opportunity to present comments to CDRH Senior Staff. Attendees from CDRH may respond to questions presented by industry and other members of the public.

In advance of the meeting, additional information, including a meeting agenda with a speakers' schedule, will be made available on the Internet. This information will be placed on file in the public docket (docket number found in brackets in the heading of this document), which is available at *http://www.regulations.gov*. This information will also be available at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select the appropriate meeting from the list).

III. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. The transcript may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

Dated: July 8, 2010.

Nancy Stade,

Acting Associate Director for Regulations and Policy, Center for Devices and Radiological Health.

[FR Doc. 2010–17068 Filed 7–13–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number NIOSH 141–A]

Preventing Deaths and Injuries of Fire Fighters Using Risk Management Principles at Structure Fires

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of issuance of Final Guidance Publication.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the availability of the publication entitled "Preventing Deaths and Injuries of Fire Fighters Using Risk Management Principles at Structure Fires."

The final document can be found at: *http://www.cdc.gov/niosh/docs/2010-153/*.

Background and Summary of Document: NIOSH has developed this publication to assist the U.S. fire service in preventing fire fighter injuries and deaths at structure fires. Established fire service risk management principles suggest that caution should be exercised in abandoned, vacant and unoccupied structures and in situations where there is no clear evidence indicating that people are trapped inside the structure and can be saved. This publication summarizes fatality statistics from the National Fire Protection Association as well as the NIOSH Fire Fighter Fatality Investigation and Prevention Program (FFFIPP) databases. The publication describes four case studies on the deaths of five fire fighters and injuries to 10 others during fire suppression operations in and around structures with considerable fire involvement where there were indications that the structures were unoccupied. The publication presents a number of recommendations for preventing similar occurrences of fire fighter injuries and deaths. The primary audiences are expected to be fire commissioners, fire chiefs, fire department and municipal managers, fire fighters, labor unions, safety and health professionals, trainers, fire investigators, State fire marshals, and other interested parties.

This guidance publication does not have the force and effect of law.

Document Review Process: Following development of the initial draft, the document was reviewed by peers and external stakeholders within the fire service and revisions were made based upon these reviews. The revised draft document was posted in the **Federal Register** for public review and comment from January 5 to March 9, 2009. Public comments submitted to NIOSH Public Docket 141 can be viewed at the Web site *http://www.cdc.gov/niosh/docket/nioshdocket0141.html*. The draft document was revised to address these public comments. The most substantive revisions were to change the title and focus of the document from fighting fires in unoccupied structures to using established risk management principles at all structure fires, regardless of the occupancy status. The majority of comments received during the public comment period made it clear that the U.S. fire service would not support the recommendation that fire fighters avoid entering unoccupied structures, the focus of the original draft. A final draft containing revisions made to address comments received during the public comment period was reviewed by representatives from both the International Association of Fire Chiefs (IAFC) and the International Association of Fire Fighters (IAFF).

FOR FURTHER INFORMATION CONTACT: Timothy R. Merinar, Safety Engineer, Division of Safety Research, CDC/

NIOSH, 1095 Willowdale Road, H1808, Morgantown, West Virginia 26505, Phone 304–285–5916, e-mail *tmerinar@cdc.gov.*

Reference: Web address for this document: *http://www.cdc.gov/niosh/docs/2010-153/.*

Dated: July 7, 2010.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2010–17171 Filed 7–13–10; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Form I–912; New Information Collection; Comment Request

ACTION: 60-Day Notice of Information Collection Under Review; Form I–912, Request for an Individual Fee Waiver; OMB Control No. 1615-New.

* * * * *

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until September 13, 2010.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), USCIS, Chief, Regulatory Products Division, 111 Massachusetts Avenue NW., Washington, DC 20529–2210. Comments may also be submitted to DHS via facsimile to 202–272–8352 or via e-mail at *rfs.regs@dhs.gov.* When submitting comments by e-mail, please make sure to add OMB Control No. 1615-New in the subject box. Written comments and suggestions from the public and affected agencies concerning the collection of information should address one or more of the following four points:

(1) 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;

(2) Evaluate the accuracy of the agencies 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 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.

Overview of this Information Collection:

(1) *Type of Information Collection:* New information collection.

(2) *Title of the Form/Collection:* Request for an Individual Fee Waiver.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I–912; U.S. Citizenship and Immigration Services (USCIS).

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. The collection of information on Form I–912 is necessary in order for U.S. Citizenship and Immigration Services (USCIS) to make a determination that the applicant is unable to pay the application fee for certain immigration benefits.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 85,000 responses at 1 hour and 10 minutes (1.166 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 99,110 annual burden hours.

If you need a copy of the information collection instrument, please visit the Web site at: *http://www.regulations.gov/.*

We may also be contacted at: USCIS, Regulatory Products Division, 111 Massachusetts Avenue, NW., Washington, DC 20529–2210, Telephone number 202–272–8377.

Dated: July 8, 2010.

Sunday Aigbe,

Chief, Regulatory Products Division, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2010–17114 Filed 7–13–10; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2010–0013]

Agency Information Collection Activities: Submission for OMB Review; Comment Request, OMB No. 1660–0026; State Administrative Plan for the Hazard Mitigation Grant Program

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice; 30-day notice and request for comments; revision of a currently approved information collection; OMB No. 1660–0026; No Form.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission will describe the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort and resources used by respondents to respond) and cost, and the actual data collection instruments FEMA will use.

DATES: Comments must be submitted on or before August 13, 2010.

ADDRESSES: Submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the Desk Officer for the Department of Homeland Security, Federal Emergency Management Agency, and sent via electronic mail to *oira.submission@omb.eop.gov* or faxed to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Records Management Division, 1800 South Bell Street, Arlington, VA 20598–3005, facsimile number (202) 646–3347, or e-mail address *FEMA-Information-Collections-Management@dhs.gov.*

SUPPLEMENTARY INFORMATION:

Collection of Information

Title: State Administrative Plan for the Hazard Mitigation Grant Program.

Type of information collection: Revision of a currently approved information collection.

OMB Number: 1660–0026.

Form Titles and Numbers: No Form.

Abstract: The State Administrative Plan is a procedural guide that details how the State will administer the Hazard Mitigation Grant Program (HMGP). An approved plan is a prerequisite of receiving HMGP funds and is used by FEMA in making a determination of the approval for a grant and how much each grant will be. The administrative plan may take any form including a chapter within a comprehensive State mitigation program strategy.

Affected Public: State, local, or Tribal Government.

Estimated Number of Respondents: 32.

Frequency of Response: On Occasion.

Estimated Average Hour Burden per Respondent: 16 Hours.

Estimated Total Annual Burden Hours: 512 Hours.

Estimated Cost: There are no capital, operations and maintenance, or start-up costs associated with this collection.

Dated: July 7, 2010.

Tammi Hines,

Acting Director, Records Management Division, Mission Support Bureau, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2010–17084 Filed 7–13–10; 8:45 am]

BILLING CODE 9110–13–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2010–0041]

Agency Information Collection Activities: Proposed Collection; Comment Request, 1660–0036; Federal Emergency Management Agency Individual Assistance Customer Satisfaction Surveys

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice; 60-day notice and request for comments; revision of a currently approved information collection OMB No. 1660–0036; Caller Services Registration Survey, FEMA Form 007–0–3; Caller Services Helpline Survey, FEMA Form 007–0–5; Internet Registration Survey, FEMA Form 070–0–2; Internet Inquiry Survey; Program Effectiveness & Recovery Survey, FEMA Form 070–0–20; Casework Representative Survey, FEMA Form 007–0–6; Direct Housing Operations Survey, FEMA Form 007–0–4; Special Needs Representative Survey, FEMA Form 007–0–8; Disaster Recovery Center Survey, FEMA Form 007–0–7; Communication and Process Survey, FEMA Form 007–0–9, Contact Survey, FEMA Form 007–0–10, Correspondence and Process Survey, FEMA Form 007–0–11, E–Communications Survey, FEMA Form 007–0–12, Evacuations Survey, FEMA Form 007–0–13, Follow-Up Program Effectiveness and Recovery Survey, FEMA Form 007–0–14, Rapid Temporary Repair Survey, FEMA Form 007–0–15, Recovery Inventory Survey, FEMA Form 007–0–16, Return Home Survey, FEMA Form 007–0–17, and Site Recertification Survey, FEMA Form 007–0–18.

SUMMARY: The Federal Emergency Management Agency, 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 a proposed revision of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this Notice seeks comments concerning which is necessary for assessment and improvement of the delivery of disaster assistance. The forms serve as survey tools used to evaluate customer perceptions of effectiveness, timeliness and satisfaction with initial, continuing and final delivery of disaster-related assistance.

DATES: Comments must be submitted on or before September 13, 2010.

ADDRESSES: To avoid duplicate submissions to the docket, please use only one of the following means to submit comments:

(1) *Online.* Submit comments at *http://www.regulations.gov* under docket ID FEMA–2010–0041. Follow the instructions for submitting comments.

(2) *Mail.* Submit written comments to Office of Chief Counsel, Regulation and Policy Team, DHS/FEMA, 500 C Street, SW., Room 835, WASH, DC 20472–3100.

(3) *Facsimile.* Submit comments to (703) 483–2999.

(4) *E-mail.* Submit comments to *FEMA-POLICY@dhs.gov.* Include docket ID FEMA–2010–0041 in the subject line.

All submissions received must include the agency name and docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice that is available on the Privacy and Use Notice link on the Administration Navigation Bar of *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Maggie Billing, Program Analyst, Customer Satisfaction Analysis Section, Texas National Processing Service Center, Recovery Directorate, FEMA at 940 891–8709 or *maggie.biling@dhs.gov* for additional information. You may contact the Office of Records Management for copies of the proposed collection of information at facsimile number (202) 646–3347 or e-mail address: *FEMA-Information-Collections@dhs.gov.*

SUPPLEMENTARY INFORMATION: This collection is in accordance with Executive Order 12862 requiring all Federal agencies to survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services. The Government Performance and Results Act (GPRA) requires agencies to set missions and goals and measure performance against them. FEMA will fulfill these requirements by collecting customer service and program information through surveys of the Recovery Directorate's external customers.

Collection of Information

Title: Federal Emergency Management Agency Individual Assistance Customer Satisfaction Surveys.

Type of Information Collection: Revision of a currently approved information collection.

OMB Number: 1660–0036.

Form Titles and Numbers: Caller Services Registration Survey, FEMA Form 007–0–3; Caller Services Helpline Survey, FEMA Form 007–0–5; Internet Registration Survey, FEMA Form 070–0–2; Internet Inquiry Survey; Program Effectiveness & Recovery Survey, FEMA Form 070–0–20; Casework Representative Survey, FEMA Form 007–0–6; Direct Housing Operations Survey, FEMA Form 007–0–4; Special Needs Representative Survey, FEMA Form 007–0–8; Disaster Recovery Center Survey, FEMA Form 007–0–7; Communication and Process Survey, FEMA Form 007–0–9, Contact Survey, FEMA Form 007–0–10, Correspondence and Process Survey, FEMA Form 007–0–11, E–Communications Survey, FEMA Form 007–0–12, Evacuations Survey, FEMA Form 007–0–13, Follow-Up Program Effectiveness and Recovery Survey, FEMA Form 007–0–14, Rapid Temporary Repair Survey, FEMA Form 007–0–15, Recovery Inventory Survey, FEMA Form 007–0–16, Return Home

Survey, FEMA Form 007–0–17, and Site Recertification Survey, FEMA Form 007–0–18.

Abstract: Federal agencies are required to survey their customers to determine the kind and quality of services customers want and their level of satisfaction with existing services. FEMA Managers use the survey results to measure program performance against standards for performance and customer service; measure achievement of GPRA and strategic planning objectives; and generally gauge and make improvements to disaster services that increase customer satisfaction and program effectiveness.

Affected Public: Individuals and Households.

Estimated Total Annual Burden Hours: 10,186.

ANNUAL HOUR BURDEN

Data collection activity/instrument	No. of respondents	Frequency of responses	Hour burden per response	Annual responses	Total annual burden hours
Caller Services Registration Survey	5,000	1	0.1000	5,000	500
Caller Services Helpline Survey	5,000	1	0.1000	5,000	500
Casework Representative Survey	5,000	1	0.1000	5,000	500
Internet Registration Survey	5,000	1	0.1000	5,000	500
Internet Inquiry Survey	5,000	1	0.1000	5,000	500
Program Effectiveness & Recovery Survey	12,000	1	0.2000	12,000	2,400
Special Needs Representative Survey	5,000	1	0.1166	5,000	583
Direct Housing Operations Survey	1,770	3	0.1000	5,310	531
Disaster Recovery Center Survey	6,300	1	0.1333	6,300	840
Surveys Sub Total	50,070	.....	.....	53,610	6,854
Diagnostics:					
Communication and Process Survey	400	1	0.2500	400	100
Contact Survey	400	1	0.2500	400	100
Correspondence and Process Survey	800	1	0.2500	800	200
E-Communications Survey	400	1	0.2500	400	100
Evacuations	400	1	0.2500	400	100
Follow-Up Program Effectiveness & Recovery Survey	1600	1	0.2500	1600	400
Rapid Temporary Repair Survey	400	1	0.2500	400	100
Recovery Inventory Survey	800	1	0.2500	800	200
Return Home Survey	400	1	0.2500	400	100
Site Recertification Survey	400	1	0.2500	400	100
Diagnostics Sub Total	6,000	.....	.....	6,000	1,500
Focus Group	144	1	2.0000	144	288
Same Respondents Travel to Focus Group	144	1	1.0000	144	144
One-on-One Interviews	350	1	2.0000	350	700
On-Line Interviews	350	1	2.0000	350	700
Focus Groups Sub Total	988	.....	.....	988	1,832
Total	57,058	.....	.....	60,598	10,186

Estimated Cost: There are no annual capital start-up or annual operations and maintenance costs. The annual non-labor cost is $4,320.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) 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; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) 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.

Dated: July 2, 2010.

Tammi Hines,

Director, Office of Records Management, Office of Management, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2010–17086 Filed 7–13–10; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2010–0015]

Agency Information Collection Activities: Submission for OMB Review; Comment Request, OMB No. 1660–0086; National Flood Insurance Program—Mortgage Portfolio Protection Program (MPPP)

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice; 30-day notice and request for comments; revision of a currently approved information collection; OMB No. 1660–0086; No Form.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection

abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission will describe the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort and resources used by respondents to respond) and cost, and the actual data collection instruments FEMA will use.

DATES: Comments must be submitted on or before August 13, 2010.

ADDRESSES: Submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the Desk Officer for the Department of Homeland Security, Federal Emergency Management Agency, and sent via electronic mail to *oira.submission@omb.eop.gov* or faxed to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Records Management Division, 1800 South Bell Street, Arlington, VA 20598–3005, facsimile number (202) 646–3347, or e-mail address *FEMA-Information-Collections-Management@dhs.gov.*

SUPPLEMENTARY INFORMATION:

Collection of Information

Title: National Flood Insurance Program—Mortgage Portfolio Protection Program (MPPP).

Type of Information Collection: Revision of a currently approved information collection.

OMB Number: 1660–0086.

Form Titles and Numbers: No Forms.

Abstract: A Write-Your-Own (WYO) Company that wishes to participate in the MPPP must review the information listed in the Mortgage Portfolio Protection Program Agreement and complete the acknowledgement either agreeing to participate in the MPPP or electing to continue under just the WYO guidelines. This acknowledgment is used to determine which WYO Companies will be writing insurance under the MPPP and which ones choose only to sell flood insurance through the regular WYO Program. A lender wishing to obtain flood insurance through an MPPP participating insurance company must review the Financial Assistance/Subsidy Arrangement and acknowledge the terms by signing the notice of acceptance provided with the Arrangement. This acceptance is used to verify that the lender understands the terms of the agreement so that they can properly apply for flood insurance.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 341.

Frequency of Response: Annually.

Estimated Average Hour Burden per Respondent: .5 Hours

Estimated Total Annual Burden Hours: 170.5 Hours.

Estimated Cost: There are no record keeping, capital, start-up or maintenance costs associated with this information collection.

Dated: July 7, 2010.

Tammi Hines,

Acting Director, Records Management Division, Mission Support Bureau, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2010–17085 Filed 7–13–10; 8:45 am]

BILLING CODE 9110–11–P

DEPARTMENT OF THE INTERIOR

National Park Service

60-Day Notice of Intention to Request Clearance of Collection of Information; Opportunity for Public Comment

AGENCY: National Park Service, Interior.

ACTION: Notice and request for comments.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 and 5 CFR Part 1320, Reporting and Record Keeping Requirements, the National Park Service (NPS) invites public comments on an extension of a currently approved information collection Office of Management and Budget (OMB) Control # 1024–0233.

DATES: Public comments on the Information Collection Request (ICR) will be accepted on or before September 13, 2010.

ADDRESSES: You may submit comments directly to Ms. Jo A. Pendry, Chief, Commercial Services Program, National Park Service, 1849 C Street, NW. (2410), Washington, DC 20240, by fax at 202/371–2090, or electronically to *jo_pendry@nps.gov.* All responses to this notice will be summarized and included in the request for the OMB approval. All comments will become a matter of public record.

FOR FURTHER INFORMATION CONTACT: Jo A. Pendry, phone: 202–513–7156 or at the address above.

SUPPLEMENTARY INFORMATION:

Title: Leasing Regulations—36 CFR 18.

OMB Control Number: 1024–0233.

Expiration Date of Approval: November 30, 2010.

Type of Request: Extension of a currently approved information collection.

Description of Need: The information is being collected to meet the requirements of Section 802 of the National Park Omnibus Management Act of 1998, concerning the granting of a legislative authority, policies, and requirements for the solicitation, award and administration of National Park Service leases for property located within area of the national park system.

Description of Respondents: Persons or entities seeking a leasing opportunity with the National Park Service.

Estimate of Burden: Approximately 7 hours per response.

Estimated Number of Respondents: 627 per year.

Estimated Number of Responses per Respondent: One.

Estimated Total Annual Burden on Respondents: 4,389 hours.

Comments are invited on: (1) The practical utility of the information being gathered; (2) the accuracy of the burden hour estimate; (3) ways to enhance the quality, utility, and clarity of the information being collected; and (4) ways to minimize the burden to respondents, including use of automated information collection techniques or other forms of information technology. 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. Please refer to OMB control number 1024–0233 in all correspondence.

Dated: July 8, 2010.

Cartina Miller,

NPS Information Collection Clearance Officer .

[FR Doc. 2010–17081 Filed 7–13–10; 8:45 am]

BILLING CODE 4312–53–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Implementation of Question 10 of 25 CFR Part 170, Subpart C, Indian Reservation Roads Program

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of Tribal Consultations.

SUMMARY: The Bureau of Indian Affairs (BIA) is announcing tribal consultations to discuss a proposed change in how BIA and the Federal Highway Administration (FHWA) will implement Question 10 of 25 CFR Part 170, Subpart C. Question 10 determines the percentages that certain transportation facilities contribute to the calculation of the Relative Need Distribution Factor (RNDF) formula for Indian Reservation Road (IRR) Program funds. The determination is significant because a facility's eligibility for Federal funds will be used to determine the amount of IRR funds a tribe may be eligible to receive. The proposed change will affect the allocation of funding among tribes.

FOR FURTHER INFORMATION CONTACT: LeRoy Gishi, Chief, Division of Transportation, BIA, 1951 Constitution Ave., NW., MS–320–SIB, Washington, DC 20240, telephone (202) 513–7711; or Robert W. Sparrow, Jr., IRR Program Manager, Federal Highway Administration, 1200 New Jersey Ave, NE, Room E61–311, Washington, DC 20159, telephone (202) 366–9483.

SUPPLEMENTARY INFORMATION: Federally recognized tribes are invited to attend one or more of the following consultation sessions regarding how BIA and the Federal Highway Administration (FHWA) will implement Question 10 of 25 CFR Part 170, Subpart C. Question 10 states, in part:

10. Do All IRR Transportation Facilities in the IRR Inventory Count at 100 Percent of their CTC and VMT?

No. The CTC and VMT must be computed at the non-Federal share requirement for matching funds for any transportation facility that is added to the IRR inventory and is eligible for funding for construction or reconstruction with Federal funds, other than Federal Lands Highway Program funds.

BIA currently determines a facility's percentage contribution based on ownership. BIA proposes to change its approach by utilizing the facility's functional classification as the determining factor. The IRR Program falls under the Federal Highway Administration's Federal Lands Highway Program. This approach will closely align the IRR Program with the FHWA Federal-Aid classification.

Meeting Dates and Locations

The consultation sessions will be held on the following dates, at the following locations:

Meeting date	Location	Time
July 28, 2010	Providence, RI	1 p.m.–5 p.m.
August 17, 2010	Albuquerque, NM	9 a.m.–1 p.m.
August 18, 2010	Las Vegas, NV	9 a.m.–1 p.m.
August 19, 2010	Sacramento, CA	1 p.m.–5 p.m.
August 31, 2010	Billings, MT	9 a.m.–1 p.m.
September 1, 2010	Minneapolis, MN	1 p.m.–5 p.m.
September 14, 2010	Anchorage, AK	9 a.m.–1 p.m.
September 15, 2010	Seattle, WA	1 p.m.–5 p.m.
September 21, 2010	Oklahoma City, OK	9 a.m.–1 p.m.
September 22, 2010	Rapid City, SD	1 p.m.–5 p.m.

Meeting Agenda (All Times Local)

9 a.m.–9:15 a.m. (or 1 p.m.–1:15 p.m.) Welcome, Introductions, Ground Rules
9:15 a.m.–9:30 a.m. (or 1:15 p.m.–1:30 p.m.) Opening and Overview
9:30 a.m.–10:30 a.m. (or 1:30 p.m.–2:30 p.m.) Question 10 Directive
10:30 a.m.–12:45 p.m. (or 2:30 p.m.–4:45 p.m.) Public Comment and Questions
12:45 p.m.–1 p.m. (or 4:45 p.m.–5 p.m.) Closing Comments
1 p.m. (or 5 p.m.) Adjourn

Dated: July 7, 2010.

Larry Echo Hawk,

Assistant Secretary-Indian Affairs.

[FR Doc. 2010–17174 Filed 7–13–10; 8:45 am]

BILLING CODE 4310–6W–P

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Public Meeting

AGENCY: National Park Service, Interior.

ACTION: Notice of public meeting for the National Park Service (NPS) Alaska Region's Subsistence Resource Commission (SRC) program.

SUMMARY: The Denali National Park SRC plans to meet to develop and continue work on NPS subsistence hunting program recommendations and other related subsistence management issues. The NPS SRC program is authorized under Title VIII, Section 808 of the Alaska National Interest Lands Conservation Act, Public Law 96–487, to operate in accordance with the provisions of the Federal Advisory Committee Act.

Public Availability of Comments: The meeting is open to the public and will have time allocated for public testimony. The public is welcome to present written or oral comments to the SRC. The meeting will be recorded and meeting minutes will be available upon request from the park superintendent in approximately six weeks. Before including your address, telephone number, e-mail address, or other personal identifying information in your written or oral comments, 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.

Denali National Park SRC Meeting Date and Location: The Denali National Park SRC meeting will be held on Saturday, August 28, 2010, from 9 a.m. to 4:30 p.m. at the Cantwell Community Hall, Tel. (907) 786–2591, in Cantwell, AK. The meeting may end early if all business is completed. If the meeting date and location are changed due to lack of a quorum, inclement weather or local circumstances, the park superintendent will provide public notice.

FOR FURTHER INFORMATION CONTACT: *For Further Information on The Denali National Park SRC Meeting Contact:* Amy Craver, Subsistence Manager, (907) 683–2294, Denali National Park and Preserve, P.O. Box 9, Denali Park, AK 99755, or Clarence Summers, Subsistence Manager, NPS Alaska Regional Office, at (907) 644–3603.

Proposed SRC Meeting Agenda

The proposed meeting agenda for each meeting includes the following:
1. Call to order
2. SRC Roll Call and Confirmation of Quorum
3. SRC Chair and Superintendent's Welcome and Introductions
4. Administrative Announcements
5. Review and Approve Agenda

6. Approval of Minutes from Last SRC Meeting
7. SRC Member Reports
8. Public and Other Agency Comments
9. SRC Membership
10. Old Business
   a. Denali Subsistence Management Plan
   b. Subsistence Uses of Horns, Antlers, Bones and Plants EA Update
11. New Business
   a. Subsistence Manager Update
   1. Federal Subsistence Board—Fish and Wildlife Update
   2. Federal Subsistence Board Program Review Update
   3. Alaska Board of Game Update
   4. Denali National Park and Preserve Subsistence Projects
   b. Ranger Report Update
   c. Resource Management Program Update
   d. Fire Management Program Update
12. Public and other Agency Comments
13. SRC Work/Training Session
14. Set Time and Place for next SRC Meeting
15. Adjournment

Sue E. Masica,

Regional Director, Alaska.

[FR Doc. 2010–17082 Filed 7–13–10; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—DVD Copy Control Association

Notice is hereby given that, on June 7, 2010, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), DVD Copy Control Association ("DVD CCA") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Renesas Electronics Corporation (formerly known as NEC Electronics Corporation), Kawasaki, JAPAN; Nutron International Co., Ltd., Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA; and Toshiba Samsung Storage Technology, Suwon-si, Gyeonggi-do, REPUBLIC OF KOREA, have been added as parties to this venture.

Also, General Instrument Corp. d/b/a Motorola, Horsham, PA; Nanjing Wanlida Technology Co., Ltd., Zhangzhou City, Fujian, PEOPLE'S REPUBLIC OF CHINA; and Synchronicity Mastering Services, LLC, Salt Lake City, UT, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and DVD CCA intends to file additional written notifications disclosing all changes in membership.

On April 11, 2001, DVD CCA filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on August 3, 2001 (66 FR 40727).

The last notification was filed with the Department on March 10, 2010. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on May 7, 2010 (75 FR 25294).

Patricia A. Brink,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 2010–16859 Filed 7–13–10; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993; Advanced Media Workflow Association, Inc.

Notice is hereby given that, on June 22, 2010, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 et seq. ("the Act"), Advanced Media Workflow Association, Inc. has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, John A. Hoehn (individual member), Pennsville, NJ; Cristiano Nuernberg (individual member), Cambridge, MA; Matt Pearcey (individual member), Wells, UNITED KINGDOM; and Jason Schwartz (individual member), Las Vegas, NV, have been added as parties to this venture. Also, eBus Limited, Auckland, NEW ZEALAND; Lifetime, New York, NY; RPPtv, Midhurst, K. Sussex, UNITED KINGDOM; and Matt Beard (individual member), Maud, Peterchard, UNITED KINGDOM, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Advanced Media Workflow Association, Inc. intends to file additional written notifications disclosing all changes in membership.

On March 28, 2000, Advanced Media Workflow Association, Inc. filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on June 29, 2000 (65 FR 40127).

The last notification was filed with the Department on March 18, 2010. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on May 6, 2010 (75 FR 24971).

Patricia A. Brink,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 2010–16863 Filed 7–13–10; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Connected Media Experience, Inc.

Notice is hereby given that, on May 28, 2010, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ('the Act'), Connected Media Experience, Inc. ("CNN") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Warner Music Group, New York, NY; Push Entertainment LTD., Bath, UNITED KINGDOM; MOD Systems Incorporated, Seattle, WA; PacketVideo Corporation, San Diego, CA; BACH Technology AS, Bergen, NORWAY; Sony Corporation of America, Los Angeles, CA; Recording Industry Association of America, Washington, DC; Tunewiki, Santa Monica, CA; MC Squared Incorporated, Pennington, NJ; Related Content Database Inc., San Francisco, CA; Manu Sporny, Blacksburg, VA; and Yves Raimond,

London, UNITED KINGDOM, have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and CMX intends to file additional written notifications disclosing all changes in membership.

On March 12, 2010, CMX filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on April 16, 2010 (75 FR 20003).

Patricia A. Brink,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 2010–16862 Filed 7–13–10; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Development of High Toughness, Low Viscosity Resin for Reinforcing Pothole Patching Materials, TIP Award No. 7ONANB1OHO19

Notice is hereby given that, on May 20, 2010, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), Development of High Toughness, Low Viscosity Resin for Reinforcing Pothole Patching Materials, TIP Award No. 7ONANB1OHO19 ("Resin for Reinforcing") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties to the venture and (2) the nature and objectives of the venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to Section 6(b) of the Act, the identities of the parties to the venture are: Materia, Inc, Pasadena, CA; The University of California Los Angeles, Los Angeles, CA; The City of Los Angeles, Los Angeles, CA; and Department of Public Works, Bureau of Street Services, Los Angeles, CA. The general area of Resin for Reinforcing's planned activity is to repair but also reduce the traffic congestion and driver time delay.

The activities of this venture project will be partially funded by an award from the Technology Innovation Program, National Institute of Standards and Technology, U.S. Department of Commerce.

Patricia A. Brink,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 2010–16860 Filed 7–13–10; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Open SystemC Initiative

Notice is hereby given that, on June 4, 2010, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), Open SystemC Initiative ("OSCI") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Global Unichip Corp., Hsinchu City, TAIWAN, has been added as a party to this venture. Also, CoWare, Inc., Santa Clara, CA, has withdrawn as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and OSCI intends to file additional written notifications disclosing all changes in membership.

On October 9, 2001, OSCI filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on January 3, 2002 (67 FR 350).

The last notification was filed with the Department on March 4, 2010. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on April 16, 2010 (75 FR 20003).

Patricia A. Brink,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 2010–16861 Filed 7–13–10; 8:45 am]

BILLING CODE 4410–11–M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (10–077)]

NASA Advisory Council; Exploration Committee; 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 announces a meeting of the Exploration Committee of the NASA Advisory Council.

DATES: Tuesday, August 3, 2010, 8 a.m.–6:15 p.m., and Wednesday, August 4, 2010, 8 a.m.–11:30 a.m. (All times are p.d.t.)

ADDRESSES: NASA Jet Propulsion Laboratory, 4800 Oak Grove Drive, Pasadena, California 91109—Building 180, Room 101 (August 3, 8 a.m.–12 p.m. and August 4, 8 a.m.– 11:30 a.m.); and von Karman Auditorium (August 3, 1 a.m.–6:15 p.m.)

FOR FURTHER INFORMATION CONTACT: Ms. Jane Parham, Exploration, Exploration Systems Mission Directorate, National Aeronautics and Space Administration Headquarters, 300 E Street SW., Washington, DC 20546, (202) 358–1715; *jane.parham@nasa.gov.*

SUPPLEMENTARY INFORMATION: The agenda topics for the meeting will include:

- Exploration, Constellation, and Human Research Programs Status.
- Heavy Lift and Propulsion Technology.
- International Space Cooperation and Other Partnerships.
- Joint Session with NASA Advisory Council Technology & Innovation Committee: Human Exploration Framework Team (HEFT), Cross-Cutting Capability Demonstration Missions, and NASA New Technology Initiatives.

The meeting will be open to the public up to the seating capacity of the room. It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants. For the sessions in Building 180, Room 101, (i.e., August 3 and 4 morning sessions), visitors will need to sign in and show a valid government-issued picture identification such as driver's license or passport to enter the Jet Propulsion Laboratory campus, and must state they are attending the NASA Advisory Council Exploration Committee meeting in Building 180, Room 101. No later

than July 20, 2010, all non-U.S. citizens must submit the following information to Ms. Jane Parham, Room 7C27, NASA Headquarters, 300 E Street, SW., Washington, DC 20546; fax (202) 358–3406: Name, current address, citizenship, company affiliation (if applicable) to include address, telephone number, and their title, place of birth, date of birth, U.S. visa information to include type, number, and expiration date, U.S. Social Security Number (if applicable), Permanent Resident Alien card number and expiration date (if applicable), place and date of entry into the U.S., and passport information to include country of issue, number, and expiration date.

For questions, please call Jane Parham at (202) 358–1715.

Dated: July 8, 2010.

P. Diane Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2010–17063 Filed 7–13–10; 8:45 am]

BILLING CODE P

POSTAL REGULATORY COMMISSION

[Order No. 485; Docket No. R2010–4]

Postal Rate Changes

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: Under a 2006 postal reform law, a new approach to implementing rate changes for market dominant postal products, which include First–Class Mail, was adopted. In general, the new approach envisions annual rate adjustments based on changes in a specified Consumer Price Index (CPI). However, the law includes a provision allowing rate changes in excess of CPI under extraordinary or exceptional circumstances, contingent on a Commission determination on certain considerations. The Postal Service is invoking this provision for the first time and, in a filing with the Commission, is seeking an overall percentage increase of about 5.6 percent for market dominant products beginning January 2, 2011. It is also seeking some classification changes. This document provides the public with notice of the Postal Service's filing, a brief description of the contents, a discussion of the Commission's role and responsibilities, and an outline of related procedural steps.

DATES: Key dates include:

1. July 19, 2010: first technical conference.

2. August 5, 2010: deadline for filing suggested questions to be directed to Postal Service during public hearing.

3. August 10-12: public hearings.

4. Deadline for issuance of Commission determination.

See **SUPPLEMENTARY INFORMATION** section for dates of additional technical conferences (if needed) and deadlines for initial and reply comments.

ADDRESSES: Submit comments and other filings electronically via the Commission's Filing Online system. Those who cannot submit comments and filings electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for advice on alternative filing methods.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at *http//www.prc.gov* or 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

On July 6, 2010, the Postal Service filed a proposed rate adjustment pursuant to 39 U.S.C. 3622(d)(1)(E) and 39 CFR 3010.60, *et seq.,* of the Commission's rules.[1] The filing seeks "to increase rates for market dominant products in excess of the otherwise applicable limitations of 39 U.S.C. 3622(b)(1)(A) and 39 CFR 3010.11." *Id.* at 11. The proposed prices represent an aggregate increase of approximately 5.6 percent and are to be implemented on January 2, 2011. *Id.*

II. Background and Postal Service Filing

As part of the comprehensive changes enacted by the Postal Accountability and Enhancement Act of 2006 (PAEA), 120 Stat. 3198, Congress has authorized the Postal Service to adjust rates for market–dominant products on the basis of "extraordinary or exceptional circumstances," provided the Commission determines that "such adjustment is reasonable and equitable and necessary to enable the Postal Service, under best practices of honest, efficient, and economical management, to maintain and continue the development of postal services of the kind and quality adapted to the needs of the United States."[2] 39 U.S.C. 3622(d)(1)(E).

Section 3622(d)(1)(E) also required the Commission to establish procedures that permit exigent rate adjustments to be made on an expedited basis. *Id.* Commission determinations that a proposed exigent rate adjustment is "reasonable and equitable and necessary" can only be made "after notice and opportunity for a public hearing and comment, and within 90 days after any request by the Postal Service." *Id.* On October 29, 2007, the Commission adopted a new subpart E to its part 3010 market dominant product regulations. 39 CFR part 3010, subpart E. Subpart E established "a functional and flexible framework" for exigent rate cases. Order No. 43, at 65–73. Because of the statutory requirement that determinations on proposed exigent rate adjustments be made within 90 days of the date of filing, it was necessary for the Commission to adopt "streamlined proceedings" for exigent rate cases. *See id.* at 65–66 and 39 CFR 3010.64.

On May 7, 2010, the Commission announced that a technical conference would be held on June 16, 2010, to discuss procedures for handling the exigent rate case that the Postmaster General had previously suggested might be filed.[3] The Commission viewed the conference as an opportunity to discuss unique procedural considerations and to identify possible solutions to potential issues "that might otherwise complicate fair and meaningful participation by interested persons." Order No. 456 at 2. In a subsequent order, the Commission solicited topics for discussion at the conference.[4]

Participants in the June 16 conference discussed a broad spectrum of topics, including, for example, the desirability of technical conferences, the nature and extent of permissible discovery, the manner in which participants would be permitted to submit questions to the Commission for response by the Postal

[1] Exigent Request of the United States Postal Service, July 6, 2010 (Exigent Request).

[2] Rate adjustments under section 3622(d)(1)(E) for extraordinary or exceptional circumstances are commonly referred to as "exigent" rate adjustments, although the term "exigent" does not appear in the statute. Recognizing that the legal standard for assessing section 3622(d)(1)(E) rate adjustments is the "extraordinary and exceptional circumstances" standard, the Commission shall for convenience refer to rate adjustments proposed under section 3622(d)(1)(E) as "exigent rate adjustments" and to cases containing such rate adjustments as "exigent rate cases." *See also* Docket No. RM2007–1, Order Establishing Ratemaking Regulations for Market Dominant and Competitive Products, October 29, 2007, at 66 (Order No. 43).

[3] Docket No. PI2010–3, Notice and Order Providing for Technical Conference, May 7, 2010 (Order No. 456) at 1.

[4] Docket No. PI2010–3, Proposals for Topics of Discussion During the Technical Conference in Response to Order No. 456, June 9, 2010.

Service, and procedures for filing written comments.[5]

In its July 6 filing, the Postal Service states that the Exigent Request is only one of several steps that it has taken to improve its financial condition. Exigent Request at 2. It states further that without the authority to increase rates beyond current limitations, it would be confined to an overall rate increase of only 0.578 percent, an amount which it asserts would prevent it "from making discernible progress towards closing the multi–billion dollar shortfall between projected expenses and projected revenues for FY 2011." *Id.* at 2–3. The Postal Service states that while the proposed increases will not eliminate the revenue shortfall, this is one of the few options that can reasonably be expected to have a short–term positive impact. *Id.* at 3.

In support of its filing, the Postal Service asserts that the circumstances it faces are "extraordinary or exceptional" and that the proposed rates are reasonable, equitable, and necessary. *Id.* at 4–8. The Postal Service goes on to describe the structure of its proposed rate adjustment stating that the concept it has followed involves the identification of available price caps by class, the presentation of an explanation of why the revenue generated from increases limited by price caps would be inadequate, and the presentation of an alternative proposed set of higher–percentage price increases. *Id.* at 9. The proposed increases are evaluated against factors set forth in the Commission's rules. *Id.* at 10. According to the Postal Service, this methodology could be viewed as an exercise in borrowing against future price caps and that if future circumstances permit, the Postal Service might be able to "pay back" some or all of the exigent increase by basing future price increases on price caps calculated below levels that future CPI–U calculations might otherwise indicate. *Id.* at 10–11.

Using its proposed methodology, the Postal Service states that the percentage changes by class implicit in its proposed exigent prices are as follows:

First–Class Mail: 5.417%
Standard Mail: 5.616%
Periodicals: 8.035%
Package Services: 6.700%
Special Services: 5.225%

Cumulatively, these percentage increases result in an overall percentage increase for market dominant products of approximately 5.6 percent. *Id.* at 15.

All of the proposed rates are set forth on Attachment A to the Exigent Request.[6] The Postal Service also includes several proposed changes to the mail classification schedule (MCS) in the Exigent Request.

The Postal Service states that while it has attempted to minimize the scope of MCS changes, some beneficial programs requiring MCS changes are warranted. Exigent Request at 19. The following changes are identified:

- In First–Class Mail, a Reply Rides Free Program is added for Presorted Letters.
- For First–Class Mail Parcels, a Single–Piece Commercial price category is added.
- In Standard Mail, a Saturation and High Density Incentive Program is added.
- The Standard Mail Not Flat–Machinable/Parcels product is renamed Standard Parcels and, as renamed, is divided into Marketing parcels and Fulfillment parcels. The Not Flat–Machinables price category is replaced by a Regular Marketing Parcels category.
- For Bound Printed Matter, half–pound rate cells are eliminated.
- Standard Mail denominations for Stamped Envelopes are eliminated.

All of the proposed changes are shown in legislative format based upon the Postal Service's understanding of the current version of the MCS draft. *Id.* Supporting justification for the proposal is provided in the statements of three postal officials: Joseph Corbett, Chief Financial Officer; Stephen J. Masse, Vice President, Finance and Planning; and James M. Kiefer, Pricing Economist. Mr. Corbett provides financial context for the request for an exigent rate increase. Mr. Masse relates the financial context to the increases proposed for the different mailing services products. Mr. Kiefer explains the policy reasons for the pricing decisions underlying proposed rates.

Also provided are Attachment A which shows the requested rate schedules and changes to the Mail Classification Schedule; Attachment B which provides calculations underlying what the CPI–U cap would be if the Postal Service were to file a Type 1 rate adjustment; Attachment C which is a list of supporting materials; and Attachment D which is an application for non–public treatment of a non–public annex.

III. Subsequent Procedural Steps

The Postal Service's July 6, 2010 exigent rate case filing is the first such filing tobe made since enactment by the PAEA of section 3622(d)(1)(E). The Commission's regulations in subpart E of part 3010 govern the filing. In adopting those regulations, the Commission acknowledged that further procedures might be needed to ensure an orderly but expeditious proceeding that protects the rights of all interested persons to participate. Order No. 43 at 33.

The June 16 conference has provided the Commission with a number of potentially useful suggestions and comments. One of the suggestions was that the Commission include a tentative schedule in the Commission's initial order. Tr. 1/40–41. The following schedule responds to that suggestion:

July 6, 2010 Exigent Request filed.
July 19, 2010 First Technical Conference (topics to be determined), to start at 2 p.m.
July 23, 2010 Second Technical Conference (if needed).
July 27, 2010 Third Technical Conference (if needed).
August 5, 2010 Deadline for filing suggested questions to be asked of the Postal Service during the public hearing. 39 CFR 3010.65(c).
August 10–12, 2010 Public Hearings.
August 17, 2010 Deadline for filing initial comments. 39 CFR 3010.65(f).
September 2, 2010 Deadline for filing reply comments. 39 CFR3010.65(g).
October 4, 2010 Deadline for Commission determination. 39 CFR 3010.66.

Absent specific notice to the contrary, all technical conferences and hearings will convene at 9:30 a.m., eastern daylight time in the Commission's hearing room in Suite 200, 901 New York Ave., NW., Washington, DC 20268–0001. Further review of the Postal Service filing may warrant adoption of additional procedural dates and/or requirements. If so, the Commission will issue further procedural orders as it deems advisable or necessary in order to ensure both efficiency and fairness. In that connection, the Commission has taken under advisement the further comments and suggestions made by participants at the June 16, 2010 conference.[7]

Comments may address, among other things: (1) The suffiency of the justification for an exigent rate increase; (2) the adequacy of the justification for increases in the amounts requested by the Postal Service; and (3) whether the specific rate adjustments requested are reasonable and equitable. *See* rule 3010.65(f).

To be included in the formal docket being established in this proceeding,

[5] *See* Docket No. PI2010–3, Technical Conference, June 16, 2010, TR 1.

[6] The Exigent Request is posted on the Postal Regulatory Commission's Web site at *http//www.prc.gov/docs/68/68792/request.final.pdf.*

[7] All future procedural rulings will be posted in Docket No. R2010–4 on the Commission's website at *http//www.prc.gov.* Interested persons are urged to monitor that docket to stay abreast of such further rulings.

submissions must be filed online as provided by rule 9 of the Commission's rules of practice, 39 CFR 3001.9, unless a waiver is obtained.[8] All submissions that do not conform to the rules of practice for online filings and do not obtain a waiver from the online filing requirements will be treated as informal statements of views and shall be placed in a separate file to be maintained by the Secretary as provided in 39 CFR 3001.20b.

IV. Public Representative

Pursuant to 39 U.S.C. 505, the Commission hereby appoints James Waclawski to serve as officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding. Technical assistance will be provided by Pamela A. Thompson and Natalie L. Rea. Neither Mr. Waclawski nor any staff assigned to assist him shall participate in or provide any advice on any Commission decision in this proceeding other than in their designated capacity.

V. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. R2010–4 to consider matters raised in the Postal Service's July 6, 2010 filing.

2. Subject to further orders, the Commission adopts the procedural schedule as set forth in the body of this order.

3. The Commission will sit en banc in this proceeding.

4. Pursuant to 39 U.S.C. 505, the Commission appoints James Waclawski to represent the interests of the general public in this proceeding.

5. The Secretary shall arrange for publication of this order in the **Federal Register.**

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2010–17056 Filed 7–13–10; 8:45 am]

BILLING CODE 7710–FW–S

SMALL BUSINESS ADMINISTRATION

Notice of Action Subject to Intergovernmental Review Under Executive Order 12372

AGENCY: U.S. Small Business Administration.

ACTION: Notice of Action Subject to Intergovernmental Review.

SUMMARY: The Small Business Administration (SBA) is notifying the public that it intends to grant the pending applications of 39 existing Small Business Development Centers (SBDCs) for refunding on January 1, 2011 subject to the availability of funds. Twenty states do not participate in the EO 12372 process; therefore, their addresses are not included. A short description of the SBDC program follows in the supplementary information below.

The SBA is publishing this notice at least 90 days before the expected refunding date. The SBDCs and their mailing addresses are listed below in the address section. A copy of this notice also is being furnished to the respective State single points of contact designated under the Executive Order. Each SBDC application must be consistent with any area-wide small business assistance plan adopted by a State-authorized agency.

DATES: A State single point of contact and other interested State or local entities may submit written comments regarding an SBDC refunding within 30 days from the date of publication of this notice to the SBDC.

ADDRESSES:

ADDRESSES OF RELEVANT SBDC STATE DIRECTORS

Mr. Greg Panichello, State Director, Salt Lake Community College, 9750 South 300 West, Sandy, UT 84070, (801) 957–3481.

Ms. Michelle Abraham, State Director, University of South Carolina, 1710 College Street, Columbia, SC 29208, (803) 777–4907.

Ms. Diane R. Howerton, Regional Director, University of California, Merced, 550 East Shaw, Suite 105A, Fresno, CA 93710, (559) 241–7406.

Ms. Debbie Trujillo, Regional Director, SW Community College District, 900 Otey Lakes Road, Chula Vista, CA 91910, (619) 482–6388.

Mr. Casey Jeszenka, SBDC Director, University of Guam, P.O. Box 5014—U.O.G. Station, Mangilao, GU 96923, (671) 735–2590.

Mr. Dan Ripke, Regional Director, California State University, Chico, Building 35, CSU Chico, Chico, CA 95929, (530) 898–4598.

Ms. Priscilla Lopez, Regional Director, California State University, Fullerton, 800 North State College Blvd., Fullerton, CA 92834, (714) 278–2719.

Mr. Herbert Thweatt, Director, American Samoa Community College, P.O. Box 2609, Pago Pago, American Samoa 96799, 011–684–699–4830.

Jerry Cartwright, State Director, University of West Florida, 401 East Chase Street, Suite 100, Pensacola, FL 32502, (850) 473–7800.

Mr. Sam Males, State Director, University of Nevada Reno, College of Business Admin., Room 411, Reno, NV 89557–0100, (775) 784–1717.

Mr. Mark DeLisle, State Director, University of Southern Maine, 96 Falmouth Street, Portland, ME 04103, (509) 358–7765.

Ms. Sheneui Weber, Regional Director, Long Beach Community College, 4040 Paramount Blvd., Suite 107, Lakewood, CA 90712, (562) 938–5004.

Ms. Kristin Johnson, Regional Director, Humboldt State University, Office of Economic & Community Dev., 1 Harpst Street, 2006A, Siemens Hall, Arcata, CA 95521, (707) 826–3920.

FOR FURTHER INFORMATION CONTACT: Antonio Doss, Associate Administrator for SBDCs, U.S. Small Business Administration, 409 Third Street, SW., Sixth Floor, Washington, DC 20416.

SUPPLEMENTARY INFORMATION:

Description of the SBDC Program

A partnership exists between SBA and an SBDC. SBDCs offer training, counseling and other business development assistance to small businesses. Each SBDC provides services under a negotiated Cooperative Agreement with the SBA. SBDCs operate on the basis of a state plan to provide assistance within a state or geographic area. The initial plan must have the written approval of the Governor. Non-Federal funds must match Federal funds. An SBDC must operate according to law, the Cooperative Agreement, SBA's regulations, the annual Program Announcement, and program guidance.

Program Objectives

The SBDC program uses Federal funds to leverage the resources of states, academic institutions and the private sector to:

(a) Strengthen the small business community;

(b) Increase economic growth;

(c) Assist more small businesses; and

(d) Broaden the delivery system to more small businesses.

[8] Formal intervention is not necessary.

SBDC Program Organization

The lead SBDC operates a statewide or regional network of SBDC service centers. An SBDC must have a full-time Director. SBDCs must use at least 80 percent of the Federal funds to provide services to small businesses. SBDCs use volunteers and other low-cost resources as much as possible.

SBDC Services

An SBDC must have a full range of business development and technical assistance services in its area of operations, depending upon local needs, SBA priorities and SBDC program objectives. Services include training and counseling to existing and prospective small business owners in management, marketing, finance, operations, planning, taxes, and any other general or technical area of assistance that supports small business growth.

The SBA district office and the SBDC must agree upon the specific mix of services. They should give particular attention to SBA's priority and special emphasis groups, including veterans, women, exporters, the disabled, and minorities.

SBDC Program Requirements

An SBDC must meet programmatic and financial requirements imposed by statute, regulations or its Cooperative Agreement. The SBDC must:

(a) Locate service centers so that they are as accessible as possible to small businesses;

(b) Open all service centers at least 40 hours per week, or during the normal business hours of its state or academic Host Organization, throughout the year;

(c) Develop working relationships with financial institutions, the investment community, professional associations, private consultants and small business groups; and

(d) Maintain lists of private consultants at each service center.

Dated: July 9, 2010.

Antonio Doss,

Associate Administrator for Small Business Development Centers.

[FR Doc. 2010–17137 Filed 7–13–10; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments and Recommendations

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Small Business Administration's intentions to request approval on a new and/or currently approved information collection.

DATES: Submit comments on or before September 13, 2010.

ADDRESSES: Send all comments regarding whether these information collections are necessary for the proper performance of the function of the agency, whether the burden estimates are accurate, and if there are ways to minimize the estimated burden and enhance the quality of the collections, to: Carol Fendler, System Accountant, Office of Investment, Small Business Administration, 409 3rd Street, 8th Floor, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Carol Fendler, System Accountant, Office of Investment, 202–205–7559, *carol.fendler@sba.gov,* Curtis B. Rich, Management Analyst, 202–205–7030, *curtis.rich@sba.gov.*

SUPPLEMENTARY INFORMATION: To obtain the information needed to carry out its oversight responsibilities under the Small Business Investment Act, Small Business Administration (SBA) requires licensed small business investment companies to submit financial statements, with supplementary schedules tailored to current regulatory requirements, on SBA Form 468. SBA uses this information to monitor financial condition and regulatory compliance of Small Business Investment Companies (SBIC), and for credit analysis when considering whether to approve requests for financial assistance to SBICs.

Title: "SBIC Financial Reports".

Description of Respondents: Small Business Investment Companies.

Form Numbers: 468, 468.1, 468.2, 468.3, 468.4.

Annual Responses: 1,265.

Annual Burden: 21,175.

To obtain the information needed to carry out its program evaluation and oversight responsibilities under the Small Business Investment Act. SBA requires licensed small business investment companies to provide information on SBA Form 1031 each time financing is extended to a small business concern. SBA uses this information to complied statistics on the SBIC program as a provider of capital to small business and to monitor the regulator regulatory compliance of individual SBICs.

Title: "Portfolio Financing Report".

Description of Respondents: Small Business Investment Companies.

Form Number: 1031.

Annual Responses: 3,700.

Annual Burden: 740.

Jacqueline White,

Chief, Administrative Information Branch.

[FR Doc. 2010–16935 Filed 7–13–10; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

Federal Register Meeting Notice; Webinar About Regional Innovation Clusters RFP

AGENCY: U.S. Small Business Administration (SBA)

ACTION: Notice of open webinar meeting to discuss Regional Innovation Clusters (RIC) Request for Proposals (RFP) No. SBAHQ–10–R–0021.

SUMMARY: The SBA is issuing this notice to announce the date of a webinar it is hosting to answer questions from potential Offerors about the Regional Innovation Clusters RFP. For more information please go to *http://www.sba.gov/clusters/index.html*. The RFP may be found on *http://www.fedbizopps.gov.*

Logistical Information: The webinar will be held on Thursday, July 15, 2010. For details, please visit *http://www.sba.gov/clusters/index.html.*

SUPPLEMENTARY INFORMATION: The Small Business Administration (SBA) has issued a Request for Proposals (RFP) to solicit proposals from existing regional innovation clusters to provide business training, counseling, mentoring, commercialization and technology transfer services, and other services that support the growth and development of small businesses in the cluster area and industries. SBA intends to make multiple fixed-price contract awards, each with a one-year base term with an option for an additional year. Annual proposal costs should not exceed $600,000 and all contracts will be subject to applicable contract cost principles and procedures (Federal Acquisition Regulation Subpart 31). SBA will select regional innovation clusters in communities across the country that meet its specified criteria. Offerors will be asked to demonstrate that they have partnerships, technical capacity, and local assets to support their existing regional cluster, as well as experience fostering small business development and growth opportunities. SBA will evaluate offers based on a number of criteria, including the impact the services will have on the region's economic growth, creation of sustainable jobs and the opportunities the regional innovation cluster will provide for small businesses. The RFP was posted on *http://*

www.fedbizopps.gov on about July 8, 2010. All responsible sources may submit an offer that will be considered by the agency. Offerors need to be registered in the Central Contractor Registration database, which can be found at *http://www.ccr.gov,* and have a DUNS Number established by Dun & Bradstreet (*see https://fedgov.dnb.com*)

Meaghan Burdick,

Deputy Chief of Staff.

[FR Doc. 2010–17070 Filed 7–13–10; 8:45 am]

BILLING CODE;P

SMALL BUSINESS ADMINISTRATION

Webinar About Advanced Defense Technologies RFP

AGENCY: U.S. Small Business Administration (SBA).

ACTION: Notice of open webinar meeting to discuss Advanced Defense Technologies (ADT) Request for Proposals (RFP) No. SBAHQ–10–R–0022.

SUMMARY: The SBA is issuing this notice to announce the date of a webinar it is hosting to answer questions from potential Offerors about the Advanced Defense Technologies RFP. Please visit *http://www.sba.gov/clusters/index.html* for more information. The RFP may be found on *http://www.fedbizopps.gov.*

LOGISTICAL INFORMATION: The webinar will be held on Monday, July 19, 2010. For details, please visit *http://www.sba.gov/clusters/index.html.*

SUPPLEMENTARY INFORMATION: The Small Business Administration has issued a Request for Proposals (RFP) to solicit proposals from existing regional innovation clusters specializing in defense technologies to provide counseling, training, mentoring, matchmaking and other services to support small business development and growth in cluster areas and industries. SBA intends to make awards to multiple regional innovation clusters that can help meet critical Department of Defense technology needs. SBA intends to award fixed-price contracts with a one-year base term with an option for an additional year. Proposed annual costs should not exceed $600,000, and all awarded contracts will be subject to applicable contract cost principles and procedures (Federal Acquisition Regulation Part 31). SBA will select regional innovation clusters in communities across the country with established cluster focus areas that meet its specified criteria. Some areas of high-growth potential include, but are not limited to, advanced robotics, advanced defense systems, power/energy innovations, cyber-security and applied lightweight materials. Offerors should demonstrate that they have the partnerships, technical capacity, and local assets to support their existing regional innovation clusters, as well as experience fostering small business development and growth opportunities. Experience working with the Department of Defense Small Business Innovation Research and defense technology development programs is preferred. Offerors with Defense Security Service Facility Clearances who can hold security clearances and discuss classified material on site are preferred but not required. The RFP was posted on *http://www.fedbizopps.gov* on July 8, 2010. All responsible sources may submit an offer which will be considered by the agency. Offerors need to be registered in the Central Contractor Registration database, which can be found at *http://www.ccr.gov,* and have a DUNS Number established by Dun & Bradstreet (see *https://fedgov.dnb.com*).

Meaghan Burdick,

Deputy Chief of Staff.

[FR Doc. 2010–17071 Filed 7–13–10; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Small Business Size Standards: Waiver of the Nonmanufacturer Rule

AGENCY: U.S. Small Business Administration.

ACTION: Notice of Waiver to the Nonmanufacturer Rule for Herbicides, Insecticides, and Fungicides, under Product Service Code (PSC) 6840, under North American Industry Classification System (NAICS) code 325320, Pesticides and Other Agricultural Chemical Manufacturing.

SUMMARY: The U.S. Small Business Administration (SBA) is granting a waiver of the Nonmanufacturer Rule for Herbicides, Insecticides, and Fungicides, under PSC 6840, under NAICS code 325320. The basis for waiver is that no small business manufacturers are supplying this class of product to the Federal government. The effect of this waiver will be to allow otherwise qualified small businesses to supply the products of any manufacturer on a Federal contract set aside for small businesses, Service-Disabled Veteran-Owned (SDVO) small businesses or Participants in SBA's 8(a) Business Development (BD) Program.

DATES: This waiver is effective July 29, 2010.

FOR FURTHER INFORMATION CONTACT: Ms. Amy Garcia, Procurement Analyst, by telephone at (202) 205–6842; by FAX at (202) 481–1630; or by e-mail at *amy.garcia@sba.gov.*

SUPPLEMENTARY INFORMATION: Section 8(a)(17) of the Small Business Act (Act), 15 U.S.C. 637(a)(17), and SBA's implementing regulations require that recipients of Federal supply contracts set aside for small businesses, SDVO small businesses, or Participants in the SBA's 8(a) BD Program must provide the product of a small business manufacturer or processor, if the recipient is other than the actual manufacturer or processor of the product. This requirement is commonly referred to as the Nonmanufacturer Rule. 13 CFR 121.406(b), 125.15(c). Section 8(a)(17)(b)(iv) of the Act authorizes SBA to waive the Nonmanufacturer Rule for any "class of products" for which there are no small business manufacturers or processors available to participate in the Federal market.

In order to be considered available to participate in the Federal market for a class of products, a small business manufacturer must have submitted a proposal for a contract solicitation or received a contract from the Federal government within the last 24 months. 13 CFR 121.1202(c). The SBA defines "class of products" based on the Office of Management and Budget's NAICS. In addition, SBA uses PSCs to further identify particular products within the NAICS code to which a waiver would apply.

The SBA received a request on January 7, 2010, to waive the Nonmanufacturer Rule for Herbicides, Insecticides, and Fungicides, PSC 6840, under NAICS code 325320, Pesticides and Other Agricultural Chemical Manufacturing.

On May 19, 2010, SBA published in the **Federal Register** a notice of intent to waive the Nonmanufacturer Rule for the above listed items. SBA explained in the notice that it was soliciting comments and sources of small business manufacturers of this class of products. No comments were received in response to this notice. In addition, SBA conducted market research using the Dynamic Small Business Search database and no small business manufacturers that participate in the Federal market were identified. Thus, SBA has determined that there are no small business manufacturers of these classes of products, and is therefore granting the waiver of the Nonmanufacturer Rule for Herbicides, Insecticides, and Fungicides, under PSC

6840, under NAICS code 325320, Pesticides and Other Agricultural Chemical Manufacturing.

Karen Hontz,

Director, Office of Government Contracting.

[FR Doc. 2010–17072 Filed 7–13–10; 8:45 am]

BILLING CODE 8025–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–62461; File No. SR–NYSE–2010–50]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by New York Stock Exchange LLC Amending NYSE Rule 46 To Permit the Exchange Chairman To Designate More or Less Than Twenty (20) Floor Governors, as Needed

July 7, 2010.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the "Act") [2] and Rule 19b–4 thereunder, [3] notice is hereby given that on June 25, 2010, New York Stock Exchange LLC ("NYSE" or the "Exchange") 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 self-regulatory organization. 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

The Exchange proposes to amend NYSE Rule 46 to permit the Exchange Chairman to designate more or less than twenty (20) Floor Governors, as needed. The text of the proposed rule change is available at the Exchange, the Commission's Web site at *http://www.sec.gov*, 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 the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend NYSE Rule 46 (Floor Officials—Appointment) to permit the Exchange Chairman to designate more or less than twenty (20) Floor Governors, as needed.[4]

Current NYSE Rule 46:

NYSE Rule 46 permits the Chairman of the Exchange to, in consultation with the Executive Floor Governors of the Exchange and the NYSE Regulation ("NYSER") Board of Directors, designate twenty (20) individual members as Floor Governors, subject to approval by the Exchange's Board of Directors.

Pursuant to Rules 46 and 46A, Floor Governors are one of several ranks of the broader category of Floor Officials, including, in order of increasing seniority, Floor Officials, Senior Floor Officials, Executive Floor Officials, Floor Governors and Executive Floor Governors. As such, Floor Governors are drawn from the ranks of experienced NYSE Floor members.[5]

As part of the NYSER Board's advisory function, NYSER staff examine the fitness of the individuals designated as prospective Floor Officials and administer a mandatory education program, which all candidates for Floor Official, including Floor Governor, must complete. NYSER also administers a qualifying examination to newly-named Floor Officials, who must pass the exam prior to being recommended by the NYSER Board for appointment; however, upon being named as a Floor Governor, an individual does not need to retake the exam.[6]

In addition to their regular obligations as either Floor brokers or Designated Market Makers, Floor Governors, who serve as volunteers, are empowered to perform such duties as are prescribed to them under the Rules of the Exchange. As noted above, under Rule 46 Floor Governors are also considered Floor Officials and may perform such duties as are prescribed to Floor Officials under Exchange Rules. In addition, Floor Governors may, as needed, perform any duty, make any decision, or take any action assigned to or required of an Executive Floor Governor in accordance with Exchange Rules, or as may be designated by the Exchange Board.

For example, Floor Governors play a role in managing the Exchange's Trading Floor during unusual or volatile market situations. Under NYSE Rule 123D, members are to consult with a Floor Governor when the opening (reopening) price in a stock is anticipated to be at a significant disparity from the prior close. In addition, under Rule 123D an intra-day trading halt requires approval from a Floor Governor (or two Floor Officials). Under Rule 18, Floor Governors are part of the Compensation Review Panel for resolving claims due to Exchange system failures. Pursuant to Rule 75, Floor Governors are sometimes involved in the resolution of certain trade disputes. And, pursuant to Rule 123C(9), a Floor Governor is sometimes also needed to supervise extreme order imbalances at the Close of trading when an Executive Floor Governor is unavailable.

Proposed Amendments to NYSE Rule 46:

The Exchange proposes to amend NYSE Rule 46 to permit the Chairman of the Exchange to appoint more or less than twenty (20) Floor Governors, as needed.

Currently, the Exchange has seventeen (17) Floor Governors. At the present time, the Exchange believes that adding more Floor Governors, as needed, will help the Exchange to manage the Trading Floor more effectively and, consequently, to better serve investors and the public interest. As the recent market events of May 6, 2010, demonstrated, swift response to unusual and volatile market events on the Trading Floor helped to limit the disruption of the market for Exchange-listed securities and the harm to Exchange customers, as well as the market as a whole, and Floor Governors were involved in this process.

Notwithstanding the foregoing, removing the requirement to appoint a specific number of Floor Governors will not change the Exchange's goal of having, at all times, enough personnel on the Trading Floor, including Floor Officials, Senior Floor Officials, Executive Floor Officials, Floor Governors and Executive Floor

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Exchange's corporate affiliate, NYSE Amex LLC ("NYSE Amex"), submitted a companion rule filing proposing corresponding amendments to NYSE Amex Equities Rule 46. *See* SR–NYSEAmex–2010–65.

[5] *See* Securities Exchange Act Release No. 57627 (April 4, 2008), 73 FR 19919 (April 11, 2008) (SR–NYSE–2008–19, describing amendments to NYSE Rule 46).

[6] *See* Securities Exchange Act Release No. 57627 (April 4, 2008), 73 FR 19919 (April 11, 2008).

Governors, as well as Exchange officers and staff, to properly oversee the NYSE market.[7] In addition, the Exchange does not propose to change in any way the nature of Floor Governor duties or responsibilities.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934, as amended (the "Act"),[8] in general, and furthers the objectives of Section 6(b)(5) of the Act,[9] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, 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.

The Exchange believes that the proposed rule change supports the objectives of the Act and will provide a benefit to the market while also protecting investors and the public interest. By having more Floor Governors, as currently needed, the Exchange believes it will be better able to manage the Trading Floor, particularly in unusual market conditions. In addition, while the Exchange currently seeks the ability to appoint more than 20 Floor Governors, it reserves the right to have fewer than 20 Floor Governors as conditions warrant and as required to protect investors and the public interest.

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

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, it has become effective pursuant to 19(b)(3)(A) of the Act[10] and Rule 19b–4(f)(6)[11] thereunder.

The Exchange has asked the Commission to waive the 5-day prefiling requirement and the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange has stated that it is requesting these waivers in light of recent market events and in connection with the Russell rebalancing on June 25, 2010, on which day the Exchange has stated that it expects an increase in trading volume and market volatility. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, because such waiver will enable the Exchange to appoint more than twenty (20) Floor Governors to help the Exchange to manage the Trading Floor more effectively in time for the Russell rebalancing on June 25, 2010. For this reason, the Commission hereby waives the 30-day operative delay requirement and designates the proposed rule change as operative upon filing.[12]

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate 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–NYSE–2010–50 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–NYSE–2010–50. 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, 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–NYSE–2010–50 and should be submitted on or before August 4, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–17112 Filed 7–13–10; 8:45 am]

BILLING CODE 8011–01–P

[7] While the Exchange currently seeks the ability to appoint more than 20 Floor Governors, it reserves the right to have fewer than 20 Floor Governors as conditions warrant.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Commission is waiving this 5-day pre-filing requirement.

[12] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–62462; File No. SR–NYSEAmex–2010–65]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by NYSE Amex LLC Amending Rule 46—NYSE Amex Equities To Permit the Exchange Chairman To Designate More or Less Than Twenty (20) Floor Governors, as Needed

July 7, 2010.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on June 25, 2010, 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 and II below, which Items have been prepared by the self-regulatory organization. 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

The Exchange proposes to amend Rule 46—NYSE Amex Equities to permit the Exchange Chairman to designate more or less than twenty (20) Floor Governors, as needed. The text of the proposed rule change is available at the Exchange, the Commission's Web site at *http://www.sec.gov,* 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.

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 46—NYSE Amex Equities (Floor Officials—Appointment) to permit the Exchange Chairman to designate more or less than twenty (20) Floor Governors, as needed.[4]

Current Rule 46—NYSE Amex Equities:

NYSE Amex Equities Rule 46 permits the Chairman of the Exchange to, in consultation with the Executive Floor Governors of the Exchange and the NYSE Regulation ("NYSER") Board of Directors, designate twenty (20) individual members as Floor Governors, subject to approval by the Exchange's Board of Directors.

Pursuant to NYSE Amex Equities Rules 46 and 46A, Floor Governors are one of several ranks of the broader category of Floor Officials, including, in order of increasing seniority, Floor Officials, Senior Floor Officials, Executive Floor Officials, Floor Governors and Executive Floor Governors. As such, Floor Governors are drawn from the ranks of experienced NYSE Amex Equities Floor members.[5]

As part of the NYSER Board's advisory function, NYSER staff examine the fitness of the individuals designated as prospective Floor Officials and administer a mandatory education program, which all candidates for Floor Official, including Floor Governor, must complete. NYSER also administers a qualifying examination to newly-named Floor Officials, who must pass the exam prior to being recommended by the NYSER Board for appointment; however, upon being named as a Floor Governor, an individual does not need to retake the exam.[6]

In addition to their regular obligations as either Floor brokers or Designated Market Makers, Floor Governors, who serve as volunteers, are empowered to perform such duties as are prescribed to them under the Rules of the Exchange. As noted above, under Rule 46—NYSE Amex Equities Floor Governors are also considered Floor Officials and may perform such duties as are prescribed to Floor Officials under Exchange Rules. In addition, Floor Governors may, as needed, perform any duty, make any decision, or take any action assigned to or required of an Executive Floor Governor in accordance with Exchange Rules, or as may be designated by the Exchange Board.

For example, Floor Governors play a role in managing the Exchange's Trading Floor during unusual or volatile market situations. Under Rule 123D—NYSE Amex Equities, members are to consult with a Floor Governor when the opening (reopening) price in a stock is anticipated to be at a significant disparity from the prior close. In addition, under Rule 123D—NYSE Amex Equities an intra-day trading halt requires approval from a Floor Governor (or two Floor Officials). Under Rule 18—NYSE Amex Equities, Floor Governors are part of the Compensation Review Panel for resolving claims due to Exchange system failures. Pursuant to Rule 75—NYSE Amex Equities, Floor Governors are sometimes involved in the resolution of certain trade disputes. And, pursuant to Rule 123C(9)—NYSE Amex Equities, a Floor Governor is sometimes also needed to supervise extreme order imbalances at the Close of trading when an Executive Floor Governor is unavailable.

Proposed Amendments to Rule 46—NYSE Amex Equities:

The Exchange proposes to amend Rule 46—NYSE Amex Equities to permit the Chairman of the Exchange to appoint more or less than twenty (20) Floor Governors, as needed.

Currently, the Exchange has seventeen (17) Floor Governors. At the present time, the Exchange believes that adding more Floor Governors, as needed, will help the Exchange to manage the Trading Floor more effectively and, consequently, to better serve investors and the public interest. As the recent market events of May 6, 2010, demonstrated, swift response to unusual and volatile market events on the Trading Floor helped to limit the disruption of the market for Exchange-listed securities and the harm to Exchange customers, as well as the market as a whole, and Floor Governors were involved in this process.

Notwithstanding the foregoing, removing the requirement to appoint a specific number of Floor Governors will not change the Exchange's goal of having, at all times, enough personnel on the Trading Floor, including Floor Officials, Senior Floor Officials, Executive Floor Officials, Floor Governors and Executive Floor Governors, as well as Exchange officers

[4] The Exchange's corporate affiliate, New York Stock Exchange LLC ("NYSE"), submitted a companion rule filing proposing corresponding amendments to NYSE Rule 46. *See* SR–NYSE–2010–50.

[5] *See* Securities Exchange Act Release No. 57627 (April 4, 2008), 73 FR 19919 (April 11, 2008) (SR–NYSE–2008–19, describing amendments to NYSE Rule 46, on which NYSE Amex Equities Rule 46 is based).

[6] *See* Securities Exchange Act Release No. 57627 (April 4, 2008), 73 FR 19919 (April 11, 2008).

and staff, to properly oversee the NYSE Amex Equities market.[7] In addition, the Exchange does not propose to change in any way the nature of Floor Governor duties or responsibilities.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934, as amended (the "Act"),[8] in general, and furthers the objectives of Section 6(b)(5) of the Act,[9] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, 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.

The Exchange believes that the proposed rule change supports the objectives of the Act and will provide a benefit to the market while also protecting investors and the public interest. By having more Floor Governors, as currently needed, the Exchange believes it will be better able to manage the Trading Floor, particularly in unusual market conditions. In addition, while the Exchange currently seeks the ability to appoint more than 20 Floor Governors, it reserves the right to have fewer than 20 Floor Governors as conditions warrant and as required to protect investors and the public interest.

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

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, it has become effective pursuant to 19(b)(3)(A) of the Act[10] and Rule 19b–4(f)(6)[11] thereunder.

The Exchange has asked the Commission to waive the five-day prefiling requirement and the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange has stated that it is requesting these waivers in light of recent market events and in connection with the Russell rebalancing on June 25, 2010, on which day the Exchange has stated that it expects an increase in trading volume and market volatility. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, because such waiver will enable the Exchange to appoint more than twenty (20) Floor Governors to help the Exchange to manage the Trading Floor more effectively in time for the Russell rebalancing on June 25, 2010. For this reason, the Commission hereby waives the 30-day operative delay requirement and designates the proposed rule change as operative upon filing.[12]

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate 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 Comment

- 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–2010–65 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–2010–65. 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, 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–2010–65 and should be submitted on or before August 4, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–17113 Filed 7–13–10; 8:45 am]

BILLING CODE 8010–01–P

[7] While the Exchange currently seeks the ability to appoint more than 20 Floor Governors, it reserves the right to have fewer than 20 Floor Governors as conditions warrant.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Commission is waiving this five-day pre-filing requirement.

[12] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[13] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice: 7087]

Bureau of Verification, Compliance, and Implementation; Imposition of Sanctions Against Foreign Entities, Including a Ban on U.S. Government Procurement

AGENCY: Department of State.

ACTION: Notice.

SUMMARY: A determination has been made that a number of foreign entities and one foreign person have engaged in activities that warrant the imposition of measures pursuant to Section 3 of the Iran, North Korea, and Syria Nonproliferation Act. The Act provides for penalties on entities and individuals for the transfer to or acquisition from Iran since January 1, 1999, the transfer to or acquisition from Syria since January 1, 2005, or the transfer to or acquisition from North Korea since January 1, 2006, of equipment and technology controlled under multilateral control lists (Missile Technology Control Regime, Australia Group, Chemical Weapons Convention, Nuclear Suppliers Group, Wassenaar Arrangement) or otherwise having the potential to make a material contribution to the development of weapons of mass destruction (WMD) or cruise or ballistic missile systems. The latter category includes (a) items of the same kind as those on multilateral lists but falling below the control list parameters, when it is determined that such items have the potential of making a material contribution to WMD or cruise or ballistic missile systems, (b) other items with the potential of making such a material contribution, when added through case-by-case decisions, and (c) items on U.S. national control lists for WMD/missile reasons that are not on multilateral lists.

DATES: *Effective Date:* July 14, 2010.

FOR FURTHER INFORMATION CONTACT: On general issues: Stephen J. Tomchik, Bureau of Verification, Compliance, and Implementation, Department of State, Telephone (202) 647–7383. For U.S. Government procurement ban issues: Kimberly Triplett, Office of the Procurement Executive, Department of State, Telephone: (703) 875–4079.

SUPPLEMENTARY INFORMATION: Pursuant to Sections 2 and 3 of the Iran, North Korea, and Syria Nonproliferation Act (Pub. L. 109–353), the U.S. Government determined on June 30, 2010, that the measures authorized in Section 3 of the Act shall apply to the following foreign persons identified in the report submitted pursuant to Section 2(a) of the Act:

BelTechExport (Belarus) and any successor, sub-unit, or subsidiary thereof;

Mr. Karl Lee (China);

Dalian Sunny Industries (China) also known as: LIMMT (Dalian) Metallurgy and Minerals Co., LIMMT (Dalian) Economic and Trade Organization, and Liaoning Industry & Trade Co., Ltd. (China) and any successor, sub-unit, or subsidiary thereof;

Shanghai Technical By-Products International (STBPI) (China) and any successor, sub-unit, or subsidiary thereof;

Zibo Chemet Equipment Company (China) and any successor, sub-unit, or subsidiary thereof;

Defense Industries Organization (Iran) and any successor, sub-unit, or subsidiary thereof;

Shahid Bakeri Industries Group (SBIG) (Iran) and any successor, sub-unit, or subsidiary thereof;

Korea Mining Development Corporation (KOMID) (North Korea) and any successor, sub-unit, or subsidiary thereof;

Accordingly, pursuant to the provisions of the Act, the following measures are imposed on these entities:

1. No department or agency of the United States Government may procure, or enter into any contract for the procurement of any goods, technology, or services from these foreign persons, except to the extent that the Secretary of State otherwise may have determined;

2. No department or agency of the United States Government may provide any assistance to the foreign persons, and these persons shall not be eligible to participate in any assistance program of the United States Government, except to the extent that the Secretary of State otherwise may have determined;

3. No United States Government sales to the foreign persons of any item on the United States Munitions List are permitted, and all sales to these persons of any defense articles, defense services, or design and construction services under the Arms Export Control Act are terminated; and

4. No new individual licenses shall be granted for the transfer to these foreign persons of items the export of which is controlled under the Export Administration Act of 1979 of the Export Administration Regulations, and any existing such licenses are suspended.

These measures shall be implemented by the responsible departments and agencies of the United States Government and will remain in place for two years from the effective date, except to the extent that the Secretary of State may subsequently determine otherwise. A new determination will be made in the event that circumstances change in such a manner as to warrant a change in the duration of sanctions.

Dated: July 7, 2010.

Rose E. Gottemoeller,

Assistant Secretary of State for Verification, Compliance, and Implementation, Department of State.

[FR Doc. 2010–17178 Filed 7–13–10; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. AB 31 (Sub-No. 42X)]

Grand Trunk Western Railroad Company—Abandonment Exemption—in Macomb County, MI

Grand Trunk Western Railroad Company (GTW) filed a verified notice of exemption under 49 CFR pt. 1152 Subpart F–*Exempt Abandonments* to abandon its line of railroad between milepost 0.00 and milepost 0.42, a distance of 0.42 miles, in Richmond, Macomb County, Mich. The line traverses United States Postal Service Zip Code 48062.[1]

GTW has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) there is no overhead traffic to be rerouted over other lines; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7 (environmental report), 49 CFR 1105.8 (historic report), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 USC 10502(d) must be filed.

[1] By letter filed on July 7, 2010, GTW amended its notice of exemption.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on August 13, 2010, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[2] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[3] and trail use/rail banking requests under 49 CFR 1152.29 must be filed by July 26, 2010. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by August 3, 2010, with the Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to GTW's representative: Thomas J. Healey, 17641 S. Ashland Avenue, Homewood, Ill. 60430–1345.

If the verified notice contains false or misleading information, the exemption is void *ab initio.*

GTW has filed a combined environmental and historic report which addresses the effects, if any, of the abandonment on the environment and historic resources. SEA will issue an environmental assessment (EA) by July 19, 2010. Interested persons may obtain a copy of the EA by writing to SEA (Room 1100, Surface Transportation Board, Washington, DC 20423–0001) or by calling SEA, at (202) 245–0305. Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), GTW shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the line. If consummation has not been effected by GTW's filing of a notice of consummation by July 14, 2011, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available on our Web site at "*http://www.stb.dot.gov.*"

Decided: July 8, 2010.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2010–17117 Filed 7–13–10; 8:45 am]

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[2] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Section of Environmental Analysis (SEA) in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Serv. Rail Lines,* 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[3] Each OFA must be accompanied by the filing fee, which is currently set at $1,500. *See* 49 CFR 1002.2(f)(25).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Request Approval From the Office of Management and Budget of a New Information Collection Activity, Request for Comments; AST Collection of Voluntary Lessons Learned From External Sources

AGENCY: Federal Aviation Administration (FAA), DOT

ACTION: Notice and request for comments.

SUMMARY: The FAA invites public comments about our intention to request the Office of Management and Budget (OMB) to approve a new information collection. The FAA/AST will collect lessons learned from members of the commercial space industry in order to carry out the safety responsibilities in 49 U.S.C Chapter 701 Section 70103(c).

DATES: Please submit comments by September 13, 2010.

FOR FURTHER INFORMATION CONTACT: Carla Scott on (202) 267–9895, or by e-mail at: *Carla.Scott@faa.gov.*

SUPPLEMENTARY INFORMATION:

Federal Aviation Administration (FAA)

Title: AST Collection of Voluntary Lessons Learned from External Sources.

Type of Request: New collection.

OMB Control Number: 2120–XXXX.

Form(s): There are no FAA forms associated with this collection.

Affected Public: A total of 20 Respondents.

Frequency: The information is collected on occasion.

Estimated Average Burden per Response: Approximately 1 hour per response.

Estimated Annual Burden Hours: An estimated 30 hours annually.

Abstract: The FAA/AST collects lessons learned from members of the commercial space industry in order to carry out the safety responsibilities in 49 U.S.C Chapter 701 Section 70103(c). These responsibilities include "encourage, facilitate, and promote the continuous improvement of the safety of launch vehicles designed to carry humans." The FAA/AST collects and shares lessons learned between members of the amateur rocket community, experimental permit holders, licensed launch and reentry operators, and licensed launch and reentry site operators to ensure the safe and successful outcome of launch activities, allowing AST to meet our public safety goals without creating a regulatory burden.

ADDRESSES: Send comments to the FAA at the following address: Ms. Carla Scott, Room 712, Federal Aviation Administration, IT Enterprises Business Services Division, AES–200, 800 Independence Ave., SW., Washington, DC 20591.

Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimates of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued in Washington, DC, on July 8, 2010.

Carla Scott,

FAA Information Collection Clearance Officer, IT Enterprises Business Services Division, AES–200.

[FR Doc. 2010–17132 Filed 7–13–10; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2010–0193]

Pipeline Safety: Information Collection Activities

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, PHMSA invites comments on an information collection under Office of Management and Budget (OMB) Control No. 2137–0598, titled "Incorporation by Reference of Industry Standard on Leak Detection." PHMSA is preparing to

request approval from OMB for a renewal of the current information collection.

DATES: Interested persons are invited to submit comments on or before September 13, 2010.

ADDRESSES: Comments may be submitted in the following ways:

E–Gov Web Site: http://www.regulations.gov. This site allows the public to enter comments on any **Federal Register** notice issued by any agency.

Fax: 1–202–493–2251.

Mail: Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building, Room W12–140, Washington, DC 20590–0001.

Hand Delivery: Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Instructions: Identify the docket number, PHMSA–2010–0193, at the beginning of your comments. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. You should know that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, *etc.*) Therefore, you may want to review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477) or visit *http://www.regulations.gov* before submitting any such comments.

Docket: For access to the docket or to read background documents or comments, go to *http://www.regulations.gov* at any time or to Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. If you wish to receive confirmation of receipt of your written comments, please include a self-addressed, stamped postcard with the following statement: "Comments on PHMSA–2010–0193." The Docket Clerk will date-stamp the postcard prior to returning it to you via the U.S. mail. Please note that due to delays in the delivery of U.S. mail to Federal offices in Washington, DC, we recommend that persons consider an alternative method (Internet, fax, or professional delivery service) of submitting comments to the docket and ensuring their timely receipt at DOT.

FOR FURTHER INFORMATION CONTACT: Cameron Satterthwaite by telephone at 202–366–1319, by fax at 202–366–4566, or by mail at U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 1200 New Jersey Avenue, SE., PHP–30, Washington, DC 20590–0001.

SUPPLEMENTARY INFORMATION: Section 1320.8(d), Title 5, Code of Federal Regulations requires PHMSA to provide interested members of the public and affected agencies an opportunity to comment on information collection and recordkeeping requests. This notice identifies an information collection request that PHMSA will be submitting to OMB for renewal and extension. The information collection expires October 31, 2010, and is identified under Control No. 2137–0598, titled: "Incorporation by Reference of Industry Standard on Leak Detection." This information collection is contained in 49 CFR Part 195. The following information is provided for each information collection: (1) Title of the information collection; (2) OMB control number; (3) Type of request; (4) Abstract of the information collection activity; (5) Description of affected public; (6) Estimate of total annual reporting and recordkeeping burden; and (7) Frequency of collection. PHMSA will request a three-year term of approval for this information collection activity.

PHMSA requests comments on the following information collection:

Title: Incorporation by Reference of Industry Standard on Leak Detection.

OMB Control Number: 2137–0598.

Type of Request: Renewal of a currently approved information collection.

Abstract: Section 195.444 of the Federal pipeline safety regulations requires operators of single phase hazardous liquid pipeline facilities that use computational pipeline monitoring (CPM) leak detection systems to comply with the standards set out in American Petroleum Institute (API) publication API 1130. API 1130 requires operators to record and retain certain information in connection with the operation and testing of CPM systems. Compliance with API 1130, including its record keeping requirements, supports pipeline safety by ensuring the proper functioning of CPM leak detection systems.

Affected Public: Operators of hazardous liquid pipelines.

Estimated Number of responses: 50.

Estimated Annual Burden Hours: 100 hours.

Frequency of collection: On occasion.

Comments are invited on:

(a) The need for the proposed collection of information 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 proposed collection of information, including 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 the use of appropriate automated, electronic, mechanical, or other technological collection techniques.

Issued in Washington, DC, on July 8, 2010.

Linda Daugherty,

Deputy Associate Administrator for Policy and Programs.

[FR Doc. 2010–17078 Filed 7–13–10; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

Notice of Fiscal Year 2010 Border Grant Funding and Solicitation for Applications

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice.

SUMMARY: FMCSA announces the availability of Fiscal Year (FY) 2010 Border Enforcement Grant (BEG) funding and solicits applications. Applications must be submitted at the Federal Grant Web site, *http://www.grants.gov.* Eligible projects for funding with BEG are identified in the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users.

DATES: The deadline for applications is July 30, 2010. If additional funding remains available, the Agency will consider applications submitted after July 30, 2010, on a case-by-case basis.

ADDRESSES: You must submit applications for BEG funding at the Federal Grant Web site, *http://www.grants.gov.*

FOR FURTHER INFORMATION CONTACT: Ms. Carla Vagnini, (202) 366–3771, Federal Motor Carrier Safety Administration, Office of Safety Programs, North American Borders Division (MC–ESB), 1200 New Jersey Avenue, SE., Washington, DC 20590. Office hours are from 7 a.m. to 4:30 p.m., ET., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: The Consolidated Appropriations Act, 2010 [Pub. L 111–117, December 16, 2009, 123 Stat. 3034] provides grant funding for commercial motor vehicle (CMV) safety programs as authorized under the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU) [Pub. L. 109–59, August 10, 2005, 119 Stat. 1144]. This notice announces the availability of, and solicits applications for, approximately $6,000,000 in un-awarded FY 2010 funding for BEG projects.

Section 4110 of SAFETEA–LU established the BEG program. The purpose of this discretionary grant program is to provide funding for border CMV safety programs and related enforcement activities and projects. An entity or a State that shares a land border with another country is eligible to receive this grant funding. Eligible awardees include State governments, local governments, and entities (for example, an accredited post-secondary public or private educational institution such as a university). Requests from entities must be coordinated with the State lead CMV inspection agency. Planned activities must be conducted by State agencies, local governments, and organizations representing government agencies that use and train qualified officers and employees in coordination with State motor vehicle safety agencies. Individuals and businesses are not eligible to receive BEG funding. Applications must include a Border Enforcement Plan and meet the maintenance of expenditure (MOE) requirement. See link for the MOE explanation, *http://www.fmcsa.dot.gov/safety-security/grants/beg/moe.aspx.* The Border Enforcement Plan should be a performance-based proposal that represents innovative strategies to support, enrich, or evaluate CMV safety border programs.

BEG funding decisions take into consideration the State or entity's performance on previous BEG awards; ability to expend the awarded funds within the BEG performance year; and compliance of planned activities with the BEG national criteria established by FMCSA. Priority will be given to proposals for programs which:

- Ensure southern Border States are meeting all Federal requirements to allow access to Mexico-domiciled carriers beyond the border commercial zones;
- Increase the number of CMV safety inspections and commercial driver license (CDL), operating authority, and financial responsibility checks in Border States focusing on international traffic;
- Improve the capability to conduct CMV safety inspections at remote and other sites near the border (Use the list of eligible items in 49 CFR 350.311, relating to the Motor Carrier Safety Assistance Program, as a guide.);
- Develop appropriate telecommunication systems and coordination procedures with Federal inspection agencies and others. Appropriate telecommunication systems means those that relate directly to the accessing and transfer of CMV safety data and information including telecommunications systems and other items necessary to implement the International Trade Data Systems (ITDS);
- Involve other innovative initiatives designed to improve the compliance status of CMVs, drivers, and carriers entering the United States from Canada or Mexico;
- Involve research initiatives focused on cross-border enforcement and related issues; and
- Involve targeted inspections of CMVs on corridors where there is a significant amount of international traffic.

As established by SAFETEA–LU, the Federal share of these funds will be 100 percent, and there is no matching requirement.

Applications must be submitted electronically at the Federal Grants web site (*http://www.grants.gov*). Users must register in order to use Grants.gov. Registration can take between 3 to 5 business days or as long as two weeks if all steps are not completed in a timely manner. To register, visit *http://www.grants.gov/applicants/get_registered.jsp.* After registration, follow these steps to apply for the BEG:

1. Access the grant application page at *https://apply07.grants.gov/apply/forms_apps_idx.html.*

2. Type in the Catalogue of Federal Domestic Assistance (CFDA) Number "20.233" to retrieve and download the BEG application package.

3. Complete and save the BEG application off-line using Adobe® software. You can obtain Adobe Reader® free of charge at *http://www.adobe.com.*

4. Submit the BEG application package electronically at *http://www.grants.gov/applicants/apply_for_grants.jsp.*

Issued on: July 9, 2010.

William A. Quade,

Associate Administrator for Enforcement and Program Delivery.

[FR Doc. 2010–17135 Filed 7–13–10; 8:45 am]

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Federal Register

Wednesday,
July 14, 2010

Part II

Department of Health and Human Services

45 CFR Parts 160 and 164

Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health Act; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 160 and 164

RIN: 0991–AB57

Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health Act

AGENCY: Office for Civil Rights, Department of Health and Human Services.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Health and Human Services (HHS or "the Department") is issuing this notice of proposed rulemaking to modify the Standards for Privacy of Individually Identifiable Health Information (Privacy Rule), the Security Standards for the Protection of Electronic Protected Health Information (Security Rule), and the rules pertaining to Compliance and Investigations, Imposition of Civil Money Penalties, and Procedures for Hearings (Enforcement Rule) issued under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The purpose of these modifications is to implement recent statutory amendments under the Health Information Technology for Economic and Clinical Health Act ("the HITECH Act" or "the Act"), to strengthen the privacy and security protection of health information, and to improve the workability and effectiveness of these HIPAA Rules.

DATES: Submit comments on or before September 13, 2010.

ADDRESSES: You may submit comments, identified by RIN 0991–AB57, by any of the following methods (please do not submit duplicate comments):

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.

• *Regular, Express, or Overnight Mail:* U.S. Department of Health and Human Services, Office for Civil Rights, Attention: HITECH Privacy and Security Rule Modifications, Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue, SW., Washington, DC 20201. Please submit one original and two copies.

• *Hand Delivery or Courier:* Office for Civil Rights, Attention: HITECH Privacy and Security Rule Modifications, Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue, SW., Washington, DC 20201. Please submit one original and two copies. (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 mail drop slots located in the main lobby of the building.)

Inspection of Public Comments: All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. We will post all comments received before the close of the comment period at *http://www.regulations.gov.* Because comments will be made public, they should not include any sensitive personal information, such as a person's social security number; date of birth; driver's license number, State identification number or foreign country equivalent; passport number; financial account number; or credit or debit card number. Comments also should not include any sensitive health information, such as medical records or other individually identifiable health information, or any non-public corporate or trade association information, such as trade secrets or other proprietary information.

FOR FURTHER INFORMATION CONTACT: Andra Wicks, 202–205–2292.

SUPPLEMENTARY INFORMATION:

The discussion below includes a description of the statutory and regulatory background of the proposed rules, a section-by-section description of the proposed modifications, and the impact statement and other required regulatory analyses. We solicit public comment on the proposed rules. Persons interested in commenting on the provisions of the proposed rules can assist us by preceding discussion of any particular provision or topic with a citation to the section of the proposed rule being discussed.

I. Statutory and Regulatory Background

The regulatory modifications proposed below concern several sets of rules that implement the Administrative Simplification provisions of title II, subtitle F, of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191), which added a new part C to title XI of the Social Security Act (sections 1171–1179 of the Social Security Act, 42 U.S.C. 1320d–1320d–8). The Health Information Technology for Economic and Clinical Health (HITECH) Act, which was enacted as title XIII of division A and title IV of division B of the American Recovery and Reinvestment Act of 2009 (ARRA), Public Law 111–5, modifies certain provisions of the Social Security Act pertaining to the Administrative Simplification Rules (HIPAA Rules) and requires certain modifications to the HIPAA Rules themselves.

A. HIPAA Administrative Simplification—Statutory Background

The Administrative Simplification provisions of HIPAA provided for the establishment of national standards for the electronic transmission of certain health information, such as standards for certain health care transactions conducted electronically and code sets and unique health care identifiers for health care providers and employers. The Administrative Simplification provisions of HIPAA also required the establishment of national standards to protect the privacy and security of personal health information and established civil money and criminal penalties for violations of the Administrative Simplification provisions. The Administrative Simplification provisions of HIPAA apply to three types of entities, which are known as "covered entities": health care providers who conduct covered health care transactions electronically, health plans, and health care clearinghouses.

B. HIPAA Administrative Simplification—Regulatory Background

The rules proposed below concern the privacy and security standards issued pursuant to HIPAA, as well as the enforcement rules that implement HIPAA's civil money penalty authority. The Standards for Privacy of Individually Identifiable Health Information, known as the "Privacy Rule," were issued on December 28, 2000, and amended on August 14, 2002. *See* 65 FR 82462, as amended at 67 FR 53182. The Security Standards for the Protection of Electronic Protected Health Information, known as the "Security Rule," were issued on February 20, 2003. *See* 68 FR 8334. The Compliance and Investigations, Imposition of Civil Money Penalties, and Procedures for Hearings regulations, collectively known as the "Enforcement Rule," were issued as an interim final rule on April 17, 2003 (68 FR 18895), and revised and issued as a final rule, following rulemaking, on February 16, 2006 (71 FR 8390).

The Privacy Rule protects individuals' medical records and other individually

identifiable health information created or received by or on behalf of covered entities, known as "protected health information." The Privacy Rule protects individuals' health information by regulating the circumstances under which covered entities may use and disclose protected health information and by requiring covered entities to have safeguards in place to protect the privacy of the information. As part of these protections, covered entities are required to have contracts or other arrangements in place with business associates that perform functions for or provide services to the covered entity and that require access to protected health information to ensure that these business associates likewise protect the privacy of the health information. The Privacy Rule also gives individuals rights with respect to their protected health information, including rights to examine and obtain a copy of their health records and to request corrections.

The Security Rule, which applies only to protected health information in electronic form, requires covered entities to implement certain administrative, physical, and technical safeguards to protect this electronic information. As with the Privacy Rule, the Security Rule requires covered entities to have contracts or other arrangements in place with their business associates that provide satisfactory assurances that the business associates will appropriately safeguard the electronic protected health information they receive, create, maintain, or transmit on behalf of the covered entities.

The Enforcement Rule establishes rules governing the compliance responsibilities of covered entities with respect to cooperation in the enforcement process. It also provides rules governing the investigation by the Department of compliance by covered entities, both through the investigation of complaints and the conduct of compliance reviews. It establishes rules governing the process and grounds for establishing the amount of a civil money penalty where the Department has determined a covered entity has violated a requirement of a HIPAA Rule. Finally, the Enforcement Rule establishes rules governing the procedures for hearings and appeals where the covered entity challenges a violation determination.

C. The HITECH Act—Statutory Background

The HITECH Act, enacted on February 17, 2009, is designed to promote the widespread adoption and standardization of health information technology. Subtitle D of title XIII, entitled "Privacy," supports this goal by adopting amendments designed to strengthen the privacy and security protections of health information established by HIPAA. These provisions include extending the applicability of certain of the Privacy and Security Rules' requirements to the business associates of covered entities; requiring HIPAA covered entities and business associates to provide for notification of breaches of "unsecured protected health information"; establishing new limitations on the use and disclosure of protected health information for marketing and fundraising purposes; prohibiting the sale of protected health information; requiring the consideration of a limited data set as the minimum necessary amount of information; and expanding individuals' rights to access and receive an accounting of disclosures of their protected health information, and to obtain restrictions on certain disclosures of protected health information to health plans. In addition, subtitle D adopts provisions designed to strengthen and expand HIPAA's enforcement provisions. We provide a brief overview of the relevant statutory provisions below.

In the area of business associates, the Act makes a number of changes. First, section 13401 of the Act applies certain provisions of the Security Rule that apply to covered entities directly to their business associates and makes business associates liable for civil and criminal penalties for the failure to comply with these provisions. Similarly, section 13404 makes business associates of covered entities civilly and criminally liable under the Privacy Rule for making uses and disclosures of protected health information that do not comply with the terms of their business associate contracts. The Act also provides that the additional privacy and security requirements of subtitle D of the Act are applicable to business associates and that such requirements shall be incorporated into business associate contracts. Finally, section 13408 of the Act requires that organizations that provide data transmission of protected health information to a covered entity or business associate and that require routine access to such information, such as Health Information Exchange Organizations, Regional Health Information Organizations, and E-prescribing Gateways, as well as vendors that contract with covered entities to offer personal health records to patients as part of the covered entities' electronic health records, shall be treated as business associates for purposes of the HITECH Act and the HIPAA Privacy and Security Rules and required to enter into business associate contracts.

Section 13402 of the Act sets forth the breach notification provisions, requiring covered entities and business associates to provide notification following discovery of a breach of unsecured protected health information. Additionally, section 13407 of the Act, enforced by the Federal Trade Commission (FTC), applies similar breach notification provisions to vendors of personal health records and their third party service providers.

Section 13405 of the Act requires the Department to modify certain Privacy Rule provisions. In particular, section 13405 sets forth certain circumstances in which covered entities must comply with an individual's request for restriction of disclosure of his or her protected health information, provides for covered entities to consider a limited data set as the minimum necessary for a particular use, disclosure, or request of protected health information, and requires the Secretary to issue guidance to address what constitutes minimum necessary under the Privacy Rule. Section 13405 also requires the Department to modify the Privacy Rule to require covered entities that use or maintain electronic health records to provide individuals, upon request, with an accounting of disclosures of protected health information through an electronic health record for treatment, payment, or health care operations; generally prohibits the sale of protected health information without a valid authorization from the individual; and strengthens an individual's right to an electronic copy of their protected health information, where a covered entity uses or maintains an electronic health record.

Section 13406 of the Act requires the Department to modify the marketing and fundraising provisions of the Privacy Rule. With respect to marketing, the Act requires authorizations for certain health-related communications, which are currently exempted from the definition of marketing, if the covered entity receives remuneration in exchange for making the communication. The Act also strengthens an individual's right under the Privacy Rule to opt out of fundraising communications by requiring the Department to modify the Privacy Rule so that covered entities must provide individuals with a clear and conspicuous opportunity to opt out of receiving fundraising

communications and by requiring that an opt out be treated as a revocation of authorization under the Privacy Rule.

Section 13410 of the Act addresses enforcement in a number of ways. First, section 13410(a) provides that the Secretary's authority to impose a civil money penalty will only be barred to the extent a criminal penalty has been *imposed*, rather than in cases in which the offense in question merely constitutes an offense criminally *punishable.* In addition, section 13410(a) of the Act requires the Secretary to formally investigate any complaint where a preliminary investigation of the facts indicates a possible violation due to willful neglect and to impose a penalty where a violation is found in such cases. Section 13410(c) of the Act provides, for purposes of enforcement, for the transfer to the HHS Office for Civil Rights of any civil money penalty or monetary settlement collected under the Privacy and Security Rules and also requires the Department to establish by regulation a methodology for distributing to harmed individuals a percentage of the civil money penalties and monetary settlements collected under the Privacy and Security Rules. Effective as of February 18, 2009, section 13410(d) of the Act also modified the civil money penalty structure for violations of the HIPAA Rules by implementing a tiered increase in the amount of penalties based on culpability. In addition, as of February 18, 2009, section 13410(e) of the Act also granted State Attorneys General the authority to enforce the HIPAA Rules by bringing civil actions on behalf of State residents in court.

Section 13421 states that HIPAA's State preemption provisions at 42 U.S.C. 1320d–7 shall apply to the provisions of subtitle D of the HITECH Act in the same manner as they do to HIPAA's provisions.[1] Section 13423 of the Act provides a general effective date of February 18, 2010, for most of its provisions, except where a different effective date is otherwise provided.

The Act also provides for the development of guidance, reports, and studies in a number of areas, including guidance on appropriate technical safeguards to implement the HIPAA Security Rule (section 13401(c)); for purposes of breach notification, guidance on the methods and technologies for rendering protected health information unusable, unreadable, or indecipherable to unauthorized individuals (section 13402(h)); guidance on what constitutes the minimum necessary amount of information for purposes of the Privacy Rule (section 13405(b)); a report by the Government Accountability Office (GAO) regarding recommendations for a methodology under which harmed individuals may receive a percentage of civil money penalties and monetary settlements under the HIPAA Privacy and Security Rules (section 13410(c)); a report to Congress on HIPAA Privacy and Security enforcement (section 13424(a)); a study and report on the application of privacy and security requirements to non-HIPAA covered entities (section 13424(b)); guidance on de-identification (section 13424(c)); and a study on the Privacy Rule's definition of "psychotherapy notes" at 45 CFR 164.501, with regard to including test data that is related to direct responses, scores, items, forms, protocols, manuals, or other materials that are part of a mental health evaluation (section 13424(f)).

Finally, the Act includes provisions for education by HHS on health information privacy and for periodic audits by the Secretary. Section 13403(a) provides for the Secretary to designate HHS regional office privacy advisors to offer guidance and education to covered entities, business associates, and individuals on their rights and responsibilities related to Federal privacy and security requirements for protected health information. Section 13403(b) requires the HHS Office for Civil Rights, not later than 12 months after enactment, to develop and maintain a multi-faceted national education initiative to enhance public transparency regarding the uses of protected health information, including programs to educate individuals about potential uses of their protected health information, the effects of such uses, and the rights of individuals with respect to such uses. Section 13411 requires the Secretary to provide for periodic audits to ensure covered entities and business associates comply with the applicable requirements of the HIPAA Privacy and Security Rules.

We discuss many of the Act's statutory provisions in more detail below where we describe section-by-section how these proposed regulations would implement those provisions of the Act. However, we do not discuss in detail the breach notification provisions in sections 13402 of the Act or the modified civil money penalty structure in section 13410(d) of the Act, which as explained below, have been the subject of previous rulemakings. In addition, we do not address in this rulemaking the accounting for disclosures requirement in section 13405 of the Act, which is tied to the adoption of a standard under the HITECH Act at subtitle A of title XIII of ARRA, or the penalty distribution methodology requirement in section 13410(c) of the Act, which is to be based on the recommendations noted above to be developed at a later date by the GAO. These provisions will be the subject of future rulemakings. Further, we clarify that we are not issuing regulations with respect to the new authority of the State Attorneys General to enforce the HIPAA Rules. Finally, other than the guidance required by section 13405(b) of the Act with respect to what constitutes minimum necessary, this proposed rule does not address the studies, reports, guidance, audits, or education efforts required by the HITECH Act.

D. The HITECH Act—Regulatory Background

As noted above, certain of the HITECH Act's privacy and security provisions have already been the subject of rulemakings and related actions. In particular, the Department published interim final regulations to implement the breach notification provisions at section 13402 of the Act for HIPAA covered entities and business associates in the **Federal Register** on August 24, 2009 (74 FR 42740), effective September 23, 2009. Similarly, the FTC published final regulations implementing the breach notification provisions at section 13407 for personal health record vendors and their third party service providers on August 25, 2009 (74 FR 42962), effective September 24, 2009. For purposes of determining to what information the HHS and FTC breach notification regulations apply, the Department also issued, first on April 17, 2009 (published in the **Federal Register** on April 27, 2009, 74 FR 19006), and then later with its interim final rule, the guidance required by the HITECH Act under 13402(h) specifying the technologies and methodologies that render protected health information unusable, unreadable, or indecipherable to unauthorized individuals. In addition, to conform the provisions of the Enforcement Rule to the new tiered and increased civil money penalty structure made effective by the HITECH Act on the day after enactment, or February 18, 2009, the Department published an interim final rule on October 30, 2009 (74 FR 56123), effective November 30, 2009.

[1] We note that section 13421 of the HITECH Act and HIPAA's State preemption provisions do not affect the applicability of other Federal law, such as the Confidentiality of Alcohol and Drug Abuse Patient Records Regulation at 42 CFR Part 2, to a covered entity's use or disclosure of health information.

II. General Issues

A. Effective and Compliance Dates

As noted above, section 13423 of the Act provides that the provisions in subtitle D took effect one year after enactment, *i.e.,* on February 18, 2010, except as specified otherwise. There are a number of exceptions to this general rule. Some provisions were effective the day after enactment, *i.e.,* February 18, 2009. For example, the tiered and increased civil money penalty provisions of section 13410(d) were effective for violations occurring after the date of enactment. Sections 13402 and 13407 of the Act regarding breach notification required interim final rules within 180 days of enactment, with effective dates 30 days after the publication of such rules. Other provisions of the Act have later effective dates. For example, the provision at section 13410(a)(1) of the Act providing that the Secretary's authority to impose a civil money penalty will only be barred to the extent a criminal penalty has been *imposed,* rather than in cases in which the offense in question merely constitutes an offense that is criminally *punishable,* becomes effective for violations occurring on or after February 18, 2011. The rules proposed below generally pertain to the statutory provisions that became effective on February 18, 2010, or, in a few cases, on a later date.

We note that the final rule will not take effect until after most of the provisions of the HITECH Act became effective on February 18, 2010. We recognize that it will be difficult for covered entities and business associates to comply with the statutory provisions until after we have finalized our changes to the HIPAA Rules. In addition, we recognize that covered entities and business associates will need some time beyond the effective date of the final rule to come into compliance with the final rule's provisions. In light of these considerations, we intend to provide covered entities and business associates with 180 days beyond the effective date of the final rule to come into compliance with most of the rule's provisions. We believe that providing a 180-day compliance period best comports with section 1175(b)(2) of the Social Security Act, 42 U.S.C. 1320d–4, and our implementing provision at 45 CFR 160.104(c)(1), which require the Secretary to provide at least a 180-day period for covered entities to comply with modifications to standards and implementation specifications in the HIPAA Rules. While the Social Security Act and the HIPAA Rules permit the Secretary to further delay the compliance date for small health plans, we do not believe that it is necessary to do so for this rule both because most of the changes being proposed are discrete modifications to existing requirements of the HIPAA Rules, as well as because the Department is proposing an additional one-year transition period to modify certain business associate agreements, which should provide sufficient relief to all covered entities, including small health plans. The Department welcomes comment on the assumption that it is not necessary to extend the compliance date for small health plans.

We also expect that for future modifications to the HIPAA Rules, in most cases, a 180-day compliance period will suffice. Accordingly, we propose to add a provision at § 160.105 to address the compliance date generally for implementation of new or modified standards in the HIPAA Rules. Proposed § 160.105 would provide that with respect to new standards or implementation specifications or modifications to standards or implementation specifications in the HIPAA Rules, except as otherwise provided, covered entities and business associates must comply with the applicable new standards or implementation specifications or modifications to standards or implementation specifications no later than 180 days from the effective date of any such change. Where future modifications to the HIPAA Rules necessitate a longer compliance period, we would provide so accordingly in the regulatory text. We propose to retain the compliance date provisions at §§ 164.534 and 164.318, which provide the compliance dates of April 14, 2003, and April 20, 2005, for initial implementation of the HIPAA Privacy and Security Rules, respectively, for historical purposes only.

We note that proposed § 160.105 regarding the compliance date of new or modified standards or implementation specifications would not apply to modifications to the provisions of the HIPAA Enforcement Rule because such provisions are not standards or implementation specifications (as the terms are defined at § 160.103). Such provisions are in effect and apply at the time the final rule becomes effective or as otherwise specifically provided. We also note that our proposed general rule for a 180-day compliance period for new or modified standards would not apply where we expressly provide a different compliance period in the regulation for one or more provisions. For purposes of this proposed rule, this would mean that the 180-day compliance period would not govern the time period required to modify those business associate agreements that qualify for the longer transition period proposed in § 164.532. We seek comments on any potential unintended consequences of establishing a 180-day compliance date as a regulatory default, with the noted exceptions.

B. Other Proposed Changes

While passage of the HITECH Act necessitates much of the rulemaking below, it does not account for all of the proposed changes to the HIPAA Privacy, Security, and Enforcement Rules encompassed in this rulemaking. The Department is taking this opportunity to improve the workability and effectiveness of all three sets of HIPAA Rules. The Privacy Rule has not been amended since 2002, and the Security Rule has not been amended since 2003. While the Enforcement Rule was amended in the October 30, 2009, interim final rule to incorporate the enforcement-related HITECH statutory changes that are already effective, it has not been otherwise substantively amended since 2006. In the intervening years, HHS has accumulated a wealth of experience with these rules, both from public contact in various forums and through the process of enforcing the rules. In addition, we have identified a number of needed technical corrections to the rules. Accordingly, we propose a number of modifications that we believe will eliminate ambiguities in the rules and/or make them more workable and effective. Further, we propose a few modifications to conform the HIPAA Privacy Rule to provisions in the Patient Safety and Quality Improvement Act of 2005 (PSQIA). We address the substantive proposed changes in the section-by-section description of the proposed rule below. Technical corrections are discussed at the end of the section-by-section description of the other proposed amendments to the rules.

III. Section-by-Section Description of the Proposed Amendments to Subparts A and B of Part 160

Subpart A of part 160 of the HIPAA Rules contains general provisions that apply to all of the HIPAA Rules. Subpart B of part 160 contains the regulatory provisions implementing HIPAA's preemption provisions. We propose to amend a number of these provisions. Some of the proposed changes are necessitated by the statutory changes made by the HITECH Act, while others are of a technical or conforming nature.

A. Subpart A—General Provisions, Section 160.101—Statutory Basis and Purpose

This section sets out the statutory basis and purpose of the HIPAA Rules. We propose a technical change to include a reference to the provisions of the HITECH Act upon which most of the regulatory changes proposed below are based.

B. Subpart A—General Provisions, Section 160.102—Applicability

This section sets out to whom the HIPAA Rules apply. We propose to add a new paragraph (b) to make clear, consistent with the provisions of the HITECH Act that are discussed more fully below, that the standards, requirements, and implementation specifications of the subchapter apply to business associates, where so provided.

C. Subpart A—General Provisions, Section 160.103—Definitions

Section 160.103 contains definitions of terms that appear throughout the HIPAA Rules. For ease of reference, we propose to move several definitions currently found at § 160.302 to § 160.103 without substantive change to the definitions themselves. This category includes definitions of the following terms: "ALJ," "civil money penalty," and "violation or violate." As the removal of these definitions, along with the removal of other definitions discussed below (*e.g.,* "administrative simplification provision" and "respondent"), would leave § 160.302 unpopulated, we propose to reserve that section. We also propose to remove a comma from the definition of "disclosure" inadvertently inserted into the definition in a prior rulemaking, which is not intended as a substantive change to the definition. In addition, we propose to replace the term "individually identifiable health information" with "protected health information" in the definition of "standard" to better reflect the scope of the Privacy and Security Rules. Further, we propose the following definitional changes:

1. Definition of "Administrative Simplification Provision"

This definition is currently located in the definitions section of subpart C of part 160 of the HIPAA Enforcement Rule. We propose to remove the definition of this term from § 160.302 and move it to the definitions section located at § 160.103 for clarity and convenience, as the term is used repeatedly throughout the entire part 160. We also propose to add to the definition a reference to sections 13400–13424 of the HITECH Act.

2. Definition of "Business Associate"

Sections 164.308(b) of the Security Rule and 164.502(e) of the Privacy Rule require a covered entity to enter into a contract or other written agreement or arrangement with its business associates. The purpose of these contracts or other arrangements, generally known as business associate agreements, is to provide some legal protection when protected health information is being handled by another person (a natural person or legal entity) on behalf of a covered entity. The HIPAA Rules define "business associate" generally to mean a person who performs functions or activities on behalf of, or certain services for, a covered entity that involve the use or disclosure of protected health information. Examples of business associates include third party administrators or pharmacy benefit managers for health plans, claims processing or billing companies, transcription companies, and persons who perform legal, actuarial, accounting, management, or administrative services for covered entities and who require access to protected health information. We propose a number of modifications to the definition of "business associate." In particular, we propose to modify the definition to conform the term to the statutory provisions of PSQIA, 42 U.S.C. 299b–21, *et seq.,* and the HITECH Act. Additional modifications are made for the purpose of clarifying circumstances when a business associate relationship exists and for general clarification of the definition.

a. Inclusion of Patient Safety Organizations

We propose to add patient safety activities to the list of functions and activities a person may undertake on behalf of a covered entity that give rise to a business associate relationship. PSQIA, at 42 U.S.C. 299b–22(i)(1), provides that Patient Safety Organizations (PSOs) must be treated as business associates when applying the Privacy Rule. PSQIA provides for the establishment of PSOs to receive reports of patient safety events or concerns from providers and provide analyses of events to reporting providers. A reporting provider may be a HIPAA covered entity and, thus, information reported to a PSO may include protected health information that the PSO may analyze on behalf of the covered provider. The analysis of such information is a patient safety activity for purposes of PSQIA and the Patient Safety Rule, 42 CFR 3.10, *et seq.* While the HIPAA Rules as written would encompass a PSO as a business associate when the PSO was performing quality analyses and other activities on behalf of a covered health care provider, we propose this change to the definition of business associate to more clearly align the HIPAA and Patient Safety Rules.

We note that in some cases a covered health care provider, such as a public or private hospital, may have a component PSO that performs patient safety activities on behalf of the health care provider. *See* 42 CFR 3.20. In such cases, the component PSO would not be a business associate of the covered entity but rather the persons performing patient safety activities would be workforce members of the covered entity. However, if the component PSO contracts out some of its patient safety activities to a third party, the third party would be a business associate of the covered entity. In addition, if a component PSO of one covered entity performs patient safety activities for another covered entity, such component PSO would be a business associate of the other covered entity.

b. Inclusion of Health Information Organizations (HIO), E–Prescribing Gateways, and Other Persons That Facilitate Data Transmission; as Well as Vendors of Personal Health Records

Section 13408 of the HITECH Act, which became effective on February 18, 2010, provides that an organization, such as a Health Information Exchange Organization, E-prescribing Gateway, or Regional Health Information Organization, that provides data transmission of protected health information to a covered entity (or its business associate) and that requires access on a routine basis to such protected health information must be treated as a business associate for purposes of the Act and the HIPAA Privacy and Security Rules. Section 13408 also provides that a vendor that contracts with a covered entity to allow the covered entity to offer a personal health record to patients as part of the covered entity's electronic health record shall be treated as a business associate. Section 13408 requires that such organizations and vendors enter into a written business associate contract or other arrangement with the covered entity in accordance with the HIPAA Rules.

In accordance with the Act, we propose to modify the definition of "business associate" to explicitly designate these persons as business

associates. Under proposed paragraphs (3)(i) and (ii) of the definition, the term "business associate" would include: (1) A Health Information Organization, E-prescribing Gateway, or other person that provides data transmission services with respect to protected health information to a covered entity and that requires routine access to such protected health information; and (2) a person who offers a personal health record to one or more individuals on behalf of a covered entity.

Section 13408 of the Act makes reference to Health Information Exchange Organizations; however, we instead include in the proposed definition the term "Health Information Organization" because it is our understanding that "Health Information Organization" is the more widely recognized and accepted term to describe an organization that oversees and governs the exchange of health-related information among organizations.[2] Section 13408 of the Act also specifically refers to Regional Health Information Organizations. However, we do not believe the inclusion of the term in the definition of "business associate" is necessary as a Regional Health Information Organization is simply a Health Information Organization that governs health information exchange among organizations within a defined geographic area.[3] Further, the specific terms of "Health Information Organization" and "E-prescribing Gateway" are merely illustrative of the types of organizations that would fall within this paragraph of the definition of "business associate." We request comment on the use of these terms within the definition and whether additional clarifications or additions are necessary.

Section 13408 also provides that the data transmission organizations that the Act requires to be treated as business associates are those that require access to protected health information on a routine basis. Conversely, data transmission organizations that do not require access to protected health information on a routine basis would not be treated as business associates. This is consistent with our prior interpretation of the definition of "business associate," through which we have indicated that entities that act as mere conduits for the transport of protected health information but do not access the information other than on a random or infrequent basis are not business associates. *See http://www.hhs.gov/ocr/privacy/hipaa/faq/providers/business/245.html.* In contrast, however, entities that manage the exchange of protected health information through a network, including providing patient locator services and performing various oversight and governance functions for electronic health information exchange, have more than "random" access to protected health information and thus, would fall within the definition of "business associate."

c. Inclusion of Subcontractors

We propose to add language in paragraph (3)(iii) of the definition of "business associate" to provide that subcontractors of a covered entity—*i.e.,* those persons that perform functions for or provide services to a business associate, other than in the capacity as a member of the business associate's workforce, are also business associates to the extent that they require access to protected health information. We also propose to include a definition of "subcontractor" in § 160.103 to make clear that a subcontractor is a person who acts on behalf of a business associate, other than in the capacity of a member of the workforce of such business associate. Even though we use the term "subcontractor," which implies there is a contract in place between the parties, we note that the definition would apply to an agent or other person who acts on behalf of the business associate, even if the business associate has failed to enter into a business associate contract with the person. We request comment on the use of the term "subcontractor" and its proposed definition.

The proposed modifications are similar in structure and effect to the Privacy Rule's initial extension of privacy protections from covered entities to business associates through contract requirements to protect downstream protected health information. The proposed provisions avoid having privacy and security protections for protected health information lapse merely because a function is performed by an entity that is a subcontractor rather than an entity with a direct relationship with a covered entity. Allowing such a lapse in privacy and security protections may allow business associates to avoid liability imposed upon them by sections 13401 and 13404 of the Act, thus circumventing the congressional intent underlying these provisions. The proposed definition of "subcontractor" also is consistent with Congress' overall concern that the privacy and security protections of the HIPAA Rules extend beyond covered entities to those entities that create or receive protected health information in order for the covered entity to perform its health care functions. For example, as discussed above, section 13408 makes explicit that certain types of entities providing services to covered entities—*e.g.,* vendors of personal health records—shall be considered business associates. Therefore, consistent with Congress' intent in sections 13401 and 13404 of the Act, as well as its overall concern that the HIPAA Rules extent beyond covered entities to those entities that create or receive protected health information, we propose that downstream entities that work at the direction of or on behalf of a business associate and handle protected health information would also be required to comply with the applicable Privacy and Security Rule provisions in the same manner as the primary business associate, and likewise would incur liability for acts of noncompliance. We note, and further explain below, that this proposed modification would not require the covered entity to have a contract with the subcontractor; rather, the obligation would remain on each business associate to obtain satisfactory assurances in the form of a written contract or other arrangement that a subcontractor will appropriately safeguard protected health information. For example, under this proposal, if a business associate, such as a third party administrator, hires a company to handle document and media shredding to securely dispose of paper and electronic protected health information, then the shredding company would be directly required to comply with the applicable requirements of the HIPAA Security Rule (*e.g.,* with respect to proper disposal of electronic media) and the Privacy Rule (*e.g.,* with respect to limiting its uses and disclosures of the protected health information in accordance with its contract with the business associate).

d. Exceptions to Business Associate

We also propose to move the provisions at §§ 164.308(b)(2) and 164.502(e)(1)(ii) to the definition of business associate. These provisions provide that in certain circumstances, such as when a covered entity discloses protected health information to a health care provider concerning the treatment of an individual, a covered entity is not required to enter into a business

[2] Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, The National Alliance for Health Information Technology Report to the Office of the National Coordinator For Health Information Technology: Defining Key Health Information Terms, Pg. 24 (2008).

[3] *Id.* at 25.

associate contract or other arrangement with the recipient of the protected health information. While we do not change the meaning of these provisions, we believe these limitations on the scope of "business associate" are more appropriately placed in the definition as exceptions to the term to make clear that the Department does not consider the recipients of the protected health information in these circumstances to be business associates. The movement of these exceptions and refinement of the definition of "business associate" also would help clarify that a person is a business associate if it meets the definition of "business associate," even if a covered entity, or business associate with respect to a subcontractor, fails to enter into the required contract with the business associate.

e. Technical Changes to the Definition

For clarity and consistency, we also propose to change the term "individually identifiable health information" in the current definition of "business associate" to "protected health information," since a business associate has no obligations under the HIPAA Rules with respect to individually identifiable health information that is not protected health information.

3. Definition of "Compliance Date"

The term "compliance date" currently refers only to covered entities. We propose a technical change to include business associates in the term, in light of the HITECH Act amendments, which apply certain provisions of the HIPAA Rules to business associates.

4. Definition of "Electronic Media"

The term "electronic media" was originally defined in the Transactions and Code Sets Rule issued on August 17, 2000 (65 FR 50312) and was included in the definitions at § 162.103. That definition was subsequently revised and moved to § 160.103. The purpose of the revision was to clarify that—

> the physical movement of electronic media from place to place is not limited to magnetic tape, disk, or compact disk. This clarification removes a restriction as to what is considered to be physical electronic media, thereby allowing for future technological innovation. We further clarified that transmission of information not in electronic form before the transmission, for example, paper or voice, is not covered by this definition.

68 FR 8339, Feb. 20, 2003.

We propose to revise the definition of "electronic media" in the following ways. First, we would revise paragraph (1) of the definition to conform it to current usage, as set forth in "Guidelines for Media Sanitization" (*Definition of Medium,* NIST SP 800–88, Glossary B, p. 27 (2006)). The NIST definition, which was updated subsequent to the issuance of the Privacy and Security Rules, was developed in recognition of the likelihood that the evolution of development of new technology would make use of the term "electronic storage media" obsolete in that there may be "storage material" other than "media" that house electronic data. Second, we would add to paragraph (2) of the definition of "electronic media" a reference to intranets, to clarify that intranets come within the definition. Third, we propose to change the word "because" to "if" in the final sentence of paragraph (2) of the definition of "electronic media." The definition assumed that no transmissions made by voice via telephone existed in electronic form before transmission; the evolution of technology has made this assumption obsolete. This modification would extend the policy described in the preamble discussion quoted above, but correct its application to current technology, where some voice technology is digitally produced from an information system and transmitted by phone.

5. Definition of "Protected Health Information"

We propose to modify the definition of "protected health information" at § 160.103 to provide that the Privacy and Security Rules do not protect the individually identifiable health information of persons who have been deceased for more than 50 years. This proposed modification is explained more fully below in Section VI.E. of the preamble where we discuss the proposed changes to the Privacy Rule related to the protected health information of decedents.

6. Definition of "Respondent"

The definition of the term "Respondent," which is currently in § 160.302, would be moved to § 160.103. A reference to "business associate" would be added following the reference to "covered entity" in recognition of the potential liability imposed on business associates for violations of certain provisions of the Privacy and Security Rules by sections 13401 and 13404 of the Act.

7. Definition of "State"

The HITECH Act at section 13400, which became effective February 18, 2010, includes a definition of "State" to mean "each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands." This definition varies from paragraph (2) of the HIPAA definition of "State" at § 160.103, which does not include reference to American Samoa and the Northern Mariana Islands. Thus, for consistency with the definition applied to the HIPAA Rules by the HITECH Act, we propose to add reference to American Samoa and the Commonwealth of the Northern Mariana Islands in paragraph (2) of the definition of "State" at § 160.103.

8. Definition of "Workforce"

The HITECH Act is directly applicable to business associates and has extended liability for compliance with certain provisions of the Privacy and Security Rules to business associates. Because some provisions of the Act and the Privacy and Security Rules place obligations on the business associate with respect to workforce members, we propose to revise the definition of "workforce member" in § 160.103 to make clear that such term includes the employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a business associate, is under the direct control of the business associate.

D. Subpart B—Preemption of State Law, Section 160.201—Statutory Basis

We propose to modify § 160.201 regarding the statutory basis for the preemption of State law provisions to add a reference to section 264(c) of HIPAA, which contains the statutory basis for the exception to preemption at § 160.203(b) for State laws that are more stringent than the HIPAA Privacy Rule. We also propose to add a reference to section 13421(a) of the HITECH Act, which applies HIPAA's preemption rules to the HITECH Act's privacy and security provisions. Finally, we propose to re-title the provision to read "Statutory basis" instead of "Applicability."

We also take this opportunity to make clear that section 264(c)(2) of HIPAA and § 160.203(b) do not create a Federal evidentiary privilege. Additionally, we take this opportunity to make clear that neither the HIPAA statute nor its implementing regulations give effect to State physician-patient privilege laws or provisions of State law relating to the privacy of individually identifiable health information for use in Federal court proceedings. Therefore, consistent with the Supremacy Clause, any State law that was preempted prior to HIPAA because of conflicts with a Federal law would continue to be preempted. Nothing in HIPAA or its implementing regulations is intended to expand the

scope of State laws, regardless of whether they are more or less stringent than Federal law.

E. Subpart B—Preemption of State Law, Section 160.202—Definitions.

1. Definition of "Contrary"

The term "contrary" is currently defined in § 160.202 to make clear when the preemption provisions of HIPAA apply to State law. Consistent with the limited application of the HIPAA provisions to covered entities only, the current definition of the term "contrary" does not include reference to business associates. However, section 13421(a) of the HITECH Act provides that the HIPAA preemption provision (section 1178 of the Social Security Act) applies to the provisions and requirements under the HITECH Act "in the same manner" as it would apply under the HIPAA provisions. Thus, the preemption provisions would apply to business associates, who are now, by virtue of the HITECH Act, required to comply with certain provisions of the HIPAA Rules and are subject to penalties for noncompliance, as discussed elsewhere. Thus, we propose to amend the definition of "contrary" by inserting references to business associates in paragraph (1) of the definition. We also expand the reference to the HITECH statutory provisions in paragraph (2) of the definition to encompass all of the sections of subtitle D of the HITECH Act, rather than merely to section 13402, which was added by the breach notifications regulations. These changes would give effect to section 13421(a).

2. Definition of "More Stringent"

The term "more stringent" is part of the statutory preemption language under HIPAA. HIPAA preempts State law that is contrary to a HIPAA privacy standard unless, among other exceptions, the State law is more stringent than the contrary HIPAA privacy standard. The current regulatory definition of "more stringent" does not include business associates. We propose to amend the definition to add a reference to business associates, for the reasons set out in the preceding discussion.

IV. Section-by-Section Description of the Proposed Amendments to the Enforcement Rule—Subparts C and D of Part 160

Section 13410 of the HITECH Act made several amendments that directly impact the Enforcement Rule, which applies to the Secretary's enforcement of all of the HIPAA Administrative Simplification Rules, as well as the recently promulgated Breach Notification Rule. We issued an interim final rule on October 30, 2009, 74 FR 56123, to address the HITECH Act amendments impacting the Enforcement Rule that became effective on February 18, 2009. For context, we describe those modifications to the Enforcement Rule briefly below. We then provide a section-by-section description of the other section 13410 amendments that are part of this proposed rule.

In addition, sections 13401 and 13404 of the HITECH Act impose direct civil money penalty liability on business associates for violations of the HITECH Act and certain Privacy and Security Rule provisions. In doing so, sections 13401(b) and 13404(c) of the Act provide that section 1176 of the Social Security Act shall apply to a violation by a business associate "in the same manner" as it would apply to a covered entity with respect to such a violation. Both provisions are, by virtue of section 13423, effective February 18, 2010.

The provisions of subparts C and D of part 160 currently apply by their terms solely to covered entities. Accordingly, to implement sections 13401(b) and 13404(c) of the Act, we propose to revise a number of provisions in both subparts to reflect this statutory change by adding the term "business associate" where appropriate, following a reference to "covered entity." For ease, we list the sections in which the term "business associate" is added here rather than repeat the change in each discussion of the sections below: §§ 160.300; 160.304; 160.306(a) and (c); 160.308; 160.310; 160.312; 160.316; 160.401; 160.402; 160.404(b); 160.406; 160.408(c) and (d); and 160.410(a) and (c).

In addition to these references, we propose to add a paragraph in § 160.402(c)(2) to describe a business associate's liability for the actions of its agents, in accordance with the Federal common law of agency. This proposed modification is discussed more fully below in the discussion of § 160.402(c).

As noted above, the Department issued an interim final rule (IFR) on October 30, 2009, revising the Enforcement Rule to incorporate the provisions required by section 13410(d) of the HITECH Act that immediately took effect: Four categories of violations that reflect increasing levels of culpability, the corresponding tiers of civil money penalty amounts, and the revised limitations placed on the Secretary's authority to impose penalties. More specifically, the IFR revised subpart D of the Enforcement Rule to transfer the definitions of "reasonable cause," "reasonable diligence," and "willful neglect" from § 160.410(a) to a new definitions section at § 160.401. The IFR revised § 160.404 to incorporate, for violations occurring on or after February 18, 2009, the new penalty scheme required by section 13410(d), as follows: For violations in which it is established that the covered entity did not know and, by exercising reasonable diligence, would not have known that the covered entity violated a provision, an amount not less than $100 or more than $50,000 for each violation; for a violation in which it is established that the violation was due to reasonable cause and not to willful neglect, an amount not less than $1000 or more than $50,000 for each violation; for a violation in which it is established that the violation was due to willful neglect and was timely corrected, an amount not less than $10,000 or more than $50,000 for each violation; and for a violation in which it is established that the violation was due to willful neglect and was not timely corrected, an amount not less than $50,000 for each violation; except that a penalty for violations of the same requirement or prohibition under any of these categories may not exceed $1,500,000 in a calendar year. It also revised the affirmative defenses in § 160.410 for violations occurring on or after February 18, 2009, to remove a covered entity's lack of knowledge as an affirmative defense and to provide an affirmative defense when violations not due to willful neglect are corrected within 30 days. Finally, the IFR added a requirement that a notice of proposed determination pursuant to § 160.420 also reference the applicable category of violation. Readers are encouraged to refer to the IFR for a more detailed discussion of these topics as well as the Enforcement Rule's statutory and regulatory background. *See* 74 FR 56123, 56124, Oct. 30, 2009.

The rules proposed below would revise many provisions of subparts C and D of part 160. However, the Department's current interpretations of the regulatory provisions at subparts C and D continue unchanged, except to the extent they are inconsistent with the changes to those provisions, as indicated below.

A. Subpart C—Compliance and Investigations, Section 160.304—Principles for Achieving Compliance

Section 160.304 identifies cooperation and assistance as two overarching principles for achieving compliance. The principle of cooperation, in § 160.304(a), states that "[t]he Secretary will, to the extent practicable, seek the cooperation of covered entities in

obtaining compliance with the applicable administrative simplification provisions."

Section 13410(a) of the HITECH Act adds a new subsection (c) to section 1176 of the Social Security Act:

(c) NONCOMPLIANCE DUE TO WILLFUL NEGLECT.—

(1) IN GENERAL.—A violation of a provision of this part due to willful neglect is a violation for which the Secretary is required to impose a penalty under subsection (a)(1).

(2) REQUIRED INVESTIGATION.—For purposes of paragraph (1), the Secretary shall formally investigate any complaint of a violation of a provision of this part if a preliminary investigation of the facts of the complaint indicate such a possible violation due to willful neglect.

Section 13410(b)(1) makes the provisions of section 13410(a) effective February 18, 2011.

Under section 1176(c), HHS is required to impose a civil money penalty for violations due to willful neglect. Accordingly, although the Secretary often will still seek to correct indications of noncompliance through voluntary corrective action, there may be circumstances (such as circumstances indicating willful neglect), where the Secretary may seek to proceed directly to formal enforcement. As a conforming amendment, HHS proposes to add the phrase, "and consistent with the provisions of this subpart," to § 160.304(a) to recognize the statutory revision.

B. Subpart C—Compliance and Investigations, Section 160.306(c)—Complaints to the Secretary

Section 160.306(c) of the Enforcement Rule currently provides the Secretary with discretion to investigate HIPAA complaints, through use of the word "may." The new willful neglect provisions, at section 1176(c)(2) of the Social Security Act, will require HHS to investigate "any complaint of a violation of a provision of this part if a preliminary investigation of the facts of the complaint indicates * * * a possible violation due to willful neglect."

HHS proposes to implement section 1176(c)(2) by adding a new paragraph (1) at § 160.306(c) to provide that the Secretary *will* investigate any complaint filed under this section when a preliminary review of the facts indicates a possible violation due to willful neglect. As a practical matter, HHS currently conducts a preliminary review of every complaint received and proceeds with the investigation in every eligible case where its preliminary review of the facts indicate a possible violation of the HIPAA Rules. Nevertheless, we propose this addition to § 160.306 to make clear our intention to pursue an investigation where a preliminary review of the facts indicates a possible violation due to willful neglect.

HHS proposes to conform the remainder of § 160.306(c) accordingly. The new § 160.306(c)(2) (presently, the initial sentence of § 160.306(c)) would be revised by replacing "complaints" with "any other complaint" to distinguish the Secretary's discretion with respect to complaints for which HHS's preliminary review of the facts does not indicate a possible violation due to willful neglect from the statutory requirement to investigate *all* complaints for which HHS's preliminary review of the facts indicates a possible violation due to willful neglect, as set out in the new § 160.306(c)(1). The current second sentence of § 160.306(c), which addresses the content of an investigation, would be renumbered as § 160.306(c)(3) and amended by changing the first word of the sentence from "such" to "an," to signal the provision's application to any investigation, regardless of whether a preliminary review of the facts indicates a possible violation due to willful neglect.

C. Subpart C—Compliance and Investigations, Section 160.308—Compliance Reviews

Section 160.308 provides that the Secretary may conduct compliance reviews. Use of the word "may" in this section makes clear that this is a discretionary activity. While complaints and not compliance reviews are specifically mentioned in the statutory language of section 13410(a)(1)(B) of the Act regarding willful neglect, HHS proposes to also amend § 160.308 to provide that the Secretary will conduct a compliance review to determine whether a covered entity or business associate is complying with the applicable administrative simplification provision when a preliminary review of the facts indicates a possible violation due to willful neglect. This revision to § 160.308 furthers Congress' intent to strengthen enforcement with respect to potential violations due to willful neglect and ensures that investigations, whether or not initiated by complaint, are handled in a consistent manner. Also, the current language of § 160.308 would be redesignated as paragraph (b), and the words "in any other circumstance" would be added to the end of this paragraph to indicate that the discretionary authority of this paragraph applies to cases where the preliminary review of the facts does not indicate a possible violation due to willful neglect. Note that if HHS initiates an investigation of a complaint because its preliminary review of the facts indicates a possible violation due to willful neglect, HHS would not also be required to initiate a compliance review under this section, since it would be duplicative to do so.

D. Subpart C—Compliance and Investigations, Section 160.310—Responsibilities of Covered Entities

Section 160.310 explains a covered entity's responsibilities during complaint investigations and compliance reviews to make information available to the Secretary and to cooperate with the Secretary. Section 160.310(c)(3) provides that any protected health information obtained by the Secretary in connection with an investigation or compliance review will not be disclosed by the Secretary, except as necessary for determining and enforcing compliance with the HIPAA Rules or if otherwise required by law. We propose to also allow the Secretary to disclose protected health information if permitted under the Privacy Act at 5 U.S.C. 552a(b)(7). Section 552a(b)(7) permits the disclosure of a record on an individual contained within a Privacy Act protected system of records to another agency or instrumentality of any governmental jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law and if the agency has made a written request to the agency that maintains the record. This proposed change is necessary to permit the Secretary to cooperate with other law enforcement agencies, such as the State Attorneys General pursuing HIPAA actions on behalf of State residents pursuant to section 13410(e) of the Act, or the Federal Trade Commission, pursuing remedies under other consumer protection authorities.

E. Subpart C—Compliance and Investigations, Section 160.312—Secretarial Action Regarding Complaints and Compliance Reviews

Where noncompliance is indicated, § 160.312 requires the Secretary to attempt to resolve situations by informal means. Section 1176(c)(2) of the Social Security Act, as added by section 13410(a) of the HITECH Act, will require formal investigation of a complaint "if a preliminary investigation of the facts of the complaint indicate * * * a possible

violation due to willful neglect." Further, section 1176(c)(1) of the Social Security Act, as added by section 13410(a) of the HITECH Act, will require the Secretary to impose a civil money penalty where HHS makes a finding of a violation involving willful neglect. In addition to the proposed modification to § 160.306(c)(1), in light of the new provisions at section 1176(c), we propose to make clear that HHS is not required to attempt to resolve cases of noncompliance due to willful neglect by informal means. To do so, we propose to replace the word "will" in § 160.312(a)(1) with "may." While this change would permit HHS to proceed with a willful neglect determination as appropriate, it would also permit HHS to seek to resolve complaints and compliance reviews that did not indicate willful neglect by informal means (*e.g.,* where the covered entity or business associate did not know and by exercising reasonable diligence would not have known of a violation, or where the violation is due to reasonable cause).

It should be noted that this amendment would not change the substance of the response set forth in the April 18, 2005, preamble to the proposed Enforcement Rule, at 70 FR 20224, 20245–6, regarding objections to the 60-day time limit for filing a request for a hearing. In that response, HHS indicated that it was not reasonable to assume that a notice of proposed determination would be served on a respondent with no warning because the covered entity would necessarily be made aware of, and have the opportunity to address, HHS's compliance concerns throughout the investigative period preceding the notice of proposed determination. This proposed change to § 160.312 would allow the Secretary to proceed directly to a notice of proposed determination without first attempting to resolve the matter informally. This proposed revision does not change the fact that during the course of a complaint investigation or a compliance review, a covered entity or business associate would be made aware of, and have the opportunity to address, HHS's compliance concerns.

F. Subpart D—Imposition of Civil Money Penalties, Section 160.401—Definitions

Section 160.401 provides definitions of the terms "reasonable cause," "reasonable diligence," and "willful neglect." As discussed in the interim final rule, at 74 FR 56123, 56126–7, given section 13410(d) of the Act's use of these terms to describe the increasing levels of culpability for which increasing minimum levels of penalties may be imposed, HHS transferred these definitions from their prior placement at § 160.410(a) to signal the definitions' broader application to the entirety of subpart D of part 160. However, because section 13410(d) of the Act referred to these terms but did not amend these definitions, the interim final rule did not alter their content. HHS encourages readers, as it did in the interim final rule, to refer to prior preambles to the Enforcement Rule for detailed discussions of these terms at 70 FR 20224, 20237–9 and 71 FR 8390, 8409–11.

While the provisions of section 13410 of the Act do not explicitly require modification of these definitions, HHS is concerned that the *mens rea* demarcation between the categories of culpability associated with the new tiers of civil money penalty amounts is not sufficiently clear based on the existing definitions. As a result, certain violations (*i.e.,* those of which a covered entity or business associate has or should have knowledge, but does not have the conscious intent or reckless indifference associated with willful neglect) might not fit squarely within one of the established tiers. Therefore, HHS proposes to amend the definition of reasonable cause to clarify the scope of violations fitting within that definition.

HHS does not propose to otherwise modify the definitions associated with the categories of culpability of the amended section 1176(a) of the Social Security Act. However, we wish to clarify how the Secretary intends to apply these terms within this newly established context, to assist covered entities and business associates in tailoring their compliance activities appropriately. Accordingly, the discussion below also addresses the terms associated with the other categories of culpability (*i.e.,* knowledge, reasonable diligence, and willful neglect).

1. Reasonable Cause

Reasonable cause is currently defined, at § 160.401, to mean "circumstances that would make it unreasonable for the covered entity, despite the exercise of ordinary business care and prudence, to comply with the administrative simplification provision violated." This definition is consistent with the Supreme Court's ruling in *United States* v. *Boyle,* 469 U.S. 241, 245 (1985), which focused on whether circumstances were beyond the regulated person's control, thereby making compliance unreasonable. *See* 70 FR 20224, 20238. Prior to the HITECH Act, section 1176 of the Social Security Act treated reasonable cause as a partial limitation on the Secretary's authority to impose a civil money penalty. That is, by establishing that a violation was due to reasonable cause and not willful neglect and was either corrected within a 30-day period or such additional period as the Secretary determined to be appropriate, a covered entity or business associate would bar the Secretary's imposition of a civil money penalty.

As described above, section 13410(d) of the HITECH Act revised section 1176 of the Social Security Act to establish four tiers of increasing penalty amounts to correspond to the levels of culpability associated with the violation. The first category of violation (and lowest penalty tier) covers situations where the covered entity or business associate did not know, and by exercising reasonable diligence would not have known, of a violation. The second category of violation (and next highest penalty tier) applies to violations due to reasonable cause and not to willful neglect. The third and fourth categories (and second-highest and highest penalty tiers) apply to circumstances where the violation was due to willful neglect that is corrected within a certain time period and willful neglect that is not so corrected, respectively. The importance of *mens rea,* or state of mind, in determining the degree of culpability is clear with respect to the first, third, and fourth categories, in that there is no *mens rea* with respect to the lowest category of violation, while the existence of *mens rea* is presumed with respect to the third and fourth categories of violation.

However, the current definition of reasonable cause does not address *mens rea* with respect to the second category of violations. HHS therefore proposes to amend the definition of "reasonable cause" in § 160.401 to clarify the full scope of violations that will come within the reasonable cause category of violations, including those circumstances that would make it unreasonable for the covered entity or business associate, despite the exercise of ordinary business care and prudence, to comply with the administrative simplification provisions violated, as well as those circumstances in which a covered entity or business associate has knowledge of a violation but lacks the conscious intent or reckless indifference associated with the willful neglect category of violations. To that end, HHS proposes to replace the current definition of "reasonable cause" with the following:

an act or omission in which a covered entity or business associate knew, or by exercising reasonable diligence would have known, that the act or omission violated an administrative simplification provision, but in which the covered entity or business associate did not act with willful neglect.

As modified, the definition of "reasonable cause" will continue to recognize those circumstances that would make it unreasonable for the covered entity or business associate, despite the exercise of ordinary business care and prudence, to comply with the administrative simplification provisions violated. Consider the following example:

A covered entity received an individual's request for access but did not respond within the time periods provided for in § 164.524(b)(2). HHS's investigation reveals that the covered entity had compliant access policies and procedures in place, but that it had received an unusually high volume of requests for access within the time period in question. While the covered entity had responded to the majority of access requests received in that time period in a timely manner, it had failed to respond in a timely manner to several requests for access. The covered entity did respond in a timely manner to all requests for access it received subsequent to the time period in which the violations occurred.

In this example, the covered entity had knowledge of the violations but the investigation revealed circumstances that would make it unreasonable for the covered entity, despite the exercise of ordinary business care and prudence, to comply with the administrative simplification provisions violated. The investigation also revealed that the covered entity acted in a way that demonstrated a good faith attempt to comply with § 164.524(b)(2) by having compliant policies and procedures in place, responding to the majority of access requests in a timely manner, and otherwise responding to subsequent requests as required. In contrast, had the investigation revealed that the series of access requests occurred over a longer period of time, and that the covered entity did not attempt to address the backlog or communicate with the individuals, in writing, regarding the reasons for the delay or the date by which the covered entity would complete its action on the requests, the notice of proposed determination might alternatively categorize the violation as being due to willful neglect.

The modified definition of reasonable cause will also encompass those circumstances in which a covered entity or business associate has knowledge of the violation but lacks the conscious intent or reckless indifference associated with willful neglect. Consider the following example:

A covered entity presented an authorization form to a patient for signature to permit a disclosure for marketing purposes that did not contain the core elements required by § 164.508(c). HHS's investigation reveals that the covered entity was aware of the requirement for an authorization for a use or disclosure of protected health information for marketing and had attempted to draft a compliant authorization but had not included in the authorization the core elements required under § 164.508.

In this example, the covered entity failed to act with the ordinary care and business prudence of one seeking to comply with the Privacy Rule. Therefore, the violation cannot be considered to come within the category of violation that is associated with violations where the covered entity did not know (and by exercising reasonable diligence would not have known) of the violation. Yet, because the covered entity had attempted to draft a compliant authorization, it cannot be established that the omission was due to willful neglect involving either a conscious, intentional failure or reckless indifference to the obligation to comply with § 164.508. Unless otherwise resolved by informal means, HHS would have grounds to find that the violation was due to reasonable cause.

2. Knowledge and Reasonable Diligence

Prior rulemaking preambles discussing the Enforcement Rule explain the concept of knowledge, as it applies to the limitations (*i.e.,* affirmative defenses) that section 1176(b) of the Social Security Act places on the Secretary's authority to impose a civil money penalty. As they explain, "the knowledge involved must be knowledge that [a] violation has occurred, not just knowledge of the facts constituting the violation." *See* 71 FR 8390, 8410, Feb. 16, 2006. Moreover, a covered entity or business associate cannot assert an affirmative defense associated with its "lack of knowledge" if such lack of knowledge has resulted from its failure to inform itself about compliance obligations or to investigate received complaints or other information indicating likely noncompliance. *See* 70 FR 20224, 20237–8, Apr. 18, 2005 and 71 FR 8390, 8410–11, Feb. 16, 2006.

Section 13410(d) of the Act establishes the category of violations where the covered entity or business associate did not know (and by exercising reasonable diligence would not have known) of a violation as warranting the lowest range of civil money penalty amounts. The HITECH Act incorporated the concepts of knowledge and reasonable diligence from HIPAA, and it did not revise their substance. HHS therefore expects to apply these existing concepts to the newly established penalty structure consistent with its prior interpretations. Consider the following examples:

1. A covered health care provider with a direct treatment relationship with an individual patient failed to provide the patient a complete notice of privacy practices in compliance with § 164.520(c). HHS's investigation reveals that the covered entity has a compliant notice of privacy practices, policies and procedures for provision of the notice, and appropriate training of its workforce regarding the notice and its distribution. The violation resulted from a printing error that failed to print two pages of the notice of privacy practices. The printing error affected a small number of the covered entity's supply of notices and was an isolated failure to provide an individual with the covered entity's notice of privacy practices.

2. A business associate failed to terminate a former employee's access privileges to electronic protected health information in compliance with § 164.308(a)(3)(ii)(C). HHS's investigation reveals that the business associate's policies and procedures require the termination of such access within a reasonable time period. The HHS investigation reveals that the business associate attempted to terminate the former employee's access in accordance with its policy, but that it instead terminated the access of a current employee who had the same name as the former employee.

In both examples, HHS's investigations reveal that the covered entity or business associate has compliant policies and procedures in place, as well as some action by each covered entity or business associate indicating its intent to implement the respective Privacy Rule requirements. The investigations also reveal noncompliance that the exercise of reasonable diligence would not have avoided.

HHS also notes that, in some circumstances, we expect that the knowledge of an employee or agent of a covered entity or business associate may determine whether a violation implicates the "did not know" or "reasonable cause" categories of violation. That is, absent an exception under the Federal common law of agency, the knowledge of an employee or agent will generally be imputed to its principal (*i.e.,* the covered entity or business associate). *See* 70 FR 20224, 20237 and 71 FR 8390, 8402–3 (discussing imputation of knowledge under the Federal common law of agency and violations attributed to a covered entity, respectively). Consider the following example:

A hospital employee accessed the paper medical record of his ex-spouse while he was on duty to discover her current address for a personal reason, knowing that such access is not permitted by the Privacy Rule and contrary to the policies and procedures of the hospital. HHS's investigation reveals that the covered entity had appropriate and reasonable safeguards regarding employee access to medical records, and that it had delivered appropriate training to the employee.

In this example, the "did not know" category of violation is implicated with respect to the covered entity because the *mens rea* element of knowledge cannot be established. That is, while the employee's act is attributed to the covered entity, the employee's knowledge of the violation cannot be imputed to the covered entity because the employee was acting adversely to the covered entity. The Federal common law of agency does not permit the imputation of knowledge to the principal where the agent consciously acts in a manner that is adverse to the principal.

3. Willful Neglect

Willful neglect is defined, at § 160.401, to mean the "conscious, intentional failure or reckless indifference to the obligation to comply with the administrative simplification provision violated." The term not only presumes actual or constructive knowledge on the part of the covered entity that a violation is virtually certain to occur but also encompasses a conscious intent or degree of recklessness with regard to its compliance obligations.

While the HITECH Act references willful neglect in several provisions, it does not revise the term's definition. HHS therefore expects to apply the current definition of willful neglect to all newly established contexts in the same manner as previously discussed. Consider the following examples:

1. A covered entity disposed of several hard drives containing electronic protected health information in an unsecured dumpster, in violation of § 164.530(c) and § 164.310(d)(2)(i). HHS's investigation reveals that the covered entity had failed to implement any policies and procedures to reasonably and appropriately safeguard protected health information during the disposal process.

2. A covered entity failed to respond to an individual's request that it restrict its uses and disclosures of protected health information about the individual. HHS's investigation reveals that the covered entity does not have any policies and procedures in place for consideration of the restriction requests it receives and refuses to accept any requests for restrictions from individual patients who inquire.

3. A covered entity's employee lost an unencrypted laptop that contained unsecured protected health information. HHS's investigation reveals the covered entity feared its reputation would be harmed if information about the incident became public and, therefore, decided not to provide notification as required by § 164.400 *et seq.*

The facts in these examples demonstrate that the covered entities had actual or constructive knowledge of their various violations. In addition, the covered entities' failures to develop or implement compliant policies and procedures or to respond to incidents as required by § 164.400 *et seq.* demonstrate either conscious intent or reckless disregard with respect to their compliance obligations. In the second example, the covered entity's refusal to accept any requests for restrictions from individual patients who inquire would be grounds for a separate finding of a violation due to willful neglect.

4. Correction of Willful Neglect Violations

We also note that while a covered entity's or business associate's correction of a willful neglect violation will not bar the imposition of a civil money penalty, such correction may foreclose the Secretary's authority to impose a penalty from the highest penalty tier prescribed by section 1176(a)(1) of the Social Security Act. While not all violations can be corrected, in the sense of being fully undone or remediated, HHS has previously set forth a broad interpretation of "corrected," in light of the statute's association of the term with "failure to comply." *See* 71 FR 8390, 8411 (recognizing that the term "corrected" could include correction of a covered entity's noncompliant procedure by making the procedure compliant). For example, in the event a covered entity's or business associate's inadequate safeguards policies and procedures result in an impermissible disclosure, the disclosure violation itself could not be fully undone or corrected. The safeguards violation, however, could be "corrected" in the sense that the noncompliant policies and procedures could be brought into compliance. In any event, corrective action will always be required of a covered entity or business associate.

G. Subpart D—Imposition of Civil Money Penalties, Section 160.402—Basis for a Civil Money Penalty

Section 160.402(a) provides the general rule that the Secretary will impose a civil money penalty upon a covered entity if the Secretary determines that the covered entity violated an administrative simplification provision. Paragraphs (b) and (c) of this section explain the basis for a civil money penalty against a covered entity where more than one covered entity is responsible for a violation, where an affiliated covered entity is responsible for a violation, and where an agent of a covered entity is responsible for a violation. As explained above, this proposed rule would add references to "business associate" where appropriate in this section to effectuate the HITECH Act's imposition of liability on business associates for violations of the HITECH Act and certain Privacy and Security Rule provisions.

Further, in paragraph (c), which provides the basis for the imposition of a civil money penalty against a covered entity for the acts of its agent, in accordance with the Federal common law of agency, we propose to add a parallel provision providing for civil money penalty liability against a business associate for the acts of its agent. Thus, we propose to add a new paragraph (2) to § 160.402(c) to provide that a business associate is liable, in accordance with the Federal common law of agency, for a civil money penalty for a violation based on the act or omission of any agent of the business associate, including a workforce member or subcontractor, acting within the scope of the agency.

The existing language of § 160.402(c) regarding the liability of covered entities for the acts of their agents would be redesignated as paragraph (1), with one substantive change. This section currently provides an exception for covered entity liability for the acts of its agent in cases where the agent is a business associate, the relevant contract requirements have been met, the covered entity did not know of a pattern or practice of the business associate in violation of the contract, and the covered entity did not fail to act as required by the Privacy or Security Rule with respect to such violations. We propose to remove this exception to principal liability for the covered entity so that the covered entity remains liable for the acts of its business associate agents, regardless of whether the covered entity has a compliant business associate agreement in place. This change is necessary to ensure, where the covered entity has contracted out a particular obligation under the HIPAA Rules, such as the requirement to provide individuals with a notice of privacy practices, that the covered entity remains liable for the failure of its business associate to perform that obligation on the covered entity's behalf.

We do not believe this proposed change would place any undue burden on covered entities, since covered entities are customarily liable for the acts of their agents under agency common law. We note that this proposed regulatory change does not create liability for covered entities with respect to business associates that are not agents, *e.g.,* independent contractors. The determination of whether a business associate is an agent of a covered entity, or whether a subcontractor is an agent of a business associate, will be based on the facts of the relationship, such as the level of control over the business associate's or subcontractor's conduct.

H. Subpart D—Imposition of Civil Money Penalties, Section 160.408—Factors Considered in Determining the Amount of a Civil Money Penalty

1. Determination of Penalty Amounts Prior to the HITECH Act

Section 160.408 implements section 1176(a)(2) of the Social Security Act, which requires the Secretary, when imposing a civil money penalty, to apply the provisions of section 1128A of the Social Security Act "in the same manner as such provisions apply to the imposition of a civil money penalty under section 1128A." As currently written, Section 1128A requires the Secretary to take into account—

(1) The nature of the claims and the circumstances under which they were presented,

(2) The degree of culpability, history of prior offenses and financial condition of the person presenting the claims, and

(3) Such other matters as justice may require.

Like other regulations that implement section 1128A, HHS tailored these factors by breaking them down into their component elements and providing a more specific list of circumstances, within each component, that apply to the context of HIPAA Rule violations. Because the Enforcement Rule applies to a number of rules, which apply to an enormous number of entities and circumstances, HHS left to the Secretary's discretion the decisions of whether and how (*i.e.,* as either aggravating or mitigating) to consider the following factors in determining the amount of a civil money penalty:

(a) The nature of the violation, in light of the purpose of the rule violated.

(b) The circumstances, including the consequences, of the violation, including but not limited to * * * [specific circumstances]

(c) The degree of culpability of the covered entity, including but not limited to * * * [specific circumstances]

(d) Any history of prior compliance with the administrative simplification provisions, including violations, by the covered entity, including but not limited to * * * [specific circumstances]

(e) The financial condition of the covered entity, including but not limited to * * * [specific circumstances]

(f) Such other matters as justice may require.

See 70 FR 20224, 20235–6 and 71 FR 8390, 8407–9 for a discussion of HHS's interpretation of the factors currently enumerated in § 160.408.

2. Determination of Penalty Amounts After the HITECH Act

As discussed in more detail in the IFR, section 13410(d) of the HITECH Act modified section 1176(a)(1) of the Social Security Act in several ways, including the establishment of tiers of penalty amounts that are associated with increasing levels of culpability. It also added a provision to section 1176(a)(1) of the Social Security Act directing HHS to "base such determination [of the appropriate penalty amount] on the nature and extent of the violation and the nature and extent of the harm resulting from such violation." The HITECH Act did not modify section 1176(a)(2) (requiring application of section 1128A). In addition, many of the factors currently identified by § 160.408 already pertain to the nature of the violation and the resulting harm. Section 160.408(a), for example, identifies the nature of the violation for consideration; paragraph (b) addresses the circumstances, including the consequences, of the violation (*e.g.,* physical harm, financial harm and whether the violation hindered or facilitated an individual's ability to obtain health care); and paragraph (f) addresses such other matters as justice may require. Thus, HHS did not modify § 160.408 in the IFR.

Upon further consideration of the statutory mandates and the significantly broader range of penalty amounts available, HHS believes it is appropriate to amend the structure of § 160.408, to make explicit the new statutory requirement that the Secretary consider the nature and extent of the violation and the nature and extent of the harm resulting from the violation, in addition to those factors enumerated in section 1128A. Thus, HHS proposes to revise § 160.408(a) and (b), as discussed below, to require the Secretary's consideration of the nature and extent of the violation, as well as the nature and extent of the harm resulting from violation, in addition to those factors referenced by section 1128A. We would exclude, however, the factor presently identified as § 160.408(c) (the degree of culpability of covered entity), which originated in section 1128A. Congress' revision of section 1176(a)(1) of the Social Security Act to establish increasing tiers of penalty amounts that reflect increasing degrees of culpability renders consideration of the degree of culpability as an aggravating or mitigating factor redundant. In contrast, HHS is not proposing to amend the Secretary's discretion with respect to the non-exhaustive list of specific circumstances that may be considered.

In addition, HHS proposes to reorganize the remaining, specific circumstances under § 160.408(a) and (b) to better reflect the categories to which they are now attributed, to add another circumstance for consideration under each, as described below, to explicitly provide that the Secretary's consideration of all specific circumstances is optional, and to modify the phrase "prior violations" in subsections (c)(1) and (2) to read "indications of noncompliance."

a. The Nature and Extent of the Violation

HHS proposes to revise subsection (a) to identify "[t]he nature and extent of the violation," as the first factor the Secretary must consider in determining a civil money penalty amount. While the "the nature of the violation" was previously identified for consideration, as it is grounded in section 1128A, the current list of factors in § 160.408 does not specifically reference "the extent of the violation," which section 1176(a) now requires. We also propose to transfer "the time period during which the violation(s) occurred," to this factor and to add, "the number of individuals affected," since both circumstances might be indicative measures of "the nature and extent of the violation." Our compliance and enforcement experience to date further supports the addition of the latter, particularly with respect to potential violations that negatively affect numerous individuals (*e.g.,* where disclosure of protected health information in multiple explanation of benefits statements that were mailed to the wrong individuals resulted from one inadequate safeguard but affected a large number of beneficiaries). We recognize these specific circumstances might also be considered under § 160.406, with respect to counting violations. In this regard, we direct readers' attention to 71 FR 8390, 8409 (responding to a comment expressing concern that the overlap of certain variables proposed in § 160.406 with factors proposed in § 160.408 might result in compound liability by asserting that since

consideration of such circumstances may be relevant to each separable element of the penalty calculation, their consideration will be different in nature).

b. The Nature and Extent of the Harm Resulting From the Violations

HHS proposes to revise subsection (a) to identify "[t]he nature and extent of the harm resulting from the violation" as the second factor the Secretary must consider. This minor amendment merely conforms the factor's language to the amended statutory language and continues to include the optional consideration of several specific circumstances which might be indicative of harm. In addition to these specific circumstances, HHS proposes to add reputational harm to make clear that reputational harm is as cognizable a form of harm as physical or financial harm.

c. The History of Prior Compliance With the Administrative Simplification Provisions

HHS proposes to modify the phrase "prior violations" in § 160.408(c)(1) and (2) to read "indications of noncompliance." As defined in § 160.302, "violation" or "violate" means, "as the context may require, failure to comply with an administrative simplification provision." Use of the term is generally reserved, however, to circumstances in which the Department has made a formal finding of a violation through a notice of proposed determination. As explained in 71 FR 8390, 8408, a covered entity's general history of HIPAA compliance is relevant in determining the amount of a civil money penalty within the penalty range. When we reviewed this language of § 160.408(c)(1) and (2) for the purposes of this rulemaking, we noticed that the regulatory text uses the term "violation" which is generally reserved for use in a notice of proposed determination. We are proposing to change this terminology to "indications of noncompliance" to make the regulatory language consistent with HHS' policy of considering a covered entity's general history of HIPAA compliance.

I. Section 160.410—Affirmative Defenses

Section 160.410 currently implements the limitations placed on the Secretary's authority to impose a civil money penalty under section 1176(b) of the Act. As amended by the IFR, § 160.410 is organized to implement section 13410(d) of the HITECH Act in a way that distinguishes the affirmative defenses available to covered entities and business associates prior to, on, or after February 18, 2009, the day after section 13410(d) of the HITECH Act became effective. *See* 74 FR 56123, Oct. 30, 2009, for a detailed discussion of the IFR's recent amendments.

Section 13410(a)(1) revises section 1176(b) to replace the phrase, "if the act constitutes an offense *punishable* under section 1177" with "a penalty *has been imposed* under section 1177 with respect to such act." This statutory change is effective February 18, 2011.

HHS proposes to amend § 160.410 to implement the revision of section 1176(b)(1) of the Social Security Act by providing in a new paragraph (a)(1) that the affirmative defense of criminally "punishable" is applicable to penalties imposed prior to February 18, 2011. A new paragraph (a)(2) in that section would make clear that, on or after February 18, 2011, the Secretary's authority to impose a civil money penalty will only be barred to the extent a covered entity or business associate can demonstrate that a penalty has been imposed under 42 U.S.C. 1320d–6 with respect to such act. As a conforming change, current paragraphs (a)(2) and (a)(3) are renumbered as paragraphs (b)(1) and (b)(2), respectively, and current paragraph (b) is renumbered as paragraph (c).

As an additional conforming change, HHS also proposes to amend § 160.410(a)(3)(i) (which has been redesignated as § 160.410(b)(2)(i)) to replace the term "reasonable cause" with the unrevised text of its current definition. This will ensure that the current definition is applied to violations occurring prior to February 18, 2009, thereby avoiding any potential issues regarding a retroactive application of the revised term.

J. Section 160.412—Waiver

We propose conforming changes to this section, to align the cross-references to § 160.410 with the proposed revisions to that section discussed above.

K. Subpart D—Imposition of Civil Money Penalties, Section 160.418—Penalty Not Exclusive

We propose to revise this section to incorporate a reference to the provision of the Patient Safety and Quality Improvement Act of 2005 at 42 U.S.C. 299b–22 that provides that penalties are not to be imposed under both that act and the Privacy Rule for the same violation.

V. Section-by-Section Description of the Proposed Amendments to Subpart A of Part 164 and the Security Rule in Subpart C of Part 164

The HITECH Act made several amendments that directly impact current provisions of the HIPAA Security Rule. We discuss the proposed changes to the Security Rule as a result of the HITECH Act in our section-by-section description below. We also discuss various technical and conforming proposed changes to the Security Rule, as well as proposed changes to provisions in subpart A of part 164, which applies to both the Security and Privacy Rules.

A. Technical Changes to Subpart A—General Provisions

1. Section 164.102—Statutory Basis

This section sets out the statutory basis of part 164. We propose a technical change to include a reference to the provisions of sections 13400 through 13424 of the HITECH Act upon which the regulatory changes proposed below are based.

2. Section 164.104—Applicability

This section sets out to whom part 164 applies. We propose to replace the existing paragraph (b) with an applicability statement for business associates, consistent with the provisions of the HITECH Act that are discussed more fully below. Proposed paragraph (b) would make clear that, where provided, the standards, requirements, and implementation specifications of the HIPAA Privacy, Security, and Breach Notification Rules apply to business associates. We propose to remove as unnecessary the existing language in § 164.104(b) regarding the obligation of a health care clearinghouse to comply with § 164.105 relating to organizational requirements of covered entities.

3. Section 164.105—Organizational Requirements

a. Section 164.105

Section 164.105 outlines the organizational requirements and implementation specifications for health care components of covered entities and for affiliated covered entities. As § 164.105 now also applies to subpart D of part 164 regarding breach notification for unsecured protected health information, we propose to remove several references to subparts C and E throughout this section to make clear that the provisions of this section also apply to the new subpart D of this part. In addition, we propose the following modifications to this section.

b. Section 164.105(a)(2)(ii)(C)–(E)

We propose to modify this section to remove as unnecessary paragraphs (C) and (D), which pertain to the obligation of a covered entity to ensure that any component that performs business associate-like activities and is included in the health care component complies with the requirements of the Privacy and Security Rules, and to re-designate paragraph (E) as (C). A covered entity's obligation to ensure that a health care component complies with the Privacy and Security Rules is already set out at § 164.105(a)(2)(ii). In addition, in light of a business associate's new direct liability for compliance with certain of the Security and Privacy Rule provisions, we request comment on whether we should require, rather than permit as is currently the case under § 164.105(a)(2)(iii)(C), a covered entity that is a hybrid entity to include a component that performs business associate-like activities within its health care component so that such components are directly subject to the Rules.

c. Section 164.105(a)(2)(iii)(C)

We propose to modify this section to re-designate § 164.105(a)(2)(iii)(C) as (D), and to include a new paragraph (C), which makes clear that, with respect to a hybrid entity, the covered entity itself, and not merely the health care component, remains responsible for complying with §§ 164.314 and 164.504 regarding business associate arrangements and other organizational requirements. This proposed modification is intended to recognize that hybrid entities may need to execute legal contracts and conduct other organizational matters at the level of the legal entity rather than at the level of the health care component.

d. Section 164.105(b)(1)

We propose to fix a minor typographical error in this paragraph by redesignating the second paragraph (1) as paragraph (2).

e. Section 164.105(b)(2)(ii)

We propose to simplify this paragraph by collapsing subparagraphs (A), (B), and (C) regarding the obligations of an affiliated entity to comply with the Privacy and Security Rules into one provision, and to expand the reference to compliance with the "part" so that the breach notification obligations in subpart D are also included.

4. Section 164.106—Relationship to Other Parts

We propose to add a reference to business associates, consistent with their inclusion elsewhere throughout the other HIPAA Rules.

B. Modifications to the HIPAA Security Rule in Subpart C

1. References to Business Associates

The Security Rule, as it presently stands, does not directly apply to business associates of covered entities. However, section 13401 of the HITECH Act, which became effective on February 18, 2010, provides that the Security Rule's administrative, physical, and technical safeguards requirements in §§ 164.308, 164.310, and 164.312, as well as its policies and procedures and documentation requirements in § 164.316, shall apply to business associates in the same manner as these requirements apply to covered entities, and that business associates shall be civilly and criminally liable for penalties for violations of these provisions.

Accordingly, to implement section 13401 of the HITECH Act, we propose to insert references to "business associate" in subpart C, as appropriate, following references to "covered entity" to make clear that these provisions of the Security Rule also apply to business associates. In particular, we propose to modify the following sections by adding references to business associates: §§ 164.302 (applicability), 164.304 (definitions of "administrative safeguard" and "physical safeguard"), 164.308, 164.310, 164.312, and 164.316. In addition, we propose the changes below to the Security Rule.

2. Section 164.306—Security Standards: General Rules

Section 13401 of the HITECH Act pertaining to requirements on business associates does not specifically make reference to § 164.306 of the Security Rule. However, § 164.306 sets out the general rules that apply to all of the security standards and implementation specifications that follow. Thus, for example, § 164.306(b)(2) sets out the particular factors that covered entities must take into account in deciding which security measures to use, and § 164.306(d) sets out the general rule that required implementation specifications must be implemented and the process and basis for implementing addressable implementation specifications. Accordingly, §§ 164.308, 164.310, and 164.312 provide that the administrative, physical, and technical safeguards of the Security Rule must be implemented "in accordance with § 164.306." We do not believe that Congress intended to apply enumerated Security Rule sections to business associates in a different manner than to covered entities, as evidenced by the statutory language that these sections should be applied to business associates "in the same manner that such sections apply to the covered entity." For these reasons, we also propose to revise § 164.306 to insert the word "business associate," as appropriate, so that the general rules found at § 164.306 apply to business associates in the same manner as covered entities.

In addition, we propose technical revisions to § 164.306(e) to more clearly indicate that to maintain security measures that continue to meet the requirements of §§ 164.308, 164.310, and 164.312, covered entities and business associates must review and modify such security measures and update documentation accordingly under § 164.316(b)(2)(iii).

3. Section 164.308—Administrative Safeguards

First, as noted above, we propose to modify § 164.308 to include throughout appropriate references to business associates. Second, we propose a technical change to § 164.308(a)(3)(ii)(C) regarding security termination procedures for workforce members, to add the words "or other arrangement with" after "employment of" in recognition of the fact that not all workforce members are employees (*e.g.,* some may be volunteers) of a covered entity or business associate. Third, we propose to remove the reference to § 164.306 in paragraph (b)(1) as unnecessary. Fourth, as discussed below, we propose a number of modifications to the provisions in this section regarding business associate contracts and other arrangements to conform to and address modifications proposed in the definition of "business associate," including the proposed inclusion of subcontractors within the scope of "business associate."

Section 164.308(b) provides that a covered entity may permit a business associate to create, receive, maintain, or transmit electronic protected health information only if the covered entity has a contract or other arrangement in place to ensure the business associate will appropriately safeguard the protected health information. Section 164.308(b)(2) contains several exceptions to this general rule for certain situations that do not give rise to a business associate relationship, such as where a covered entity discloses electronic protected health information to a health care provider concerning the treatment of an individual. We propose to remove these exceptions from § 164.308(b)(2), since as discussed

above, we propose to include these as exceptions to the definition of "business associate."

In addition, we propose to modify § 164.308(b)(1) and (2) to clarify the new proposed requirements on business associates with regard to subcontractors. As described above with respect to the definition of "business associate" in § 160.103, we propose to include in the definition subcontractors that create, receive, maintain, or transmit protected health information on behalf of a business associate. However, we do not intend this proposed modification to mean that a covered entity is required to have a contract with the subcontractor. Rather, such obligation is to remain with the business associate who contracts with the subcontractor. Accordingly, in § 164.308(b)(1), we propose to clarify that covered entities are not required to obtain satisfactory assurances in the form of a contract or other arrangement with a business associate that is a subcontractor. In § 164.308(b)(2), we then propose to make clear that it is the business associate that must obtain the required satisfactory assurances from the subcontractor to protect the security of electronic protected health information.

We propose to remove the provision at § 164.308(b)(3), which provides that a covered entity that violates the satisfactory assurances it provided as a business associate of another covered entity will be in noncompliance with the Security Rule's business associate provisions, as a covered entity's actions as a business associate of another covered entity are now directly regulated by the Security Rule's provisions that apply to business associates.

Finally, in § 164.308(b)(4) (renumbered as § 164.308(b)(3)), which requires documentation of the required satisfactory assurances through a written contract or other arrangement, we propose to add a reference to the new paragraph at § 164.308(b)(2) regarding business associates and subcontractors.

4. Section 164.314—Organizational Requirements

Section 13401 of the HITECH Act does not include § 164.314 among the provisions for which business associates are directly liable. However, section 13401 does state that § 164.308 applies to business associates "in the same manner" that the provision applies to covered entities. Section 164.308(b) requires a covered entity's business associate agreements to conform to the requirements of § 164.314. Accordingly, in order for § 164.308(b) to apply to business associates in the same manner as it applies to covered entities, we have revised § 164.314 to reflect that it is also applicable to agreements between business associates and subcontractors that create, receive, maintain, or transmit electronic protected health information.

We also propose a number of modifications to the business associate contract requirements in § 164.314 to streamline the provisions. First, we propose to remove § 164.314(a)(1)(ii) regarding the steps a covered entity must take if it knows of a material breach or violation by the business associate of the contract. A parallel provision exists in the Privacy Rule's business associate contract provisions at § 164.504 and, since a business associate for purposes of the Security Rule is also always a business associate for purposes of the Privacy Rule, the inclusion of a duplicate provision in the Security Rule is unnecessary. For the same reason, we also propose to remove the contract provision at § 164.314(a)(2)(i)(D) authorizing the termination of the contract by the covered entity if it is determined the business associate has violated a material term of the contract. A parallel provision exists in the Privacy Rule at § 164.504(e)(2)(iii). Also, because the Privacy Rule has a parallel provision, we remove the specific requirements under § 164.314(a)(2)(ii) for other arrangements, such as a memorandum of understanding when both a covered entity and business associate are governmental entities, and instead simply refer to the requirements of § 164.504(e)(3).

Second, we propose the following modifications to the remaining contract provision requirements: (1) In § 164.314(a)(2)(i)(A), we streamline the provision to simply indicate a business associate's obligation to comply with the Security Rule; (2) in § 164.314(a)(2)(i)(B), we revise the language with respect to ensuring subcontractors implement reasonable and appropriate safeguards to refer to the proposed requirement at § 164.308(b)(4) that would require a business associate to enter into a contract or other arrangement with a subcontractor to protect the security of electronic protected health information; and (3) in § 164.314(a)(2)(i)(C), with respect to the reporting of security incidents by business associates to covered entities, we make clear that the business associate contract must provide that the business associate will report to the covered entity breaches of unsecured protected health information as required by § 164.410 of the breach notification rules.

Third, we add a provision at § 164.314(a)(2)(iii) that provides that the requirements of this section for contracts or other arrangements between a covered entity and business associate would apply in the same manner to contracts or other arrangements between business associates and subcontractors required by the proposed requirements of § 164.308(b)(4). For example, to comply with proposed § 164.314(a)(2)(i)(C), a business associate contract between a business associate and a business associate subcontractor must provide that the subcontractor report any security incident of which it becomes aware, including breaches of unsecured protected health information as required by § 164.410, to the business associate. Thus, if a breach of unsecured protected health information occurs at or by a subcontractor, the subcontractor must notify the business associate of the breach, which then must notify the covered entity of the breach. The covered entity then notifies the affected individuals, the Secretary, and, if applicable, the media, of the breach, unless it has delegated such responsibilities to a business associate.

Finally, we propose to remove the reference to subcontractors in § 164.314(b)(2)(iii) regarding amendment of group health plan documents as a condition of disclosure of protected health information to a plan sponsor, to avoid confusion with the use of the term subcontractor when referring to subcontractors that are business associates. This modification does not constitute a substantive change to § 164.314(b).

VI. Section-by-Section Description of the Proposed Amendments to the Privacy Rule

The HITECH Act made a number of amendments that affect current provisions of the Privacy Rule. In the section-by-section description of the proposed regulatory changes below, we discuss the HITECH Act requirements and the regulatory provisions affected by them, as well as certain other substantive proposed changes to the Privacy Rule intended to improve the workability and effectiveness of the Rule and to conform the Privacy Rule to PSQIA. At the end of this discussion, we also briefly list a number of proposed technical corrections and conforming changes to the Privacy Rule that are not otherwise addressed elsewhere.

A. Section 164.500—Applicability

We propose to revise § 164.500 to include new § 164.500(c) and to

redesignate the current § 164.500(c) as (d). In accordance with section 13404 of the HITECH Act, which applies certain of the Privacy Rule requirements to business associates, as discussed more fully below, § 164.500(c) would now clarify that, where provided, the standards, requirements, and implementation specifications of the Privacy Rule apply to business associates.

B. Section 164.501—Definitions

1. Definition of "Health Care Operations"

PSQIA, 42 U.S.C. 299b–21 *et seq.,* provides, among other things, that PSOs are to be treated as business associates of covered health care providers. Further, PSQIA provides that the patient safety activities of PSOs in relation to HIPAA covered health care providers are deemed to be health care operations under the Privacy Rule. *See* 42 U.S.C. 299b–22(i).

We propose to amend paragraph (1) of the definition of "health care operations" to include a reference to patient safety activities, as defined in the PSQIA implementing regulation at 42 CFR 3.20. Many health care providers participating in the voluntary patient safety program authorized by PSQIA are HIPAA covered entities; PSQIA acknowledges that such providers must also comply with the Privacy Rule and deems patient safety activities to be health care operations under the Privacy Rule. While such activities are already encompassed within paragraph (1) of the definition, which addresses various quality activities, we propose to expressly include patient safety activities within paragraph (1) of the definition of health care operations to expressly conform the definition to PSQIA and to eliminate the potential for any confusion. This modification would also address public comments the Department received during the rulemaking period for the PSQIA implementing regulations, which urged the Department to modify the definition of "health care operations" in the Privacy Rule to expressly reference patient safety activities so that the intersection of the Privacy and PSQIA Rules would be clear. *See* 73 FR 70732, 70780, November 21, 2008.

2. Definition of "Marketing"

The Privacy Rule requires covered entities to obtain a valid authorization from individuals before using or disclosing protected health information to market a product or service to them. *See* § 164.508(a)(3). Section 164.501 defines "marketing" as making a communication about a product or service that encourages recipients of the communication to purchase or use the product or service. Paragraph (1) of the definition includes a number of exceptions to marketing for certain health-related communications. In particular, the Privacy Rule does not consider the following communications to be marketing: (1) Communications made to describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communications, including communications about: the entities participating in a healthcare provider network or health plan network; replacement of, or enhancements to, a health plan; and health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits; (2) communications made for the treatment of the individual; and (3) communications for case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual. Thus, a covered entity is permitted to make these excepted communications without an individual's authorization as either treatment or health care operations communications, as appropriate, under the Privacy Rule. In addition, the Privacy Rule does not require a covered entity to obtain individual authorization to communicate face-to-face or to provide only promotional gifts of nominal value to the individual. *See* § 164.508(a)(3)(i). However, a covered entity must obtain prior written authorization from an individual to send communications to the individual about non-health related products or services or to give or sell the individual's protected health information to a third party for marketing. *See* the current paragraph (2) of the definition of "marketing" in the Privacy Rule. Still, concerns have remained about the ability under these provisions for a third party to pay a covered entity in exchange for the covered entity to send health-related communications to an individual about the third party's products or services.

Section 13406(a) of the HITECH Act, which became effective on February 18, 2010, addresses these marketing provisions. In particular, section 13406(a) of the HITECH Act limits the health-related communications that may be considered health care operations and thus, that are excepted from the definition of "marketing" under the Privacy Rule to the extent a covered entity receives or has received direct or indirect payment in exchange for making the communication. In cases where the covered entity would receive such payment, the HITECH Act at section 13406(a)(2)(B) requires that the covered entity obtain the individual's valid authorization prior to making the communication, or, if applicable, prior to its business associate making the communication on its behalf in accordance with its written contract. Section 13406(a)(2)(A) of the HITECH Act includes an exception to the payment limitation for communications that describe only a drug or biologic that is currently being prescribed to the individual as long as any payment received by the covered entity in exchange for making the communication is reasonable in amount. Section 13406(a)(3) of the Act provides that the term "reasonable in amount" shall have the meaning given such term by the Secretary in regulation. Finally, section 13406(a)(4) of the Act clarifies that "direct or indirect payment" does not include any payment for treatment of the individual. We believe Congress intended with these provisions to curtail a covered entity's ability to use the exceptions to the definition of "marketing" in the Privacy Rule to send communications to the individual that were motivated more by commercial gain or other commercial purpose rather than for the purpose of the individual's health care, despite the communication's being about a health-related product or service.

To implement the marketing limitations of the HITECH Act, we propose a number of modifications to the definition of "marketing" in the Privacy Rule at § 164.501. In particular, we propose to: (1) Revise the exceptions to marketing to better distinguish the exceptions for treatment communications from those communications made for health care operations; (2) add a definition of "financial remuneration;" (3) provide that health care operations communications for which financial remuneration is received are marketing and require individual authorization; (4) provide that written treatment communications for which financial remuneration is received are subject to certain notice and opt out conditions set out at § 164.514(f)(2); (5) provide a limited exception from the remuneration prohibition for refill reminders; and (6) remove the paragraph regarding an arrangement between a covered entity and another

entity in which the covered entity receives remuneration in exchange for protected health information. We propose to revise §§ 164.514(f)(2) and 164.520(b)(1)(iii)(A) to include the notice and opt out conditions that would attach to written treatment communications about products or services sent by a health care provider to an individual in exchange for financial remuneration by the third party whose product or service is being described. We also propose to make a conforming change to the authorization requirements for marketing at § 164.508(a)(3)(ii). We describe these proposed modifications in more detail below.

In paragraph (1) of the definition of "marketing," we propose to maintain the general concept that "marketing" means "to make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service." In paragraph (2) of the definition, we propose to include three exceptions to this definition to encompass certain treatment and health care operations communications about health-related products or services. First, at proposed paragraph (2)(iii), we would exclude from the definition of "marketing" certain health care operations communications, except where, as provided by section 13406(a)(2) of the HITECH Act, the covered entity receives financial remuneration in exchange for making the communication. This provision would encompass the health care operations activities currently described in paragraph (1)(i) of the definition of "marketing," which include communications to describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication. In addition, the provision would encompass health care operations communications for case management or care coordination, contacting of individuals with information about treatment alternatives, and related functions, to the extent these activities do not fall within the definition of treatment. These are activities that currently fall within paragraph (1)(iii) of the definition of "marketing."

Although the HITECH Act uses the term "direct or indirect payment" to describe the limitation on permissible health care operations disclosures, we have substituted the term "financial remuneration" to avoid confusion since the Privacy Rule defines and uses the term "payment" to mean payment for health care and since the Privacy Rule's authorization requirements for marketing at § 164.508(a)(3) use the term "remuneration." We propose to define "financial remuneration" in paragraph (3) of the definition of "marketing" to mean direct or indirect payment from or on behalf of a third party whose product or service is being described. We also propose to make clear, in accordance with section 13406(a)(4) of the HITECH Act, that financial remuneration does not include any direct or indirect payment for the treatment of an individual. Additionally, because the HITECH Act refers expressly to "payment," rather than remuneration more generally, we have specified that only the receipt of financial remuneration in exchange for making a communication, as opposed to any other type of remuneration, is relevant for purposes of the definition of marketing. We propose a small conforming change to § 164.508(a)(3) to add the term "financial" before "remuneration" and to refer to the definition of "financial remuneration" for consistency with the HITECH Act and the proposed changes to the definition of "marketing."

We also emphasize that financial remuneration for purposes of the definition of "marketing" must be in exchange for making the communication itself and be from or on behalf of the entity whose product or service is being described. For example, authorization would be required prior to a covered entity making a communication to its patients regarding the acquisition of new state of the art medical equipment if the equipment manufacturer paid the covered entity to send the communication to its patients. In contrast, an authorization would not be required if a local charitable organization, such as a breast cancer foundation, funded the covered entity's mailing to patients about the availability of new state of the art medical equipment, such as mammography screening equipment, since the covered entity would not be receiving remuneration by or on behalf of the entity whose product or service was being described. Furthermore, it would not constitute marketing and no authorization would be required if a hospital sent flyers to its patients announcing the opening of a new wing where the funds for the new wing were donated by a third party, since the financial remuneration to the hospital from the third party was not in exchange for the mailing of the flyers.

Second, in paragraph (2)(ii) of the definition, we propose to include the statutory exception to marketing at section 13406(a)(2)(A) for communications regarding refill reminders or otherwise about a drug or biologic that is currently being prescribed for the individual, provided any financial remuneration received by the covered entity for making the communication is reasonably related to the covered entity's cost of making the communication. Congress expressly identified these types of communications as being exempt from the remuneration limitation only to the extent that any payment received for making the communication is reasonable in amount. We request comment on the scope of this exception, that is, whether communications about drugs that are related to the drug currently being prescribed, such as communications regarding generic alternatives or new formulations of the drug, should fall within the exception. In addition, we considered proposing a requirement that a covered entity could only receive financial remuneration for making such a communication to the extent it did not exceed the actual cost to make the communication. However, we were concerned that such a requirement would impose the additional burden of calculating the costs of making each communication. Instead, we propose to allow costs that are reasonably related to the covered entity's cost of making the communication. We request comment on the types and amount of costs that should be allowed under this provision.

Third, proposed paragraph (2)(i) would exclude from marketing treatment communications about health-related products or services by a health care provider to an individual, including communications for case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual, provided, however, that if the communications are in writing and financial remuneration is received in exchange for making the communications, certain notice and opt out conditions are met. We note that while section 13406(a) of the HITECH Act expressly provides that a communication to an individual about a health-related product or service where the covered entity receives payment from a third party in exchange for making the communication shall not be considered a *health care operation* (emphasis added) under the Privacy Rule, and thus is marketing, it is unclear how Congress intended these provisions to apply to treatment communications between a health care provider and a patient. Specifically, it is unclear whether Congress intended to restrict

only those subsidized communications about products and services that are less essential to an individual's health care (*i.e.,* those classified as health care operations communications) or all subsidized communications about products and services, including treatment communications. Given this ambiguity and to avoid preventing communications to the individual by a health care provider about health related products or services that are necessary for the treatment of the individual, we do not propose to require individual authorization where financial remuneration is received by the provider from a third party in exchange for sending the individual treatment communications about health-related products or services. However, to ensure the individual is aware that he or she may receive subsidized treatment communications from his or her provider and has the opportunity to elect not to receive them, we propose to require a statement in the notice of privacy practices when a provider intends to send such subsidized treatment communications to an individual, as well as the opportunity for the individual to opt out of receiving such communications. In particular, the proposed rule would exclude from marketing and the authorization requirements written subsidized treatment communications only to the extent that the following requirements proposed at § 164.514(f)(2) are met: (1) The covered health care provider's notice of privacy practices includes a statement informing individuals that the provider may send treatment communications to the individual concerning treatment alternatives or other health-related products or services where the provider receives financial remuneration from a third party in exchange for making the communication, and the individual has a right to opt out of receiving such communications; and (2) the treatment communication itself discloses the fact of remuneration and provides the individual with a clear and conspicuous opportunity to elect not to receive any further such communications. Similar to the modifications discussed below regarding fundraising communications, the opt out method provided to an individual for subsidized treatment communications may not cause the individual to incur an undue burden or more than a nominal cost. We encourage covered entities to consider the use of a toll-free phone number, an e-mail address, or similar opt out mechanism that would provide individuals with a simple, quick, and inexpensive way to opt out of receiving future communications. We note that we would consider requiring individuals to write and send a letter to the covered entity asking not to receive future communications to constitute an undue burden on the individual for purposes of this proposed requirement. We request comment on how the opt out should apply to future subsidized treatment communications. For example, we request comment on whether the opt out should prevent all future subsidized treatment communications by the provider or just those dealing with the particular product or service described in the current communication. We also request comment on the workability of requiring health care providers that intend to send subsidized treatment communications to individuals to provide an individual with the opportunity to opt out of receiving such communications prior to the individual receiving the first communication and what mechanisms could be put into place to implement the requirement.

Given that the new marketing limitations on the receipt of remuneration by a covered entity would apply differently depending on whether a communication is for treatment or health care operations purposes, it is important to emphasize the difference between the two types of communications. We note first that communications by health plans concerning health-related products or services included in a plan of benefits or for case management or care coordination are never considered treatment for purposes of the Privacy Rule but rather would always be health care operations and require individual authorization under the proposed rule if financial remuneration is involved. With respect to subsidized communications by a health care provider about health-related products or services for case management or care coordination or to recommend alternative treatments or settings of care, whether the communication would require individual authorization, or a statement in the notice and an opportunity to opt out, would depend on to what extent the provider is making the communication in a population-based fashion (health care operations) or to further the treatment of a particular individual based on that individual's health care status or condition (treatment). For example, a covered health care provider who sends a pregnant patient a brochure recommending a specific birthing center suited to the patient's particular needs is recommending a setting of care specific to the individual's condition, which constitutes treatment of the individual. If the health care provider receives financial remuneration in exchange for making the communication, the provider would be required to have included a statement in its notice of privacy practices informing individuals that it may send subsidized treatment communications to the individual and that the individual has a right to opt out of such communications, and to disclose the fact of remuneration with the communication and provide the individual with information on how to opt out of receiving future such communications. In contrast, a health care provider who sends a blanket mailing to all patients with information about a new affiliated physical therapy practice would not be making a treatment communication. Rather, the provider would be making a communication for health care operations if it does not receive any financial remuneration for the communication, but would be making a communication for marketing if it does receive financial remuneration.

We are aware of the difficulty in making what may be in some cases close judgments as to which communications are for treatment purposes and which are for health care operations purposes. We also are aware of the need to avoid unintended adverse consequences to a covered health care provider's ability to provide treatment to an individual. Therefore, we request comment on the above proposal with regard to these issues, as well as the alternatives of excluding treatment communications altogether even if they involve financial remuneration from a third party or requiring individual authorization for both treatment and health care operations communications made in exchange for financial remuneration.

We note that face to face communications about products or services between a covered entity and an individual and promotional gifts of nominal value provided by a covered entity are not impacted by these proposed changes to the definition of "marketing." These communications may continue to be made without obtaining an authorization under § 164.508 or meeting the notice and opt out requirements of § 164.514(f)(2). We also clarify that communications made by covered entities to individuals promoting health in general, such as communications about the importance of maintaining a healthy diet or getting an annual physical are still not considered to be marketing. These types

of communications do not constitute marketing because they are not promoting a specific product or service, and thus do not meet the definition of "marketing." Similarly, communications about government and government-sponsored programs do not fall within the definition of "marketing" as there is no commercial component to communications about benefits available through public programs.

Finally, we have proposed to remove the language at paragraph (2) from the definition of "marketing" at § 164.501. The current language defines as marketing an arrangement between a covered entity and any other entity in which the covered entity discloses protected health information to the other entity, in exchange for remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service. This language describes a situation which, as explained more fully below, would now constitute a "sale" of protected health information under section 13405(d) of the HITECH Act and § 164.508(a)(4) of this proposed rule. Because we propose to modify § 164.508 to implement section 13405(d) of the HITECH Act by prohibiting the sale of protected health information without an authorization, we propose to remove this paragraph from the definition of "marketing" as unnecessary and to avoid confusion.

C. Business Associates

1. Section 164.502—Uses and Disclosures

The Privacy Rule currently does not directly govern business associates. However, the provisions of the HITECH Act make specific requirements of the Privacy Rule applicable to business associates, and create direct liability for noncompliance by business associates with regard to those Privacy Rule requirements. In particular, section 13404 of the HITECH Act, which became effective February 18, 2010, addresses the application of the provisions of the HIPAA Privacy Rule to business associates of covered entities. Section 13404(a) discusses the application of contract requirements to business associates, paragraph (b) applies the provision of § 164.504(e)(1)(ii) regarding knowledge of a pattern of activity or practice that constitutes a material breach or violation of a contract to business associates, and paragraph (c) applies the HIPAA civil and criminal penalties to business associates. We discuss paragraphs (a) and (b) of section 13404 of the HITECH Act below. We address section 13404(c) regarding the application of penalties to violations by business associates above in the discussion of the proposed changes to the Enforcement Rule.

Section 13404(a) of the HITECH Act creates direct liability for business associates by providing that in the case of a business associate of a covered entity that obtains or creates protected health information pursuant to a written contract or other arrangement as described in § 164.502(e)(2) of the Privacy Rule, the business associate may use and disclose such protected health information only if such use or disclosure is in compliance with the applicable business associate contract requirements of § 164.504(e) of the Rule. Additionally, section 13404(a) applies the other privacy requirements of the HITECH Act to business associates just as they apply to covered entities.

Accordingly, we propose to modify § 164.502(a) of the Privacy Rule containing the general rules for uses and disclosures of protected health information to address the permitted and required uses and disclosures of protected health information by business associates. First, we propose to revise § 164.502(a) to provide that a business associate, like a covered entity, may not use or disclose protected health information except as permitted or required by the Privacy Rule or the Enforcement Rule. Second, we propose to revise the titles of § 164.502(a)(1) and (2) regarding permitted and required uses and disclosures to make clear that these paragraphs apply only to covered entities. Note that in § 164.502(a)(2)(ii), we also propose a technical change to replace the term "subpart" with "subchapter" to make clear that a covered entity is required to disclose protected health information to the Secretary as needed to determine compliance with any of the HIPAA Rules and not just the Privacy Rule.

Third, we propose to add new provisions at § 164.502(a)(4) and (5) to address the permitted and required uses and disclosures of protected health information by business associates.[4] In accordance with section 13404(a) of the HITECH Act, proposed § 164.502(a)(4) would allow business associates to use or disclose protected health information only as permitted or required by their business associate contracts or other arrangements pursuant to § 164.504(e), or as required by law. If a covered entity and business associate have failed to enter into a business associate contract or other arrangement, then the business associate may use or disclose protected health information only as necessary to perform its obligations for the covered entity (pursuant to whatever agreement sets the general terms for the relationship between the covered entity and business associate) or as required by law; any other use or disclosure would violate the Privacy Rule. In addition, proposed § 164.502(a)(4) makes clear that a business associate would not be permitted to use or disclose protected health information in a manner that would violate the requirements of the Privacy Rule, if done by the covered entity, except that the business associate would be permitted to use or disclose protected health information for the purposes specified under § 164.504(e)(2)(i)(A) or (B), pertaining to uses and disclosures for the proper management and administration of the business associate and the provision of data aggregation services for the covered entity, if such uses and disclosures are permitted by its business associate contract or other arrangement.

Section 164.502(a)(5) would require business associates to disclose protected health information either when required by the Secretary under subpart C of part 160 of this subchapter to investigate or determine the business associate's compliance with this subchapter, or to the covered entity, individual, or individual's designee, as necessary to satisfy a covered entity's obligations under § 164.524(c)(2)(ii) and (3)(ii), as modified, with respect to an individual's request for an electronic copy of protected health information. As section 13405(e) requires covered entities that maintain protected health information in an electronic health record to provide an individual, or the individual's designee, with a copy of such information in an electronic format, if the individual so chooses, and as section 13404(a) applies section 13405(e) to business associates as well, we propose to include such language in § 164.502(a)(5).

We propose to modify the minimum necessary standard at § 164.502(b) to require that when business associates use, disclose, or request protected health information, they limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request. Applying the minimum necessary standard is a condition of the permissibility of many uses and disclosures of protected health information. Thus, a business associate

[4] We propose to reserve § 164.502(a)(3) for provisions implementing modifications to the Privacy Rule required by the Genetic Information Nondiscrimination Act of 2008 (GINA), which were proposed on October 7, 2009. *See* 74 FR 51698.

is not making a permitted use or disclosure under the Privacy Rule if it does not apply the minimum necessary standard, where appropriate. Additionally, the HITECH Act at section 13405(b) addresses the application of minimum necessary and, in accordance with section 13404(a), also applies such requirements to business associates. We note that we have not added references to "business associate" to other provisions of the Privacy Rule that address uses and disclosures by covered entities. This is because we found such changes to be unnecessary, since a business associate generally may only use or disclose protected health information in the same manner as a covered entity (therefore any Privacy Rule limitation on how a covered entity may use or disclose protected health information automatically extends to business associates).

Section 164.502(e) sets out the requirements for disclosures to business associates. We propose in § 164.502(e)(1)(i) to provide that covered entities are not required to obtain satisfactory assurances from business associates that are subcontractors. Rather, as we previously discussed with regard to proposed modifications to the Security Rule pertaining to business associates, and as we discuss further below, we propose in the Privacy and Security Rules to require that business associates obtain satisfactory assurances, through a written contract or other arrangement, from subcontractors that provide that the subcontractor will comply with the applicable requirements of the Rules. Accordingly, each business associate subcontractor would be subject to the terms and conditions of a business associate agreement with a business associate, eliminating the need for a similar agreement with the covered entity itself.

We also propose to move the current exceptions to business associates at § 164.502(e)(1)(ii) to the revised definition of business associates found in § 160.103 for the reasons discussed in that section.

We propose a new § 164.502(e)(1)(ii) that provides that a business associate may disclose protected health information to a business associate that is a subcontractor, and to allow the subcontractor to create or receive protected health information on behalf of the business associate, if the business associate obtains satisfactory assurances, in accordance with § 164.504(e)(1)(i), that the subcontractor will appropriately safeguard the information. As such, the business associate must enter into a contract or other arrangement that complies with § 164.504(e)(1)(i) with business associate subcontractors, in the same manner that covered entities are required to enter into contracts or other arrangements with their business associates. As we discussed with regard to the requirements of the Security Rule regarding business associates, we believe that business associates are in the best position to ensure that subcontractors comply with the requirements of the Privacy Rule. For example, a covered entity may choose to contract with a business associate (contractor) to use or disclose protected health information on its behalf, the business associate may choose to obtain the services of (and exchange protected health information with) a subcontractor (subcontractor 1), and that subcontractor may, in turn, contract with another subcontractor (subcontractor 2) for services involving protected health information. Under the current rules, the covered entity would be required to obtain a business associate agreement with the contractor, the contractor would have a contractual requirement to obtain the same satisfactory assurances from subcontractor 1, and subcontractor 1 would in turn have a contractual requirement to obtain the same satisfactory assurances from subcontractor 2. The proposed revisions to the Privacy and Security Rules would not change the parties to the contracts. However, the contractor and subcontractors 1 and 2 all would now be business associates with direct liability under the HIPAA Rules, and would be required to obtain business associate agreements with the parties with whom they contract for services that involve access to protected health information. (*Note,* however, as discussed above with respect to the definition of "business associate," direct liability under the HIPAA Rules attaches regardless of whether the contractor and subcontractors have entered into business associate agreements.) The proposed revisions ensure that the covered entity does not have a new obligation to enter into separate contracts with the business associate subcontractors.

We propose to remove § 164.502(e)(1)(iii), which provides that a covered entity that violates the satisfactory assurances it provided as a business associate of another covered entity will be in noncompliance with the Privacy Rule's business associate provisions, given that new proposed § 164.502(a)(4) would restrict directly the uses and disclosures of protected health information by a business associate, including a covered entity acting as a business associate, to those uses and disclosures permitted by its business associate agreement.

2. Section 164.504(e)—Business Associate Agreements

Section 164.504, among other provisions, contains the specific requirements for business associate contracts and other arrangements. As discussed previously, section 13404 of the HITECH Act provides that a business associate may use and disclose protected health information only if such use or disclosure is in compliance with each applicable requirement of § 164.504(e), and also applies the provisions of § 164.504(e)(1)(ii), which outline the actions that must be taken if the business associate has knowledge of a breach of the contract, to business associates. We propose a number of modifications to this section to implement these provisions and to reflect the Department's new regulatory authority with respect to business associates, as well as to reflect a covered entity's and business associate's new obligations under subpart D to provide for notification in the case of breaches of unsecured protected health information.

Section 164.504(e)(1)(ii) provides that a covered entity is not in compliance with the business associate requirements if the covered entity knew of a pattern of activity or practice of the business associate that constituted a material breach or violation of the business associate's obligation under the contract or other arrangement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and if such steps were unsuccessful, terminated the contract or arrangement or, if termination is not feasible, reported the problem to the Secretary. We propose to revise § 164.504(e)(1)(ii) to remove the requirement that covered entities report to the Secretary when termination of a business associate contract is not feasible. In light of a business associate's direct liability for civil money penalties for violations of the HIPAA Rules and both a covered entity's and business associate's obligations under subpart D to report breaches of unsecured protected health information to the Secretary, we have other mechanisms through which we expect to learn of such breaches and misuses of protected health information by a business associate. We also propose to add a new provision at § 164.504(e)(1)(iii) applicable to business associates with respect to subcontractors to mirror the requirements on covered entities in

§ 164.504(e)(1)(ii) (minus the requirement to report to the Secretary if termination of a contract is not feasible). Thus, proposed § 164.504(e)(1)(iii) would require a business associate, if it knew of a pattern or practice of activity of its business associate subcontractor that constituted a material breach or violation of the subcontractor's contract or other arrangement, to take reasonable steps to cure the breach of the subcontractor or to terminate the contract, if feasible. We believe this proposed provision would implement the intent of section 13404(b) of the HITECH Act, and aligns the requirements for business associates with regard to business associate subcontractors with the requirements for covered entities with regard to their business associates. In other words, a business associate that is aware of noncompliance by its business associate subcontractor must respond to the situation in the same manner as a covered entity that is aware of noncompliance by its business associate.

While business associates are now directly liable for civil money penalties under the HIPAA Rules for impermissible uses and disclosures as described above, business associates are still contractually liable to covered entities pursuant to their business associate contracts, as provided for and required by § 164.504(e). We propose certain modifications to these contract requirements. First, we propose to revise § 164.504(e)(2)(ii)(B) through (D) to require the following: in (B), that business associates comply, where applicable, with the Security Rule with regard to electronic protected health information; in (C), that business associates report breaches of unsecured protected health information to covered entities, as required by § 164.410; and in (D), that, in accordance with § 164.502(e)(1)(ii), business associates ensure that any subcontractors that create or receive protected health information on behalf of the business associate agree to the same restrictions and conditions that apply to the business associate with respect to such information. These proposed revisions align the requirements for the business associate contract with the requirements in the HITECH Act and elsewhere within the HIPAA Rules.

Additionally with regard to business associate contract requirements, we propose to insert a new provision at § 164.502(e)(2)(ii)(H) and to renumber the current paragraphs (H) and (I) accordingly. Section 164.502(e)(2)(ii)(H), as proposed, would require that, to the extent the business associate is to carry out a covered entity's obligation under this subpart, the business associate must comply with the requirements of the Privacy Rule that apply to the covered entity in the performance of such obligation. The HITECH Act places direct liability for uses and disclosures and for the other HITECH Act requirements on business associates. Beyond such direct liability, this provision clarifies that a business associate is contractually liable not only for uses and disclosures of protected health information, but also for all other requirements of the Privacy Rule, as they pertain to the performance of the business associate's contract. For example, if a third party administrator, as a business associate of a group health plan, fails to distribute the plan's notice of privacy practices to participants on a timely basis, the third party administrator would not be directly liable under the HIPAA Rules, but would be contractually liable, for the failure. However, we emphasize that in this example, even though the business associate is not directly liable under the HIPAA Rules for failure to provide the notice, the covered entity remains directly liable for failure to provide the individuals with its notice of privacy practices because it is the covered entity's ultimate responsibility to do so, despite its having hired a business associate to perform the function.

We also propose to revise § 164.504(e)(3) regarding other arrangements for governmental entities to include references to the Security Rule requirements for business associates to streamline the two rules and, as discussed above, to avoid having to repeat such provisions in the Security Rule.

To implement the requirements of sections 13404(a) of the HITECH Act, we propose to include a new § 164.504(e)(5) that applies the requirements of § 164.504(e)(2) through (e)(4) to the contract or other arrangement between a business associate and its business associate subcontractor as required by § 164.502(e)(1)(ii) in the same manner as such requirements apply to contracts or other arrangements between a covered entity and its business associate. As such, the business associate is required by § 164.502(e)(1)(ii) and by this section to enter into business associate contracts, or other arrangements that comply with the Privacy and Security Rules, with their business associate subcontractors in the same manner that covered entities are required to enter into contracts or other arrangements with their business associates.

Finally, we propose to remove the reference to subcontractors in § 164.504(f)(2)(ii)(B) to avoid confusion with the use of the term subcontractor when referring to subcontractors as business associates. For the same reason, we propose to remove the reference to subcontractors in § 164.514(e)(4)(ii)(C)(4) to avoid confusion with the use of the term subcontractor when referring to subcontractors as business associates. We do not intend these proposed modifications to constitute substantive changes.

3. Section 164.532—Transition Provisions

We understand that covered entities and business associates are concerned with the anticipated administrative burden and cost to implement the revised business associate contract provisions of the Privacy and Security Rules. Covered entities may have existing contracts that are not set to terminate or expire until after the compliance date of the modifications to the Rules, and we understand that a six month compliance period may not provide enough time to reopen and renegotiate all contracts. In response to these concerns, we propose to relieve some of the burden on covered entities and business associates in complying with the revised business associate provisions by adding a transition provision to grandfather certain existing contracts for a specified period of time. The Department's authority to add the transition provision is set forth in § 160.104(c), which allows the Secretary to establish the compliance date for any modified standard or implementation specification, taking into account the extent of the modification and the time needed to comply with the modification. We also note that the Final Privacy Rule, 65 FR 82462 (Dec. 28, 2000), and the Modifications to the HIPAA Privacy Rule, 67 FR 53182 (Aug. 14, 2002), both included transition provisions to ensure that important functions of the health care system were not impeded (*e.g.,* to prevent disruption of ongoing research). Similarly, the proposed transition period, here, will prevent rushed and hasty changes to thousands of on-going existing business associate agreements. The following discussion addresses the issue of the business associate transition provisions.

We propose new transition provisions at § 164.532(d) and (e) to allow covered entities and business associates (and business associates and business associate subcontractors) to continue to operate under certain existing contracts for up to one year beyond the

compliance date of the revisions to the Rules. The additional transition period would be available to a covered entity or business associate if, prior to the publication date of the modified Rules, the covered entity or business associate had an existing contract or other written arrangement with a business associate or subcontractor, respectively, that complied with the prior provisions of the HIPAA Rules and such contract or arrangement was not renewed or modified between the effective date and the compliance date of the modifications to the Rules. The proposed provisions are intended to allow those covered entities and business associates with contracts with business associates and subcontractors, respectively, that qualify as described above to continue to disclose protected health information to the business associate or subcontractor, or to allow the business associate or subcontractor to create or receive protected health information on behalf of the covered entity or business associate, for up to one year beyond the compliance date of the modifications, regardless of whether the contract meets the applicable contract requirements in the modifications to the Rules. With respect to business associates and subcontractors, this proposal would grandfather existing written agreements between business associates and subcontractors entered into pursuant to 45 CFR 164.504(e)(2)(i)(D), which requires the business associate to ensure that its agents with access to protected health information agree to the same restrictions and conditions that apply to the business associate. The Department proposes to deem such contracts to be compliant with the modifications to the Rules until either the covered entity or business associate has renewed or modified the contract following the compliance date of the modifications, or until the date that is one year after the compliance date, whichever is sooner.

In cases where a contract renews automatically without any change in terms or other action by the parties (also known as "evergreen contracts"), the Department intends that such evergreen contracts will be eligible for the extension and that deemed compliance would not terminate when these contracts automatically roll over. These transition provisions apply to covered entities and business associates only with respect to written contracts or other written arrangements as specified above, and not to oral contracts or other arrangements.

These transition provisions only apply to the requirement to amend contracts; they do not affect any other compliance obligations under the HIPAA Rules. For example, beginning on the compliance date of this rule, a business associate may not use or disclose protected health information in a manner that is contrary to the Privacy Rule, even if the business associate's contract with the covered entity has not yet been amended.

D. Section 164.508—Uses and Disclosures for Which an Authorization is Required

Section 164.508 of the Privacy Rule permits a covered entity to use and disclose protected health information only if it has obtained a valid authorization (*i.e.,* one that meets the requirements of the section), unless such use or disclosure is otherwise permitted or required by the Privacy Rule. Section 164.508 also lists two specific circumstances in which an authorization must be obtained: (1) Most uses and disclosures of psychotherapy notes; and (2) uses and disclosures for marketing.

1. Sale of Protected Health Information

Section 13405(d) of the HITECH Act adds a third circumstance that requires authorization, specifically the sale of protected health information. Section 13405(d)(1) prohibits a covered entity or business associate from receiving direct or indirect remuneration in exchange for the disclosure of protected health information unless the covered entity has obtained a valid authorization from the individual pursuant to § 164.508 that states whether the protected health information can be further exchanged for remuneration by the entity receiving the information. Section 13405(d)(2) sets forth several exceptions to the authorization requirement. These exceptions are where the purpose of the exchange of information for remuneration is for: (1) Public health activities, as described in § 164.512(b); (2) research purposes as described in §§ 164.501 and 164.512(i), if the price charged for the information reflects the costs of preparation and transmittal of the data; (3) treatment of the individual; (4) the sale, transfer, merger, or consolidation of all or part of a covered entity and for related due diligence; (5) services rendered by a business associate pursuant to a business associate agreement and at the specific request of the covered entity; (6) providing an individual with access to his or her protected health information pursuant to § 164.524; and (7) such other purposes as the Secretary determines to be necessary and appropriate by regulation. Section 13405(d)(4) of the Act provides that the prohibition on sale of protected health information shall apply to disclosures occurring 6 months after the date of the promulgation of final regulations implementing this section.

To implement section 13405(d) of the HITECH Act, we propose to add new provisions at § 164.508(a)(4) regarding the sale of protected health information. In proposed § 164.508(a)(4)(i), we propose to require a covered entity to obtain an authorization for any disclosure of protected health information in exchange for direct or indirect remuneration. This authorization must state that the disclosure will result in remuneration to the covered entity. In proposed § 164.508(a)(4)(ii), we propose to except several disclosures of protected health information, made in exchange for remuneration, from this authorization requirement. These exceptions, as discussed more fully below, generally follow the statutory exceptions described in the above paragraph.

The proposed language in § 164.508(a)(4)(i) generally follows the statutory language of section 13405(d)(1) in prohibiting the disclosure of protected health information without an authorization if the covered entity receives direct or indirect remuneration from or on behalf of the recipient of the protected health information. As required by the Act, this proposed provision would apply to business associates as well as to covered entities.

We do not include language in proposed § 164.508(a)(4) to require that the authorization under § 164.508 specify whether the protected health information disclosed by the covered entity for remuneration can be further exchanged for remuneration by the entity receiving the information. We believe the intent of this statutory language was to ensure that, as currently required by § 164.508 for marketing, the authorization include a statement as to whether remuneration will be received by the covered entity with respect to the disclosures subject to the authorization. Otherwise, the individual would not be put on notice that the disclosure involves remuneration and thus, would not be making an informed decision as to whether to sign the authorization. Accordingly, we propose to require that the § 164.508(a)(4)(i) authorization include a statement that the covered entity is receiving direct or indirect remuneration in exchange for the protected health information. This requirement would ensure that individuals can make informed decisions regarding whether to authorize disclosure of their protected health information when the disclosure

will result in remuneration to the covered entity. We also note, with respect to the recipient of the information, if protected health information is disclosed for remuneration by a covered entity or business associate to another covered entity or business associate in compliance with the authorization requirements at proposed § 164.508(a)(4)(i), the recipient covered entity or business associate could not redisclose that protected health information in exchange for remuneration unless a valid authorization is obtained in accordance with proposed § 164.508(a)(4)(i) with respect to such redisclosure. We request comment on these provisions.

In proposed § 164.508(a)(4)(ii), we set forth the exceptions to the authorization requirement of proposed paragraph (a)(4)(i). We propose the exceptions provided for by section 13405(d)(2) of the HITECH Act, but we also propose to exercise the authority granted to the Secretary in section 13405(d)(2)(G) to include an additional exception that we deem to be similarly necessary and appropriate. We invite public comment on the proposed exceptions to this authorization requirement and whether there are additional exceptions that should be included in the final regulation.

The exception at proposed § 164.508(a)(4)(ii)(A) covers exchanges for remuneration for public health activities pursuant to §§ 164.512(b) or 164.514(e). This exception largely tracks the statutory language; however, we have added a reference to § 164.514(e), to ensure that a covered entity or business associate that discloses protected health information for public health activities in limited data set form is also excepted from the authorization requirement. We believe it is consistent with the statutory language to also except the disclosure of a limited data set where Congress has already excepted the disclosure of fully identifiable protected health information for the same purpose from the remuneration prohibition. With respect to the exception for public health disclosures, section 13405(d)(3)(A) of the HITECH Act requires that the Secretary evaluate the impact of restricting this exception to require that the price charged for the data reflects only the costs of preparation and transmittal of the data on research or public health activities, including those conducted by or for the use of the Food and Drug Administration (FDA). Section 13405(d)(3)(B) further provides that if the Secretary finds that such further restriction will not impede such activities, the Secretary may include the restriction in the regulations. While we do not propose to include such a restriction on the remuneration that may be received for disclosures for public health purposes at this time, we request public comment on this issue to assist us in evaluating the impact of any such restriction.

The proposed exception at § 164.508(a)(4)(ii)(B) generally tracks the statutory language and excepts from the authorization requirement disclosures of protected health information for research purposes, pursuant to §§ 164.512(i) or 164.514(e), in which the covered entity receives remuneration, as long as the remuneration received by the covered entity is a reasonable, cost-based fee to cover the cost to prepare and transmit the information for research purposes. We request public comment on the types of costs that should be permitted under this provision. As discussed above with respect to the exception for public health activities, we also propose to add a reference to § 164.514(e) to ensure that this exception likewise applies to the disclosure of protected health information in limited data set form for research purposes.

Proposed § 164.508(a)(4)(ii)(C) would create an exception from the authorization requirement for disclosures of protected health information for treatment and payment purposes, in which the covered entity receives remuneration. Though the Act only addressed treatment, we have expressly included disclosures for payment purposes and have also included reference to § 164.506(a), which sets forth the standard for disclosures of protected health information for treatment and payment purposes. We also propose to except disclosures made for payment for health care from the remuneration limitation to make clear that we do not consider the exchange of protected health information to obtain "payment," as such term is defined in the Privacy Rule at § 164.501, to be a sale of protected health information and thus, subject to the authorization requirements in this section.

Section 13405(d)(2)(D) of the HITECH Act excepts from the authorization requirement disclosures described in paragraph (6)(iv) of the definition of health care operations at § 164.501, *i.e.,* disclosures for the sale, transfer, merger, or consolidation of all or part of a covered entity with another covered entity, or an entity that following such activity will become a covered entity, and due diligence related to such activity. Proposed § 164.508(a)(4)(ii)(D) would accordingly except from the authorization requirement disclosures of protected health information for the events described in paragraph (6)(iv). We also add a reference to § 164.506(a), the provision which permits a covered entity to disclose protected health information for health care operations purposes.

Proposed § 164.508(a)(4)(ii)(E) would except from the authorization requirements disclosures of protected health information to or by a business associate for activities that the business associate undertakes on behalf of a covered entity pursuant to §§ 164.502(e) and 164.504(e), as long as the only remuneration provided is by the covered entity to the business associate for the performance of such activities. We have modified the statutory language to provide specific references to the provisions of the Privacy Rule that set forth the standards through which covered entities may make disclosures of protected health information to business associates and the standards for business associate contracts which govern the relationship between covered entities and their business associates. This proposed exception would exempt from the authorization requirement in § 164.508(a)(4)(i) a disclosure of protected health information by a covered entity to a business associate or by a business associate to a third party on behalf of the covered entity as long as any remuneration received by the business associate was for payment for the activities performed by the business associate pursuant to a business associate contract.

Proposed § 164.508(a)(4)(ii)(F) would except from the authorization requirement disclosures of protected health information by a covered entity to an individual when requested under §§ 164.524 or 164.528. While section 13405(d)(2)(F) explicitly refers only to disclosures under § 164.524, we are exercising our authority under section 13405(d)(2)(G) of the HITECH Act (discussed below) to include in this proposed section disclosures under § 164.528 as necessary and appropriate. Section 164.502(a)(2)(i) requires covered entities to disclose protected health information relating to an individual to that individual upon request pursuant to §§ 164.524 or 164.528. Section 164.524 permits a covered entity to impose a reasonable, cost-based fee for the provision of access to an individual's protected health information, upon request. Section 164.528 requires a covered entity to provide a requesting individual with an accounting of disclosures without

charge in any 12-month period but permits a covered entity to impose a reasonable, cost-based fee for each subsequent request for an accounting of disclosures during that 12-month period. Therefore, as a disclosure of protected health information under § 164.528 is similar to a disclosure under § 164.524 in that a covered entity may be paid a fee for making the disclosure, we have included disclosures pursuant to requests for accountings of disclosures in this exception. We note that this exception would not permit a covered entity to require that an individual pay a fee that is not otherwise permitted by §§ 164.524 or 164.528.

We propose an additional exception at § 164.508(a)(4)(ii)(G), pursuant to the authority granted to the Secretary in section 13405(d)(2)(G) of the HITECH Act to except from the authorization requirements at proposed § 164.508(a)(4)(i) disclosures that are required by law as permitted under § 164.512(a). Section 164.512(a) permits covered entities to use or disclose protected health information to the extent that such use or disclosure is required by law. We propose to add this exception to ensure that a covered entity can continue to disclose protected health information, where required by law, even if the covered entity receives remuneration for the disclosure. We request comment on the inclusion of such an exception.

Finally, we propose an additional exception at § 164.508(a)(4)(ii)(H), pursuant to the authority granted to the Secretary in section 13405(d)(2)(G), to except from the authorization requirements at proposed § 164.508(a)(4)(i) a disclosure of protected health information for any other purpose permitted by and in accordance with the applicable requirements of subpart E, as long as the only remuneration received by the covered entity is a reasonable, cost-based fee to cover the cost to prepare and transmit the protected health information for such purpose or is a fee otherwise expressly permitted by other law. We have included this proposed exception as necessary and appropriate to ensure that the proposed authorization requirement does not deter covered entities from disclosing protected health information for permissible purposes under subpart E just because they routinely receive payment equal to the cost of preparing, producing, or transmitting the protected health information. We emphasize that this exception would not apply if a covered entity received remuneration above the actual cost incurred to prepare, produce, or transmit the protected health information for the permitted purpose, unless such fee is expressly permitted by other law.

We recognize that many States have laws in place to limit the fees a health care provider can charge to prepare, copy, and transmit medical records. Some States simply require any reasonable costs incurred by the provider in making copies of the medical records to be paid for by the requesting party, while other States set forth specific cost limitations with respect to retrieval, labor, supplies, and copying costs and allow charges equal to actual mailing or shipping costs. Many of these State laws set different cost limitations based on the amount and type of information to be provided, taking into account whether the information is in paper or electronic form as well as whether the requested material includes x-rays, films, disks, tapes, or other diagnostic imaging. We intend that the reference in proposed § 164.508(a)(4)(ii)(H) to fees expressly permitted by other laws to include fees permitted by such State laws. Therefore, if a covered entity discloses protected health information in exchange for remuneration that conforms to an applicable State law with respect to such fees, the exception would apply and no authorization pursuant to § 164.508(a)(4)(i) would be required. We do note, however, that of the States that do have such laws in place, there is great variation regarding the types of document preparation activities for which a provider can charge as well as the permissible fee schedules for such preparation activities. We invite public comment on our proposal to include in § 164.508(a)(4)(ii)(H) a general exception for disclosures made for permissible purposes for which the covered entity received remuneration that was consistent with applicable State law.

We propose a conforming change to § 164.508(b)(1)(i) to include a reference to the authorization requirement in proposed § 164.508(a)(4)(i).

2. Research

a. Compound Authorizations

Section 164.508(b)(4) of the Privacy Rule prohibits covered entities from conditioning treatment, payment, enrollment in a health plan, or eligibility for benefits on the provision of an authorization. This limitation is intended to prevent covered entities from coercing individuals into signing an authorization for a use or disclosure that is not necessary to carry out the services that the covered entity provides to the individual. However, this section permits a covered entity to condition the provision of research-related treatment on obtaining the individual's authorization in limited situations, such as for a clinical trial. Permitting the use of protected health information is part of the decision to receive care through a clinical trial, and health care providers conducting such trials are able to condition research-related treatment on the individual's willingness to authorize the use or disclosure of protected health information for research associated with the trial.

Section 164.508(b)(3) generally prohibits what are termed "compound authorizations," *i.e.,* where an authorization for the use and disclosure of protected health information is combined with any other legal permission. However, § 164.508(b)(3)(i) carves out an exception to this general prohibition, permitting the combining of an authorization for a research study with any other written permission for the same study, including another authorization or consent to participate in the research. Nonetheless, § 164.508(b)(3)(iii) prohibits combining an authorization that conditions treatment, payment, enrollment in a health plan, or eligibility for benefits with an authorization for another purpose for which treatment, payment, enrollment, or eligibility may not be conditioned. This limitation on certain compound authorizations was intended to help ensure that individuals understand that they may decline the activity described in the unconditioned authorization yet still receive treatment or other benefits or services by agreeing to the conditioned authorization.

The impact of these authorization requirements and limitations can be seen during clinical trials that are associated with a corollary research activity, such as when protected health information is used or disclosed to create or to contribute to a central research database or repository. For example, § 164.508(b)(3)(iii) prevents covered entities from obtaining a single authorization for the use or disclosure of protected health information for a research study that includes both treatment as part of a clinical trial and tissue banking of specimens (and associated protected health information) collected, since a research-related treatment authorization generally is conditioned and a tissue banking authorization generally is not conditioned. Various groups, including researchers and professional organizations, have expressed concern at this lack of integration. The Secretary's Advisory Committee for Human Research Protections in 2004

(Recommendation V, in a letter to the Secretary of HHS, available at *http://www.hhs.gov/ohrp/sachrp/hipaalettertosecy090104.html*), as well as the Institute of Medicine (IOM) in its 2009 Report, "Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research" (Recommendation II.B.2), also made specific recommendations to allow combined authorizations for clinical trials and biospecimen storage. Research-related treatment offered through a clinical trial is nearly always conditioned upon signing the informed consent to participate in the trial and the authorization to use or disclose the individual's protected health information for the trial. Thus, covered entities must obtain separate authorizations from research participants for a clinical trial that also collects specimens with associated protected health information for a central repository. For clinical research trials that may have thousands of participants, documenting and storing twice as many authorizations is a major concern. There is also a concern that multiple forms may be confusing for research subjects. The Department has received reports that recruitment into clinical trials has been hampered, in part, because the multiplicity of forms for research studies dissuades individuals from participating in research. We have also heard that redundant information provided by two authorization forms (one for the clinical study and another for related research) diverts an individual's attention from other content that describes how and why the personal health information may be used.

While seeking Institutional Review Board (IRB) or Privacy Board waiver of the authorization requirement is an option under § 164.512 of the Privacy Rule, an IRB or Privacy Board is less likely to approve a request for a waiver of authorization for a foreseeable use or disclosure of protected health information to create and maintain or contribute to a central tissue or information repository if the covered entity is planning to seek informed consent from the individual for this purpose. Accordingly, the waiver provisions generally do not resolve concerns expressed by the research community.

We agree that allowing a covered provider to combine research authorizations would streamline the process for obtaining an individual's authorization for research and would make the documentation responsibilities of these covered entities more manageable. Such a modification would also result in an authorization that would be simpler and, therefore, more meaningful to the individual (in contrast to the individual receiving multiple forms that may be confusing). We, therefore, propose to amend § 164.508(b)(3)(i) and (iii) to allow a covered entity to combine conditioned and unconditioned authorizations for research, provided that the authorization clearly differentiates between the conditioned and unconditioned research components and clearly allows the individual the option to opt in to the unconditioned research activities. These provisions would allow covered entities to combine authorizations for scenarios that often occur in research studies. For example, a covered entity would be able to combine an authorization permitting the use and disclosure of protected health information associated with a specimen collection for a central repository and authorization permitting use and disclosure of protected health information for clinical research that conditions research-related treatment on the execution of a HIPAA authorization.

While the proposed modifications do not alter the core elements or required statements integral to a valid authorization, covered entities would have some flexibility with respect to how they met the authorization requirements. For example, covered entities could facilitate an individual's understanding of a compound authorization by describing the unconditioned research activity on a separate page of a compound authorization. They could also cross-reference relevant sections of a compound authorization to minimize the potential for redundant language. In addition, a covered entity could use a separate check-box for the unconditioned research activity to signify whether an individual has opted-in to the unconditioned research activity, while maintaining one signature line for the authorization. Alternatively, a covered entity could choose to provide a distinct signature line for the unconditioned authorization to signal that the individual is authorizing optional research that will not affect research-related treatment. We request comment on additional methods that would clearly differentiate to the individual the conditioned and unconditioned research activities on the compound authorization.

b. Authorizing Future Research Use or Disclosure

Research often involves obtaining health information and biological specimens to create a research database or repository for future research. For example, this frequently occurs where clinical trials are paired with corollary research activities, such as the creation of a research database or repository where information and specimens obtained from a research participant during the trial are transferred and maintained for future research. It also is our understanding that IRBs in some cases may approve an informed consent document for a clinical trial that also asks research participants to permit future research on their identifiable information or specimens obtained during the course of the trial, or may review an informed consent for a prior clinical trial to determine whether a subsequent research use is encompassed within the original consent.

The Department has interpreted the Privacy Rule, however, to require that authorizations for research be study specific for purposes of complying with the Rule's requirement at § 164.508(c)(1)(iv) that an authorization must include a description of each purpose of the requested use or disclosure. *See* 67 FR 53182, 53226, Aug. 14, 2002. In part, the Department's interpretation was based on a concern that patients could lack necessary information in the authorization to make an informed decision about the future research, due to a lack of information about the future research at the time the authorization was obtained. In addition, it was recognized that not all uses and disclosures of protected health information for a future research purpose would require a covered entity to re-contact the individual to obtain another authorization, to the extent other conditions in the Privacy Rule were met. For example, a covered entity could obtain a waiver of authorization from an IRB or Privacy Board as provided under § 164.512(i) or use or disclose only a limited data set pursuant to a data use agreement under § 164.514(e) for the future research purpose.

Subsequent to its issuing this interpretation, the Department has heard concerns from covered entities and researchers that the Department's interpretation encumbers secondary research, and limits an individual's ability to agree to the use or disclosure of their protected health information for future research without having to be re-contacted to sign multiple authorization forms at different points in the future. In addition, many commenters noted that the Department's interpretation limiting the scope of a HIPAA authorization for research appeared to diverge from the current practice under the Common Rule with respect to the

ability of a researcher to seek subjects' consent to future research so long as the future research uses are described in sufficient detail to allow an informed consent. These commenters, as well as the Secretary's Advisory Committee for Human Research Protections in 2004 (Recommendation IV, in a letter to the Secretary of HHS, available at *http://www.hhs.gov/ohrp/sachrp/hipaalettertosecy090104.html*) and the IOM in its 2009 Report entitled "Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research" (Recommendation II.B.1), have urged the Department to allow the HIPAA authorization to permit future research use and disclosure of protected health information or, at a minimum, for the Department to modify its interpretation to allow the authorization to encompass certain future use and disclosure of protected health information for research, provided certain parameters are met.

Given these concerns, in addition to the modifications mentioned in the prior section, the Department is considering whether to modify its interpretation that an authorization for the use or disclosure of protected health information for research be research-study specific. In particular, the Department is considering a number of options and issues in this area, including whether: (1) The Privacy Rule should permit an authorization for uses and disclosures of protected health information for future research purposes to the extent such purposes are adequately described in the authorization such that it would be reasonable for the individual to expect that his or her protected health information could be used or disclosed for such future research; (2) the Privacy Rule should permit an authorization for future research only to the extent the description of the future research included certain elements or statements specified by the Privacy Rule, and if so, what should those be; and (3) the Privacy Rule should permit option (1) as a general rule but require certain disclosure statements on the authorization in cases where the future research may encompass certain types of sensitive research activities, such as research involving genetic analyses or mental health research, that may alter an individual's willingness to participate in the research. We request comment on each of these options, including their impact on the conduct of research and patient understanding of authorizations.

We note that any modification in this area would not alter an individual's right to revoke the authorization for the use or disclosure of protected health information for future research at any time and that the authorization would have to include a description of how the individual may do so. We request comment on how a revocation would operate with respect to future downstream research studies.

The Department does not propose any specific modifications to the Privacy Rule at this time but requests public comment on the options identified above, as well as any others, for purposes of addressing this issue at the time the final rule is issued, if appropriate. In addition, any change in interpretation will be closely coordinated with the HHS Office for Human Research Protections (OHRP) and the FDA to ensure the Privacy Rule policies are appropriately harmonized with those under the HHS human subjects protections regulations (45 CFR part 46) and FDA human subjects protections regulations governing informed consent for research (21 CFR part 50).

E. Protected Health Information About Decedents

1. Section 164.502(f)—Period of Protection for Decedent Information

Section 164.502(f) requires covered entities to protect the privacy of a decedent's protected health information generally in the same manner and to the same extent that is required for the protected health information of living individuals. Thus, if an authorization is required for the use or disclosure of protected health information, a covered entity may use or disclose a decedent's protected health information in that situation only if the covered entity obtains an authorization from the decedent's personal representative. The personal representative for a decedent is the executor, administrator, or other person who has authority under applicable law to act on behalf of the decedent or the decedent's estate. The Department has heard a number of concerns since the publication of the Privacy Rule that it can be difficult to locate a personal representative to authorize the use or disclosure of the decedent's protected health information, particularly after an estate is closed. Furthermore, archivists, biographers and historians have expressed frustration regarding the lack of access to ancient or old records of historical value held by covered entities, even when there are likely few remaining individuals concerned with the privacy of such information. Archives and libraries may hold medical records that are centuries old. Furthermore, fragments of health information may be found throughout all types of archival holdings, such as correspondence files, diaries, and photograph collections, that are also in some cases centuries old. Currently, to the extent such information is maintained by a covered entity, it is subject to the Privacy Rule. For example, currently the Privacy Rule would apply in the same manner to the casebook of a 19th century physician as it would to the medical records of current patients of a physician.

Accordingly, we propose to amend § 164.502(f) to require a covered entity to comply with the requirements of the Privacy Rule with regard to the protected health information of a deceased individual for a period of 50 years following the date of death. We also propose to modify the definition of "protected health information" at § 160.103 to make clear that the individually identifiable health information of a person who has been deceased for more than 50 years is not protected health information under the Privacy Rule. We believe that fifty years is an appropriate time span, because by approximately covering the span of two generations we believe it will both protect the privacy interests of most, if not all, living relatives, or other affected individuals, and it reflects the difficulty of obtaining authorizations from personal representatives as time passes. A fifty-year period of protection also was suggested at a prior National Committee for Vital and Health Statistics (NCVHS) (the public advisory committee which advises the Secretary on the implementation of the Administrative Simplification provisions of HIPAA, among other issues) meeting, at which committee members heard testimony from archivists regarding the problems associated with applying the Privacy Rule to very old records. *See http://ncvhs.hhs.gov/050111mn.htm.* We request public comment on the appropriateness of this time period.

We note that these proposed modifications would have no impact on a covered entity's permitted disclosures related to decedents for law enforcement purposes (§ 164.512(f)(4)), to coroners or medical examiners and funeral directors (§ 164.512(g)), for research that is solely on the protected health information of decedents (§ 164.512(i)(1)(iii)), and for organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, or tissue for the purpose of facilitating organ, eye or tissue donation and transplantation (§ 164.512(h)).

These disclosures are governed by other provisions of the Privacy Rule.

2. Section 164.510(b)—Disclosures About a Decedent to Family Members and Others Involved in Care

Section 164.510(b) describes how a covered entity may use or disclose protected health information to persons, such as family members or others, who are involved in an individual's care or payment related to the individual's health care. We have received a number of questions about the scope of the section, specifically with regard to the protected health information of decedents. We have heard concerns that family members, relatives, and others, many of whom may have had access to the health information of the deceased individual prior to death, have had difficulty obtaining access to such information after the death of the individual, because many do not qualify as a "personal representative" under § 164.502(g)(4).

As such, we propose to amend § 164.510(b) to add a new paragraph (5), which would permit covered entities to disclose a decedent's information to family members and others who were involved in the care or payment for care of the decedent prior to death, unless doing so is inconsistent with any prior expressed preference of the individual that is known to the covered entity. We propose to add conforming cross-references to paragraphs (b)(1)(i) and (ii) and (b)(4). We note that this disclosure would be permitted, but would not be required. We request comment on any unintended consequences that this permissive disclosure provision might cause.

We also note that these modifications do not change the authority of a decedent's personal representative with regard to the decedent's protected health information. Thus, a personal representative may continue to request access to or an accounting of a decedent's protected health information, and may continue to authorize uses and disclosures of the decedent's protected health information that are not otherwise permitted or required by the Privacy Rule.

F. Section 164.512(b)—Disclosure of Student Immunizations to Schools

The Privacy Rule, in § 164.512(b), recognizes that covered entities must balance protecting the privacy of health information with sharing health information with those responsible for ensuring public health and safety, and permits covered entities to disclose the minimum necessary protected health information to public health authorities or other designated persons or entities without an authorization for public health purposes specified by the Rule. Covered entities may disclose protected health information: (1) To a public health authority that is legally authorized to collect or receive the information for the purpose of preventing or controlling disease, injury, or disability (such as reporting communicable diseases, births, and deaths, or conducting public health interventions, investigations, and surveillance); (2) to a public health authority or other appropriate government authority to report child abuse if the authority is legally authorized to receive such reports; (3) to a person or entity subject to the jurisdiction of the FDA about the quality, safety, or effectiveness of an FDA-regulated product or activity for which the person or entity has responsibility (such as reporting adverse drug events to the drug manufacturer); (4) to notify a person that (s)he is at risk of contracting or spreading a disease or condition, as authorized by law, to carry out a public health intervention or investigation; and (5) to an employer under limited circumstances and conditions when the employer needs the information to comply with Occupational Safety and Health Administration (OSHA) or Mine Safety and Health Administration (MSHA) requirements. Any other disclosures that do not conform to these provisions, and that are not otherwise permitted by the Rule, require the individual's prior written authorization.

Schools play an important role in preventing the spread of communicable diseases among students by ensuring that students entering classes have been immunized. Most States have "school entry laws" which prohibit a child from attending school unless the school has proof that the child has been appropriately immunized. Typically, schools ensure compliance with those requirements by requesting the immunization records from parents (rather than directly from a health care provider), particularly because the Privacy Rule generally requires written authorization by the child's parent before a covered health care provider may disclose protected health information directly to the school. Some States allow a child to enter school provisionally for a period of 30 days while the school waits for the necessary immunization information.

We have heard concerns that the Privacy Rule may make it more difficult for parents to provide, and for schools to obtain, the necessary immunization documentation for students, which may prevent students' admittance to school. The NCVHS submitted these concerns to the HHS Secretary and recommended that HHS regard disclosure of immunization records to schools to be a public health disclosure. *See http://www.ncvhs.hhs.gov/040617l2.htm.*

As such, we propose to amend § 164.512(b)(1) by adding a new paragraph that permits covered entities to disclose proof of immunization to schools in States that have school entry or similar laws. While written authorization that complies with § 164.508 would no longer be required for disclosure of such information, the covered entity would still be required to obtain agreement, which may be oral, from a parent, guardian or other person acting *in loco parentis* for the individual, or from the individual him- or herself, if the individual is an adult or emancipated minor. Because the proposed provision would permit a provider to accept a parent's oral agreement to disclose immunization results to a school—as opposed to a written agreement—there is a potential for a miscommunication and later objection by the parent. We, therefore, request comment on whether the Privacy Rule should require that a provider document any oral agreement under this provision to help avoid such problems, or whether a requirement for written documentation would be overly cumbersome, on balance. We also request comment on whether the rule should mandate that the disclosures go to a particular school official and if so, who that should be.

In addition, the Privacy Rule does not currently define the term "school" and we understand that the types of schools subject to the school entry laws may vary by State. For example, depending on the State, such laws may apply to public and private elementary or primary schools and secondary schools (kindergarten through 12th grade), as well as daycare and preschool facilities, and post-secondary institutions. Thus, we request comment on the scope of the term "school" for the purposes of this section and whether we should include a specific definition of "school" within the regulation itself. In addition, we request comment on the extent to which schools that may not be subject to these school entry laws but that may also require proof of immunization have experienced problems that would warrant their being included in this category of public health disclosures.

Finally, we note that once a student's immunization records are obtained and maintained by an educational institution or agency to which the Family Educational Rights and Privacy

Act (FERPA) applies, the records are protected by FERPA, rather than the HIPAA Privacy Rule. *See* paragraphs (2)(i) and (2)(ii) of the definition of "protected health information" at § 160.103, which exclude from coverage under the Privacy Rule student records protected by FERPA. In addition, for more information on the intersection of FERPA and HIPAA, readers are encouraged to consult the Joint HHS/ED Guidance on the Application of FERPA and HIPAA to Student Health Records, available at *http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/hipaaferpajointguide.pdf.*

G. Section 164.514(d)—Minimum Necessary

Section 164.502(b)(1) of the Privacy Rule requires covered entities to limit uses and disclosures of, and requests for, protected health information to "the minimum necessary to accomplish the intended purpose of the use, disclosure, or request." Section 164.502(b)(2) outlines situations in which the minimum necessary rule does not apply. With respect to uses of protected health information, § 164.514(d)(2) requires covered entities to identify workforce members who need access to protected health information, to identify the categories and conditions of such access, and to make reasonable efforts to limit access consistent with such policies. With respect to disclosures of, and requests for, protected health information, § 164.514(d)(3) and (4) require that covered entities adopt policies and procedures addressing minimum necessary, including with regard to uses and disclosures that occur routinely.

Section 13405(b)(1)(A) of the HITECH Act provides that a covered entity shall be treated as being in compliance with the minimum necessary requirements with respect to the use or disclosure of or the request for protected health information "only if the covered entity limits such protected health information, to the extent practicable, to the limited data set (as defined in section 164.514(e)(2) of such title) or, if needed by such entity, to the minimum necessary." Section 13405(b)(1)(B) requires the Secretary to issue guidance on what constitutes "minimum necessary" within 18 months after the date of enactment. This guidance must take into account the guidance required by section 13424(c), relating to the de-identification of protected health information, as well as "the information necessary to improve patient outcomes and to detect, prevent, and manage chronic disease." Section 13405(b)(1)(C) provides that the provisions of paragraph (A) no longer apply as of the effective date of the guidance issued under paragraph (B).

Section 13405(b)(2) provides that, with respect to disclosures of protected health information, the covered entity or business associate making the disclosure shall determine what constitutes the minimum necessary. Section 13405(b)(3) provides that section 13405(b)(1) does not affect the application of the exceptions to the minimum necessary requirement, while section 13405(b)(4) provides that nothing in subsection (b) is to be construed as affecting the use or disclosure of or request for de-identified health information.

Section 13405(b)(1)(A) requires that covered entities consider the feasibility of utilizing the limited data set in complying with the minimum necessary requirements of the Privacy Rule. However, that provision also permits a covered entity to employ its traditional minimum necessary policies and procedures if it decides that the limited data set will not meet the needs of the particular use, disclosure, or request in question. The requirement of this section, moreover, is an interim one; under section 13405(b)(1)(C), issuance of the guidance required by section 13405(b)(1)(B) effectively sunsets the requirement of section 13405(b)(1)(A).

For purposes of the required guidance, we take this opportunity to solicit public comment on what aspects of the minimum necessary standard covered entities and business associates believe would be most helpful to have the Department address in the guidance and the types of questions entities may have about how to appropriately determine the minimum necessary for purposes of complying with the Privacy Rule. We propose to leave the current regulatory text unchanged in this rulemaking as the issuance of the required guidance will obviate the need to make any regulatory modifications in this area.

H. Section 164.514(f)—Fundraising

Section 164.514(f)(1) of the Privacy Rule permits a covered entity to use, or disclose to a business associate or an institutionally related foundation, the following protected health information for its own fundraising purposes without an individual's authorization: (1) Demographic information relating to an individual; and (2) the dates of health care provided to an individual. Section 164.514(f)(2) of the Privacy Rule requires a covered entity that plans to use or disclose protected health information for fundraising under this paragraph to inform individuals in its notice of privacy practices that it may contact them to raise funds for the covered entity. In addition, § 164.514(f)(2) requires that a covered entity include in any fundraising materials it sends to an individual a description of how the individual may opt out of receiving future fundraising communications and that a covered entity must make reasonable efforts to ensure that individuals who do opt out are not sent future fundraising communications.

Section 13406(b) of the HITECH Act, which became effective on February 18, 2010, requires the Secretary to provide by rule that a covered entity provide the recipient of any fundraising communication with a clear and conspicuous opportunity to opt out of receiving any further fundraising communications. Additionally, section 13406(b) states that if an individual does opt out of receiving further fundraising communications, the individual's choice to opt out must be treated as a revocation of authorization under § 164.508 of the Privacy Rule.

We propose a number of changes to the Privacy Rule's fundraising requirements to implement these statutory provisions. First, we propose to strengthen the opt out by requiring that a covered entity provide, with each fundraising communication sent to an individual under these provisions, a clear and conspicuous opportunity for the individual to elect not to receive further fundraising communications. To satisfy this requirement, we also propose to require that the method for an individual to elect not to receive further fundraising communications may not cause the individual to incur an undue burden or more than nominal cost. We encourage covered entities to consider the use of a toll-free phone number, an e-mail address, or similar opt out mechanism that would provide individuals with a simple, quick, and inexpensive way to opt out of receiving future communications. We note that we would consider requiring individuals to write and send a letter to the covered entity asking not to receive future fundraising communications to constitute an undue burden on the individual for purposes of this proposed requirement.

We also propose to provide that a covered entity may not condition treatment or payment on an individual's choice with respect to receiving fundraising communications. We believe this modification would implement the language in section 13406(b) of the HITECH Act that provides that an election by an

individual not to receive further fundraising communications shall be treated as a revocation of authorization under the Privacy Rule. The legislative history of the HITECH Act indicates that it was Congress' intent with this language that the protections that apply under § 164.508 to an individual who has revoked an authorization similarly apply to an individual who has opted out of fundraising communications, "including the right not to be denied treatment as a result of making that choice." *See* H.R. Conf. Rep. 111–16, p. 498. Therefore, we make clear in this proposed rule that a covered entity would not be permitted to condition treatment or payment for care on an individual's choice of whether to receive fundraising communications.

Further, we propose to provide that a covered entity may not send fundraising communications to an individual who has elected not to receive such communications. This proposed language would strengthen the current requirement at § 164.514(f)(2)(iii) that a covered entity make "reasonable efforts" to ensure that those individuals who have opted out of receiving fundraising communications are not sent such communications. We have proposed stronger language to make clear the expectation that covered entities abide by an individual's decision not to receive fundraising communications, as well as to make the fundraising opt out operate more like a revocation of authorization, consistent with the statutory language and legislative history of section 13406(b) of the HITECH Act discussed above.

With respect to the operation of the opt out, we request comment regarding to what fundraising communications the opt out should apply. For example, if an individual receives a fundraising letter and opts out of receiving future fundraising communications, should the opt out apply to all future fundraising communications or should and can the opt out be structured in a way to only apply to the particular fundraising campaign described in the letter? In addition, given that we would require the opt out method to be simple and quick for the individual to exercise, such as the use of a phone number or e-mail address, we request comment on whether the Rule should allow a similar method, short of the individual signing an authorization, by which an individual who has previously opted out can put his or her name back on an institution's fundraising list.

We propose to retain the requirement that a covered entity that intends to contact the individual to raise funds under these provisions must include a statement to that effect in its notice of privacy practices. However, we do propose to modify the required statement slightly, as indicated below in the discussion of the notice requirements at § 164.520, by requiring that the notice also inform individuals that they have a right to opt out of receiving such communications. We also propose to move all of the fundraising requirements described above to § 164.514(f)(1), given that the proposed provisions for subsidized treatment communications discussed above now would be located at § 164.514(f)(2).

In addition to the above modifications proposed in response to the HITECH Act, we also solicit public comment on the requirement at § 164.514(f)(1) which limits the information a covered entity may use or disclose for fundraising demographic information about and dates of health care service provided to an individual. Since the promulgation of the Privacy Rule, certain covered entities have raised concerns regarding this limitation, maintaining that the Privacy Rule's prohibition on the use or disclosure of certain treatment information without an authorization, such as the department of service where care was received and outcomes information, harms their ability to raise funds from often willing and grateful patients. In particular, covered entities have argued that the restrictions in the Privacy Rule prevent them from targeting their fundraising efforts and avoiding inappropriate solicitations to individuals who may have had a bad treatment outcome, and obtaining an individual's authorization for fundraising as the individual enters or leaves the hospital for treatment is often impracticable or inappropriate. NCVHS also held a hearing and heard public testimony on this issue in July 2004. After considering the testimony provided, the NCVHS recommended to the Secretary that the Privacy Rule should allow covered entities to use or disclose information related to the patient's department of service (broad designations, such as surgery or oncology, but not narrower designations or information relating to diagnosis or treating physician) for fundraising activities without patient authorization. NCVHS also recommended that a covered entity's notice of privacy practices inform patients that their department of service information may be used in fundraising, and that patients should be afforded the opportunity to opt out of the use of their department of service information for fundraising or all fundraising contacts altogether. *See http://www.ncvhs.hhs.gov/040902lt1.htm.*

In light of these concerns and the prior recommendation of the NCVHS, the Department takes this opportunity to solicit public comment on whether and how the current restriction on what information may be used and disclosed should be modified to allow covered entities to more effectively target fundraising and avoid inappropriate solicitations to individuals, as well as to reduce the need to send solicitations to all patients. In particular, we solicit comment on: (1) Whether the Privacy Rule should allow additional categories of protected health information to be used or disclosed for fundraising, such as department of service or similar information, and if so, what those categories should be; (2) the adequacy of the minimum necessary standard to appropriately limit the amount of protected health information that may be used or disclosed for fundraising purposes; or (3) whether the current limitation should remain unchanged. We also solicit comment on whether, if additional information is permitted to be used or disclosed for fundraising absent an authorization, covered entities should be required to provide individuals with an opportunity to opt out of receiving any fundraising communications before making the first fundraising solicitation, in addition to the opportunity to opt out with every subsequent communication. We invite public comment on whether such a pre-solicitation opt out would be workable for covered entities and individuals and what mechanisms could be put into place to implement the requirement.

I. Section 164.520—Notice of Privacy Practices for Protected Health Information

Section 164.520 of the Privacy Rule sets out the requirements for most covered entities to have and to distribute a notice of privacy practices (NPP). The NPP must describe the uses and disclosures of protected health information a covered entity is permitted to make, the covered entity's legal duties and privacy practices with respect to protect protected health information, and the individual's rights concerning protected health information.

With regard to the description of permitted uses and disclosures, § 164.520(b)(1)(ii) requires a covered entity to include separate statements about the uses and disclosures that the covered entity intends to make for certain treatment, payment, or health care operations activities. Further, § 164.520(b)(1)(ii)(E) currently requires

that the NPP contain a statement that any uses and disclosures other than those permitted by the Privacy Rule will be made only with the written authorization of the individual, and that the individual has the right to revoke an authorization pursuant to § 164.508(b)(5). The purpose of this statement is to put individuals on notice that covered entities may make certain uses and disclosures only with an authorization from the individual.

Section 164.520(b)(1)(iv) requires that the NPP contain statements regarding the rights of individuals with respect to their protected health information and a brief description of how individuals may exercise such rights. Section 164.520(b)(1)(iv)(A) currently requires a statement and a brief description addressing an individual's right to request restrictions on the uses and disclosures of protected health information pursuant to § 164.522(a), including the fact that the covered entity is not required to agree to this request.

We propose to amend § 164.520(b)(1)(ii)(E) to require that the NPP include a statement that describes the uses and disclosures of protected health information that require an authorization under § 164.508(a)(2) through (a)(4), and to provide that other uses and disclosures not described in the notice will be made only with the individual's authorization. The proposed provision would ensure that covered entities provide notice to individuals indicating that most disclosures of protected health information for which the covered entity receives remuneration would require the authorization of the individual. Such uses and disclosures may have previously been permitted under other provisions of the Rule but now require authorization, as discussed in connection with proposed § 164.508(a)(4).

We propose to require, in addition, that covered entities provide notice that most uses and disclosures of psychotherapy notes and for marketing purposes require an authorization so that individuals will be made aware of all situations in which authorization is required. We are concerned that omission of such a specific statement may be somewhat misleading or confusing, in that the NPP would state that the covered entity may use or disclose protected health information without authorization for purposes of treatment, payment, and health care operations and some individuals might assume that psychotherapy notes and marketing would be covered by these permissions.

Section 164.520(b)(1)(iii) requires a covered entity to include in its NPP separate statements about certain activities if the covered entity intends to engage in any of the activities. In particular, § 164.520(b)(1)(iii) requires a separate statement in the notice if the covered entity intends to contact the individual to provide appointment reminders or information about treatment alternatives or other health-related benefits or services; to contact the individual to fundraise for the covered entity; or, with respect to a group health plan, to disclose protected health information to the plan sponsor.

We propose the following changes to these provisions. First, we propose to modify § 164.520(b)(1)(iii)(A) to align the required statement with the proposed modifications related to marketing and subsidized treatment communications. A covered health care provider that intends to send treatment communications to the individual in accordance with proposed § 164.514(f)(2) concerning treatment alternatives or other health-related products or services where the provider receives financial remuneration in exchange for making the communication would be required to inform the individual in advance in the NPP, as well as inform the individual that he or she has the opportunity to opt out of receiving such communications. Second, at § 164.520(b)(1)(iii)(B) we propose to require that if a covered entity intends to contact the individual to raise funds for the entity as permitted under § 164.514(f)(1), the covered entity must not only inform the individual in the NPP of this intention but also that the individual has the right to opt out of receiving such communications.

We also propose to modify the requirement of § 164.520(b)(1)(iv)(A) which requires covered entities to notify individuals of the individuals' right to request restrictions. This provision currently includes a requirement that the NPP state that the covered entity is not required to agree to such a request. Since this statement will no longer be accurate when the modifications to proposed § 164.522(a)(1)(vi) that are required by the HITECH Act are made (*see* discussion in the following section), proposed § 160.520(b)(1)(iv)(A) would require, in addition, that the statement include an exception for requests under § 164.522(a)(1)(vi).

Under subpart D of part 164, covered entities now have new obligations to comply with the requirements for notification to affected individuals, the media, and the Secretary following a breach of unsecured protected health information. We request comment on whether the Privacy Rule should require a specific statement regarding this new legal duty and what particular aspects of this new duty would be important for individuals to be notified of in the NPP.

The proposed modifications to § 164.520 represent material changes to the NPP of covered entities. Section 164.520(b)(3) requires that when there is a material change to the NPP, covered entities must promptly revise and distribute the NPP as outlined by § 164.520(c). Section 164.520(c)(1)(i)(C) requires that health plans provide notice to individuals covered by the plan within 60 days of any material revision to the NPP. We recognize that revising and redistributing a NPP may be costly for health plans and request comment on ways to inform individuals of this change to privacy practices without unduly burdening health plans. In particular, we are considering a number of options in this area: (1) Replace the 60-day requirement with a requirement for health plans to revise their NPPs and redistribute them (or at least notify members of the material change to the NPP and how to obtain the revised NPP) in their next annual mailing to members after a material revision to the NPP, such as at the beginning of the plan year or during the open enrollment period; (2) provide a specified delay or extension of the 60-day timeframe for health plans; (3) retain the provision generally to require health plans to provide notice within 60-days of a material revision but provide that the Secretary will waive the 60-day timeframe in cases where the timing or substance of modifications to the Privacy Rule call for such a waiver; or (4) make no change, and thus, require that health plans provide notice to individuals within 60 days of the material change to the NPP that would be required by this proposed rule. We request comment on these options, as well as on any other options for informing individuals in a timely manner of this proposed or other material changes to the NPP.

Section 164.520(c)(2)(iv) requires that when a health care provider with a direct treatment relationship with an individual revises the NPP, the health care provider must make the NPP available upon request on or after the effective date of the revision and must comply with the requirements of § 164.520(c)(2)(iii) to have the NPP available at the delivery site and to post the notice in a clear and prominent location. We do not believe these requirements will be overly burdensome on health care providers and do not propose changes to them, but we request comment on this issue.

J. Section 164.522(a)—Right To Request Restriction of Uses and Disclosures

Section 164.522(a) of the Privacy Rule requires covered entities to permit individuals to request that a covered entity restrict uses or disclosures of their protected health information for treatment, payment, and health care operations purposes, as well as for disclosures to family members and certain others permitted under § 164.510(b). While covered entities are not required to agree to such requests for restrictions, if a covered entity does agree to restrict the use or disclosure of an individual's protected health information, the covered entity must abide by that restriction, except in emergency circumstances when the information is required for the treatment of the individual. Section 164.522 also includes provisions for the termination of such a restriction and requires that covered entities that have agreed to a restriction document the restriction in writing.

Section 13405(a) of the HITECH Act, which became effective February 18, 2010, requires that when an individual requests a restriction on disclosure pursuant to § 164.522, the covered entity agree to the requested restriction unless otherwise required by law, if the request for restriction is on disclosures of protected health information to a health plan for the purpose of carrying out payment or health care operations and if the restriction applies to protected health information that pertains solely to a health care item or service for which the health care provider involved has been paid out of pocket in full. This statutory requirement overrides the provision in § 164.522(a)(1)(ii) that the covered entity is not required to agree to requests for restrictions and requires that we modify the regulation.

To implement section 13405(a), we propose to add a new § 164.522(a)(1)(vi) to describe the elements of the required restriction. We also propose to add conforming language to § 164.522(a)(1)(ii) to reflect the mandatory nature of the restriction as required by the statute. Finally, we propose conforming modifications to § 164.522(a)(2) and (3), which address terminating and documentation of restrictions. We discuss these modifications in more detail below.

We propose to add a new paragraph (vi) to § 164.522(a)(1), which would require a covered entity, upon request from an individual, to agree to a restriction on the disclosure of protected health information to a health plan if: (A) the disclosure is for the purposes of carrying out payment or healthcare operations and is not otherwise required by law; and (B) the protected health information pertains solely to a health care item or service for which the individual, or person on behalf of the individual other than the health plan, has paid the covered entity in full. We also propose to modify the language in § 164.522(a)(1)(ii), which states that a covered entity is not required to agree to a restriction, to refer to this exception to that general rule. We note that under the Privacy Rule, a covered entity may make a disclosure to a business associate of another covered entity only where the disclosure would be permitted directly to the other covered entity. Thus, in cases where an individual has exercised his or her right to have a restriction placed under this paragraph on a disclosure to a health plan, the covered entity is also prohibited from making such disclosure to a business associate of the health plan.

Section 13405(a) makes clear that an individual has a right to have disclosures regarding certain health care items or services for which the individual pays out of pocket in full restricted from a health plan. We believe the Act provides the individual with the right to determine for which health care items or services the individual wishes to pay out of pocket and restrict. Thus, we do not believe a covered entity could require individuals who wish to restrict disclosures about only certain health care items or services to a health plan to restrict disclosures of protected health information regarding all health care to the health plan—*i.e.,* to require an individual to have to pay out of pocket for all services to take advantage of this right regardless of the particular health care item or service about which the individual requested the restriction. We believe such a policy would be contrary to Congressional intent, in that it would discourage individuals from requesting restrictions in situations where Congress clearly intended they be able to do so. For example, an individual who regularly visits the same provider for the treatment of both asthma and diabetes must be able to request, and have the provider honor, a restriction on the disclosure of diabetes-related treatment to the health plan as long as the individual pays out of pocket for this care. The provider cannot require that the individual apply the restriction to all care given by the provider and, as a result, cannot require the individual to pay out of pocket for both the diabetes and asthma-related care in order to have the restriction on the diabetes care honored. We encourage covered entities to work with individuals who wish to restrict certain information from disclosure to health plans to determine the best method for ensuring that the appropriate information is restricted from disclosure to a health plan.

Due to the myriad of treatment interactions between covered entities and individuals, we recognize that this provision may be more difficult to implement in some circumstances than in others, and we request comment on the types of interactions between individuals and covered entities that would make requesting or implementing a restriction more difficult. For example, an individual visits a provider for treatment of a condition, and the individual requests the provider not disclose information about the condition to the health plan and pays out of pocket for the care. The provider prescribes a medication to treat the condition, and the individual also wishes to restrict the health plan from receiving information about the medication. Many providers electronically send prescriptions to the pharmacy to be filled so that the medication is ready when the individual arrives to pick it up; however, at the point the individual arrives at the pharmacy, the pharmacy would have already sent the information to the health plan for payment, not permitting the individual an opportunity to request a restriction at the pharmacy. A provider who knows that an individual intends to request such a restriction can always provide the individual with a paper prescription to take to the pharmacy, allowing the individual an opportunity to request that the pharmacy restrict the disclosure of information relating to the medication. However, this might not be practical in every case, especially as covered entities begin to replace paper-based systems with electronic systems. We request comment on this issue, and we ask specifically for suggestions of methods through which a provider, using an automated electronic prescribing tool, could alert the pharmacy that the individual may wish to request that a restriction be placed on the disclosure of their information to the health plan and that the individual intends to pay out of pocket for the prescription.

Additionally, we request comment on the obligation of covered health care providers that know of a restriction to inform other health care providers downstream of such restriction. For example, a provider has been treating an individual for an infection for several

months pursuant to the individual's requested restriction that none of the protected health information relating to the treatment of the infection be disclosed to the individual's health plan. If the individual requests that the provider send a copy of his medical records to another health care provider for treatment, what, if any, obligation should the original provider have to notify the recipient provider (including a pharmacy filling the individual's prescription) that the individual has placed a restriction upon much of the protected health information in the medical record? We request comment on whether a restriction placed upon certain protected health information should apply to, and the feasibility of it continuing to attach to, such information as it moves downstream, or if the restriction should no longer apply until the individual visits the new provider for treatment or services, requests a restriction, and pays out of pocket for the treatment. In addition, we request comment on the extent to which technical capabilities exist that would facilitate notification among providers of restrictions on the disclosure of protected health information, how widely these technologies are currently utilized, and any limitations in the technology that would require additional manual or other procedures to provide notification of restrictions.

In accordance with the HITECH Act, proposed § 164.522(a)(1)(vi)(A) would permit a covered entity to disclose protected health information to a health plan if such disclosure is required by law, despite an individual's request for a restriction. We note that the term "required by law" is defined at § 164.103. We request comment on examples of types of disclosures that may fall under this provision.

With respect to the proposed requirement in § 164.522(a)(1)(vi)(B) that the covered entity be paid in full for the health care item or service for which the individual requests a restriction, we have added some language to the statutory provision to ensure that this requirement not be limited to solely the individual as the person paying the covered entity for the individual's care. There are many situations in which family members or other persons may pay for the individual's treatment. Thus, this proposed paragraph would provide that as long as the covered entity is paid for the services by the individual or another person on behalf of the individual other than the health plan, the covered entity would be required to abide by the restriction.

With regard to proposed § 164.522(a)(1)(vi)(B), we emphasize that when an individual requests a restriction of information to a health plan and pays out of pocket for the treatment or service, the individual should not expect that this payment will count towards the individual's out of pocket threshold with respect to his or her health plan benefits. As the very nature of this provision is to restrict information from flowing to the health plan, the health plan will be unaware of any payment for treatment or services for which the individual has requested a restriction, and thus, this out of pocket payment cannot be used to reach the threshold for benefits a health plan offers.

We request public comment on how this provision will function with respect to HMOs. A provider who contracts with an HMO generally receives a fixed payment from an HMO based on the number of patients seen and not based on the treatment or service provided, and an individual patient of that provider pays a flat co-payment for every visit regardless of the treatment or service received. Therefore, it is our understanding that under most current HMO contracts with providers an individual could not pay the provider for the treatment or service received. Thus, individuals who belong to an HMO may have to use an out-of-network provider if they wish to ensure that certain protected health information is not disclosed to the HMO. We request public comment on this issue.

Finally, with respect to proposed § 164.522(a)(1)(vi)(B), we emphasize that if an individual's out of pocket payment for a health care item or service to restrict disclosure of the information to a health plan is not honored (for example, the individual's check bounces), the covered entity may then submit the information to the health plan for payment as the individual has not fulfilled the requirements necessary to obtain a restriction. We do not believe that the statutory intent was to permit individuals to avoid payment to providers for the health care services they provide. Therefore, if an individual does not pay in full for the treatment or services provided to the individual, then the provider is under no obligation to restrict the information and may disclose the protected health information to the health plan to receive payment. However, we expect covered entities to make some attempt to resolve the payment issue with the individual prior to sending the protected health information to the health plan, such as by notifying the individual that his or her payment did not go through and to give the individual an opportunity to submit payment. We request comment on the extent to which covered entities must make reasonable efforts to secure payment from the individual prior to submitting protected health information to the health plan for payment.

We propose to modify § 164.522(a)(2) and (3) regarding terminating restrictions and documentation of restrictions to reflect the addition of these new requirements. First, we would modify the language in § 164.522(a)(2) to remove the term "its agreement to" to clarify that the termination provisions apply to all restrictions, even those which are mandatory for the covered entity. Similarly, we would modify the language in § 164.522(a)(3) regarding documentation to remove the words "that agrees to a restriction" to make clear that the documentation requirements apply to all restrictions, including those that would be required by proposed paragraph (a)(1)(vi).

Additionally, we propose to modify § 164.522(a)(2)(iii) to conform to proposed paragraph (a)(1)(vi), requiring the mandatory restrictions for certain disclosures to health plans. In particular, in cases in which a covered entity is required to agree to a restriction under this section, we propose to add a new paragraph (A) to paragraph (a)(2)(iii) to clarify that a covered entity may not unilaterally terminate such a restriction.

The proposed modifications would operate as follows with respect to termination of a restriction under proposed paragraph (a)(1)(vi). For example, an individual who has requested a restriction on the disclosure of protected health information to a health plan about a particular health care service visits the provider for follow-up treatment, asks the provider to bill the health plan for the follow-up visit, and does not request a restriction at the time, nor pays out of pocket for the follow-up treatment. In such circumstances, there is no restriction in effect with respect to the follow-up treatment. However, the provider may need to submit information about the original treatment to the health plan so that it can determine the medical appropriateness or medical necessity of the follow-up care provided to the individual. At this time, we would consider the lack of a restriction with respect to the follow-up treatment to extend to any protected health information necessary to effect payment for such treatment, even if such information pertained to prior treatment that was subject to a restriction. We encourage covered entities to have an open dialogue with individuals to

ensure that they are aware that protected health information may be disclosed to the health plan unless they request an additional restriction and pay out of pocket for the follow-up care. We request public comment on this issue.

K. Section 164.524—Access of Individuals to Protected Health Information

Section 164.524 of the Privacy Rule currently establishes, with limited exceptions, an enforceable means by which individuals have a right to review or obtain copies of their protected health information, to the extent such information is maintained in the designated record set(s) of a covered entity. An individual's right of access exists regardless of the format of the protected health information, and the standards and implementation specifications that address individuals' requests for access and timely action by the covered entity (*i.e.,* provision of access, denial of access, and documentation) apply to an electronic environment in a similar manner as they do to a paper-based environment. *See The HIPAA Privacy Rule's Right of Access and Health Information Technology* (providing guidance with respect to how § 164.524 applies in an electronic environment and how health information technology can facilitate providing individuals with this important privacy right), available at: *http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/healthit/eaccess.pdf*.

Section 13405(e) of the HITECH Act, which became effective February 18, 2010, strengthens the Privacy Rule's right of access with respect to covered entities that use or maintain an electronic health record on an individual. Section 13405(e) provides that when a covered entity uses or maintains an electronic health record with respect to protected health information of an individual, the individual shall have a right to obtain from the covered entity a copy of such information in an electronic format and the individual may direct the covered entity to transmit such copy directly to the individual's designee, provided that any such choice is clear, conspicuous, and specific. Section 13405(e) also provides that any fee imposed by the covered entity for providing such an electronic copy shall not be greater than the entity's labor costs in responding to the request for the copy.

Section 13405(e) applies by its terms only to protected health information in electronic health records. However, incorporating these new provisions in such a limited manner in the Privacy Rule could result in a complex set of disparate requirements for access to protected health information in electronic health records systems versus other types of electronic records systems. As such, the Department proposes to use its authority under section 264(c) of HIPAA to prescribe the rights individuals should have with respect to their individually identifiable health information to strengthen the right of access as provided under section 13405(e) of the HITECH Act more uniformly to all protected health information maintained in one or more designated record sets electronically, regardless of whether the designated record set is an electronic health record. We discuss our proposed amendments to each provision implicated by section 13405(e) more specifically below.

Section 164.524(c)(2) of the Privacy Rule requires a covered entity to provide the individual with access to the protected health information in the form or format requested by the individual, if it is readily producible in such form or format, or, if not, in a readable hard copy form or such other form or format as agreed to by the covered entity and the individual. Section 13405(e) of the HITECH Act expands this requirement by explicitly requiring a covered entity that uses or maintains an electronic health record with respect to protected health information to provide the individual with a copy of such information in an electronic format.

We propose to implement this statutory provision, in conjunction with our broader authority under section 264(c) of HIPAA, by requiring, in proposed § 164.524(c)(2)(ii), that if the protected health information requested is maintained electronically in one or more designated record sets, the covered entity must provide the individual with access to the electronic information in the electronic form and format requested by the individual, if it is readily producible, or, if not, in a readable electronic form and format as agreed to by the covered entity and the individual. This provision would require any covered entity that electronically maintains the protected health information about an individual, in one or more designated record sets, to provide the individual with an electronic copy of such information (or summary or explanation if agreed to by the individual in accordance with proposed § 164.524(c)(2)(iii)) in the electronic form and format requested or in an otherwise agreed upon form and format. While an individual's right of access to an electronic copy of protected health information is currently limited under the Privacy Rule by whether the form or format requested is readily producible, covered entities that maintain such information electronically in a designated record set would be required under these proposed modifications to provide some type of electronic copy, if requested by an individual.

Because we do not want to bind covered entities to standards that may not yet be technologically mature, we propose to permit covered entities to make some other agreement with individuals as to an alternative means by which they may provide a readable electronic copy, to the extent the requested means is not readily producible. If, for example, a covered entity received a request to provide electronic access via a secure Web-based portal, but the only readily producible version of the protected health information was in portable document format (PDF), proposed § 164.524(c)(2)(ii) would require the covered entity to provide the individual with a PDF copy of the protected health information, if agreed to by the covered entity and the individual. We note that while there may be circumstances where a covered entity determines that it can comply with the Privacy Rule's right of access by providing individuals with limited access rights to their electronic health record, such as through a secure Web-based portal, nothing under the current Rule or proposed modifications would require a covered entity to do so where the covered entity determines it is not reasonable or appropriate.

We note that the option of arriving at an alternative agreement that satisfies both parties is already part of the requirement to provide access under § 164.524(c)(2)(i), so extension of such a requirement to electronic access should present few implementation difficulties. Further, as with other disclosures of protected health information, in providing the individual with an electronic copy of protected health information through a Web-based portal, e-mail, on portable electronic media, or other means, covered entities should ensure that reasonable safeguards are in place to protect the information. We also note that the proposed modification presumes that covered entities have the capability of providing an electronic copy of protected health information maintained in their designated record set(s) electronically through a secure Web-based portal, via e-mail, on portable electronic media, or other manner. We invite public comment on this presumption.

Section 164.524(c)(3) of the Privacy Rule currently requires the covered entity to provide the access requested by the individual in a timely manner, which includes arranging with the individual for a convenient time and place to inspect or obtain a copy of the protected health information, or mailing the copy of protected health information at the individual's request. The Department has previously interpreted this provision as requiring a covered entity to mail the copy of protected health information to an alternative address requested by the individual, provided the request was clearly made by the individual and not a third party. Section 13405(e)(1) of the HITECH Act provides that if the individual chooses, he or she shall have a right to direct the covered entity to transmit an electronic copy of protected health information in an electronic health record directly to an entity or person designated by the individual, provided that such choice is clear, conspicuous, and specific.

Based on section 13405(e)(1) of the HITECH Act and our authority under section 264(c) of HIPAA, we propose to expand § 164.524(c)(3) to expressly provide that, if requested by an individual, a covered entity must transmit the copy of protected health information directly to another person designated by the individual. This proposed amendment is consistent with the Department's prior interpretation on this issue and would apply without regard to whether the protected health information is in electronic or paper form. We propose to implement the requirement of section 13405(e)(1) that the individual's "choice [be] clear, conspicuous, and specific" by requiring that the individual's request be "in writing, signed by the individual, and clearly identify the designated person and where to send the copy of protected health information." We note that the Privacy Rule allows for electronic documents to qualify as written documents for purposes of meeting the Rule's requirements, as well as electronic signatures to satisfy any requirements for a signature, to the extent the signature is valid under applicable law. Thus, a covered entity could employ an electronic process for receiving an individual's request to transmit a copy of protected health information to his or her designee under this proposed provision. Whether the process is electronic or paper-based, a covered entity must implement reasonable policies and procedures under § 164.514(h) to verify the identity of any person who requests protected health information, as well as implement reasonable safeguards under § 164.530(c) to protect the information that is used or disclosed.

Section 164.524(c)(4) of the Privacy Rule currently permits a covered entity to impose a reasonable, cost-based fee for a copy of protected health information (or a summary or explanation of such information). However, such a fee may only include the cost of: (1) The supplies for, and labor of, copying the protected health information; (2) the postage associated with mailing the protected health information, if applicable; and (3) the preparation of an explanation or summary of the protected health information, if agreed to by the individual. With respect to providing a copy (or summary or explanation) of protected health information from an electronic health record in electronic form, however, section 13405(e)(2) of the HITECH Act provides that a covered entity may not charge more than its labor costs in responding to the request for the copy.

In response to section 13405(e)(2) of the HITECH Act, we propose to amend § 164.524(c)(4)(i) to identify separately the labor for copying protected health information, whether in paper or electronic form, as one factor that may be included in a reasonable cost-based fee. While we do not propose more detailed considerations for this factor within the regulatory text, we retain all prior interpretations of labor with respect to paper copies—that is, that the labor cost of copying may not include the costs associated with searching for and retrieving the requested information. With respect to electronic copies, we believe that a reasonable cost-based fee includes costs attributable to the labor involved to review the access request and to produce the electronic copy, which we expect would be negligible. However, we would not consider a reasonable cost-based fee to include a standard "retrieval fee" that does not reflect the actual labor costs associated with the retrieval of the electronic information or that reflects charges that are unrelated to the individual's request (*e.g.,* the additional labor resulting from technical problems or a workforce member's lack of adequate training). We invite public comment on this aspect of our rulemaking, specifically with respect to what types of activities related to managing electronic access requests should be compensable aspects of labor.

We also propose to amend § 164.524(c)(4)(ii) to provide separately for the cost of supplies for creating the paper copy or electronic media (*i.e.,* physical media such as a compact disc (CD) or universal serial bus (USB) flash drive), if the individual requests that the electronic copy be provided on portable media. This reorganization and the addition of the phrase "electronic media" reflects our understanding that since section 13405(e)(2) of the HITECH Act permits only the inclusion of labor costs in the charge for electronic copies, it by implication excludes charging for the supplies that are used to create an electronic copy of the individual's protected health information, such as the hardware (computers, scanners, *etc.*) or software that is used to generate an electronic copy of an individual's protected health information in response to an access request. We note this limitation is in contrast to a covered entity's ability to charge for supplies for hard copies of protected health information (*e.g.,* the cost of paper, the prorated cost of toner and wear and tear on the printer). *See* 65 FR 82462, 82735, Dec. 28, 2000 (responding to a comment seeking clarification on "capital cost for copying" and other supply costs by indicating that a covered entity was free to recoup all of their reasonable costs for copying). We believe this interpretation is consistent with the fact that, unlike a hard copy, which generally exists on paper, an electronic copy exists independent of media, and can be transmitted securely via multiple methods (*e.g.,* e-mail, a secure Web-based portal, or an individual's own electronic media) without accruing any ancillary supply costs.

We also note, however, that our interpretation of the statute would permit a covered entity to charge a reasonable and cost-based fee for any electronic media it provided, as requested or agreed to by an individual who does not provide their own. For example, a covered entity can offer to make protected health information available on an encrypted USB flash drive, and can charge a reasonable cost-based fee for the flash drive. If, however, an individual has brought his or her own electronic media (such as a recordable CD), requested that an electronic copy be placed on it, and the covered entity's systems are readily able to do so, then the covered entity would not be allowed to require the individual to purchase an encrypted USB flash drive instead. Likewise, if an individual requests that an electronic copy be sent via unencrypted e-mail, the covered entity should advise the individual of the risks associated with unencrypted e-mail, but the covered entity would not be allowed to require the individual to instead purchase a USB flash drive.

While we propose to renumber the remaining factors in § 164.524(c)(4), we

do not propose to amend their substance. With respect to § 164.524(c)(4)(iii), however, we note that our interpretation of the statute would permit a covered entity to charge for postage if an individual requests that the covered entity transmit portable media containing an electronic copy through mail or courier (*e.g.,* if the individual requests that the covered entity save protected health information to a CD and then mail the CD to a designee).

Finally, we are requesting comment on one aspect of the right to access and obtain a copy of protected health information which the HITECH Act did not amend. In particular, the HITECH Act did not change the timeliness requirements for provision of access in § 164.524(b). Under the current requirements, a request for access must be approved or denied, and if approved, access or a copy of the information provided, within 30 days of the request. In cases where the records requested are only accessible from an off-site location, the covered entity has an additional 30 days to respond to the request. In extenuating circumstances where access cannot be provided within these timeframes, the covered entity may have a one-time 30-day extension if the individual is notified of the need for the extension within the original timeframes.

With regard to the timeliness of the provision of access, we are aware that with the advance of electronic health records, there is an increasing expectation and capacity to provide individuals with almost instantaneous electronic access to the protected health information in those records through personal health records or similar electronic means. On the other hand, we are not proposing to limit the right to electronic access of protected health information to certified electronic health records, and the variety of electronic systems that are subject to this proposed requirement would not all be able to comply with a timeliness standard based on personal health record capabilities. It is our assumption that a single timeliness standard that would address a variety of electronic systems, rather than having a multitude of standards based on system capacity, would be the preferred approach to avoid workability issues for covered entities. Even under a single standard, nothing would prevent electronic health record systems from being developed through the HITECH Act's standards and certification process with the technological capabilities to exceed the Privacy Rule's timeliness requirements for providing access to individuals. Based on the assumption that a single standard would be the preferred approach, we are interested in public comment on an appropriate, common timeliness standard for the provision of access by covered entities with electronic designated record sets generally. We would appreciate comment on aspects of existing systems that would create efficiencies in processing of requests for electronic information, as well as those aspects of electronic systems that would provide little change from the time required for processing a paper record. Alternatively, we request comment on whether the current standard could be altered for all systems, paper and electronic, such that all requests for access should be responded to without unreasonable delay and not later than 30 days.

We are also interested in public comment on whether, contrary to our assumption, a variety of timeliness standards based on the type of electronic designated record set is the preferred approach and if so, how we should operationalize such an approach. For example, how should we identify and characterize the various electronic designated record sets to which the different standards would apply, such as personal health records, electronic health records, and others? What functionality within these electronic systems would drive the need for more or less time to provide an individual with electronic access? What timeliness standards would be appropriate for the different systems? What timeliness standard(s) would be required of entities with protected health information spread across hybrid systems that have different functionalities? What would be the impact of and challenges to having multiple timeliness standards for access?

Finally, we request comment on the time necessary for covered entities to review access requests and make necessary determinations, such as whether the granting of access would endanger the individual or other persons so as to better understand how the time needed for these reviews relates to the overall time needed to provide the individual with access. Further, we request comment generally on whether the provision which allows a covered entity an additional 30 days to provide access to the individual if the protected health information is maintained off-site should be eliminated altogether for both paper and electronic records, or at least for protected health information maintained or archived electronically because the physical location of electronic data storage is not relevant to its accessibility.

L. Other Technical and Conforming Changes

We propose to make a number of technical and conforming changes to the Privacy Rule to fix minor problems such as incorrect cross-references, mistakes of grammar, and typographical errors. Technical and conforming changes of this nature are described and explained in the table below.

Regulation §	Current language	Proposed change	Reason for change
164.510(b)(2)(iii)	"based the exercise of professional judgment".	Insert "on" after "based"	Correct typographical error.
164.512(b)(1)	"Permitted disclosures" and "may disclose".	Insert "uses and" and "use or" before "disclosures" and "disclose," respectively.	Correct inadvertent omission.
164.512(e)(1)(iii)	"seeking protecting health information".	Change "protecting" to "protected"	Correct typographical error.
164.512(e)(1)(vi)	"paragraph (e)(1)(iv) of this section"	Change "(e)(1)(iv)" to "(e)(1)(v)"	Correct cross-reference.
164.512(k)(3)	"authorized by 18 U.S.C. 3056, or to foreign heads of state . . ., or to for the conduct of investigations".	Remove the comma after "U.S.C. 3056" and the "to" before "for".	Correct typographical errors.

In addition to the technical changes listed in the table above, we propose to make a few changes that are technical or conforming in nature, but for which the reason for the change is more programmatic in nature. These are as follows:

Section 164.506(c)(5) permits a covered entity to disclose protected health information "to another covered entity that participates in the organized health care arrangement." We propose to change the words "another covered entity that participates" to "other participants" because not all participants in an organized health care arrangement may be covered entities; for example, some physicians with staff privileges at a hospital may not be covered entities.

Section 164.510(a)(1)(ii) permits the disclosure of directory information to members of the clergy and other persons who ask for the individual by name. We propose to add the words "use or" to this permission, to cover the provision of such information to clergy who are part of a facility's workforce.

Section 164.510(b)(3) covers uses and disclosures of protected health information when the individual is not present to agree or object to the use or disclosure, and, as pertinent here, permits disclosure to persons only of "the protected health information that is directly relevant to the person's involvement with the individual's health care." We propose to delete the last two quoted words and substitute therefore the following: "care or payment related to the individual's health care or needed for notification purposes." This change would align the text of paragraph (b)(3) with the permissions provided for at paragraph (b)(1) of this section.

Where an employer needs protected health information to comply with workplace medical surveillance laws, such as OSHA or MSHA, § 164.512(b)(1)(v)(A) permits a covered entity to disclose, subject to certain conditions, protected health information of an individual to the individual's employer if the covered entity is a covered health care provider "who is a member of the workforce of such employer or who provides health care to the individual at the request of the employer." We propose to amend the quoted language by removing the words "who is a member of the workforce of such employer or", as the language is unnecessary.

In § 164.512(k)(1)(ii), we propose to replace the word "Transportation" with "Homeland Security." The language regarding a component of the Department of Transportation was included to refer to the Coast Guard; however, the Coast Guard was transferred to the Department of Homeland Security in 2003. In addition, at § 164.512(k)(5)(i)(E), we propose to replace the word "and" after the semi-colon with the word "or." The intent of § 164.512(k)(5)(i) is not that the existence of all of the conditions is necessary to permit the disclosure, but rather that the existence of any would permit the disclosure.

VII. Regulatory Analyses

A. Introduction

We have prepared a regulatory impact statement in compliance with Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132 on Federalism.

1. Executive Order 12866

Executive Order 12866 directs 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). A regulatory impact analysis must be prepared for major rules that have economically significant effects ($100 million or more in any one year) or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal government or communities (58 FR 51741).

We estimate that the effects of the requirement for covered entities (including indirect costs incurred by third party administrators, which frequently send out notices on behalf of health plans) to issue new notices of privacy practices, will result in new costs of $166.1 million within 12 months of the effective date of the final rule. We estimate that the private sector will bear approximately 71 percent of the costs, with State and Federal plans bearing the remaining 29 percent of the costs. As a result of the economic impact, and other costs that are expected but not quantified in the regulatory analysis below, we determined that this proposed rule is an economically significant regulatory action within the meaning of section 3(f)(4) of Executive Order 12866. We present our analysis of the costs of the proposed rule in section C below.

2. Regulatory Flexibility Act

The RFA requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. We present our regulatory flexibility analysis of this proposed rule in section E below.

The Act generally defines a "small entity" as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a nonprofit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. Because 90 percent or more of all health care providers meet the SBA size standard for a small business or are nonprofit organizations, we generally treat all health care providers as small entities for purposes of performing a regulatory flexibility analysis. The SBA size standard for health care providers ranges between $7.0 million and $34.5 million in annual receipts.

With respect to health insurers and third party administrators, the SBA size standard is $7.0 million in annual receipts. While some insurers are classified as nonprofit, it is possible they are dominant in their market. For example, a number of Blue Cross/Blue Shield insurers are organized as nonprofit entities; yet they dominate the health insurance market in the States where they are licensed. In addition, we lack the detailed information on annual receipts for insurers and plan administrators and, therefore, we do not know how many firms qualify as small entities. We welcome comments on the number of small entities in the health insurer and health plan administrator market.

3. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates would require spending in any one year $100 million in 1995 dollars, updated annually for inflation. In 2010, that threshold is approximately $135 million. UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of cost, mainly those "Federal mandate" costs resulting from: (1) Imposing enforceable duties on State, local, or Tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, State, local, or Tribal governments under entitlement programs.

We are able to identify approximately $166.1 million in costs on both the private sector and State and Federal health plans. There may be other costs we are not able to monetize because we lack data, and the proposed rule may produce savings that may offset some or all of the added costs. For this purpose, we must also separately identify costs to

be incurred by the private sector and those incurred by State and Federal entities.

As noted above, of the costs we can identify, we estimate that approximately 71 percent or $118.1 million of new costs will fall on the private sector. For the purpose of this calculation, we included all $46 million in provider costs as private sector costs. While we recognize that some providers are State or Federal entities, we do not have adequate information to estimate the number of public providers, but we believe the number to be significantly less than 10% of all providers shown in Table 1. Therefore, as we did for the RFA analysis and for ease of calculation, we assumed that all provider costs are private sector costs. We welcome comment on this assumption and any information regarding the number of the public sector providers for future analysis. With regard to identifying the costs to private sector health plans, based on the data discussed in section C below, we estimate that 60 percent of policy holders are served by private sector health plans and, therefore, have allocated 60 percent of the costs to be incurred by all health plans as private sector costs, or $72.1 million.

Similarly, we estimate that approximately 29 percent or $48 million of the new costs will fall on State and Federal plans. As noted above, based on the data discussed in section C below, we estimate that 40 percent of policy holders are served by public sector plans and, therefore, have allocated 40 percent of the costs for all health plans as public sector costs, or $48 million. Because the amount of unfunded mandates incurred separately by either the private sector or by State, local, and Tribal governments will not exceed the unfunded mandates threshold of $133 million, we are not required to perform a cost-benefit analysis under the UMRA. Nonetheless, we have prepared a cost-benefit analysis of the proposed rule in sections C and D, below, as required by Executive Order 12866 for an economically significant regulation. We welcome public comment on the analysis as it bears upon our assumptions and calculations under the UMRA.

4. Federalism

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.

The Federalism implications of the Privacy and Security Rules were assessed as required by Executive Order 13132 and published as part of the preambles to the final rules on December 28, 2000 (65 FR 82462, 82797) and February 20, 2003 (68 FR 8334, 8373), respectively. Regarding preemption, the preamble to the final Privacy Rule explains that the HIPAA statute dictates the relationship between State law and Privacy Rule requirements, and the Rule's preemption provisions do not raise Federalism issues. The HITECH Act, at section 13421(a), provides that the HIPAA preemption provisions shall apply to the HITECH provisions and requirements. While we have made minor technical changes to the preemption provisions in Subpart B of Part 160 to conform to and incorporate the HITECH Act preemption provisions, these changes do not raise new Federalism issues. The proposed changes include: (1) Amending the definitions of "contrary" and "more stringent" to reference business associates; and (2) further amending the definition of contrary to provide that State law would be contrary to the HIPAA Administrative Simplification provisions if it stands as an obstacle to the accomplishment and execution of the full purposes and objectives of not only HIPAA, but also the HITECH Act.

We do not believe that this rule will impose substantial direct compliance costs on State and local governments that are not required by statute. It is our understanding that State and local government covered entities do not engage in marketing, the sale of protected health information, or fundraising. Therefore, the proposed modifications in these areas would not cause additional costs to State and local governments. We anticipate that the most significant direct costs on State and local governments will be the cost for State and local government-owned covered entities of drafting, printing, and distributing revised notices of privacy practices, which would include the cost of mailing these notices for State health plans, such as Medicaid. However, the costs involved can be attributed to the statutory requirements.

In considering the principles in and requirements of Executive Order 13132, the Department has determined that these proposed modifications to the Privacy and Security Rules will not significantly affect the rights, roles, and responsibilities of the States.

B. Why is This Rule Needed?

The proposed rule is needed to implement several provisions of the HITECH Act that require us to amend our regulations at 45 CFR Parts 160 and 164. These amendments primarily strengthen the privacy and security protections for protected health information, as well as broaden the privacy rights of individuals.

C. Costs

1. Notifying Individuals of Their New Privacy Rights

Covered entities must provide individuals with NPPs that detail how the covered entity may use and disclose protected health information and individuals' rights with respect to their own health information. Due to the proposed modifications pursuant to the HITECH Act, covered entities must modify their NPPs and distribute them to affected individuals to advise them of the following strengthened privacy protections: (1) The addition of the sale of protected health information as a use or disclosure that requires the express written authorization of the individual; (2) a separate statement that provides advance notice to the individual if the healthcare provider receives financial remuneration from a third party to send treatment communications to the individual about that party's products or services, and the right of the individual to elect not to receive such communications; and (3) the right of the individual to restrict disclosures of protected health information to a health plan with respect to treatment services for which the individual has paid out of pocket in full.

For providers, the cost of developing a new NPP consists of drafting and printing the notice. The costs of distribution are minimal because providers will hand out the NPPs when patients come for their appointments. We estimate that drafting the updated NPPs will require approximately one-third of an hour of professional, legal time at approximately $90 per hour—or $30—that includes hourly wages of $60 plus 50 percent [5]. The total cost for attorneys for the approximately 697,000 [6] health care providers in the

[5] *http://www.bls.gov/oes/2008/may/oes231011.htm* for lawyers.

[6] We identified 701,325 entities that must prepare and deliver NPPs that are shown in Table 1 below. This includes 696,758 HIPAA covered entities that are health care providers, including hospitals, nursing facilities, doctor offices, outpatient care centers, medical diagnostic, imaging service, home health service and other ambulatory care service covered entities, medical equipment suppliers, and pharmacies. For the purposes of our calculation, we have rounded this number to 697,000. Table 1 also includes 4,567 health insurance carriers and third party administrators working on behalf of covered health plans. The cost estimates for these entities are addressed later.

U.S. is, therefore, expected to be approximately $21 million. Printing the NPPs will require paper and clerical time at a cost of $0.10 per notice. We estimate that within 12 months from the effective date of the final rule, providers will print approximately 250 million NPPs to hand to patients who visit their offices. Printing costs for 250 million NPPs will be $25 million. The total cost for providers is approximately $46 million.

For health plans, the cost of developing a new NPP consists of drafting, printing and mailing the notice. With the exception of a few large health plans, most health plans do not self-administer their plans. The majority of plans are either health insurance issuers (approximately 1,000) or utilize third party administrators that act on their behalf in the capacity as business associates. We identified approximately 3,500 third party administrators acting as business associates for approximately 446,400 ERISA plans identified by the Department of Labor. In addition, the Department of Labor identified 20,300 public non-Federal health plans that may use third party administrators. Almost all of the public and ERISA plans, we believe, employ third party administrators to administer their health plans. While the third party administrators will bear the direct costs of issuing the revised NPPs, the costs will generally be passed on to the plans that contract with them. Those plans that self-administer their own plans will also incur the costs of issuing the revised NPPs. We do not know how many plans administer as well as sponsor health plans and invite comments on the number of self-administered plans; however, unless there were many such plans it would not have much effect on these estimates.

For the approximately 4,500 health insurance issuers and health plan administrators, the cost of composing and printing the NPPs will be a similar amount per NPP to the amount calculated for providers. However, health insurers and plan administrators will have to mail the NPPs to policy holders. The costs for the mailing will consist of postage and clerical time. The cost, therefore, depends on the estimate of the number of policy holders who must receive NPPs. We did not assume that health plans would communicate with policy holders by e-mail because we have no data that indicate the extent to which insurance plans and third party administrators communicate currently with their policy holders through e-mail. We request public comment on this assumption.

Because the Privacy Rule requires that only the named insured or policy holder be notified of changes to the health plans' privacy practices even if that policy also covers dependents, we expect that only policy holders will receive the revised NPPs mandated by this rule. For public programs such as Medicare, where each individual is a policy holder, Medicare has a policy of mailing one notice or a set of program materials to a household of four or fewer beneficiaries at the same address. Although there are 45.6 million individual Medicare beneficiaries, the program only sends out 38.8 million pieces of mail per mailing.

Actuarial Research Corporation (ARC), our consultant, estimated the number of policy holders for all classes of insurance products to be approximately 183.6 million, including all public programs. The data comes from the Medical Expenditure Panel Survey from 2004–2006 projected to 2010. ARC estimated 112.6 million private sector policy holders and 71.0 million public "policy holders." The total, including more recent Medicare data, is 188.3 million persons (which results in roughly a split of 60 percent private policy holders and 40 percent public "policy holders"), whom we expect to receive NPPs from their plans. The estimates do not capture policy holders who are in hospitals or nursing homes at the time of the survey, or individuals who may have been insured under more than one plan in a year, for example, because their job status changed, they have supplemental policies, or they have more than one employer, creating duplicate coverage. Therefore, ARC recommended we use 200 million for the number of NPPs that will actually be sent.

The costs of drafting, printing, and distributing the NPP are estimated to be the following. First, drafting the NPP is estimated to require one-third hour of legal services at a cost of $30 × 4,500 insurance plans and insurance administrative entities, which equals $135,000. Second, the cost of printing the NPP, which includes the cost of paper and actual printing, is estimated to be $0.10 per notice × 200 million notices, which equals $20 million. Third, the cost of distributing the NPPs would involve clerical time to prepare the mailings and the cost of postage, which we estimate to be a unit cost of $0.50 per NPP for postage and handling using the rate of $0.44 per stamp and $0.06 for labor (the same rates we used in the Breach Notification for Unsecured Protected Health Information Regulations published in the **Federal Register** at 74 FR 42763), results in an estimated $100 million cost for distribution. The total cost for all plans for drafting, printing, and distributing the NPP therefore, is approximately $120.1 million. We note that this total may be an overestimation of the costs because many insurers may use bulk mailing rates to distribute their NPPs which would reduce their mailing costs.

The total estimated cost for both providers and health plans to notify individuals and policy holders of changes in their privacy rights is approximately $166.1 million in the first year following implementation of the rule. Annualized over 10 years at three percent and seven percent, the cost equals $194,720 and $236,489, respectively.

Table 1 below shows the number of covered entities by class of provider and insurer that would be required to issue NPPs under the proposed rule.

TABLE 1—NUMBER OF ENTITIES BY NAICS CODE[1] EXPECTED TO PREPARE AND DISTRIBUTE REVISED NPPS

NAICS	Providers/Suppliers	Entities
622	Hospitals (General Medical and Surgical, Psychiatric, Substance Abuse, Other Specialty)	4,060
623	Nursing Facilities (Nursing Care Facilities, Residential Mental Retardation Facilities, Residential Mental Health and Substance Abuse Facilities, Community Care Facilities for the Elderly, Continuing Care Retirement Communities).	34,400
6211–6213	Office of MDs, DOs, Mental Health Practitioners, Dentists, PT, OT, ST, Audiologists	419,286
6214	Outpatient Care Centers (Family Planning Centers, Outpatient Mental Health and Drug Abuse Centers, Other Outpatient Health Centers, HMO Medical Centers, Kidney Dialysis Centers, Freestanding Ambulatory Surgical and Emergency Centers, All Other Outpatient Care Centers).	13,962
6215	Medical Diagnostic, and Imaging Service Covered Entities	7,879
6216	Home Health Service Covered Entities	15,329
6219	Other Ambulatory Care Service Covered Entities (Ambulance and Other)	5,879
n/a	Durable Medical Equipment Suppliers[2]	107,567

TABLE 1—NUMBER OF ENTITIES BY NAICS CODE[1] EXPECTED TO PREPARE AND DISTRIBUTE REVISED NPPS—Continued

NAICS	Providers/Suppliers	Entities
4611	Pharmacies[3]	88,396
524114	Health Insurance Carriers	1,045
524292	Third Party Administrators Working on Behalf of Covered Health Plans	3,522
	Total Entities	701,325

[1] Office of Advocacy, SBA, *http://www.sba.gov/advo/research/data.html.*
[2] Centers for Medicare & Medicaid Services covered entities.
[3] The Chain Pharmacy Industry *http://www.nacds.org/wmspage.cfm?parm1=507.*

2. Authorization and Other Requirements for Disclosures Related to Marketing and Sale of Protected Health Information

The proposed rule would make modifications to the definition of "marketing," such that some communications to individuals about health-related products or services that are made under health care operations would now be considered marketing communications if the covered entity receives financial remuneration by a third party to make the communication. For marketing communications, individual authorization is required. In addition, the proposal would require that a health care provider that receives financial remuneration by a third party in exchange for sending a treatment communication to an individual about the third party's product or service must disclose the fact of remuneration in the communication and provide the individual with a clear and conspicuous opportunity to opt out of receiving future subsidized communications. Although this proposed rule would modify the current definition of "marketing," because we do not have information on the extent to which covered entities currently receive financial remuneration from third parties in exchange for sending information to individuals about the third parties' health-related products or services, we do not know how these modifications would change how covered entities operate. We invite public comment on this issue.

In addition, the proposed rule would require an individual authorization before a covered entity could disclose protected health information in exchange for remuneration (*i.e.,* "sell" protected health information). The proposal includes several exceptions to this authorization requirement. On its face, this proposed modification would appear to increase the burden to covered entities by requiring them to obtain authorizations in situations in which no authorization is currently required. However, we believe such a scenario is unlikely to occur. Even if covered entities attempted to obtain authorizations in compliance with the proposed modifications, we believe most individuals would not authorize these types of disclosures. It would not be worthwhile for covered entities to continue to attempt to obtain such authorizations, and as a result, we believe covered entities would simply discontinue making such disclosures. Therefore, we believe this proposed modification would have little to no impact on covered entities. We request comment on this issue.

The proposed provision requiring individual authorization prior to the sale of protected health information contains several exceptions in which protected health information could be disclosed in exchange for remuneration without first obtaining individual authorization. Most of the excepted disclosures would not impose additional requirements and, therefore, would not impose any additional burden on covered entities to implement. However, the exception for research disclosures may impose an additional burden on researchers. The exception applies to disclosure of protected health information for research as long as the remuneration received does not exceed the cost to produce and transmit the information. Researchers who purchase data from covered entities may now incur additional costs as a result of the proposed rule, in order to obtain newly required authorizations, if they are currently paying a covered entity more than the cost to produce and transmit the protected health information (unless the covered entity is willing to reduce its charges for the data). The proposed change would classify such transactions as a sale, and as such would require an individual's authorization prior to the covered entity's disclosure. This authorization requirement also may have additional effects on research, such that the need for authorization may skew the sample, or if the researcher does not have the resources to obtain the authorizations from the research subjects, the research may be jeopardized. Since we have no information on the amounts currently paid to covered entities by researchers for protected health information, we have no way to estimate the impact of the provision. We welcome any comments and information on the impact of these provisions.

3. Authorization for Compound Disclosures

The proposed rule would permit compound authorizations for research purposes as long as it is clear to individuals that they do not have to agree to both the conditioned and unconditioned components of an authorization in order to receive research-related treatment. We believe that the proposed provision would reduce burden on the research community by eliminating the need for multiple forms for research studies involving both a clinical trial and a related research repository or study. However we have no data which would permit us to estimate the amount of burden reduction associated with this proposal. We welcome public comment on this issue.

4. Uses and Disclosures of Decedents' Protected Health Information

The proposed rule would modify the current rule to limit the period for which a covered entity must protect an individual's health information to 50 years after the individual's death. We believe this will reduce the burden on both covered entities and on those seeking the protected health information of persons who have been deceased for many years by eliminating the need to search for and find a personal representative of the decedent, who in many cases may not be known or even exist after so many years, to authorize the disclosure. We believe this change would benefit family members and historians who may seek access to the medical information of these decedents for personal and public interest reasons. However, we lack any data to be able to estimate the benefits or costs of this

provision. We welcome comments on this proposed change.

5. Uses and Disclosures for Care and Notification Purposes

The proposed rule would permit covered entities to disclose a decedent's protected health information to family members, or other persons involved in the individual's care or payment for care before the individual's death, unless doing so would be inconsistent with any prior expressed preference of the individual that is known to the covered entity. The rights of the decedent's personal representative to have access to the protected health information of the decedent would remain unchanged. We believe the proposed change would reduce burden by permitting covered entities to continue to disclose protected health information to family members and other persons who were involved in an individual's care while the individual was alive after the death of the individual without needing to obtain authorization from the decedent's personal representative, who may not be known or even exist. However, we have no data to permit us to estimate the reduction in burden and we welcome comment on this change.

6. Public Health Disclosures

The proposed rule would create a new public health provision to permit disclosure of proof of a child's immunization by a covered entity to a school in States that have school entry or similar laws. This proposed change would allow a covered health care provider to release proof of immunization to a school without having to obtain a written authorization, provided the provider obtained the agreement (oral or otherwise) to the disclosure from either the parent or guardian, or the individual, if the individual is an adult or emancipated minor. We expect the proposed change to the regulations may reduce the burden on covered entities and parents in obtaining and providing written authorizations but it is unclear by how much. Since the proposed rule would require the covered entity and the responsible party for the student to agree that the covered entity may release proof of immunization, some covered entities may request the agreement in writing. In these cases, there may be little change from the current authorization requirement in terms of the burden. Because we lack data on the burden reduction, we cannot provide an estimate of the possible savings. We welcome comment on the proposed change.

7. Fundraising Requirements

The proposed rule would require that any fundraising communication sent to an individual must provide the recipient with a clear and conspicuous opportunity to opt out of receiving any further fundraising communications. If an individual elects to opt out, the fundraising entity must not send that individual additional fundraising communications. We believe that the strengthened language from the HITECH Act that requires fundraisers to clearly and conspicuously provide the recipient an opt-out choice from receiving future communication and to treat such a choice as a revocation of authorization will result in fewer unwanted fundraising communications. However, we lack the data to estimate the effects of this change. We request comment on the extent to which the requirement that the opportunity to elect not to receive further fundraising communications be clear and conspicuous would have an impact on covered entities and their current fundraising materials.

8. Individuals' Access to Protected Health Information

Under the proposed regulations, if a covered entity maintains protected health information electronically and the recipient requests copies of his or her protected health information in an electronic format, the covered entity or business associate must provide the information in the electronic format requested by the individual if readily producible in that format, or, if not, in a different electronic format agreed to by the covered entity and the individual. If the covered entity provides an individual with electronic access to protected health information, the proposed rule would only allow the covered entity to charge the costs of labor associated with the preparation of the request. The proposed rule clarifies the labor and supply costs applicable to preparation of electronic requests vs. paper requests. Labor costs to produce an electronic copy involve the cost of reviewing and preparing the copy. Supplies for an electronic copy apply only to the cost of the media, if applicable, for providing the information to the individual. If the individual provides the media (*e.g.,* a CD or flash drive), there would be no cost for the media. Similarly, if the information is transmitted via e-mail or some other electronic mode, there would be no charge for media.

It is unclear whether there will be any cost increase or decrease to either the individual or the covered entity with respect to the individual's increased access to their electronic protected health information. The fact that the proposed rule requires the covered entity to provide information in an electronic format may be, in practice, no different than the current requirement to provide protected health information to the individual in electronic format, if readily producible in such format. Both the current and proposed rules continue to permit the covered entity and individual to negotiate over the format and delivery of protected health information. By emphasizing the provision of protected health information electronically, the proposed rule may lower costs because postage costs are eliminated or reduced and labor and supply costs are significantly reduced. In conclusion, there may be some savings that result from the greater use of electronic access to protected health information, but we cannot quantify them.

9. Business Associates and Covered Entities and Their Contractual Relationships

The proposed rule would extend liability for failure to comply with the Privacy and Security Rules directly to business associates and business associate subcontractors in a manner similar to how they now apply to covered entities. The proposed rule would subject business associates to many of the same standards and implementation specifications, and to the same penalties, that apply to covered entities under the Security Rule and to some of the same standards and implementation specifications, and to the same penalties, that apply to covered entities under the Privacy Rule. Additionally, business associates would also be required to obtain satisfactory assurances in the form of a business associate agreement from subcontractors that the subcontractors will safeguard any protected health information in their possession. If the business associate learns of a pattern of activity or practice of a subcontractor that constitutes a material breach or violation of the contract, the business associate would be required to make reasonable attempts to repair the breach or correct the violation. If unsuccessful, the business associate would be required to terminate the contract, if feasible. In addition, a business associate would be required to furnish any information the Secretary requires to investigate whether the business associate is in compliance with the regulations.

In the absence of reliable data to the contrary, we assume that business associates' compliance with their

contracts range from the minimal compliance to avoid contract termination to being fully compliant. The burden of the proposed rules on business associates depends on the terms of the contract between the covered entity and business associate, and the degree to which a business associate established privacy policies and adopted security measures that comport with the HIPAA Rules. For business associates that have already taken HIPAA-compliant measures to protect the privacy and security of the protected health information in their possession, the proposed rules with their increased penalties would impose limited burden.

We assume that business associates in compliance with their contracts would have already designated personnel to be responsible for formulating the organization's privacy and security policies, performed a risk analysis, and invested in hardware and software to prevent and monitor for internal and external breaches of protected health information. We expect that most business associates make a good-faith effort to follow the terms of their contracts and comply with current security and privacy standards.

For those business associates that have not already adopted HIPAA-compliant privacy and security standards for protected health information, the risk of criminal and/or civil monetary penalties may spur them to increase their efforts to comply with the privacy and security standards. Up to this point, the consequences of failing to meet the privacy and security standards were limited to a business loss in the form of a terminated contract. In the context of the business associate's overall business, the risk of losing the contract may not be a sufficient incentive to warrant investing in added security or establishing privacy policies potentially at significant expense. There may be other more benign reasons such as ignorance of potential threats or lack of knowledgeable personnel on staff. Regardless of the reason, to avoid the risk of the far more serious penalties in this proposed rule, we expect that business associates and subcontractors that have been lax in their complying with the privacy and security standards may now take steps to enhance their security procedures and strengthen their policies for protecting the privacy of the protected health information under their control.

As stated above, we have no information on the degree of contract enforcement and compliance among business associates. We also lack information regarding the size or type of business associates that contract with covered entities. We have only rough estimates as to the overall number of business associates, which ranges from approximately one million to two million depending upon the number of business associates which serve multiple covered entities. As the area of health information technology expands, we note that the proposed rule also includes in the definition of business associates entities such as e-prescribing gateways, health information organizations or other organizations that provide data transmission services with respect to protected health information to a covered entity.

As a result of the lack of information, we can only assume that some business associates and subcontractors comply with existing privacy and security standards. For them, the proposed rules would impose only a limited burden. For business associates that do not have HIPAA-compliant privacy policies and security procedures, the proposed rules imposing criminal and civil monetary penalties directly on business associates and their subcontractors may incentivize these organizations to bolster their security and privacy policies. Depending on the current level of compliance, for some business associates, the proposed rule could impose significant burdens. We welcome comments on our analysis and especially invite information regarding the amount of burden and the number of affected business associates.

The cost to renegotiate contracts between covered entities and business associates and between business associates and subcontractors may be minimal if we assume that all parties are living up to their current contractual agreements. At the same time, we anticipate that an unknown number of contracts will have to be modified to reflect the changes in law and in the rules we propose. The time involved in modifying a contract is estimated to be one hour of a legal professional's time. Based on the Bureau of Labor Statistics reports, the average hourly wage of $60 plus an estimated additional 50 percent for benefits brings the hourly rate to $90.

Because we are allowing contracts to be phased in over one year from the compliance date or 18 months from the effective date of the final rule, we expect that the costs of modifying contracts will be incorporated into the normal renegotiation of contracts as the contracts expire. We believe that most contracts will be renegotiated over the phase-in period. In addition, the Department expects to issue revised sample business associate contract language when these rules are finalized, which may help to lessen the costs associated with contract modifications. Under these assumptions, the costs will be minimal. We request comments on the number of contracts and covered entities that will not be able to complete renegotiation of their contracts with their business associates within 18 months.

Even with the phase-in period for renegotiating contracts, we expect there will be an unknown number of covered entities and business associates that will have to renegotiate their contracts before the term of their current contracts expire because: (1) some contracts may extend beyond the eighteen month period, (2) fear of incurring civil or criminal penalties may motivate the parties to ensure they are in compliance with the new rules, and (3) the covered entity and business associate may have established only the minimum requirements and seek to strengthen their compliance under the new rules.

As stated previously, we are unsure which of these scenarios applies. We welcome comments on the extent of cost to renegotiate contracts.

D. Benefits

The proposed modifications pursuant to the HITECH Act would provide benefits to individuals. The benefits for individuals include added information on their rights through an expanded NPP and greater control over the uses and disclosures of their personal health information by expanding the requirements to obtain authorization before a covered entity or business associate can disclose their protected health information in exchange for remuneration and to restrict certain disclosures at the request of the individual. Under the proposed rule, individuals would also have easier access to their protected health information in an electronic format, and relatives and friends of deceased persons would be able to obtain the person's protected health information when there is no personal representative or without obtaining authorization under some circumstances. In addition, covered entities would only need to protect the health information of decedents for 50 years after their death, as opposed to protecting the information in perpetuity as is required by the current rule. This would also mean that the personal health information of persons who had been deceased for many years would be available to historians, researchers, and family members. Also, individuals' rights with respect to fundraising communications would be strengthened. In States that

require immunization information for school attendance, schools would have an easier time obtaining immunization records because the proposed rule would eliminate the need for written authorization.

Under the proposed rule, pursuant to the HITECH Act, an individual's health information will be afforded greater protection since business associates of covered entities would share responsibility with the covered entity for safeguarding against impermissible disclosures of protected health information. Business associates and subcontractors would be subject to criminal and civil penalties for violating the privacy and security of protected health information entrusted to them.

While we are certain that the proposed regulatory changes represent distinct benefits, we cannot monetize their value. We have no measure for valuing the benefit an individual would gain from the authorization requirement when a covered entity or business associate exchanges protected health information for remuneration. Neither do we know how much value would be added when an individual receives their protected health information in an electronic format nor the amount of time saved as a result of the public health disclosure provision for student immunizations. Also, the value that relatives and friends of a deceased person would gain from obtaining the protected health information of the decedent that they would not otherwise be able to obtain because there is no personal representative or, if there is a personal representative, without the delay of obtaining authorization, is beyond our ability to measure. We welcome comments and information that could improve our analysis of the benefits of the proposed rule.

E. Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires agencies that issue a proposed rule to analyze and consider options for reducing regulatory burden if the regulation will impose a significant burden on a substantial number of small entities. The Act requires the head of the agency to either certify that the rule would not impose such a burden or perform a regulatory flexibility analysis and consider alternatives to lessen the burden.

The proposed rule would have an impact on covered providers of health care, health insurance issuers, and third party administrators acting on behalf of health plans, which we estimate to total 701,325. Of the approximately $166.1 million in costs we are able to identify, the private sector will incur approximately 71 percent of the costs or $118.1 million. The average cost per covered entity is therefore approximately $168. We do not view this as a significant burden. We note that the 3,500 third party administrators included in this calculation serve as business associates to the approximately 446,000 ERISA plans, most of which are small entities. We have no information on how many of these plans self-administer, and we request any data the public may provide on this question. Based on the relatively small cost per covered entity, the Secretary certifies that the proposed rule would not have a significant impact on a substantial number of small entities. However, because we are not certain of all the costs this rule may impose or the exact number of small health insurers or third party administrators, we welcome comments that may further inform our analysis.

Although we certify that the proposed rule will not impose a significant burden on a substantial number of small entities, in drafting the proposed provisions of the rule, we considered alternatives for reducing the burden on small entities.

First, in the rule we are proposing to allow covered entities and business associates with existing HIPAA compliant contracts twelve months from the compliance date to renegotiate their contracts unless the contract is renewed or modified before such date. This amount of time plus the six months from the effective date of the rule to the compliance date generally gives the parties 18 months to renegotiate their agreements. We believe that the added time will reduce the cost to revise agreements because the changes the rule requires will be incorporated into the routine updating of covered entities and business associates contracts.

Second, as we did in the final Privacy Rule published August 14, 2002 (67 FR 53182, 53264–53266) we will provide sample language for revising the contracts between covered entities and business associates. While the language is generic and may not suit complex organizations with complex agreements, we believe that it will help small entities with their contract revisions and save them time and money in redrafting their contracts to conform to the new rules.

VIII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide a 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 PRA requires that we solicit comment on the following issues:

a. Whether the information collection is necessary and useful to carry out the proper functions of the agency;

b. The accuracy of the agency's estimate of the information collection burden;

c. The quality, utility, and clarity of the information to be collected; and

d. Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Under the PRA, the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section are to be considered. We explicitly seek, and will consider, public comment on our assumptions as they relate to the PRA requirements summarized in this section. To comment on this collection of information or to obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your comment or request, including your address and phone number 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.

A. Abstract

As a result of the Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5), the Office for Civil Rights (OCR) is required to revise its information collection under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules (45 CFR Parts 160 and 164). ARRA was enacted on February 17, 2009. This supporting statement revises a previously approved OCR data collection, OMB # 0990–0294. The HITECH Act requires modification of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191) implementing regulations at 45 CFR Parts 160 and 164, the HIPAA Privacy and Security Rules, to extend jurisdiction to business associates and to strengthen privacy and

security protections for health information.

We have integrated this PRA notice into the Notice of Proposed Rulemaking, because these costs represent costs to be incurred as one-time, first year implementation costs. The estimated annualized burden table below was developed using the same estimates and workload assumptions in the impact statement in the section regarding Executive Order 12866, above. Because the HIPAA Privacy and Security Rules have been in effect for several years, these numbers, as revised pursuant to the HITECH modifications, are based on past experience with the current information collection.

With respect to the § 164.520 requirement to revise the Notice of Privacy Practices, the "Number of Respondents" column represents the number of covered entities that would be required to revise their Notices of Privacy Practices pursuant to the HITECH modifications. As such, 701,500 covered entities would be required to modify their Notices of Privacy Practices. Each covered entity would have to revise one Notice of Privacy Practices, which is represented by the "Average Number of Responses per Respondent" column. We estimate that each revision would require 20 minutes to complete. As such, it would take 233,833 total burden hours for 701,500 covered entities to revise their Notices of Privacy Practices. With respect to the § 164.520 requirement for health plans to disseminate the revised Notice of Privacy Practices, the "Number of Respondents" column represents the 200 million individuals to whom the revised Notice of Privacy Practices would be sent. Each individual would receive one Notice of Privacy Practices, which is represented by the "Average Number of Responses per Respondent" column. We estimate that each health plan would need one hour to prepare 100 Notices of Privacy Practices for mailing to individuals. As such, the total burden hours it would take health plans to disseminate Notices of Privacy Practices to 200 million individuals would be two million.

With regard to the proposed business associate provisions, as discussed in Section VI of this proposed rule, we assume that business associates currently comply with the HIPAA Privacy and Security Rules, and that their contracts range from the minimal compliance to avoid contract termination to being fully compliant. Because the proposed rule provides that most business associates may renegotiate their contracts during the compliance period in the normal course of business, we anticipate no or minimal additional burden. However, for those business associates with subcontractors, we anticipate an increased burden associated with bringing their subcontractors into compliance with the HIPAA Privacy and Security Rules, specifically with regard to business associate agreements.

Currently, business associates must obtain satisfactory assurance from their subcontractors regarding their compliance with the HIPAA Privacy and Security Rules. We assume that business associates obtained this satisfactory assurance via contract with their subcontractors. This proposed rule contains a new explicit requirement that business associates enter into contracts with their subcontractors to ensure compliance with the HIPAA Privacy and Security Rules. Because most business associates already have contracts in place, this new requirement creates a minimal additional burden associated with modification of these contracts. As discussed in Section VI above, we estimated that it will require one hour of a legal professional's time to modify these contracts. We estimate the number of business associates that may have to bring subcontractors into compliance to be 1,500,000. Our estimate is based on an average of one to two million business associates. This correlates to 1,500,000 burden hours.

The overall total for respondents to comply with the information collection requirements of the Rules is 3,733,833 burden hours. We request comment on this estimate.

As discussed in the above paragraph, we consider the majority of, if not all of, the burden associated with this proposed rule to result from the requirements with regard to the Notice of Privacy Practices and costs for business associates. However, as there may be an additional minimal burden associated with other provisions of the proposed rule, we request comment on the impacts of such provisions, as follows.

With regard to the proposed marketing, sale, fundraising, and access provisions discussed above in Section VI of this proposed rule, we do not anticipate any significant increase in the burden to covered entities and business associates, because covered entities already have in place routine business policies, procedures, and forms to address the current requirements regarding an opt-out for fundraising, authorizations for marketing and sale of protected health information, and the provision of access to electronic protected health information. While the proposed rule strengthens consumer protections in each of these areas, we do not have sufficient data on the current marketing, sale, fundraising, and access activities of covered entities and their business associates to calculate the impact of the increased protections on the use of these forms and processes.

B. Estimated Annualized Burden Table

Section	Type of respondent	Number of respondents	Average number of responses per respondent	Average burden hours per response	Total burden hours
164.504	Business Associates	1,500,000	1	1	1,500,000
164.520	Revision of Notice of Privacy Practices for Protected Health Information (drafting revised language).	701,500	1	20/60	233,833
164.520	Dissemination of Notice of Privacy Practices for Protected Health Information (health plans).	200,000,000	1	1 per 100	2,000,000
Total					3,733,833

List of Subjects

45 CFR Part 160

Administrative practice and procedure, Computer technology, Electronic information system, Electronic transactions, Employer benefit plan, Health, Health care, Health facilities, Health insurance, Health records, Hospitals, Investigations, Medicaid, Medical research, Medicare, Penalties, Privacy, Reporting and record keeping requirements, Security.

45 CFR Part 164

Administrative practice and procedure, Computer technology, Electronic information system, Electronic transactions, Employer benefit plan, Health, Health care, Health facilities, Health insurance, Health records, Hospitals, Medicaid, Medical research, Medicare, Privacy, Reporting and record keeping requirements, Security.

For the reasons set forth in the preamble, the Department proposes to amend 45 CFR Subtitle A, Subchapter C, parts 160 and 164, as set forth below:

PART 160—GENERAL ADMINISTRATIVE REQUIREMENTS

1. The authority citation for part 160 is revised to read as follows:

Authority: 42 U.S.C. 1302(a); 42 U.S.C. 1320d–1320d–8; sec. 264, Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2(note)); 5 U.S.C. 552; and secs. 13400–13424, Pub. L. 111–5, 123 Stat. 258–279.

2. Revise § 160.101 to read as follows:

§ 160.101 Statutory basis and purpose.

The requirements of this subchapter implement sections 1171–1179 of the Social Security Act (the Act), as added by section 262 of Public Law 104–191, section 264 of Public Law 104–191, and sections 13400–13424 of Public Law 111–5.

3. Amend § 160.102 as follows:

a. Redesignate paragraph (b) as paragraph (c); and

b. Add new paragraph (b) to read as follows:

§ 160.102 Applicability.

* * * * *

(b) Where provided, the standards, requirements, and implementation specifications adopted under this subchapter apply to a business associate.

* * * * *

4. Amend § 160.103 as follows:

a. Revise the definitions of "business associate", "compliance date", "disclosure", "electronic media", paragraph (2) of "protected health information," and the definitions of "standard", "State", and "workforce"; and

b. Add, in alphabetical order, new definitions of "administrative simplification provision", "ALJ", "civil money penalty or penalty", "respondent", "subcontractor", and "violation or violate".

The revisions and additions read as follows:

§ 160.103 Definitions.

* * * * *

Administrative simplification provision means any requirement or prohibition established by:

(1) 42 U.S.C. 1320d–1320d–4, 1320d–7, and 1320d–8;

(2) Section 264 of Pub. L. 104–191;

(3) Sections 13400–13424 of Public Law 111–5; or

(4) This subchapter.

ALJ means Administrative Law Judge.

* * * * *

Business associate: (1) Except as provided in paragraph (4) of this definition, business associate means, with respect to a covered entity, a person who:

(i) On behalf of such covered entity or of an organized health care arrangement (as defined in this section) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, performs, or assists in the performance of:

(A) A function or activity involving the use or disclosure of protected health information, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, patient safety activities listed at 42 CFR 3.20, billing, benefit management, practice management, and repricing; or

(B) Any other function or activity regulated by this subchapter; or

(ii) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in § 164.501 of this subchapter), management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of protected health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

(2) A covered entity may be a business associate of another covered entity.

(3) *Business associate* includes:

(i) A Health Information Organization, E-prescribing Gateway, or other person that provides data transmission services with respect to protected health information to a covered entity and that requires access on a routine basis to such protected health information.

(ii) A person that offers a personal health record to one or more individuals on behalf of a covered entity.

(iii) A subcontractor that creates, receives, maintains, or transmits protected health information on behalf of the business associate.

(4) *Business associate* does not include:

(i) A health care provider, with respect to disclosures by a covered entity to the health care provider concerning the treatment of the individual.

(ii) A plan sponsor, with respect to disclosures by a group health plan (or by a health insurance issuer or HMO with respect to a group health plan) to the plan sponsor, to the extent that the requirements of § 164.504(f) of this subchapter apply and are met.

(iii) A government agency, with respect to determining eligibility for, or enrollment in, a government health plan that provides public benefits and is administered by another government agency, or collecting protected health information for such purposes, to the extent such activities are authorized by law.

(iv) A covered entity participating in an organized health care arrangement that performs a function or activity as described by paragraph (1)(i) of this definition for or on behalf of such organized health care arrangement, or that provides a service as described in paragraph (1)(ii) of this definition to or for such organized health care arrangement by virtue of such activities or services.

Civil money penalty or *penalty* means the amount determined under § 160.404 of this part and includes the plural of these terms.

* * * * *

Compliance date means the date by which a covered entity or business associate must comply with a standard, implementation specification, requirement, or modification adopted under this subchapter.

* * * * *

Disclosure means the release, transfer, provision of access to, or divulging in any manner of information outside the entity holding the information.

* * * * *

Electronic media means:

(1) Electronic storage material on which data is or may be recorded electronically, including, for example, devices in computers (hard drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card;

(2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the Internet (wide-open), extranet or intranet (using Internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-

up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media if the information being exchanged did not exist in electronic form before the transmission.

* * * * *

Protected health information * * *

(2) Protected health information excludes individually identifiable health information:

(i) In education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g;

(ii) In records described at 20 U.S.C. 1232g(a)(4)(B)(iv);

(iii) In employment records held by a covered entity in its role as employer; and

(iv) Regarding a person who has been deceased for more than 50 years.

* * * * *

Respondent means a covered entity or business associate upon which the Secretary has imposed, or proposes to impose, a civil money penalty.

* * * * *

Standard means a rule, condition, or requirement:

(1) Describing the following information for products, systems, services, or practices:

(i) Classification of components;

(ii) Specification of materials, performance, or operations; or

(iii) Delineation of procedures; or

(2) With respect to the privacy of protected health information.

* * * * *

State refers to one of the following:

(1) For a health plan established or regulated by Federal law, State has the meaning set forth in the applicable section of the United States Code for such health plan.

(2) For all other purposes, *State* means any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Subcontractor means a person who acts on behalf of a business associate, other than in the capacity of a member of the workforce of such business associate.

* * * * *

Violation or *violate* means, as the context may require, failure to comply with an administrative simplification provision.

Workforce means employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity or business associate, is under the direct control of such covered entity or business associate, whether or not they are paid by the covered entity or business associate.

5. Add § 160.105 to subpart A to read as follows:

§ 160.105 Compliance dates for implementation of new or modified standards and implementation specifications.

In accordance with § 160.104, with respect to new standards and implementation specifications or modifications to standards and implementation specifications in this subchapter that become effective after [DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER], except as otherwise provided, covered entities and business associates must comply with the applicable new standards and implementation specifications or modifications to standards and implementation specifications no later than 180 days from the effective date of any such standards or implementation specifications.

6. Revise § 160.201 to read as follows:

§ 160.201 Statutory basis.

The provisions of this subpart implement section 1178 of the Act, as added by section 262 of Public Law 104–191, section 264(c) of Public Law 104–191, and section 13421(a) of Public Law 111–5.

7. In § 160.202, revise the definition of "contrary" and paragraph (1)(i) of the definition of "more stringent" to read as follows:

§ 160.202 Definitions.

* * * * *

Contrary, when used to compare a provision of State law to a standard, requirement, or implementation specification adopted under this subchapter, means:

(1) A covered entity or business associate would find it impossible to comply with both the State and Federal requirements; or

(2) The provision of State law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of part C of title XI of the Act, section 264 of Public Law 104–191, or sections 13400–13424 of Public Law 111–5, as applicable.

More stringent * * *

(1) * * *

(i) Required by the Secretary in connection with determining whether a covered entity or business associate is in compliance with this subchapter; or

* * * * *

8. Revise § 160.300 to read as follows:

§ 160.300 Applicability.

This subpart applies to actions by the Secretary, covered entities, business associates, and others with respect to ascertaining the compliance by covered entities and business associates with, and the enforcement of, the applicable provisions of this part 160 and parts 162 and 164 of this subchapter.

§ 160.302 [Removed and Reserved]

9. Remove and reserve § 160.302.

10. Revise § 160.304 to read as follows:

§ 160.304 Principles for achieving compliance.

(a) *Cooperation.* The Secretary will, to the extent practicable and consistent with the provisions of this subpart, seek the cooperation of covered entities and business associates in obtaining compliance with the applicable administrative simplification provisions.

(b) *Assistance.* The Secretary may provide technical assistance to covered entities and business associates to help them comply voluntarily with the applicable administrative simplification provisions.

11. In § 160.306, revise paragraphs (a) and (c) to read as follows:

§ 160.306 Complaints to the Secretary.

(a) *Right to file a complaint.* A person who believes a covered entity or business associate is not complying with the administrative simplification provisions may file a complaint with the Secretary.

* * * * *

(c) *Investigation.*

(1) The Secretary will investigate any complaint filed under this section when a preliminary review of the facts indicates a possible violation due to willful neglect.

(2) The Secretary may investigate any other complaint filed under this section.

(3) An investigation under this section may include a review of the pertinent policies, procedures, or practices of the covered entity or business associate and of the circumstances regarding any alleged violation.

(4) At the time of the initial written communication with the covered entity or business associate about the complaint, the Secretary will describe the acts and/or omissions that are the basis of the complaint.

12. Revise § 160.308 to read as follows:

§ 160.308 Compliance reviews.

(a) The Secretary will conduct a compliance review to determine whether a covered entity or business associate is complying with the applicable administrative simplification provisions when a preliminary review of the facts indicates a possible violation due to willful neglect.

(b) The Secretary may conduct a compliance review to determine whether a covered entity or business associate is complying with the applicable administrative simplification provisions in any other circumstance.

13. Revise § 160.310 to read as follows:

§ 160.310 Responsibilities of covered entities and business associates.

(a) *Provide records and compliance reports.* A covered entity or business associate must keep such records and submit such compliance reports, in such time and manner and containing such information, as the Secretary may determine to be necessary to enable the Secretary to ascertain whether the covered entity or business associate has complied or is complying with the applicable administrative simplification provisions.

(b) *Cooperate with complaint investigations and compliance reviews.* A covered entity or business associate must cooperate with the Secretary, if the Secretary undertakes an investigation or compliance review of the policies, procedures, or practices of the covered entity or business associate to determine whether it is complying with the applicable administrative simplification provisions.

(c) *Permit access to information.*

(1) A covered entity or business associate must permit access by the Secretary during normal business hours to its facilities, books, records, accounts, and other sources of information, including protected health information, that are pertinent to ascertaining compliance with the applicable administrative simplification provisions. If the Secretary determines that exigent circumstances exist, such as when documents may be hidden or destroyed, a covered entity or business associate must permit access by the Secretary at any time and without notice.

(2) If any information required of a covered entity or business associate under this section is in the exclusive possession of any other agency, institution, or person and the other agency, institution, or person fails or refuses to furnish the information, the covered entity or business associate must so certify and set forth what efforts it has made to obtain the information.

(3) Protected health information obtained by the Secretary in connection with an investigation or compliance review under this subpart will not be disclosed by the Secretary, except if necessary for ascertaining or enforcing compliance with the applicable administrative simplification provisions, if otherwise required by law, or if permitted under 5 U.S.C. 552a(b)(7).

14. Revise § 160.312 to read as follows:

§ 160.312 Secretarial action regarding complaints and compliance reviews.

(a) *Resolution when noncompliance is indicated.*

(1) If an investigation of a complaint pursuant to § 160.306 or a compliance review pursuant to § 160.308 indicates noncompliance, the Secretary may attempt to reach a resolution of the matter satisfactory to the Secretary by informal means. Informal means may include demonstrated compliance or a completed corrective action plan or other agreement.

(2) If the matter is resolved by informal means, the Secretary will so inform the covered entity or business associate and, if the matter arose from a complaint, the complainant, in writing.

(3) If the matter is not resolved by informal means, the Secretary will—

(i) So inform the covered entity or business associate and provide the covered entity or business associate an opportunity to submit written evidence of any mitigating factors or affirmative defenses for consideration under §§ 160.408 and 160.410 of this part. The covered entity or business associate must submit any such evidence to the Secretary within 30 days (computed in the same manner as prescribed under § 160.526 of this part) of receipt of such notification; and

(ii) If, following action pursuant to paragraph (a)(3)(i) of this section, the Secretary finds that a civil money penalty should be imposed, inform the covered entity or business associate of such finding in a notice of proposed determination in accordance with § 160.420 of this part.

(b) *Resolution when no violation is found.* If, after an investigation pursuant to § 160.306 or a compliance review pursuant to § 160.308, the Secretary determines that further action is not warranted, the Secretary will so inform the covered entity or business associate and, if the matter arose from a complaint, the complainant, in writing.

15. In § 160.316, revise the introductory text to read as follows:

§ 160.316 Refraining from intimidation or retaliation.

A covered entity or business associate may not threaten, intimidate, coerce, harass, discriminate against, or take any other retaliatory action against any individual or other person for—

* * * * *

16. In § 160.401, revise the definition of *reasonable cause* to read as follows:

§ 160.401 Definitions.

* * * * *

Reasonable cause means an act or omission in which a covered entity or business associate knew, or by exercising reasonable diligence would have known, that the act or omission violated an administrative simplification provision, but in which the covered entity or business associate did not act with willful neglect.

* * * * *

17. Revise § 160.402 to read as follows:

§ 160.402 Basis for a civil money penalty.

(a) *General rule.* Subject to § 160.410, the Secretary will impose a civil money penalty upon a covered entity or business associate if the Secretary determines that the covered entity or business associate has violated an administrative simplification provision.

(b) *Violation by more than one covered entity or business associate.*

(1) Except as provided in paragraph (b)(2) of this section, if the Secretary determines that more than one covered entity or business associate was responsible for a violation, the Secretary will impose a civil money penalty against each such covered entity or business associate.

(2) A covered entity that is a member of an affiliated covered entity, in accordance with § 164.105(b) of this subchapter, is jointly and severally liable for a civil money penalty for a violation of part 164 of this subchapter based on an act or omission of the affiliated covered entity, unless it is established that another member of the affiliated covered entity was responsible for the violation.

(c) *Violation attributed to a covered entity or business associate.* (1) A covered entity is liable, in accordance with the Federal common law of agency, for a civil money penalty for a violation based on the act or omission of any agent of the covered entity, including a workforce member or business associate, acting within the scope of the agency.

(2) A business associate is liable, in accordance with the Federal common law of agency, for a civil money penalty for a violation based on the act or omission of any agent of the business associate, including a workforce member or subcontractor, acting within the scope of the agency.

18. In § 160.404, revise the introductory text of paragraphs (b)(2)(i), (b)(2)(iii), and (b)(2)(iv) to read as follows:

§ 160.404 Amount of a civil money penalty.

* * * * *

(b) * * *

(2) * * *

(i) For a violation in which it is established that the covered entity or business associate did not know and, by exercising reasonable diligence, would not have known that the covered entity or business associate violated such provision,

* * * * *

(iii) For a violation in which it is established that the violation was due to willful neglect and was corrected during the 30-day period beginning on the first date the covered entity or business associate liable for the penalty knew, or, by exercising reasonable diligence, would have known that the violation occurred,

* * * * *

(iv) For a violation in which it is established that the violation was due to willful neglect and was not corrected during the 30-day period beginning on the first date the covered entity or business associate liable for the penalty knew, or, by exercising reasonable diligence, would have known that the violation occurred,

* * * * *

19. Revise § 160.406 to read as follows:

§ 160.406 Violations of an identical requirement or prohibition.

The Secretary will determine the number of violations of an administrative simplification provision based on the nature of the covered entity's or business associate's obligation to act or not act under the provision that is violated, such as its obligation to act in a certain manner, or within a certain time, or to act or not act with respect to certain persons. In the case of continuing violation of a provision, a separate violation occurs each day the covered entity or business associate is in violation of the provision.

20. Revise § 160.408 to read as follows:

§ 160.408 Factors considered in determining the amount of a civil money penalty.

In determining the amount of any civil money penalty, the Secretary will consider the following factors, which may be mitigating or aggravating as appropriate:

(a) The nature and extent of the violation, consideration of which may include but is not limited to:

(1) The number of individuals affected; and

(2) The time period during which the violation occurred;

(b) The nature and extent of the harm resulting from the violation, consideration of which may include but is not limited to:

(1) Whether the violation caused physical harm;

(2) Whether the violation resulted in financial harm;

(3) Whether the violation resulted in harm to an individual's reputation; and

(4) Whether the violation hindered an individual's ability to obtain health care;

(c) The history of prior compliance with the administrative simplification provisions, including violations, by the covered entity or business associate, consideration of which may include but is not limited to:

(1) Whether the current violation is the same or similar to previous indications of noncompliance;

(2) Whether and to what extent the covered entity or business associate has attempted to correct previous indications of noncompliance;

(3) How the covered entity or business associate has responded to technical assistance from the Secretary provided in the context of a compliance effort; and

(4) How the covered entity or business associate has responded to prior complaints;

(d) The financial condition of the covered entity or business associate, consideration of which may include but is not limited to:

(1) Whether the covered entity or business associate had financial difficulties that affected its ability to comply;

(2) Whether the imposition of a civil money penalty would jeopardize the ability of the covered entity or business associate to continue to provide, or to pay for, health care; and

(3) The size of the covered entity or business associate; and

(e) Such other matters as justice may require.

21. Revise § 160.410 to read as follows:

§ 160.410 Affirmative defenses.

(a) The Secretary may not:

(1) Prior to February 18, 2011, impose a civil money penalty on a covered entity or business associate for an act that violates an administrative simplification provision if the covered entity or business associate establishes that the violation is punishable under 42 U.S.C. 1320d–6.

(2) On or after February 18, 2011, impose a civil money penalty on a covered entity or business associate for an act that violates an administrative simplification provision if the covered entity or business associate establishes that a penalty has been imposed under 42 U.S.C. 1320d-6 with respect to such act.

(b) For violations occurring prior to February 18, 2009, the Secretary may not impose a civil money penalty on a covered entity for a violation if the covered entity establishes that an affirmative defense exists with respect to the violation, including the following:

(1) The covered entity establishes, to the satisfaction of the Secretary, that it did not have knowledge of the violation, determined in accordance with the Federal common law of agency, and by exercising reasonable diligence, would not have known that the violation occurred; or

(2) The violation is—

(i) Due to circumstances that would make it unreasonable for the covered entity, despite the exercise of ordinary business care and prudence, to comply with the administrative simplification provision violated and is not due to willful neglect; and

(ii) Corrected during either:

(A) The 30-day period beginning on the first date the covered entity liable for the penalty knew, or by exercising reasonable diligence would have known, that the violation occurred; or

(B) Such additional period as the Secretary determines to be appropriate based on the nature and extent of the failure to comply.

(c) For violations occurring on or after February 18, 2009, the Secretary may not impose a civil money penalty on a covered entity or business associate for a violation if the covered entity or business associate establishes to the satisfaction of the Secretary that the violation is—

(1) Not due to willful neglect; and

(2) Corrected during either:

(i) The 30-day period beginning on the first date the covered entity or business associate liable for the penalty knew, or, by exercising reasonable diligence, would have known that the violation occurred; or

(ii) Such additional period as the Secretary determines to be appropriate based on the nature and extent of the failure to comply.

22. Revise § 160.412 to read as follows:

§ 160.412 Waiver.

For violations described in § 160.410(b)(2) or (c) that are not corrected within the period specified under such paragraphs, the Secretary may waive the civil money penalty, in whole or in part, to the extent that the payment of the penalty would be excessive relative to the violation.

23. Revise § 160.418 to read as follows:

§ 160.418 Penalty not exclusive.

Except as otherwise provided by 42 U.S.C. 1320d–5(b)(1) and 42 U.S.C. 299b–22(f)(3), a penalty imposed under this part is in addition to any other penalty prescribed by law.

PART 164—SECURITY AND PRIVACY

24. The authority citation for part 164 is revised to read as follows:

Authority: 42 U.S.C. 1302(a); 42 U.S.C. 1320d—1320d–8; sec. 264, Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320–2(note)); and secs. 13400—13424, Pub. L. 111–5, 123 Stat. 258–279.

25. Revise § 164.102 to read as follows:

§ 164.102 Statutory basis.

The provisions of this part are adopted pursuant to the Secretary's authority to prescribe standards, requirements, and implementation specifications under part C of title XI of the Act, section 264 of Public Law 104–191, and sections 13400—13424 of Public Law 111–5.

26. In § 164.104, revise paragraph (b) to read as follows:

§ 164.104 Applicability.

* * * * *

(b) Where provided, the standards, requirements, and implementation specifications adopted under this part apply to a business associate.

27. Amend § 164.105 as follows:

a. Revise the introductory text of paragraph (a)(1), the introductory text of paragraph (a)(2)(i), paragraph (a)(2)(ii), the introductory text of paragraph (a)(2)(iii), and paragraphs (a)(2)(iii)(A) and (B);

b. Redesignate paragraph (a)(2)(iii)(C) as paragraph (a)(2)(iii)(D) and add new paragraph (a)(2)(iii)(C); and

c. Revise paragraph (b).

The revisions read as follows:

§ 164.105 Organizational requirements.

(a)(1) *Standard: Health care component.* If a covered entity is a hybrid entity, the requirements of this part, other than the requirements of this section, § 164.314, and § 164.504, apply only to the health care component(s) of the entity, as specified in this section.

(2) * * *

(i) *Application of other provisions.* In applying a provision of this part, other than the requirements of this section, § 164.314, and § 164.504, to a hybrid entity:

* * * * *

(ii) *Safeguard requirements.* The covered entity that is a hybrid entity must ensure that a health care component of the entity complies with the applicable requirements of this part. In particular, and without limiting this requirement, such covered entity must ensure that:

(A) Its health care component does not disclose protected health information to another component of the covered entity in circumstances in which subpart E of this part would prohibit such disclosure if the health care component and the other component were separate and distinct legal entities;

(B) Its health care component protects electronic protected health information with respect to another component of the covered entity to the same extent that it would be required under subpart C of this part to protect such information if the health care component and the other component were separate and distinct legal entities;

(C) If a person performs duties for both the health care component in the capacity of a member of the workforce of such component and for another component of the entity in the same capacity with respect to that component, such workforce member must not use or disclose protected health information created or received in the course of or incident to the member's work for the health care component in a way prohibited by subpart E of this part.

(iii) *Responsibilities of the covered entity.* A covered entity that is a hybrid entity has the following responsibilities:

(A) For purposes of subpart C of part 160 of this subchapter, pertaining to compliance and enforcement, the covered entity has the responsibility of complying with this part.

(B) The covered entity is responsible for complying with § 164.316(a) and § 164.530(i), pertaining to the implementation of policies and procedures to ensure compliance with applicable requirements of this part, including the safeguard requirements in paragraph (a)(2)(ii) of this section.

(C) The covered entity is responsible for complying with § 164.314 and § 164.504 regarding business associate arrangements and other organizational requirements.

* * * * *

(b)(1) *Standard: Affiliated covered entities.* Legally separate covered entities that are affiliated may designate themselves as a single covered entity for purposes of this part.

(2) *Implementation specifications.*

(i) *Requirements for designation of an affiliated covered entity.* (A) Legally separate covered entities may designate themselves (including any health care component of such covered entity) as a single affiliated covered entity, for purposes of this part, if all of the covered entities designated are under common ownership or control.

(B) The designation of an affiliated covered entity must be documented and the documentation maintained as required by paragraph (c) of this section.

(ii) *Safeguard requirements.* An affiliated covered entity must ensure that it complies with the applicable requirements of this part, including, if the affiliated covered entity combines the functions of a health plan, health care provider, or health care clearinghouse, § 164.308(a)(4)(ii)(A) and § 164.504(g), as applicable.

* * * * *

28. Revise § 164.106 to read as follows:

§ 164.106 Relationship to other parts.

In complying with the requirements of this part, covered entities and, where provided, business associates, are required to comply with the applicable provisions of parts 160 and 162 of this subchapter.

29. The authority citation for subpart C of part 164 is revised to read as follows:

Authority: 42 U.S.C. 1320d–2 and 1320d–4; sec. 13401, Pub. L. 111–5, 123 Stat. 260.

30. Revise § 164.302 to read as follows:

§ 164.302 Applicability.

A covered entity or business associate must comply with the applicable standards, implementation specifications, and requirements of this subpart with respect to electronic protected health information of a covered entity.

31. In § 164.304, revise the definitions of *Administrative safeguards* and *Physical safeguards* to read as follows:

§ 164.304 Definitions.

* * * * *

Administrative safeguards are administrative actions, and policies and procedures, to manage the selection, development, implementation, and maintenance of security measures to protect electronic protected health information and to manage the conduct of the covered entity's or business associate's workforce in relation to the protection of that information.

* * * * *

Physical safeguards are physical measures, policies, and procedures to protect a covered entity's or business associate's electronic information systems and related buildings and equipment, from natural and environmental hazards, and unauthorized intrusion.

* * * * *

32. Amend § 164.306 as follows:

a. Revise the introductory text of paragraph (a) and paragraph (a)(1);

b. Revise paragraph (b)(1), the introductory text of paragraph (b)(2), and paragraphs (b)(2)(i) and (b)(2)(ii);

c. Revise paragraph (c);

d. Revise paragraph (d)(2), the introductory text of paragraph (d)(3), paragraph (d)(3)(i), and the introductory text of paragraph (d)(3)(ii); and

e. Revise paragraph (e).

The revisions read as follows:

§ 164.306 Security standards: General rules.

(a) *General requirements.* Covered entities and business associates must do the following:

(1) Ensure the confidentiality, integrity, and availability of all electronic protected health information the covered entity or business associate creates, receives, maintains, or transmits.

* * * * *

(b) * * * (1) Covered entities and business associates may use any security measures that allow the covered entity or business associate to reasonably and appropriately implement the standards and implementation specifications as specified in this subpart.

(2) In deciding which security measures to use, a covered entity or business associate must take into account the following factors:

(i) The size, complexity, and capabilities of the covered entity or business associate.

(ii) The covered entity's or the business associate's technical infrastructure, hardware, and software security capabilities.

* * * * *

(c) *Standards.* A covered entity or business associate must comply with the applicable standards as provided in this section and in § 164.308, § 164.310, § 164.312, § 164.314 and § 164.316 with respect to all electronic protected health information.

(d) * * *

(2) When a standard adopted in § 164.308, § 164.310, § 164.312, § 164.314, or § 164.316 includes required implementation specifications, a covered entity or business associate must implement the implementation specifications.

(3) When a standard adopted in § 164.308, § 164.310, § 164.312, § 164.314, or § 164.316 includes addressable implementation specifications, a covered entity or business associate must—

(i) Assess whether each implementation specification is a reasonable and appropriate safeguard in its environment, when analyzed with reference to the likely contribution to protecting electronic protected health information; and

(ii) As applicable to the covered entity or business associate—

* * * * *

(e) *Maintenance.* A covered entity or business associate must review and modify the security measures implemented under this subpart as needed to continue provision of reasonable and appropriate protection of electronic protected health information, and update documentation of such security measures in accordance with § 164.316(b)(2)(iii).

33. Amend § 164.308 as follows:

a. Revise the introductory text of paragraph (a), paragraph (a)(1)(ii)(A), paragraph (a)(1)(ii)(C), paragraph (a)(2), paragraph (a)(3)(ii)(C), paragraph (a)(4)(ii)(C), paragraph (a)(6)(ii), and paragraph (a)(8); and

b. Revise paragraph (b).

The revisions read as follows:

§ 164.308 Administrative safeguards.

(a) A covered entity or business associate must, in accordance with § 164.306:

(1) * * *

(ii) * * *

(A) *Risk analysis (Required).* Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information held by the covered entity or business associate.

* * * * *

(C) *Sanction policy (Required).* Apply appropriate sanctions against workforce members who fail to comply with the security policies and procedures of the covered entity or business associate.

* * * * *

(2) *Standard: Assigned security responsibility.* Identify the security official who is responsible for the development and implementation of the policies and procedures required by this subpart for the covered entity or business associate.

(3) * * *

(ii) * * *

(C) *Termination procedures* (Addressable). Implement procedures for terminating access to electronic protected health information when the employment of, or other arrangement with, a workforce member ends or as required by determinations made as specified in paragraph (a)(3)(ii)(B) of this section.

(4) * * *

(ii) * * *

(C) *Access establishment and modification* (Addressable). Implement policies and procedures that, based upon the covered entity's or the business associate's access authorization policies, establish, document, review, and modify a user's right of access to a workstation, transaction, program, or process.

* * * * *

(6) * * *

(ii) *Implementation specification: Response and reporting* (Required). Identify and respond to suspected or known security incidents; mitigate, to the extent practicable, harmful effects of security incidents that are known to the covered entity or business associate; and document security incidents and their outcomes.

* * * * *

(8) *Standard: Evaluation.* Perform a periodic technical and nontechnical evaluation, based initially upon the standards implemented under this rule and, subsequently, in response to environmental or operational changes affecting the security of electronic protected health information, that establishes the extent to which a covered entity's or business associate's security policies and procedures meet the requirements of this subpart.

(b)(1) *Business associate contracts and other arrangements.* A covered entity may permit a business associate to create, receive, maintain, or transmit electronic protected health information on the covered entity's behalf only if the covered entity obtains satisfactory assurances, in accordance with § 164.314(a), that the business associate will appropriately safeguard the information. A covered entity is not required to obtain such satisfactory assurances from a business associate that is a subcontractor.

(2) A business associate may permit a business associate that is a

subcontractor to create, receive, maintain, or transmit electronic protected health information on its behalf only if the business associate obtains satisfactory assurances, in accordance with § 164.314(a), that the subcontractor will appropriately safeguard the information.

(3) *Implementation specifications: Written contract or other arrangement* (Required). Document the satisfactory assurances required by paragraph (b)(1) or (b)(2) of this section through a written contract or other arrangement with the business associate that meets the applicable requirements of § 164.314(a).

34. Revise the introductory text of § 164.310 to read as follows:

§ 164.310 Physical safeguards.

A covered entity or business associate must, in accordance with § 164.306:

* * * * *

35. Revise the introductory text of § 164.312 to read as follows:

§ 164.312 Technical safeguards.

A covered entity or business associate must, in accordance with § 164.306:

* * * * *

36. Amend § 164.314 by revising paragraphs (a) and (b)(2)(iii) to read as follows:

§ 164.314 Organizational requirements.

(a)(1) *Standard: Business associate contracts or other arrangements.* The contract or other arrangement required by § 164.308(b)(4) must meet the requirements of paragraph (a)(2)(i), (a)(2)(ii), or (a)(2)(iii) of this section, as applicable.

(2) *Implementation specifications* (Required).

(i) *Business associate contracts.* The contract must provide that the business associate will—

(A) Comply with the applicable requirements of this subpart;

(B) In accordance with § 164.308(b)(2), ensure that any subcontractors that create, receive, maintain, or transmit electronic protected health information on behalf of the business associate agree to comply with the applicable requirements of this subpart by entering into a contract or other arrangement that complies with this section; and

(C) Report to the covered entity any security incident of which it becomes aware, including breaches of unsecured protected health information as required by § 164.410.

(ii) *Other arrangements.* The covered entity is in compliance with paragraph (a)(1) of this section if it has another arrangement in place that meets the requirements of § 164.504(e)(3).

(iii) *Business associate contracts with subcontractors.* The requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section apply to the contract or other arrangement between a business associate and a subcontractor required by § 164.308(b)(4) in the same manner as such requirements apply to contracts or other arrangements between a covered entity and business associate.

(b) * * *

(2) * * *

(iii) Ensure that any agent to whom it provides this information agrees to implement reasonable and appropriate security measures to protect the information; and

* * * * *

37. Revise the introductory text of § 164.316 and the third sentence of paragraph (a) to read as follows:

§ 164.316 Policies and procedures and documentation requirements.

A covered entity or business associate must, in accordance with § 164.306:

(a) * * * A covered entity or business associate may change its policies and procedures at any time, provided that the changes are documented and are implemented in accordance with this subpart.

* * * * *

38. The authority citation for subpart E of part 164 is revised to read as follows:

Authority: 42 U.S.C. 1320d–2 and 1320d–4; sec. 264 of Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)); and secs. 13400–13424, Pub. L. 111–5, 123 Stat. 258–279.

39. In § 164.500, redesignate paragraph (c) as paragraph (d) and add new paragraph (c) to read as follows:

§ 164.500 Applicability.

* * * * *

(c) Where provided, the standards, requirements, and implementation specifications adopted under this subpart apply to a business associate with respect to the protected health information of a covered entity.

* * * * *

40. Amend § 164.501 as follows:

a. Revise paragraph (1) of the definition of "health care operations"; and

b. Revise the definition of "marketing".

The revisions read as follows:

§ 164.501 Definitions.

* * * * *

Health care operations * * *

(1) Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; patient safety activities (as defined in 42 CFR 3.20); population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment;

* * * * *

Marketing: (1) Except as provided in paragraph (2) of this definition, marketing means to make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.

(2) Marketing does not include a communication made:

(i) For treatment of an individual by a health care provider, including case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual, provided, however, that if the communication is in writing and the health care provider receives financial remuneration in exchange for making the communication, the requirements of § 164.514(f)(2) are met.

(ii) To provide refill reminders or otherwise communicate about a drug or biologic that is currently being prescribed for the individual, only if any financial remuneration received by the covered entity in exchange for making the communication is reasonably related to the covered entity's cost of making the communication.

(iii) For the following health care operations activities, except where the covered entity receives financial remuneration in exchange for making the communication:

(A) To describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication, including communications about: The entities participating in a health care provider network or health plan network; replacement of, or enhancements to, a health plan; and health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits; or

(B) For case management or care coordination, contacting of individuals with information about treatment alternatives, and related functions to the extent these activities do not fall within the definition of treatment.

(3) *Financial remuneration* means direct or indirect payment from or on behalf of a third party whose product or service is being described. Direct or indirect payment does not include any payment for treatment of an individual.

* * * * *

41. In § 164.502, revise paragraphs (a), (b)(1), (e), and (f) to read as follows:

§ 164.502 Uses and disclosures of protected health information: General rules.

(a) *Standard.* A covered entity or business associate may not use or disclose protected health information, except as permitted or required by this subpart or by subpart C of part 160 of this subchapter.

(1) *Covered entities: Permitted uses and disclosures.* A covered entity is permitted to use or disclose protected health information as follows:

(i) To the individual;

(ii) For treatment, payment, or health care operations, as permitted by and in compliance with § 164.506;

(iii) Incident to a use or disclosure otherwise permitted or required by this subpart, provided that the covered entity has complied with the applicable requirements of §§ 164.502(b), 164.514(d), and 164.530(c) with respect to such otherwise permitted or required use or disclosure;

(iv) Pursuant to and in compliance with a valid authorization under § 164.508;

(v) Pursuant to an agreement under, or as otherwise permitted by, § 164.510; and

(vi) As permitted by and in compliance with this section, § 164.512, § 164.514(e), (f), or (g).

(2) *Covered entities: Required disclosures.* A covered entity is required to disclose protected health information:

(i) To an individual, when requested under, and required by § 164.524 or § 164.528; and

(ii) When required by the Secretary under subpart C of part 160 of this subchapter to investigate or determine the covered entity's compliance with this subchapter.

(3) [*Reserved]*

(4) *Business associates: Permitted uses and disclosures.* (i) A business associate may use or disclose protected health information only as permitted or required by its business associate contract or other arrangement pursuant to § 164.504(e), or as required by law. The business associate may not use or disclose protected health information in a manner that would violate the requirements of this subpart, if done by the covered entity, except for the purposes specified under § 164.504(e)(2)(i)(A) or (B) if such uses or disclosures are permitted by its contract or other arrangement.

(5) *Business associates: Required uses and disclosures.* A business associate is required to disclose protected health information:

(i) When required by the Secretary under subpart C of part 160 of this subchapter to investigate or determine the business associate's compliance with this subchapter.

(ii) To the covered entity, individual, or individual's designee, as necessary to satisfy a covered entity's obligations under § 164.524(c)(2)(ii) and (3)(ii) with respect to an individual's request for an electronic copy of protected health information.

(b) * * * (1) *Minimum necessary applies.* When using or disclosing protected health information or when requesting protected health information from another covered entity, a covered entity or business associate must make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.

* * * * *

(e)(1) *Standard: Disclosures to business associates.* (i) A covered entity may disclose protected health information to a business associate and may allow a business associate to create or receive protected health information on its behalf, if the covered entity obtains satisfactory assurance that the business associate will appropriately safeguard the information. A covered entity is not required to obtain such satisfactory assurances from a business associate that is a subcontractor.

(ii) A business associate may disclose protected health information to a business associate that is a subcontractor and may allow the subcontractor to create or receive protected health information on its behalf, if the business associate obtains satisfactory assurances, in accordance with § 164.504(e)(1)(i), that the subcontractor will appropriately safeguard the information.

(2) *Implementation specification: Documentation.* The satisfactory assurances required by paragraph (e)(1) of this section must be documented through a written contract or other written agreement or arrangement with the business associate that meets the applicable requirements of § 164.504(e).

(f) *Standard: Deceased individuals.* A covered entity must comply with the requirements of this subpart with respect to the protected health information of a deceased individual for a period of 50 years following the death of the individual.

* * * * *

42. In § 164.504, revise paragraphs (e) and (f)(2)(ii)(B) to read as follows:

§ 164.504 Uses and disclosures: Organizational requirements.

* * * * *

(e)(1) *Standard: Business associate contracts.* (i) The contract or other arrangement required by § 164.502(e)(2) must meet the requirements of paragraph (e)(2), (e)(3), or (e)(5) of this section, as applicable.

(ii) A covered entity is not in compliance with the standards in § 164.502(e) and this paragraph, if the covered entity knew of a pattern of activity or practice of the business associate that constituted a material breach or violation of the business associate's obligation under the contract or other arrangement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful, terminated the contract or arrangement, if feasible.

(iii) A business associate is not in compliance with the standards in § 164.502(e) and this paragraph, if the business associate knew of a pattern of activity or practice of a subcontractor that constituted a material breach or violation of the subcontractor's obligation under the contract or other arrangement, unless the business associate took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful, terminated the contract or arrangement, if feasible.

(2) *Implementation specifications: Business associate contracts.* A contract between the covered entity and a business associate must:

(i) Establish the permitted and required uses and disclosures of protected health information by the business associate. The contract may not authorize the business associate to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity, except that:

(A) The contract may permit the business associate to use and disclose protected health information for the proper management and administration of the business associate, as provided in paragraph (e)(4) of this section; and

(B) The contract may permit the business associate to provide data aggregation services relating to the health care operations of the covered entity.

(ii) Provide that the business associate will:

(A) Not use or further disclose the information other than as permitted or required by the contract or as required by law;

(B) Use appropriate safeguards and comply, where applicable, with subpart C of this part with respect to electronic protected health information, to prevent use or disclosure of the information other than as provided for by its contract;

(C) Report to the covered entity any use or disclosure of the information not provided for by its contract of which it becomes aware, including breaches of unsecured protected health information as required by § 164.410;

(D) In accordance with § 164.502(e)(1)(ii), ensure that any subcontractors that create or receive protected health information on behalf of the business associate agree to the same restrictions and conditions that apply to the business associate with respect to such information;

(E) Make available protected health information in accordance with § 164.524;

(F) Make available protected health information for amendment and incorporate any amendments to protected health information in accordance with § 164.526;

(G) Make available the information required to provide an accounting of disclosures in accordance with § 164.528;

(H) To the extent the business associate is to carry out a covered entity's obligation under this subpart, comply with the requirements of this subpart that apply to the covered entity in the performance of such obligation.

(I) Make its internal practices, books, and records relating to the use and disclosure of protected health information received from, or created or received by the business associate on behalf of, the covered entity available to the Secretary for purposes of determining the covered entity's compliance with this subpart; and

(J) At termination of the contract, if feasible, return or destroy all protected health information received from, or created or received by the business associate on behalf of, the covered entity that the business associate still maintains in any form and retain no copies of such information or, if such return or destruction is not feasible, extend the protections of the contract to the information and limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible.

(iii) Authorize termination of the contract by the covered entity, if the covered entity determines that the business associate has violated a material term of the contract.

(3) *Implementation specifications: Other arrangements.* (i) If a covered entity and its business associate are both governmental entities:

(A) The covered entity may comply with this paragraph and § 164.314(a)(1), if applicable, by entering into a memorandum of understanding with the business associate that contains terms that accomplish the objectives of paragraph (e)(2) of this section and § 164.314(a)(2), if applicable.

(B) The covered entity may comply with this paragraph and § 164.314(a)(1), if applicable, if other law (including regulations adopted by the covered entity or its business associate) contains requirements applicable to the business associate that accomplish the objectives of paragraph (e)(2) of this section and § 164.314(a)(2), if applicable.

(ii) If a business associate is required by law to perform a function or activity on behalf of a covered entity or to provide a service described in the definition of *business associate* in § 160.103 of this subchapter to a covered entity, such covered entity may disclose protected health information to the business associate to the extent necessary to comply with the legal mandate without meeting the requirements of this paragraph and § 164.314(a)(1), if applicable, provided that the covered entity attempts in good faith to obtain satisfactory assurances as required by paragraph (e)(2) of this section and § 164.314(a)(1), if applicable, and, if such attempt fails, documents the attempt and the reasons that such assurances cannot be obtained.

(iii) The covered entity may omit from its other arrangements the termination authorization required by paragraph (e)(2)(iii) of this section, if such authorization is inconsistent with the statutory obligations of the covered entity or its business associate.

(4) *Implementation specifications: Other requirements for contracts and other arrangements.* (i) The contract or other arrangement between the covered entity and the business associate may permit the business associate to use the protected health information received by the business associate in its capacity as a business associate to the covered entity, if necessary:

(A) For the proper management and administration of the business associate; or

(B) To carry out the legal responsibilities of the business associate.

(ii) The contract or other arrangement between the covered entity and the business associate may permit the business associate to disclose the protected health information received by the business associate in its capacity as a business associate for the purposes described in paragraph (e)(4)(i) of this section, if:

(A) The disclosure is required by law; or

(B)(*1*) The business associate obtains reasonable assurances from the person to whom the information is disclosed that it will be held confidentially and used or further disclosed only as required by law or for the purposes for which it was disclosed to the person; and

(*2*) The person notifies the business associate of any instances of which it is aware in which the confidentiality of the information has been breached.

(5) *Implementation specifications: Business associate contracts with subcontractors.* The requirements of § 164.504(e)(2) through (e)(4) apply to the contract or other arrangement required by § 164.502(e)(1)(ii) between a business associate and a business associate that is a subcontractor in the same manner as such requirements apply to contracts or other arrangements between a covered entity and business associate.

(f) * * *

(2) * * *

(ii) * * *

(B) Ensure that any agents to whom it provides protected health information received from the group health plan agree to the same restrictions and conditions that apply to the plan sponsor with respect to such information;

* * * * *

43. Revise § 164.506(c)(5) to read as follows:

§ 164.506 Uses and disclosures to carry out treatment, payment, or health care operations.

* * * * *

(c) * * *

(5) A covered entity that participates in an organized health care arrangement may disclose protected health information about an individual to other participants in the organized health care arrangement for any health care operations activities of the organized health care arrangement.

44. Amend § 164.508 as follows:

a. Revise the headings of paragraphs (a), (a)(1), and (a)(2);

b. Revise paragraph (a)(3)(ii);

c. Add new paragraph (a)(4); and

d. Revise paragraphs (b)(1)(i), and (b)(3).

The revisions and additions read as follows:

§ 164.508 Uses and disclosures for which an authorization is required.

(a) *Standard: Authorizations for uses and disclosures*—(1) *Authorization required: General rule.* * * *

(2) *Authorization required: Psychotherapy notes.* * * *

(3) * * *

(ii) If the marketing involves direct or indirect financial remuneration, as defined in paragraph (3) of the definition of marketing at § 164.501, to the covered entity from a third party, the authorization must state that such remuneration is involved.

(4) *Authorization required: Sale of protected health information.* (i) Notwithstanding any provision of this subpart, a covered entity must obtain an authorization for any disclosure of protected health information for which the disclosure is in exchange for direct or indirect remuneration from or on behalf of the recipient of the protected health information. Such authorization must state that the disclosure will result in remuneration to the covered entity.

(ii) Paragraph (a)(4)(i) of this section does not apply to disclosures of protected health information:

(A) For public health purposes pursuant to § 164.512(b) or § 164.514(e);

(B) For research purposes pursuant to § 164.512(i) or § 164.514(e), where the only remuneration received by the covered entity is a reasonable cost-based fee to cover the cost to prepare and transmit the protected health information for such purposes;

(C) For treatment and payment purposes pursuant to § 164.506(a);

(D) For the sale, transfer, merger, or consolidation of all or part of the covered entity and for related due diligence as described in paragraph (6)(iv) of the definition of health care operations and pursuant to § 164.506(a);

(E) To or by a business associate for activities that the business associate undertakes on behalf of a covered entity pursuant to §§ 164.502(e) and 164.504(e), and the only remuneration provided is by the covered entity to the business associate for the performance of such activities;

(F) To an individual, when requested under § 164.524 or § 164.528;

(G) Required by law as permitted under § 164.512(a); and

(H) Permitted by and in accordance with the applicable requirements of this subpart, where the only remuneration received by the covered entity is a reasonable, cost-based fee to cover the cost to prepare and transmit the protected health information for such purpose or a fee otherwise expressly permitted by other law.

(b) * * *

(1) * * *

(i) A valid authorization is a document that meets the requirements in paragraphs (a)(3)(ii), (a)(4)(i), (c)(1), and (c)(2) of this section, as applicable.

* * * * *

(3) *Compound authorizations.* An authorization for use or disclosure of protected health information may not be combined with any other document to create a compound authorization, except as follows:

(i) An authorization for the use or disclosure of protected health information for a research study may be combined with any other type of written permission for the same or another research study. This exception includes combining an authorization for the use or disclosure of protected health information for a research study with another authorization for the same research study, with an authorization for the creation or maintenance of a research database or repository, or with a consent to participate in research. Where a covered health care provider has conditioned the provision of research-related treatment on the provision of one of the authorizations, as permitted under paragraph (b)(4)(i) of this section, any compound authorization created under this paragraph must clearly differentiate between the conditioned and unconditioned components and provide the individual with an opportunity to opt in to the research activities described in the unconditioned authorization.

(ii) An authorization for a use or disclosure of psychotherapy notes may only be combined with another authorization for a use or disclosure of psychotherapy notes.

(iii) An authorization under this section, other than an authorization for a use or disclosure of psychotherapy notes, may be combined with any other such authorization under this section, except when a covered entity has conditioned the provision of treatment, payment, enrollment in the health plan, or eligibility for benefits under paragraph (b)(4) of this section on the provision of one of the authorizations. The prohibition in this paragraph on combining authorizations where one authorization conditions the provision of treatment, payment, enrollment in a health plan, or eligibility for benefits under paragraph (b)(4) of this section does not apply to a compound authorization created in accordance with paragraph (b)(3)(i) of this section.

* * * * *

45. Amend § 164.510 as follows:

a. Revise paragraph (a)(1)(ii) introductory text;

b. Revise paragraph (b)(1)(i), the second sentence of paragraph (b)(1)(ii), paragraph (b)(2)(iii), the first sentence of paragraph (b)(3), and paragraph (b)(4); and

c. Add new paragraph (b)(5).

The revisions and additions read as follows:

§ 164.510 Uses and disclosures requiring an opportunity for the individual to agree or to object.

* * * * *

(a) * * *

(1) * * *

(ii) Use or disclose for directory purposes such information:

* * * * *

(b) * * *

(1) * * *

(i) A covered entity may, in accordance with paragraphs (b)(2), (b)(3), or (b)(5) of this section, disclose to a family member, other relative, or a close personal friend of the individual, or any other person identified by the individual, the protected health information directly relevant to such person's involvement with the individual's health care or payment related to the individual's health care.

(ii) * * * Any such use or disclosure of protected health information for such notification purposes must be in accordance with paragraphs (b)(2), (b)(3), (b)(4), or (b)(5) of this section, as applicable.

* * * * *

(2) * * *

(iii) Reasonably infers from the circumstances, based on the exercise of professional judgment, that the individual does not object to the disclosure.

(3) * * * If the individual is not present, or the opportunity to agree or object to the use or disclosure cannot practicably be provided because of the individual's incapacity or an emergency circumstance, the covered entity may, in the exercise of professional judgment, determine whether the disclosure is in the best interests of the individual and, if so, disclose only the protected health information that is directly relevant to the person's involvement with the individual's care or payment related to the individual's health care or needed for notification purposes. * * *

(4) *Uses and disclosures for disaster relief purposes.* A covered entity may use or disclose protected health information to a public or private entity authorized by law or by its charter to assist in disaster relief efforts, for the purpose of coordinating with such entities the uses or disclosures

permitted by paragraph (b)(1)(ii) of this section. The requirements in paragraphs (b)(2), (b)(3), or (b)(5) of this section apply to such uses and disclosures to the extent that the covered entity, in the exercise of professional judgment, determines that the requirements do not interfere with the ability to respond to the emergency circumstances.

(5) *Uses and disclosures when the individual is deceased.* If the individual is deceased, a covered entity may disclose protected health information of the individual to a family member, or other persons identified in paragraph (b)(1) of this section who were involved in the individual's care or payment for health care prior to the individual's death, unless doing so is inconsistent with any prior expressed preference of the individual that is known to the covered entity.

46. Amend § 164.512 as follows:

a. Revise the introductory text of paragraph (b)(1) and the introductory text of paragraph (b)(1)(v)(A);

b. Add new paragraph (b)(1)(vi);

c. Revise the introductory text of paragraph (e)(1)(iii) and paragraph (e)(1)(vi);

d. Revise paragraph (i)(2)(iii); and

e. Revise paragraphs (k)(1)(ii), (k)(3), and (k)(5)(i)(E).

The revisions and additions read as follows:

§ 164.512 Uses and disclosures for which an authorization or opportunity to agree or object is not required.

* * * * *

(b) *Standard: Uses and disclosures for public health activities.*

(1) *Permitted uses and disclosures.* A covered entity may use or disclose protected health information for the public health activities and purposes described in this paragraph to:

* * * * *

(v) * * *

(A) The covered entity is a covered health care provider who provides health care to the individual at the request of the employer:

* * * * *

(vi) A school, about an individual who is a student or prospective student of the school, if:

(A) The protected health information that is disclosed is limited to proof of immunization;

(B) The school is required by State or other law to have such proof of immunization prior to admitting the individual; and

(C) The covered entity obtains the agreement to the disclosure from either:

(*1*) A parent, guardian, or other person acting *in loco parentis* of the individual, if the individual is an unemancipated minor; or

(*2*) The individual, if the individual is an adult or emancipated minor.

* * * * *

(e) * * *

(1) * * *

(iii) For the purposes of paragraph (e)(1)(ii)(A) of this section, a covered entity receives satisfactory assurances from a party seeking protected health information if the covered entity receives from such party a written statement and accompanying documentation demonstrating that:

* * *

* * * * *

(vi) Notwithstanding paragraph (e)(1)(ii) of this section, a covered entity may disclose protected health information in response to lawful process described in paragraph (e)(1)(ii) of this section without receiving satisfactory assurance under paragraph (e)(1)(ii)(A) or (B) of this section, if the covered entity makes reasonable efforts to provide notice to the individual sufficient to meet the requirements of paragraph (e)(1)(iii) of this section or to seek a qualified protective order sufficient to meet the requirements of paragraph (e)(1)(v) of this section.

* * * * *

(i) * * *

(2) * * *

(iii) *Protected health information needed.* A brief description of the protected health information for which use or access has been determined to be necessary by the IRB or privacy board, pursuant to paragraph (i)(2)(ii)(C) of this section;

* * * * *

(k) * * *

(1) * * *

(ii) *Separation or discharge from military service.* A covered entity that is a component of the Departments of Defense or Homeland Security may disclose to the Department of Veterans Affairs (DVA) the protected health information of an individual who is a member of the Armed Forces upon the separation or discharge of the individual from military service for the purpose of a determination by DVA of the individual's eligibility for or entitlement to benefits under laws administered by the Secretary of Veterans Affairs.

* * * * *

(3) *Protective services for the President and others.* A covered entity may disclose protected health information to authorized Federal officials for the provision of protective services to the President or other persons authorized by 18 U.S.C. 3056 or to foreign heads of state or other persons authorized by 22 U.S.C. 2709(a)(3), or for the conduct of investigations authorized by 18 U.S.C. 871 and 879.

* * * * *

(5) * * *

(i) * * *

(E) Law enforcement on the premises of the correctional institution; or

* * * * *

47. In § 164.514, revise paragraphs (e)(4)(ii)(C)(*4*) and (f) to read as follows:

§ 164.514 Other requirements relating to uses and disclosures of protected health information.

* * * * *

(e) * * *

(4) * * *

(ii) * * *

(C) * * *

(*4*) Ensure that any agents to whom it provides the limited data set agrees to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and

* * * * *

(f) *Fundraising and remunerated treatment communications.*

(1)(i) *Standard: Uses and disclosures for fundraising.* Subject to the conditions of paragraph (f)(1)(ii) of this section, a covered entity may use, or disclose to a business associate or to an institutionally related foundation, the following protected health information for the purpose of raising funds for its own benefit, without an authorization meeting the requirements of § 164.508:

(A) Demographic information relating to an individual; and

(B) Dates of health care provided to an individual.

(ii) *Implementation specifications: Fundraising requirements.* (A) A covered entity may not use or disclose protected health information for fundraising purposes as otherwise permitted by paragraph (f)(1)(i) of this section unless a statement required by § 164.520(b)(1)(iii)(B) is included in the covered entity's notice of privacy practices.

(B) With each fundraising communication sent to an individual under this paragraph, a covered entity must provide the individual with a clear and conspicuous opportunity to elect not to receive any further fundraising communications. The method for an individual to elect not to receive further fundraising communications may not cause the individual to incur an undue burden or more than a nominal cost.

(C) A covered entity may not condition treatment or payment on the individual's choice with respect to the receipt of fundraising communications.

(D) A covered entity may not send fundraising communications to an

individual under this paragraph where the individual has elected not to receive such communications under paragraph (f)(1)(ii)(B) of this section.

(2) *Standard: Uses and disclosures for remunerated treatment communications.* Where a covered health care provider receives financial remuneration, as defined in paragraph (3) of the definition of marketing at § 164.501, in exchange for making a treatment communication to an individual about a health-related product or service, such communication is not marketing and does not require an authorization meeting the requirements of § 164.508, only if the following requirements are met:

(i) The covered health care provider has included the information required by § 164.520(b)(1)(iii)(A) in its notice of privacy practices; and

(ii) The communication discloses the fact that the covered health care provider is receiving financial remuneration in exchange for making the communication and provides the individual with a clear and conspicuous opportunity to elect not to receive any further such communications. The method for an individual to elect not to receive further such communications may not cause the individual to incur an undue burden or more than a nominal cost.

* * * * *

48. In § 164.520, revise paragraphs (b)(1)(ii)(E), (b)(1)(iii), and (b)(1)(iv)(A) to read as follows:

§ 164.520 Notice of privacy practices for protected health information.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

(E) A description of the types of uses and disclosures that require an authorization under § 164.508(a)(2)–(a)(4), a statement that other uses and disclosures not described in the notice will be made only with the individual's written authorization, and a statement that the individual may revoke an authorization as provided by § 164.508(b)(5).

(iii) *Separate statements for certain uses or disclosures.* If the covered entity intends to engage in any of the following activities, the description required by paragraph (b)(1)(ii)(A) of this section must include a separate statement informing the individual of such activities, as applicable:

(A) In accordance with § 164.514(f)(2), the covered health care provider may send treatment communications to the individual concerning treatment alternatives or other health-related products or services where the provider receives financial remuneration, as defined in paragraph (3) of the definition of marketing at § 164.501, in exchange for making the communications, and the individual has a right to opt out of receiving such communications;

(B) In accordance with § 164.514(f)(1), the covered entity may contact the individual to raise funds for the covered entity and the individual has a right to opt out of receiving such communications; or

(C) In accordance with § 164.504(f), the group health plan, or a health insurance issuer or HMO with respect to a group health plan, may disclose protected health information to the sponsor of the plan.

(iv) * * *

(A) The right to request restrictions on certain uses and disclosures of protected health information as provided by § 164.522(a), including a statement that the covered entity is not required to agree to a requested restriction, except in case of a disclosure restricted under § 164.522(a)(1)(vi);

* * * * *

49. Amend § 164.522 as follows:

a. Revise paragraph (a)(1)(ii);

b. Add new paragraph (a)(1)(vi); and

c. Revise the introductory text of paragraph (a)(2), and paragraphs (a)(2)(iii), and paragraph (a)(3).

The revisions and additions read as follows:

§ 164.522 Rights to request privacy protection for protected health information.

(a)(1) * * *

(ii) Except as provided in paragraph (a)(1)(vi) of this section, a covered entity is not required to agree to a restriction.

* * * * *

(vi) A covered entity must agree to the request of an individual to restrict disclosure of protected health information about the individual to a health plan if:

(A) The disclosure is for the purpose of carrying out payment or health care operations and is not otherwise required by law; and

(B) The protected health information pertains solely to a health care item or service for which the individual, or person other than the health plan on behalf of the individual, has paid the covered entity in full.

(2) *Implementation specifications: Terminating a restriction.* A covered entity may terminate a restriction, if:

* * * * *

(iii) The covered entity informs the individual that it is terminating its agreement to a restriction, except that such termination is:

(A) Not effective for protected health information restricted under paragraph (a)(1)(vi) of this section; and

(B) Only effective with respect to protected health information created or received after it has so informed the individual.

(3) *Implementation specification: Documentation.* A covered entity must document a restriction in accordance with § 160.530(j) of this subchapter.

* * * * *

50. Amend § 164.524 as follows:

a. Revise paragraph (c)(2)(i);

b. Redesignate paragraph (c)(2)(ii) as paragraph (c)(2)(iii);

c. Add new paragraph (c)(2)(ii);

d. Revise paragraphs (c)(3) and (c)(4)(i);

e. Redesignate paragraphs (c)(4)(ii) and (c)(4)(iii) as paragraphs (c)(4)(iii) and (c)(4)(iv), respectively; and

f. Add new paragraph (c)(4)(ii).

The revisions and additions read as follows:

§ 164.524 Access of individuals to protected health information.

* * * * *

(c) * * *

(2) *Form of access requested.* (i) The covered entity must provide the individual with access to the protected health information in the form and format requested by the individual, if it is readily producible in such form and format; or, if not, in a readable hard copy form or such other form and format as agreed to by the covered entity and the individual.

(ii) Notwithstanding paragraph (c)(2)(i) of this section, if the protected health information that is the subject of a request for access is maintained in one or more designated record sets electronically and if the individual requests an electronic copy of such information, the covered entity must provide the individual with access to the protected health information in the electronic form and format requested by the individual, if it is readily producible in such form and format; or, if not, in a readable electronic form and format as agreed to by the covered entity and the individual.

* * * * *

(3) *Time and manner of access.* (i) The covered entity must provide the access as requested by the individual in a timely manner as required by paragraph (b)(2) of this section, including arranging with the individual for a convenient time and place to inspect or obtain a copy of the protected health information, or mailing the copy of the protected health information at the individual's request. The covered entity may discuss the scope, format,

and other aspects of the request for access with the individual as necessary to facilitate the timely provision of access.

(ii) If an individual's request for access directs the covered entity to transmit the copy of protected health information directly to another person designated by the individual, the covered entity must provide the copy to the person designated by the individual. The individual's request must be in writing, signed by the individual, and clearly identify the designated person and where to send the copy of protected health information.

(4) * * *

(i) Labor for copying the protected health information requested by the individual, whether in paper or electronic form;

(ii) Supplies for creating the paper copy or electronic media if the individual requests that the electronic copy be provided on portable media;

* * * * *

51. In § 164.532, revise paragraphs (d), (e)(1) and (e)(2) to read as follows:

§ 164.532 Transition provisions.

* * * * *

(d) *Standard: Effect of prior contracts or other arrangements with business associates.* Notwithstanding any other provisions of this part, a covered entity, or business associate with respect to a subcontractor, may disclose protected health information to a business associate and may allow a business associate to create, receive, or use protected health information on its behalf pursuant to a written contract or other written arrangement with such business associate that does not comply with §§ 164.308(b), 164.314(a), 164.502(e), and 164.504(e), only in accordance with paragraph (e) of this section.

(e) *Implementation specification: Deemed compliance.* (1) *Qualification.* Notwithstanding other sections of this part, a covered entity, or business associate with respect to a subcontractor, is deemed to be in compliance with the documentation and contract requirements of §§ 164.308(b), 164.314(a), 164.502(e), and 164.504(e), with respect to a particular business associate relationship, for the time period set forth in paragraph (e)(2) of this section, if:

(i) Prior to [DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER], such covered entity, or business associate with respect to a subcontractor, has entered into and is operating pursuant to a written contract or other written arrangement with the business associate that complies with the applicable provisions of §§ 164.314(a) or 164.504(e) that were in effect on such date; and

(ii) The contract or other arrangement is not renewed or modified from [DATE THAT IS 60 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER], until [DATE THAT IS 240 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER].

(2) *Limited deemed compliance period.* A prior contract or other arrangement that meets the qualification requirements in paragraph (e) of this section shall be deemed compliant until the earlier of:

(i) The date such contract or other arrangement is renewed or modified on or after [DATE THAT IS 240 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER]; or

(ii) [DATE THAT IS ONE YEAR AND 240 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER].

* * * * *

Dated: April 9, 2010.

Kathleen Sebelius,

Secretary.

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Part III

Environmental Protection Agency

40 CFR Parts 141 and 142

National Primary Drinking Water Regulations: Revisions to the Total Coliform Rule; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141 and 142

[EPA–HQ–OW–2008–0878; FRL–9166–8]

RIN 2040–AD94

National Primary Drinking Water Regulations: Revisions to the Total Coliform Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed Rule.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is proposing revisions to the 1989 Total Coliform Rule. The proposed Revised Total Coliform Rule offers a meaningful opportunity for greater public health protection beyond the current Total Coliform Rule. The proposed revisions require systems that have an indication of coliform contamination in the distribution system to assess the problem and take corrective action that may reduce cases of illnesses and deaths due to potential fecal contamination and waterborne pathogen exposure. This proposal also updates provisions in other rules that reference analytical methods and other requirements in the current TCR (*e.g.,* Public Notification and Ground Water Rules). These proposed revisions are in accordance with the Safe Drinking Water Act as amended, which requires EPA to review and revise, as appropriate, each national primary drinking water regulation promulgated under the Safe Drinking Water Act not less often than every six years. As with the current Total Coliform Rule, the proposed Revised Total Coliform Rule applies to all public water systems.

DATES: Comments must be received on or before September 13, 2010.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OW–2008–0878, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Water Docket, Environmental Protection Agency, Mailcode: 4101T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Attention Docket ID No. EPA–HQ–OW–2008–0878. In addition, please mail a copy of your comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attn: Desk Officer for EPA, 725 17th St., NW., Washington, DC 20503.
- *Hand Delivery:* EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. 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–2008–0878. 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 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, *i.e.,* CBI or other information whose disclosure is restricted by statue. 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 Water Docket, EPA Docket Center, EPA/DC, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. 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, and the telephone number for the Water Docket is (202) 566–2426.

FOR FURTHER INFORMATION CONTACT: Sean Conley, Standards and Risk Management Division, Office of Ground Water and Drinking Water (MC–4607M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564–1781; e-mail address: *conley.sean@epa.gov*. For general information, contact the Safe Drinking Water Hotline, telephone number: (800) 426–4791. The Safe Drinking Water Hotline is open Monday through Friday, excluding legal holidays, from 10 a.m. to 4 p.m. Eastern time.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Regulated Categories and Entities

Entities potentially regulated by the proposed Revised Total Coliform Rule (RTCR) are all public water systems (PWSs). Regulated categories and entities include the following:

Category	Examples of regulated entities
Industry	Privately-owned community water systems (CWSs), transient non-community water systems (TNCWSs), and non-transient non-community water systems (NTNCWSs).
State, Tribal, and local governments.	Publicly-owned CWSs, TNCWSs, and NTNCWSs.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the definition of "public water system" in § 141.2 and the section entitled "Coverage" in § 141.3 in title 40 of the Code of Federal Regulations (CFR), and the applicability criteria in § 141.850(b) of this proposed rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. Copies of This Document and Other Related Information

This document is available for download at *http://www.epa.gov/safewater/disinfection/tcr/*. For other related information, see preceding discussion on docket.

Abbreviations Used in This Document

ADWR Airline Drinking Water Rule
AGI Acute Gastrointestinal Illness
AIDS Acquired Immune Deficiency Syndrome
AIP Agreement in Principle
AWWA American Water Works Association
ATP Alternative Test Procedure
AWOP Area Wide Optimization Program
BAT Best Available Technology
C Celsius
CA Corrective Action
CBI Confidential Business Information
CCR Consumer Confidence Report
CDC Centers for Disease Control and Prevention
CFR *Code of Federal Regulations*
COI Cost of Illness
CWS Community Water System
DBPs Disinfection Byproducts
DWC Drinking Water Committee
EA Economic Analysis
EC *E. coli*
EC–MUG EC Medium with MUG
EPA United States Environmental Protection Agency
ETV Environmental Technology Verification
FR *Federal Register*
GW Ground Water
GWR Ground Water Rule
GWS Ground Water System
GWUDI Ground Water Under the Direct Influence of Surface Water
HRRCA Health Risk Reduction and Cost Analysis
HUS Hemolytic Uremic Syndrome
ICR Information Collection Request
IESWTR Interim Enhanced Surface Water Treatment Rule
M Million
MCL Maximum Contaminant Level
MCLG Maximum Contaminant Level Goal
mg/L Milligrams per Liter
ml Milliliters
MOU Memorandum of Understanding
MRDL Maximum Residual Disinfectant Level
MUG 4-methylumbelliferyl-Beta-D-glucuronide
NCWS Non-community Water System
NDWAC National Drinking Water Advisory Council
NPDWR National Primary Drinking Water Regulation
NTNCWS Non-Transient Non-Community Water System
NTU Nephelometric Turbidity Unit
OMB Office of Management and Budget
PN Public Notification
PWS Public Water System
RFA Regulatory Flexibility Act
RICP Research and Information Collection Partnership
RTCR Revised Total Coliform Rule
SAB Science Advisory Board
SBA Small Business Administration
SDWA Safe Drinking Water Act
SDWIS Safe Drinking Water Information System
SDWIS/FED Safe Drinking Water Information System Federal Version
SOP Standard Operating Procedure
Stage 1 DBPR Stage 1 Disinfectants and Disinfection Byproducts Rule
Stage 2 DBPR Stage 2 Disinfectants and Disinfection Byproducts Rule
SW Surface Water
SWTR Surface Water Treatment Rule
TC Total Coliforms
TCR Total Coliform Rule
TCRDSAC Total Coliform Rule/Distribution System Advisory Committee
TNCWS Transient Non-Community Water System
T&C Technology and Cost
US United States
UV Ultraviolet Radiation
WRF Water Research Foundation

Table of Contents

II. Background

A. Statutory Authority

The Safe Drinking Water Act (SDWA) requires the EPA to review and revise, as appropriate, each existing national primary drinking water regulation (NPDWR) at least once every six years (SDWA section 1412(b)(9), 42 U.S.C. 300g–1(b)(9)). In 2003, EPA completed its review of the Total Coliform Rule (TCR) and 68 NPDWRs for chemicals that were promulgated prior to 1997 (USEPA 2003, 68 FR 42908, July 18, 2003). The purpose of the review was to identify new health risk assessments, changes in technology, and other factors that would provide a health-related or technological basis to support a regulatory revision that would maintain or improve public health protection. In the Six-Year Review 1 determination published in July 2003 (USEPA 2003, 68 FR 42908, July 18, 2003), EPA stated its intent to revise the 1989 TCR (also referred to as the "current TCR").

B. Total Coliform Rule Distribution System Advisory Committee (TCRDSAC)

In June 2007, EPA established the Total Coliform Rule/Distribution System Advisory Committee ("TCRDSAC" or "the advisory committee") in accordance with the provisions of the Federal Advisory Committee Act, 5 U.S.C. App.2, 9 (c), to provide recommendations to EPA on revisions to the 1989 TCR and on what information about distribution system issues is needed to better understand and address possible public health impacts from potential degradation of drinking water distribution systems (USEPA 2007a, 72 FR 35869, June 29, 2007). The decision to include a review of distribution system issues was made, in part, to address recommendations made by the Stage 2 Microbial and Disinfection Byproducts Federal Advisory Committee in December 2000 (USEPA 2000b, 65 FR 83015, December 29, 2000). The TCRDSAC used available information to analyze options for revisions to the TCR. The TCRDSAC also considered research and information needed to better understand and address public health risks from contamination of distribution systems.

The advisory committee consisted of representatives of EPA, State and local public health and regulatory agencies, consumer organizations, environmental organizations, local elected officials, Indian Tribes, and drinking water suppliers. A technical workgroup was also formed to provide the advisory committee with necessary technical support and analysis to facilitate the committee's discussions. The advisory committee met on 13 occasions between July 2007 and September 2008. All advisory committee members agreed to and signed the final Agreement in Principle (AIP) in September 2008. All of the recommendations of the advisory committee are found in the signed AIP. Pursuant to the AIP, EPA agreed to propose revisions to the TCR that, to the maximum extent consistent with EPA's legal obligations, have the same substance and effect as the elements of the AIP. Each party represented on the advisory committee agreed in the AIP not to take any action to inhibit the adoption and implementation of final rule(s) to the extent it and the corresponding preamble have the same substance and effect as the elements of the AIP. EPA also agreed in the AIP to develop a Research and Information Collection Partnership (RICP) to "inform and support the drinking water community in developing future national risk management decisions pertaining to drinking water distribution systems" by providing "a formal process for systematic planning, implementation, analysis, and communication of distribution system research and information collection" (USEPA 2008c). A discussion of the RICP can be found in section V of this preamble. The AIP and details about the advisory committee can be found at EPA's Web site at: *http://www.epa.gov/safewater/disinfection/tcr/regulation_revisions.html.*

In addition to the outreach mentioned above, EPA agreed to engage in various future stakeholder meetings at least annually, to which all advisory committee members and the public at large would be invited. In April 2009, EPA held its first annual stakeholder meeting to provide draft proposed regulation updates and an opportunity for stakeholders to provide feedback on the development of the proposed RTCR.

C. Other Outreach Processes

In addition to consulting with the advisory committee, EPA engaged in several other activities as part of the Agency's outreach to stakeholders in developing the proposed RTCR. EPA held a technical workshop in Washington, DC, from January 30 to February 1, 2007, to discuss available information on the current TCR and available information regarding risks in distribution systems in support of revisions to the TCR. Other EPA outreach activities, namely the National Drinking Water Advisory Council consultation, Science Advisory Board consultation, and the Tribal consultation, are discussed in section VII of this preamble.

D. Public Health Concerns Addressed by the Proposed Revised Total Coliform Rule

1. Public Health Concerns, Fecal Contamination, and Waterborne Pathogens

The proposed RTCR aims to increase public health protection through the reduction of potential pathways of entry for fecal contamination into the distribution system. Since these potential pathways represent vulnerabilities in the distribution system whereby fecal contamination and/or waterborne pathogens, including bacteria, viruses and parasitic protozoa could possibly enter the system, the reduction of these pathways in general should lead to reduced exposure and associated risk from these contaminants. Fecal contamination and waterborne pathogens can cause a variety of illnesses, including acute gastrointestinal illness (AGI) with diarrhea, abdominal discomfort, nausea, vomiting, and other symptoms. Most AGI cases are of short duration and result in mild illness. Other more severe illnesses caused by waterborne pathogens include hemolytic uremic syndrome (HUS) (kidney failure), hepatitis, and bloody diarrhea (WHO 2004). Chronic disease such as irritable bowel syndrome, reduced kidney function, hypertension and reactive arthritis can result from infection by a waterborne agent (Clark *et al.* 2008).

When humans are exposed to and infected by waterborne enteric pathogens, the pathogens become capable of reproducing in the gastrointestinal tract. As a result, healthy humans shed pathogens in their feces for a period ranging from days to weeks. This shedding of pathogens often occurs in the absence of any signs of clinical illness. Regardless of whether a pathogen causes clinical illness in the

person who sheds it in his or her feces, the pathogen being shed may infect other people directly by person-to-person spread, contact with contaminated surfaces, and other means which are referred to as secondary spread. As a result, waterborne pathogens that are initially waterborne may subsequently infect other people through a variety of routes (WHO 2004). Sensitive subpopulations are at greater risk from waterborne disease than the general population (Gerba *et al.* 1996). For a discussion of sensitive subpopulations, see section VII.L of this preamble.

2. Indicators

Total coliforms are a group of closely related bacteria that, with a few exceptions, are not harmful to humans. Coliforms are abundant in the feces of warm-blooded animals, but can also be found in aquatic environments, in soil, and on vegetation. Coliform bacteria may be transported to surface water by run-off or to ground water by infiltration. Total coliforms are common in ambient water and may be injured by environmental stresses such as lack of nutrients, and water treatments such as chlorine disinfection, in a manner similar to most bacterial pathogens and many viral enteric pathogens (including fecal pathogens). EPA considers total coliforms to be a useful indicator that a potential pathway exists through which fecal contamination can enter the distribution system. The absence (versus the presence) of total coliforms in the distribution system indicates a reduced likelihood that fecal contamination and/or waterborne pathogens are occurring in the distribution system.

Under the current TCR, each total coliform-positive sample is assayed for either fecal coliforms or *E. coli.* Fecal coliform bacteria are a subgroup of total coliforms that traditionally have been associated with fecal contamination. Since the promulgation of the TCR, more information and understanding of the suitability of fecal coliform and *E. coli* as indicators have become available. Study has shown that the fecal coliform assay is imprecise and too often captures bacteria that do not originate in the human or mammal gut (Edberg *et al.* 2000). On the other hand, *E. coli* is a more restricted group of coliform bacteria that almost always originate in the human or animal gut (Edberg *et al.* 2000). Thus, *E. coli* is a better indicator of fecal contamination than fecal coliforms.

3. Occurrence of Fecal Contamination and Waterborne Pathogens

a. *Presence of fecal contamination.* Fecal contamination is a very general term that includes all of the organisms found in feces, both pathogenic and nonpathogenic. Fecal contamination can occur in drinking water both through use of contaminated source water as well as direct intrusion of fecal contamination into the drinking water distribution system. Lieberman *et al.* (1994) discuss the general association between fecal contamination and waterborne pathogens. Biofilms in distribution systems may harbor waterborne bacterial pathogens and accumulate enteric viruses and parasitic protozoa (Skraber *et al.* 2005; Helmi *et al.* 2008). Waterborne pathogens in biofilms may have entered the distribution system as fecal contamination from humans or animals.

Co-occurrence of indicators and waterborne pathogens is difficult to measure. The analytical methods approved by EPA to assay for *E. coli* are able to detect indicators of fecal contamination. They do not specifically identify most of the pathogenic *E. coli* strains. There are at least 700 recognized *E. coli* strains (Kaper *et al.* 2004). About 10 percent of recognized *E. coli* strains are pathogenic to humans (Feng 1995; Hussein 2007; Kaper *et al.* 2004). Pathogenic *E. coli* include *E. coli* O157:H7, which is the primary cause of hemolytic uremic syndrome (HUS) in the United States (Rangel *et al.* 2005). The U.S. Centers for Disease Control and Prevention (CDC) estimates that there are 73,000 cases of illness each year in the U.S. due to *E. coli* O157:H7 (Mead *et al.* 1999). The CDC estimates that about 15 percent of all reported *E. coli* O157:H7 cases are due to water contamination (Rangel *et al.* 2005). Active surveillance by CDC shows that 6.3 percent of *E. coli* O157:H7 cases progress to HUS (Griffin and Tauxe 1991; Gould *et al.* 2009) and about 12 percent of HUS cases result in death within four years (Garg *et al.* 2003). About 4 to 15 percent of cases are transmitted within households by secondary transmission (Parry and Salmon 1998).

Because EPA-approved standard methods for *E. coli* do not typically identify the presence of the pathogenic *E. coli* strains, an *E. coli*-positive monitoring result is an indicator of fecal contamination but is not necessarily a measure of waterborne pathogen occurrence. Specialized assays and methods are used to identify waterborne pathogens, including pathogenic *E. coli.*

One notable exception is the data reported by Cooley *et al.* (2007), which showed high concentrations of pathogenic *E. coli* strains in samples containing high concentrations of fecal indicator *E. coli.* These data are from streams and other poor quality surface waters surrounding California spinach fields associated with the 2006 *E. coli* O157:H7 foodborne outbreak. Data equivalent to these samples are not available from drinking water samples collected under the TCR.

Because *E. coli* is an indicator of fecal contamination (Edberg *et al.* 2000), and because of the general association between fecal contamination and waterborne pathogens (Lieberman *et al.* 1994; Lieberman *et al.* 2002), *E. coli* is a meaningful indicator for fecal contamination and the potential presence of associated pathogen occurrence.

b. *Waterborne disease outbreaks.* The CDC defines a waterborne disease outbreak as occurring when at least two persons (or one with amoebic meningoencephalitis) experience a similar illness after ingesting a specific drinking water (or after exposure to recreational water) contaminated with pathogens (or chemicals) (Kramer *et al.* 1996). The CDC maintains a database on waterborne disease outbreaks in the United States. The database is based upon responses to a voluntary and confidential survey form that is completed by State and local public health officials.

The National Research Council strongly suggests that the number of identified and reported outbreaks in the CDC database for surface and ground waters represents only a small percentage of actual number of waterborne disease outbreaks (NRC 1997; Bennett *et al.* 1987; Hopkins *et. al.* 1985 for Colorado data). Under-reporting occurs because most waterborne outbreaks in community water systems are not recognized until a sizable proportion of the population is ill (Perz *et al.* 1998; Craun 1996), perhaps 1 percent to 2 percent of the population (Craun 1996).

EPA drinking water regulations are designed to protect against endemic waterborne disease and to minimize waterborne outbreaks. In contrast to epidemic, endemic refers to the persistent low to moderate level or the usual ongoing occurrence of illness in a given population or geographic area (Craun *et al.* 2006).

III. Proposed Revised Total Coliform Rule

The proposed RTCR maintains and strengthens the objectives of the current

TCR and is consistent with the recommendations in the AIP. The objectives are: (1) To evaluate the effectiveness of treatment, (2) to determine the integrity of the distribution system, and (3) to signal the possible presence of fecal contamination. The proposed revision better addresses these objectives by requiring systems that may be vulnerable to fecal contamination (as indicated by their monitoring results) to do an assessment, to identify whether any sanitary defect(s) is (are) present, and to correct the defects. Therefore, the Agency anticipates greater public health protection under the proposed RTCR compared to the current TCR because of its more preventive approach to identifying and fixing problems that affect or may affect public health.

The following is an overview of the key provisions of the proposed RTCR:

• *MCLG and MCL for E. coli and coliform treatment technique for protection against potential fecal contamination.* The proposed RTCR establishes a maximum contaminant level goal (MCLG) and maximum contaminant level (MCL) for *E. coli.* It takes a preventive approach to protecting public health by establishing a coliform treatment technique for protection against potential fecal contamination. The treatment technique uses both total coliforms and *E. coli* monitoring results to start an evaluation process that, where necessary, will require the PWS to conduct follow-up corrective action that could prevent future incidences of contamination and exposure to fecal contamination and/or waterborne pathogens. See section III.A.2 of this preamble for a detailed discussion on the MCLG, MCL, and treatment technique requirements.

• *Monitoring.* As with the current TCR, PWSs will continue to monitor for total coliforms and *E. coli* according to a sample siting plan and schedule specific to the system.

Sample siting plans under the proposed RTCR must continue to be representative of the water throughout the distribution system. Under the proposed RTCR, systems have the flexibility to propose repeat sample locations that best verify and determine the extent of potential contamination of the distribution system rather than having to sample within five connections upstream and downstream of the total coliform-positive sample location. In lieu of proposing new repeat sample locations, the systems may stay with the default used under the current TCR of five connections upstream and downstream of the total coliform-positive sample location.

As with the current TCR, the proposed RTCR allows reduced monitoring for some small ground water systems. The proposed RTCR is expected to improve public health protection compared to the current TCR by requiring small ground water systems that are on or wish to conduct reduced monitoring to meet certain eligibility criteria. Examples of the criteria include a sanitary survey showing that the system is free of sanitary defects, a clean TCR compliance history for 12 months, and a recurring annual site visit by the State and/or a voluntary Level 2 assessment for systems on annual monitoring.

For small ground water systems, the proposed RTCR requires increased monitoring for high-risk systems that meet certain criteria such as unacceptable compliance history under the RTCR. The proposed RTCR specifies conditions under which systems will no longer be eligible for reduced monitoring and be required to return to routine monitoring or to monitor at an increased frequency.

The proposed RTCR requires systems on a quarterly or annual monitoring frequency (applicable only to ground water systems serving 1,000 or fewer people) to conduct additional routine monitoring the month following one or more total coliform-positive samples. Under the proposed RTCR, systems must collect at least three routine samples during the next month, unless the State waives the additional routine monitoring. This is a reduction in the required number of additional routine samples from the current TCR, which requires at least five routine samples in the month following a total coliform-positive sample for all systems serving 4,100 or fewer people.

The current TCR requires all systems serving 1,000 or fewer people to collect at least four repeat samples while PWSs serving 1,000 people or greater to collect three repeat samples. The proposed rule requires three repeat samples after a routine total coliform-positive sample, regardless of the system type and size.

See sections III.A.3 and III.A.4 of this preamble for detailed discussions of the routine monitoring and repeat sampling requirements of the proposed RTCR.

• *Seasonal systems.* The proposed RTCR establishes monitoring requirements for seasonal systems for the first time. Seasonal systems represent a special case in that the shutdown and start-up of these water systems present additional opportunities for contamination to enter or spread through the distribution system. Seasonal systems must demonstrate completion of a State-approved start-up procedure. In addition, they must designate the time period(s) for monitoring based on site-specific considerations (such as during periods of highest demand or highest vulnerability to contamination) in their State-approved sample siting plan. See section III.A.3 of this preamble for a detailed discussion of seasonal systems.

• *Assessment and corrective action.* As part of a treatment technique, all PWSs are required to assess their systems when monitoring results show that the system may be vulnerable to contamination. Systems must conduct a simple self-assessment (Level 1) or a more detailed assessment (Level 2) depending on the severity and frequency of contamination. The system is responsible for correcting any sanitary defect(s) found through either a Level 1 or Level 2 assessment. *See* section III.A.5 of this preamble for more discussion of the treatment technique requirement of the proposed RTCR.

• *Violations and public notification.* The proposed RTCR establishes an *E. coli* MCL violation, a treatment technique violation, a monitoring violation, and a reporting violation. Public notification is required for each type of violation, with the type of notification dependent on the degree of potential public health concern. This is consistent with EPA's current public notification requirements under 40 CFR part 141 subpart Q. The proposed RTCR also modifies the public notification and Consumer Confidence Report language to reflect the construct of the proposed rule. *See* sections III.A.6 and III.A.7 of this preamble for detailed discussions of violations and public notification under the proposed RTCR.

• *Transition to the RTCR.* The proposed RTCR allows all systems to transition to the new rule at their current TCR monitoring frequency, including systems on reduced monitoring under the current TCR. States will then evaluate the monitoring frequency during each sanitary survey conducted after the compliance effective date of the RTCR. This process reduces State burden by not requiring the State to determine appropriate monitoring frequency at the same time as when the State is trying to adopt primacy, develop policies, and train their own staff and the PWSs in the State.

The provisions of the proposed RTCR are contained in the new 40 CFR part 141 subpart Y, superseding 40 CFR 141.21 beginning three years following the publication of the final revised rule.

A. Proposed Rule Provisions and Rationale

1. Terms used in the proposed RTCR

a. *Provisions.* i. Clean compliance history. For the purposes of the proposed RTCR, EPA is proposing to define "clean compliance history" as a record of no maximum contaminant level (MCL) violations under 40 CFR 141.63; no monitoring violations under 40 CFR 141.21 or subpart Y; and no coliform treatment technique trigger exceedances or coliform treatment technique violations under subpart Y.

ii. Sanitary defect. EPA is proposing to define "sanitary defect" as a "defect that could provide a pathway of entry for microbial contamination into the distribution system or that is indicative of a failure or imminent failure in a barrier that is already in place" (USEPA 2008c).

iii. Seasonal systems. EPA is proposing to define a seasonal system as a non-community water system that is operated in three or fewer calendar quarters per calendar year.

b. *EPA's rationale.* i. Clean compliance history. EPA is proposing a definition of "clean compliance history" because without a definition, the use of the phrase could result in multiple interpretations. Clean compliance history is one of the criteria a system must meet to be eligible for reduced monitoring. The advisory committee recommended this definition (USEPA 2008c, AIP p. 10).

ii. Sanitary defect. The advisory committee recommended the definition of sanitary defect. The proposed RTCR takes a more preventive approach to protect public health by establishing a framework for the assessment of public water systems to identify sanitary defects and to correct them as appropriate. The first part of the proposed definition of a "sanitary defect" focuses on problems in the distribution system that may provide a pathway for contaminants to enter the distribution system and its implication for potential exposure to both microbial and chemical contaminants. The second part of the definition also recognizes the importance of having barriers in place to prevent the entry of microbial contaminants into the distribution system. Indications of failure or imminent failure of these barriers are defects that require corrective action.

Sanitary defect is a term specific to the proposed RTCR assessment and corrective action provisions. Sanitary defects are not intended to be linked directly to "significant deficiencies" under the Interim Enhanced Surface Water Treatment Rule (IESWTR) (USEPA 1998b, 63 FR 69389, December 16, 1998) and Ground Water Rule (GWR) (USEPA 2006c, 71 FR 65574, November 8, 2006), although some problems could meet either definition. Nothing in this proposed rule is intended to limit the existing authorities of States under other regulations.

The following is a list of examples of sanitary defects and defects in the distribution system coliform monitoring practices (USEPA 2008c, AIP Appendix Y, p. 41).

Examples of sanitary defects:

- Cross connection and backflow issues such as a required backflow prevention device not in place or not operating properly; or an unprotected cross connection found.
- Operator issues such as failure to follow standard operating procedures (SOPs) that protect distribution system integrity and sanitary conditions.
- Distribution system issues such as inadequate inspection and maintenance of the distribution system; loss of distribution system integrity such as main breaks; failure to maintain adequate pressure; improper flushing operations; improper construction of new, replaced, or renovated lines; inadequate disinfection during and after repair/replacement activities; or inability to maintain required residual throughout the distribution system.
- Storage issues such as overflow, vents, hatches, and other penetrations not properly configured, screened, or sealed; inadequate maintenance of storage facilities; or inadequate disinfection during and after repair/replacement activities.
- Disinfection issues such as inability to maintain required residual throughout the distribution system.

iii. Seasonal systems. Seasonal systems fall under the broader category of non-community water systems (NCWS) and therefore are subject to provisions applicable to that category of systems. However, seasonal systems have unique characteristics and timetables that make them particularly susceptible to contamination. Seasonal systems represent a special case in that the shut down and start-up of the water system present opportunities for contamination to enter or spread through the distribution system. For example, loss of pressure after a system's shut down can lead to intrusion of contaminants. Microbial growth prior to start-up can result in biofilm formation, which can lead to the accumulation of contaminants. These systems are also more susceptible to contamination due to changes in the conditions of the source water (such as variable contaminant loading due to increased septic tank or septic field use), the seasonal nature of the demand, and the stress that the system experiences. As a result, the Agency is establishing a definition for seasonal systems and setting forth provisions that mitigate the risk associated with the unique characteristics of this type of system. The advisory committee recommended that such provisions pertain to seasonal systems. See section III.A.3 of this preamble for specific provisions that seasonal systems must meet.

c. *Request for comment.* EPA requests comment on the proposed definitions and whether they work within the construct of the proposed RTCR. Specifically, EPA requests comment on the proposed definition of seasonal systems. The advisory committee recommended that seasonal systems be identified and be subject to additional regulatory requirements because the shutdown and startup of the system presents opportunities for contaminants to enter or spread through the distribution system. These results are possible in any system that shuts down and does not maintain adequate pressure throughout the distribution system. The AIP describes a seasonal system as "one which operates less than four calendar quarters per year" (USEPA 2008c). EPA has interpreted this to mean that a seasonal system is one which is shut down for at least one full calendar quarter (*i.e.,* it operates in three or fewer calendar quarters). EPA requests comment on whether this proposed definition of "seasonal system" is adequate to address the concern that motivated the advisory committee's recommendation and is consistent with its intent. For example, a system that operated from March to October would operate in all four calendar quarters and would not be considered a seasonal system, but would be subject to the same possibility of distribution system intrusion as a seasonal system that operated April to November (*i.e.,* in only three calendar quarters). Should EPA modify the definition to address this issue? If so, how should the definition be modified? Should systems that close for some specified period (*e.g.,* 30 days, 60 days, 90 days) be subject to seasonal system requirements? What should that specified period be?

Systems that operate intermittently (*e.g.,* only on weekends or only when a camp is open) may also be subject to distribution system contamination due to lack of adequate pressure. Should this be addressed? If so, how should it be addressed—through regulation, guidance, or some other approach? Is

there a specific shutdown time that should be considered for intermittent systems in developing the approach and determining which systems should be included?

In addition to the public health benefits associated with these requirements, EPA is aware of the burden that States will have in determining which systems must comply and in tracking compliance. Therefore, EPA requests comment on ways to reduce State burden and facilitate implementation of seasonal system provisions.

2. MCLG and MCL for *E. coli,* and Coliform Treatment Technique

a. *Provisions.* The current TCR established a maximum contaminant level goal (MCLG) of zero for total coliforms (including fecal coliforms and *E. coli*) and an MCL for total coliforms. EPA is proposing in the RTCR to eliminate the MCLG for total coliforms (including fecal coliforms) and the MCL for total coliforms. Under the proposed RTCR, EPA establishes an MCLG of zero and an MCL for *E. coli* and a treatment technique for coliform. The proposed MCL for *E. coli* is based on the monitoring results for total coliforms and *E. coli.* A system is in compliance with the *E. coli* MCL unless any of the following conditions occur:

- A system has an *E. coli* positive repeat sample following a total coliform-positive routine sample; or
- A routine sample is *E. coli*-positive and one of its associated repeat samples is total coliform-positive; or
- A system fails to test for *E. coli* when any repeat sample tests positive for total coliforms; or
- A system fails to take all required repeat samples following a routine sample that is positive for *E. coli.*

The proposed MCL is similar to the criteria that define the conditions (if exceeded) when a Tier 1 acute MCL violation occurs under the current TCR but with two modifications. First, the proposed MCL excludes fecal coliforms. Second, the proposed MCL also includes an additional condition by which a system violates the MCL, namely failing to collect all repeat samples following an initial *E. coli*-positive sample. Although not explicitly stated, as a logical consequence of the second condition, a system also violates the MCL when an *E. coli*-positive routine sample is followed by an *E. coli*-positive repeat sample because *E. coli* are a subset of total coliforms. EPA is also proposing a coliform treatment technique, which uses total coliforms and *E. coli* as indicators of a possible breach in the distribution system that could lead to fecal contamination.

b. *EPA's rationale.* i. Inclusion of MCLG for *E. coli* and removal of MCLG for total coliforms (including fecal coliforms). EPA is proposing in the RTCR to include an MCLG of zero for *E. coli* and to remove the current MCLG of zero for total coliforms (including fecal coliforms). This is because *E. coli* is a more specific indicator of fecal contamination and potential harmful pathogens in drinking water than are total coliforms (including fecal coliforms). Many of the organisms detected by total coliform and fecal coliform methods are not of fecal origin and do not have any direct public health implication. *See* also the discussion of fecal coliforms in section III.A.9 of this preamble. New information has become available since promulgation of the current TCR in 1989 that indicates that measurement of fecal coliforms sometimes detects organisms that may not have any connection to fecal contamination (Edberg *et al.* 2000). An MCLG of zero for *E. coli* is more appropriate than an MCLG of zero for total coliforms (including fecal coliforms) since *E. coli* is a more specific indicator of the presence of fecal contamination.

Total coliforms (including fecal coliforms) do not in and of themselves pose a public health risk, but they may indicate the presence of a pathway by which fecal contamination can occur. Therefore, the removal of the MCLG for total coliforms (including fecal coliforms) would prevent possible public confusion as a result of attributing greater public health significance to the presence of total coliforms than is warranted. EPA believes that the removal of the MCLG for total coliforms, along with the other proposed changes discussed in the succeeding paragraphs, leads to a rule that is more protective of public health, and is less confusing to the public. The proposed MCLG of zero for *E. coli* and the removal of the MCLG for total coliforms (including fecal coliforms) are also consistent with the recommendation made by the advisory committee in the AIP.

ii. Inclusion of MCL for *E. coli* and removal of MCLs for total coliforms and fecal coliforms. EPA is proposing to include in the RTCR an MCL for *E. coli* because approved analytical methods continue to be available to measure the presence of *E. coli* in water samples, *i.e.,* the presence of *E. coli* is technologically feasible to ascertain. Violation of the proposed MCL for *E. coli* signifies fecal contamination occurrence and a possible high risk of exposure to pathogens. EPA is proposing to eliminate the MCLs for total coliforms and fecal coliforms because under the proposal there is no longer an MCLG for either total coliforms or fecal coliforms, for the reasons explained earlier. The proposed MCL for *E. coli* is consistent with the recommendation made by the advisory committee in the AIP.

iii. Coliform treatment technique. The 1996 SDWA amendments authorize EPA to promulgate a treatment technique in lieu of an MCL if EPA determines that "it is not economically or technologically feasible to ascertain the level of the contaminant" (SDWA 1412(b)(7)(A)). While it is technologically feasible to ascertain levels of *E. coli* (*i.e.,* analytical methods continue to be available to measure the presence of *E. coli* in water samples), because of the intermittent nature of fecal contamination, it is not economically feasible to ascertain the level of *E. coli* occurrence below which the water may be deemed safe. This is because it is not economically feasible to monitor *E. coli* with sufficient frequency to ensure such safety.

Because total coliform bacteria are part of the soil ecosystem, positive samples are indicators of fecal contaminant entry into drinking water via a pathway from the soil. EPA is proposing a coliform treatment technique, supplemental to directly measuring *E. coli,* to provide additional protection against fecal contamination. Under the proposed coliform treatment technique, as specified in the AIP, total coliform-positive samples, in the absence of *E. coli,* are still indicators of an *E. coli* or other fecal contaminant pathway.

A PWS that exceeds a specified frequency of total coliform occurrence must conduct a Level 1 or Level 2 assessment to determine if any sanitary defect(s) exist(s) and, if found, to correct the defect(s). In addition, under the proposed treatment technique requirements, a PWS that incurs an *E. coli* MCL violation must conduct a Level 2 assessment and take remedial action if any sanitary defects are found. *See* section III.A.5 of this preamble for a full discussion of conditions that trigger and define Level 1 and Level 2 assessments.

The treatment technique requirements as proposed enhance public health protection beyond the *E. coli* MCL for the following reasons:

- The assessment and corrective action provisions of the treatment technique when the MCL for *E. coli* is exceeded require PWSs to investigate the potential causes of the fecal contamination and require timely remedial action if any sanitary defects

are found. Under the current TCR, there are no requirements for investigation and corrective action after an MCL exceedance. Without such a find-and-fix provision, the pathway for contamination may not be identified and eliminated as sampling alone may not be adequate to identify intermittent sources of fecal contamination. The assessment and corrective action provisions of the proposed rule increase the likelihood of finding and correcting any sanitary defect and reduce the chance of recurrence of fecal contamination in the future.

• Using total coliforms in addition to *E. coli* as an indicator to prompt assessment and corrective action increases the sensitivity for identifying potential pathways for contamination. As discussed in section II.D.2 of this preamble, the presence of total coliforms indicates the potential existence of a pathway through which fecal contamination could follow. The absence (versus the presence) of total coliforms in the distribution system indicates a reduced likelihood that fecal contamination and/or waterborne pathogens are occurring in the distribution system. Analyses from EPA's 2005 Six-Year Review 2 data (USEPA 2006b; USEPA 2010e) (*see* section VI.B of this preamble for details on the Six-Year Review 2 data) and from the proposed RTCR Economic Analysis (EA) occurrence modeling show that total coliform presence in drinking water is approximately 20 to 40 times higher than *E. coli* occurrence in drinking water (*see* chapter 4 of the Proposed RTCR EA (USEPA 2010a)). Similarly, under the current TCR, non-acute MCL (also referred to as monthly MCL) violations (informed by total coliform occurrence) occur roughly 10 times more often than acute MCL violations (informed by total coliform and *E. coli* occurrence, essentially equivalent to the occurrence that triggers an *E. coli* MCL violation under this proposed rule). Thus, including monitoring of total coliforms, as well as *E. coli,* as part of a treatment technique to indicate when systems must find and fix any sanitary defects, substantially increases the likelihood of identifying such defects.

• The proposed treatment technique was supported by the advisory committee and is consistent with the recommendations in the AIP. *See* AIP, pages 6–7.

c. *Request for comment.* EPA requests comment on its proposal to eliminate the MCLG and MCL provisions for total coliforms and fecal coliforms and to include an MCLG and MCL for *E. coli* and coliform treatment technique provisions based on monitoring for total coliforms and *E. coli.* EPA also requests comment on its proposed definition of the *E. coli* MCL.

3. Monitoring

a. *Provisions.* As with the current TCR, the proposed RTCR requires all PWSs to collect and test samples for total coliforms and *E. coli* according to a sample siting plan and schedule specific to the system. Under the proposed RTCR, all PWSs are still required to take repeat samples within 24 hours of learning of any routine monitoring sample that is total coliform-positive. PWSs must comply with the repeat monitoring requirements and *E. coli* analytical requirement, discussed in detail in section III.A.4 of this preamble. All samples taken for proposed RTCR compliance (routine and repeat) may occur at a customer's premises, dedicated sampling station, or other designated compliance sampling location.

Under the proposed RTCR, system sample siting plans must include routine and repeat sample sites and any sampling points necessary to meet the Ground Water Rule (GWR) requirements. The sample siting plan is subject to State review and revision. The PWS may propose repeat monitoring locations that are expected to be representative of a pathway for contamination into the distribution system (for example, near a storage tank). Instead of identifying set repeat sampling locations (*i.e.,* within five service connections upstream and downstream of the original sampling location that tested total coliform-positive), systems may elect to specify criteria for selecting their repeat sampling locations on a situational basis in a standard operating procedure (SOP), which is part of the sample siting plan. Upon State review, the PWS must demonstrate to the State's satisfaction that the sample siting plan remains representative of the water quality in the distribution system. The State may modify the SOP as needed. To address access issues, small systems must specify in their sampling plans where the two additional samples will be taken. The State may determine that monitoring at the entry point to the distribution system (especially for undisinfected ground water systems) is effective to differentiate between potential source water and distribution problems.

Under the proposed RTCR, PWSs may take more than the minimum required number of routine samples and include the results in calculating whether the total coliform treatment technique trigger for conducting an assessment has been exceeded only if the samples are taken in accordance with the sample siting plan and are representative of water throughout the distribution system (*see* sections III.A.3 and III.A.5 of this preamble).

EPA is not proposing to make substantive changes to the current TCR requirements for (1) special purpose samples, and (2) invalidation of total coliform samples. EPA is proposing a minor modification to the provision for special purpose samples by changing "total coliform MCL" to "coliform treatment technique trigger."

The following are the proposed monitoring requirements for different categories of systems.

i. Ground water NCWSs serving ≤ 1,000 people. *(a). Routine monitoring.* The proposed RTCR requires ground water NCWS serving 1,000 or fewer people to routinely monitor each quarter for total coliforms and *E. coli.* Seasonal systems under this category must routinely monitor every month (seasonal systems are discussed later in this section).

(b). *Transition to the RTCR.* The proposed RTCR requires all ground water NCWSs serving 1,000 or fewer people, including seasonal systems, to continue with their TCR monitoring schedules as of the compliance date of the RTCR, unless or until any of the conditions for increased monitoring discussed later on in this section are triggered on or after the compliance date or unless otherwise directed by the State, including through the special monitoring evaluation conducted under a sanitary survey. In addition, systems on annual monitoring, including seasonal systems, must have an initial annual site visit by the State within one year of the compliance date (or an annual voluntary Level 2 assessment by a party approved by the State) and an annual site visit each year thereafter to remain on annual monitoring.

This rule proposes that after the compliance date of the final RTCR, during each sanitary survey the State (which would be either EPA or a State that has received primacy for this rule) must perform a special monitoring evaluation to review the status of the water system, including the distribution system, to determine whether the system is on an appropriate monitoring schedule and modify the monitoring schedule as necessary. States must evaluate system factors such as the pertinent water quality and compliance history, the establishment and maintenance of contamination barriers, and other appropriate protections and validate the appropriateness of the

water system's existing monitoring schedule and modify as necessary. For seasonal systems on quarterly or annual monitoring, this evaluation must also include review of the approved sample siting plan which designates the time period(s) for monitoring based on site-specific considerations (such as during periods of highest demand or highest vulnerability to contamination). The system must collect compliance samples during these time periods.

(c). *Reduced monitoring.* The State has the discretion to reduce the monitoring frequency for well-operated ground water NCWSs from the quarterly routine monitoring to no less than annual monitoring, if the water system can demonstrate that it meets the criteria for reduced monitoring provided in this section.

To be eligible to qualify for and remain on annual monitoring after the compliance date, a ground water NCWS serving 1,000 or fewer people must meet all of the following criteria:

- The most recent sanitary survey shows the system is free of sanitary defects, has a protected water source and meets approved construction standards;
- The system must have a clean compliance history (no MCL violations or monitoring violations under the current TCR and/or proposed RTCR, no Level 1 or Level 2 trigger exceedances or treatment technique violations under the proposed RTCR) for a minimum of 12 months. (For a more detailed discussion on Level 1 and Level 2 triggers, *see* section III.A.5 of this preamble); and
- An initial site visit by the State within the last 12 months to qualify for reduced annual monitoring, and recurring annually to stay on reduced annual monitoring; and correction of all identified sanitary defects. A voluntary Level 2 assessment by a party approved by the State may be substituted for the State annual site visit in any given year.

(d). *Increased monitoring.* Ground water NCWS serving 1,000 or fewer people on quarterly or annual monitoring that experience any of the following events must begin monthly monitoring the month following the event:

- The system triggers a Level 2 assessment or two Level 1 assessments in a rolling 12 month period;
- The system has an *E. coli* MCL violation;
- The system has a coliform treatment technique violation (for example, if the system fails to conduct a Level 1 assessment or correct for sanitary defects if required to do so); or
- The system on quarterly monitoring has two monitoring violations in a rolling 12-month period or system on annual monitoring has one monitoring violation.

The system must continue monthly monitoring until the requirements in this section for returning to quarterly or annual monitoring are met.

(e). *Requirements for returning to quarterly monitoring.* To be eligible to return to quarterly monitoring, ground water NCWSs serving 1,000 or fewer people must meet all of the following criteria:

- Within the last 12 months, the system must have a completed sanitary survey or a site visit by the State or a voluntary Level 2 assessment by a party approved by the State. The system is free of sanitary defects, and has a protected water source; and
- The system has a clean compliance history (no *E. coli* MCL violations, Level 1 or 2 triggers, coliform treatment technique violations or monitoring violations) for a minimum of 12 months.

(f). *Requirements for returning to reduced annual monitoring.* To be eligible to return to reduced annual monitoring after being placed on increased monitoring, the system must meet the criteria to return to routine quarterly monitoring plus the following criteria:

- An annual site visit (recurring) by the State and correction of all identified sanitary defects. An annual voluntary Level 2 assessment may be substituted for the State annual site visit in any given year; and
- The system must have in place or adopt one or more additional enhancements to the water system barriers to contamination as approved by the State. These measures could include but are not limited to the following:

—Cross connection control, as approved by the State;
—An operator certified by an appropriate State certification program, which may include regular visits by a circuit rider;
—Continuous disinfection entering the distribution system and a residual in the distribution system in accordance with criteria specified by the State; and
—Maintenance of at least a 4-log inactivation or removal of viruses each day of the month based on daily monitoring as specified in the GWR (with allowance for a 4-hour exception).
—Other equivalent enhancements to water system barriers as approved by the State.

(g). *Seasonal systems.* The proposed rule requires all seasonal systems to demonstrate completion of a State-approved start-up procedure on and after the compliance date of the final RTCR. Seasonal systems may continue with their TCR monitoring frequency after the compliance date of the final RTCR unless or until any of the conditions for increased monitoring discussed previously are triggered on or after the compliance date or as directed by the State. Under the proposed RTCR, seasonal systems are required to take routine samples monthly.

To be eligible for reduced monitoring after the compliance date, seasonal systems must meet the following criteria:

- The system must have an approved sample siting plan that designates the time period for monitoring based on site-specific considerations (*e.g.,* during periods of highest demand or highest vulnerability to contamination). The system must collect compliance samples during this time period; and
- To be eligible for reduced quarterly monitoring, the system must also meet all the reduced monitoring criteria discussed in section III.A.3.a.i.(e) of this preamble, *Requirements for returning to quarterly monitoring.*
- To be eligible for reduced annual monitoring, the system must also meet all the reduced monitoring criteria discussed in section III.A.3.a.i.(f) of this preamble, *Requirements for returning to reduced annual monitoring.*

(h). *Additional routine monitoring.* All systems collecting samples on a quarterly or annual frequency must conduct additional routine monitoring following a single total coliform-positive sample (with or without a Level 1 trigger event). The additional routine monitoring consists of three samples in the month following the total coliform-positive sample at routine monitoring locations identified in the sample siting plan. This is a change from the current TCR additional routine monitoring requirement of taking a total of five samples the month following a total coliform-positive sample for systems that take four or fewer samples per month. In this proposal, consistent with the current TCR, the State may waive the additional routine monitoring requirement if:

- The State, or an agent approved by the State, performs a site visit before the end of the next month the system provides water to the public. Although a sanitary survey need not be performed, the site visit must be sufficiently detailed to allow the State to determine whether additional monitoring and/or any corrective action

is needed. The State cannot approve an employee of the system to perform this site visit, even if the employee is an agent approved by the State to perform sanitary surveys.

• The State has determined why the sample was total coliform-positive and establishes that the system has corrected the problem or will correct the problem before the end of the next month the system serves water to the public. In this case, the State must document this decision to waive the following month's additional monitoring requirement in writing, have it approved and signed by the supervisor of the State official who recommends such a decision, and make this document available to the EPA and public. The written documentation must describe the specific cause of the total coliform-positive sample and what action the system has taken and/or will take to correct this problem.

The State may not waive the requirement to collect three additional routine samples the next month in which the system provides water to the public solely on the grounds that all repeat samples are total coliform-negative. If the State determines that the system has corrected the contamination problem before the system takes the set of repeat samples required in § 141.858, and all repeat samples were total coliform-negative, the State may waive the requirement for additional routine monitoring the next month.

All additional routine samples are included in determining compliance with the MCL and coliform treatment technique requirements.

ii. Ground water CWSs serving ≤ 1,000 people. *(a). Routine monitoring.* The proposed RTCR requires ground water CWSs serving 1,000 or fewer people to routinely monitor each month for total coliforms and *E. coli.*

The State may reduce the monitoring frequency for ground water CWS from the monthly routine monitoring to quarterly reduced monitoring if the water system can demonstrate that it meets the criteria for reduced monitoring provided later in this section

(b). *Transition to the RTCR.* All ground water CWSs serving 1,000 or fewer people continue with their current TCR monitoring schedules unless or until any of the increased monitoring requirements in this section occur or as directed by the State.

After the compliance date of the final RTCR, the State must determine whether the system is on an appropriate monitoring schedule by performing a special monitoring evaluation during each sanitary survey to review the status of the PWS, including the distribution system. The State must evaluate system factors such as the pertinent water quality and compliance history, the establishment and maintenance of barriers to contamination, and other appropriate protections to validate the water system's existing monitoring schedule or require more frequent monitoring.

(c). *Reduced monitoring.* The State has the flexibility to reduce the monitoring frequency for well-operated ground water CWS from the monthly routine monitoring to no less than quarterly monitoring if the water system can demonstrate that it meets the criteria for reduced monitoring provided in this section.

To be eligible for quarterly reduced monitoring, ground water CWSs serving 1,000 or fewer people on monthly monitoring after the compliance date must be in compliance with State-certified operator provisions and meet each of the following criteria:

• The most recent sanitary survey shows the system is free of sanitary defects (or has an approved plan and schedule to correct them), has a protected water source, and meets approved construction standards;

• The system must have a clean compliance history (no MCL violations or monitoring violations under the current TCR and/or proposed RTCR, no Level 1 or Level 2 trigger exceedances or treatment technique violations under the proposed RTCR) for a minimum of 12 months; and

• The system must meet at least one of the following criteria:

—An annual site visit by the State or a voluntary Level 2 assessment by a party approved by the State or meeting criteria established by the State and correction of all identified sanitary defects (or an approved plan and schedule to correct them), or

—A cross connection control program, as approved by the State, or

—The system must maintain continuous disinfection entering the distribution system and a residual in the distribution system in accordance with criteria specified by the State, or

—The system must maintain at least a 4-log inactivation or removal of viruses each day of the month based on daily monitoring as specified in the GWR (with allowance for a 4-hour exception) (USEPA 2006c, 71 FR 65574, November 8, 2006); or

—Other equivalent enhancements to water systems as approved by the State.

(d). *Return to routine monitoring requirements.* When a system on quarterly monitoring experiences any of the following events the system must begin monthly monitoring:

• System triggers a Level 2 assessment or two Level 1 assessments in a rolling 12 month period;

• System has an *E. coli* MCL violation;

• System has a coliform treatment technique violation (*e.g.,* fails to conduct a Level 1 or Level 2 assessment or to correct for a sanitary defect if required to do so); or

• System has two routine monitoring violations in a rolling 12-month period.

The system must continue monthly monitoring until all the reduced monitoring requirements discussed previously in this section are met. A system that loses its certified operator must also return to monthly monitoring the month following the loss.

(e). *Additional routine monitoring.* All systems collecting samples on a quarterly frequency must conduct additional routine monitoring following a single total coliform-positive sample (with or without a Level 1 trigger event). The additional routine monitoring consists of three samples in the month following the total coliform-positive sample at routine monitoring locations identified in the sample siting plan. The current TCR additional routine monitoring requirements consist of taking a total of five samples the month following a total coliform-positive sample for systems that take four or fewer samples per month. In this proposal, consistent with the current TCR, the State may waive the additional routine monitoring requirement if:

• The State, or an agent approved by the State, performs a site visit before the end of the next month the system provides water to the public. Although a sanitary survey need not be performed, the site visit must be sufficiently detailed to allow the State to determine whether additional monitoring and/or any corrective action is needed. The State cannot approve an employee of the system to perform this site visit, even if the employee is an agent approved by the State to perform sanitary surveys.

• The State has determined why the sample was total coliform-positive and establishes that the system has corrected the problem or will correct the problem before the end of the next month the system serves water to the public. In this case, the State must document this decision to waive the following month's additional monitoring requirement in writing, have it approved and signed by the supervisor of the State official who recommends such a decision, and make this document available to the EPA and public. The written documentation must describe the specific cause of the total coliform-positive sample and what

action the system has taken and/or will take to correct this problem.

The State may not waive the requirement to collect three additional routine samples the next month in which the system provides water to the public solely on the grounds that all repeat samples are total coliform-negative. If the State determines that the system has corrected the contamination problem before the system takes the set of repeat samples required in § 141.858, and all repeat samples were total coliform-negative, the State may waive the requirement for additional routine monitoring the next month.

All additional routine samples are included in determining compliance with the MCL and the coliform treatment technique requirements.

iii. Subpart H systems of this part serving ≤ 1,000 people. The monitoring requirements for subpart H systems of this part (PWSs supplied by surface water source or ground water source under the direct influence of surface water (GWUDI)) serving 1,000 or fewer people remain the same as under the current rule (*see* § 141.856). These systems are not eligible for reduced monitoring. In addition, the proposed rule requires all seasonal systems, on and after the compliance date of the final RTCR, to demonstrate completion of a State-approved start-up procedure.

iv. PWSs serving > 1,000 people. The monitoring requirements for PWSs serving more than 1,000 people remain the same as under the current TCR (*see* § 141.857), with the exception of the applicable revisions to the repeat sampling locations provided in § 141.858 and additional routine monitoring provisions. Systems on monthly monitoring are not required to take additional routine samples the month following a total coliform-positive sample. These systems are not eligible for reduced monitoring. In addition, the proposed rule requires all seasonal systems, on and after the compliance date of the final RTCR, to demonstrate completion of a State-approved start-up procedure.

b. *EPA's rationale.* i. Sampling sites and monitoring plans. Consistent with current practice, the proposed RTCR requires systems to develop a sample siting plan that is representative of the water throughout the distribution system. EPA is proposing to maintain the provision from the current TCR that indicates that sample siting plans are subject to State review and revision. The advisory committee recommended that States review and revise sample siting plans consistent with current practice and that the State develops and implements a process to ensure the adequacy of sample siting plans including a periodic review. The advisory committee also recommended that specific elements be included in the sampling plans such as the routine and repeat sample sites and sampling locations necessary to meet the requirements of the GWR. Alternative repeat monitoring locations (*e.g.,* at storage tanks and entry points to the distribution system) are subject to State approval. The system must demonstrate to the State's satisfaction that these alternative monitoring locations are representative of the water quality in the distribution system.

By allowing systems to specify criteria for selecting their repeat sampling locations in their SOP instead of setting fixed repeat sampling locations, systems can provide a more flexible and more protective response. The system can focus the repeat samples at locations that will best verify and determine the extent of potential contamination of the distribution system based on specific situations. In addition, EPA is proposing to require State approval if a ground water system serving 1,000 or fewer people wants to use a single sample to meet both the repeat monitoring requirements of the RTCR and the source water monitoring requirements of the GWR (*see* section III.A.4 of this preamble for further discussion of this topic).

EPA is proposing to allow the use of dedicated sampling locations for the following reasons:

- To reduce potential contamination of the taps. Utilities will have more control to prevent contamination of the tap by preventing its use by unauthorized persons and allowing no routine use of the tap except for sampling;
- To facilitate access to sampling taps. Currently systems may be constrained by where they sample, *e.g.,* only at public buildings or in certain individual customer's houses.
- To improve sampling representation of the distribution system. Allowing dedicated sample taps in areas where systems have not been able to gain access will facilitate better sampling representation of the distribution system.

ii. Ground water PWSs serving ≤ 1,000 people. *(a). Routine monitoring.* The advisory committee recommended that ground water NCWSs serving 1,000 or fewer people remain under a routine quarterly monitoring as provided in the current TCR. They believed that in conjunction with the assessment and corrective action requirements, public health protection would be maintained or improved without increasing sampling costs over current TCR requirements. The advisory committee also recognized that current sampling costs are not insignificant for small systems, and wanted to recognize the good performance of systems by allowing them to be able to continue to qualify for reduced monitoring, but under the more specific and rigorous criteria described previously. To continue to provide adequate health protection, systems on reduced monitoring must adhere to criteria that ensure that barriers are in place and are effective. Furthermore, systems with problems that may indicate poor system integrity, maintenance, or operations, or systems that fail to monitor, are triggered into monthly monitoring. This approach leverages the limited resources of these small ground water NCWSs and of States, so that systems with minimal problems can minimize their costs and States can focus their resources on systems needing the greatest attention, such as systems with problems or vulnerabilities.

The advisory committee thought it best to continue with existing routine monthly monitoring requirements for ground water CWSs serving 1,000 or fewer people in order to maintain the current levels of effort to identify potential problems. Since sanitary surveys are required under the GWR and these surveys provide substantial diagnostic value and corrective action response for problems identified, specifying higher routine monitoring frequency for these systems was not deemed necessary. These systems may also qualify for reduced monitoring if they meet certain criteria.

(b). *Transition to the RTCR.* The advisory committee was concerned about the ability of the States and systems to adopt the new regulations and to make all the determinations that may be necessary to determine the appropriate monitoring frequency within three years of rule promulgation. Requiring significant changes in monitoring frequencies in a short period (*i.e.,* without a transition period) could overwhelm State resources. The advisory committee recommended phasing in the requirements and using the sanitary survey process to facilitate a successful transition and implementation. The advisory committee, therefore, recommended that these systems continue with their current monitoring frequency during a transition period and that the State review the monitoring frequency to determine whether it is appropriate during each sanitary survey (USEPA 2008c, AIP p.9). This gives the systems the opportunity to address operation

and maintenance issues to maintain existing monitoring frequency or qualify for reduced monitoring. Systems on reduced TCR monitoring stay on reduced monitoring during the transition period if they continue to meet the reduced monitoring criteria. During the special monitoring evaluation conducted as part of the periodic sanitary survey, the State will determine whether the individual systems are on the proper monitoring schedule.

(c) *Reduced monitoring.* The reduced monitoring requirements are intended to recognize that well-operated systems may be less vulnerable to contamination. Therefore, certain conditions are specified under which reduced monitoring could be allowed. These include a clean compliance history for a minimum of 12 months, and an annual visit from the State for systems taking one sample per year and correction of all identified sanitary defects. Ground water NCWSs serving 1,000 or fewer people, with a routine quarterly monitoring frequency, could qualify for reduced annual monitoring, while ground water CWSs serving 1,000 or fewer people, with a routine monthly monitoring frequency, could qualify for reduced quarterly monitoring.

For NCWSs on annual monitoring, the advisory committee believed that requiring a system to have an annual site visit or a Level 2 assessment provides at least an equivalent level of diagnosis of problems and vulnerabilities that might exist as compared to quarterly monitoring without an annual site visit. Several States have elected to conduct annual site visits while also doing annual monitoring for some NCWSs.

(d) *Increased monitoring requirements for NCWSs.* The advisory committee wanted to recognize that if certain vulnerabilities are identified in a system, the system should be required to conduct more frequent monitoring to identify and correct its problems and better protect public health. Other than sanitary surveys or other site visits, monitoring is the primary means to identify pathways for potential contamination. If the system is deemed more vulnerable to such pathways, as indicated by the increased monitoring criteria, it must conduct more monitoring.

(e) *Requirements for returning to routine monitoring and reduced monitoring.* The advisory committee believed that systems that address or correct vulnerabilities as indicated by a clean compliance history should be allowed to return to routine monitoring, and subsequently to reduced monitoring (for NCWS). This provision allows for reduced monitoring costs.

(f) *Seasonal systems.* The advisory committee recognized that seasonal systems have unique characteristics that make them more susceptible to contamination. These systems do not maintain pressure while not in operation, which can result in the intrusion of contaminants. During the time when a seasonal system is not in operation, septic tank drain fields or other pollution sources may accumulate that could affect the conditions or quality of the source water (especially for intermittent contaminants) that infrequent monitoring may not be able to capture. If monitoring is done only at the start-up, there may not be enough time for the system to reach equilibrium (*i.e.,* there might not be enough time to recognize if microorganisms from a septic tank moved to the wellhead in seasonally operated systems). Therefore, the proposed rule requires seasonal systems to monitor routinely at a monthly frequency. Seasonal systems can qualify for reduced monitoring if they meet certain criteria. For a seasonal system to be allowed to monitor at a reduced frequency, the proposed rule requires the system to have an approved sample siting plan that designates the time period for monitoring and takes into consideration site-specific conditions. A system on a reduced monitoring schedule (less than monthly) must collect samples when there is the greatest chance that contamination could be identified and, due to the variability in water demands, when systems could be most challenged.

(g) *Additional routine monitoring.* EPA is proposing to retain the requirement of taking additional routine samples the month following a total coliform-positive sample for systems on quarterly or annual monitoring. The advisory committee recognized both the benefits and the limitations of additional routine monitoring. Additional routine samples are meant to enhance the diagnostic ability and supplement the infrequent routine monitoring of systems on quarterly or annual monitoring. Without the provision of additional monitoring, systems on annual or quarterly monitoring with a total coliform-positive sample would not take any samples the following month. The advisory committee believed that additional samples collected the following month are appropriate to help recognize the problem if it still persists.

For systems required to take the additional routine samples the following month (*i.e.,* systems on quarterly or annual monitoring), the proposed RTCR changes the requirement from taking a total of five routine samples to a requirement of just three routine samples. The advisory committee recognized that it is appropriate to drop from five to three samples the following month to reduce monitoring costs while still maintaining a substantial likelihood of identifying a problem if a problem persists. EPA recognizes that a reduction in the number of samples taken could also mean a reduction in the number of positive samples found. However, the reduction in the number of additional routine samples in conjunction with the new assessment and corrective action provisions of the proposed RTCR (discussed in section III.A.5 of this preamble) leads to a rule that is ultimately more protective of public health (*i.e.,* more *E. coli MCL* violations being prevented) and improvement in water quality (*i.e.,* decrease in the total coliform and *E. coli*-positive hit rates observed as shown by the Proposed RTCR EA occurrence modeling results). *See* chapter 6 of the Proposed RTCR EA (USEPA 2010a) for more details.

For systems taking at least one sample monthly, the advisory committee recommended no additional routine samples for these systems for the following reason. Taking no additional routine samples the following month substantially reduces monitoring costs. The assessment and corrective action provisions will give systems the ability to identify and prevent the occurrence of problems. EA modeling results show that although there is a decrease in the number of *E. coli* MCL violations found with the decrease in the number of additional routine samples taken (*i.e.,* going from five samples to one during the month following a total coliform-positive), the assessment and corrective action provisions lead to more *E. coli* MCL violations being prevented compared to the current TCR (*see* Exhibit 6–7 of the Proposed RTCR EA (USEPA 2010a) for more details).

In addition, whenever a total coliform-positive occurs during routine sampling, there is also a requirement to conduct repeat sampling to determine the extent of contamination or if potential pathways to contamination persist. For small systems serving 1,000 or fewer people on monthly monitoring, if a repeat sample is total coliform-positive, at least a Level 1 assessment will be triggered. If a sanitary defect(s) is (are) found, the system is required to correct the sanitary defect(s).

For systems on monthly monitoring, the assessment and corrective action provisions and the repeat sampling provisions mitigate the need for

additional routine sampling for the following month.

iii. Subpart H systems of this part serving ≤ 1,000 people. EPA is not proposing to change the routine monitoring requirements for systems using surface water or GWUDI serving 1,000 or fewer people, which include not allowing reduced monitoring for these systems. Since systems using surface water or ground water under the influence of surface water tend to have much higher levels of contaminants in their source water, and in general have more complex operations than ground water systems, it is appropriate to allow reduced routine monitoring for ground water systems but not for subpart H systems of this part. The advisory committee recommended that no reduced routine monitoring provisions be allowed for subpart H systems of this part serving 1,000 or fewer people.

iv. Public water systems serving > 1,000 people. EPA is proposing to eliminate the additional routine samples the month following a total coliform-positive sample for PWSs serving between 1,000 and 4,100 people for the same reasons discussed previously for small ground water systems monitoring monthly. PWSs serving more than 1,000 people are currently required to routinely monitor monthly (one to four samples per month depending on size) and continue to do so under the proposed RTCR.

c. *Request for comment.* EPA requests comment on the proposed monitoring requirements for PWSs. Specifically, EPA requests comment on the following questions: Are there other issues that EPA should consider in its approach to help systems transition to the RTCR? Should EPA develop guidance that would help States identify seasonal systems and implement the RTCR requirements (*e.g.,* suggestions for start up procedures and identifying vulnerable time periods)? What start-up procedures or other provisions regarding seasonal systems would be appropriate for inclusion in such guidance? EPA also requests comment on whether seasonal systems should be required to comply with State-directed shut down procedures (in addition to start-up procedures).

EPA requests comment on the following additional questions: Should daily measurement of chlorine residual count toward the maximum residual disinfectant level (MRDL) monitoring and be one of the criteria for reduced monitoring? Should NTNCWSs be required to comply with the CWS requirements (as they are in other rules such as DBP rules) since NTNCWSs serve the same people over time and include populations that may be at greater risk (*e.g.,* schools, hospitals, nursing homes)? Will the reduced, routine, and increased monitoring requirements for NCWSs shift the fixed State resources from CWS oversight to NCWS oversight in those States with large numbers of NCWSs? If so, what might be done to limit the impact? Should EPA develop guidance on how to develop a sample siting plan? Should sample siting plans require State approval?

EPA and the advisory committee did not identify any specific issues regarding consecutive systems in the proposed RTCR. EPA requests comment on whether there are such issues and how they should be addressed in the RTCR.

4. Repeat Samples

a. *Provisions.* Under the proposed RTCR, all systems must take at least three repeat samples for each routine total coliform-positive sample. This is a change from the current TCR requirements where systems serving 1,000 or fewer people must collect at least four repeat samples while the rest of the systems must collect three repeat samples. EPA is not changing the following provisions: The 24-hour limit within which the system must collect the repeat samples; the authority of the State to extend this limit on a case-by-case basis; and the non-waiver by the State of the requirement for a system to collect repeat samples.

In addition to taking repeat samples, systems must test each routine total coliform-positive sample for *E. coli.* They must also test any repeat total coliform-positive sample for *E. coli.* As with the current TCR, if *E. coli* is present, the system must notify the State the same day it learns of the positive result or by the end of the next business day at the latest. The proposed rule is not changing the provision that a State has the discretion to allow the system to forgo *E. coli* testing in cases where the system assumes that the total coliform-positive sample is *E. coli*-positive. If the State allows a system to forgo *E. coli* testing, the system must still notify the State and comply with the *E. coli* MCL requirements specified in § 141.858.

As with the current TCR, the system must collect at least one repeat sample from the sampling tap where the original total coliform-positive sample was taken. Unless different locations are specified in its sample siting plan, the system must also collect at least one repeat sample at a tap within five service connections upstream, and at least one repeat sample at a tap within five service connections downstream of the original sampling site. The State may waive the requirement to collect at least one repeat sample upstream or downstream of the original sampling site if the total coliform-positive sample is at the end of the distribution system, or one service connection away from the end of the distribution system. The system may also propose alternative repeat monitoring locations in its sample siting plan as discussed in this section.

Under the proposed rule, ground water systems (GWSs) required to conduct triggered source monitoring under the GWR must take ground water source samples in addition to the repeat samples. However, a ground water system serving 1,000 or fewer people may use a repeat sample collected from a ground water source to meet both the repeat monitoring requirements of the proposed RTCR and the source water monitoring requirements of the GWR, but only if the State approves the use of a single sample to meet both rule requirements (*i.e.,* a dual purpose sample) and the use of *E. coli* as a fecal indicator for source water monitoring. If the sample is *E. coli*-positive, the system violates the *E. coli* MCL under the proposed RTCR and must also comply with the GWR requirements following a fecal indictor-positive sample. These provisions are consistent with the GWR.

If a system with a limited number of monitoring locations (such as a system with only one service connection or a campground with only one tap) takes more than one repeat sample at the triggered source water monitoring location, the system may reduce the number of additional source water samples by the number of repeat samples taken at that location that were not *E. coli*-positive. For example, if a system takes two dual purpose samples and one is *E. coli*-positive and the other is *E. coli*-negative, the system has an *E. coli* MCL violation under the proposed RTCR and is required to take four additional source water samples, rather than five, under the GWR (*see* 40 CFR 141.402(a)(3)). If the system takes more than one of these repeat samples at the triggered source water monitoring location and has more than one repeat sample that is *E. coli*-positive, then the system would have both an *E. coli* MCL violation under the proposed RTCR and a second fecal indicator-positive source sample under the GWR. The system would then need to also comply with the treatment technique requirements under 40 CFR 141.403.

Under the proposed rule, the system must collect all repeat samples on the same day consistent with current TCR requirements. The State may allow

systems with a single service connection to collect the required set of repeat samples over a three-day period or to collect a larger volume repeat sample(s) in one or more sample containers of any size, as long as the total volume collected is at least 300 ml.

The proposed RTCR is not changing the requirement that systems collect an additional set of repeat samples for each total coliform-positive repeat sample. As with the original set of repeat samples, the system must collect the additional repeat samples within 24 hours of being notified of the positive result, unless the State extends the time limit. The system must repeat this process until either total coliforms are not detected in one complete set of repeat samples or the system determines that the coliform treatment technique trigger has been exceeded and notifies the State. After a trigger (*see* section III.A.5 of this preamble) is reached, the system is required to conduct only one round of repeat monitoring after each total coliform-positive or *E. coli*-positive routine sample. If a trigger is reached as a result of a repeat sample being total coliform- or *E. coli*-positive, no further repeat monitoring related to that sample is necessary.

The proposed RTCR is also not changing the current TCR provision that a subsequent routine sample, which is within five service connections of the initial routine sample and is collected after an initial routine sample but before the system learns the initial routine sample is total coliform-positive, may count as a repeat sample instead.

Results of all routine and repeat samples not invalidated by the State must be used to determine whether the coliform treatment technique trigger has been exceeded (*see* section III.A.5 of this preamble for a discussion of the coliform treatment technique triggers).

b. *EPA's rationale.* i. Why EPA is maintaining a provision for repeat sampling. As with the current TCR, the proposed RTCR requires systems to take repeat samples after a total coliform-positive sample. EPA believes that sampling immediately after an initial positive sample (*i.e.,* conducting repeat sampling) increases the likelihood of identifying the source and/or nature of the possible contamination. Analysis conducted by EPA indicated that once a total coliform-positive is found, there is a much greater likelihood of finding another total coliform-positive within a short period of time of the initial finding (*see* Exhibit III–1). Repeat sampling (when total coliform-positive) can indicate a current pathway for potential external contamination into the distribution system.

EPA used the Six-Year Review 2 (USEPA 2010e) data to support statistical modeling which produced estimates of average occurrence of routine total coliform-positive samples and repeat total coliform-positive samples and to characterize how occurrence varies from system to system. EPA's occurrence model assumes that, among similar systems, the positive rate for total coliforms in routine samples varies as a beta random variable. EPA used the Six-Year Review 2 data (USEPA 2010e) to estimate the parameters for the distribution of occurrences of routine and repeat total coliform-positive samples.

Exhibit III–1 shows the relative probability of finding a total coliform-positive result from routine samples versus from repeat samples for 27 basic subsets of systems. The table combines regular routine and additional routine samples since no distinction was available for the Six-Year Review 2 data set (USEPA 2010e). The relative probability is defined as the ratio of the probability of getting a total coliform-positive result from a repeat sample to the probability of getting a total coliform-positive result from a routine sample.

EXHIBIT III–1—RELATIVE PROBABILITY OF TOTAL COLIFORM-POSITIVE SAMPLES IN ROUTINE COMPARED TO REPEAT SAMPLES

System type [1]	Average pRTTC [2] (percent)	Average pRPTC [3] (percent)	Ratio pRPTC/ pRTTC
TNCWS undisinfected GW:			
< 101	4.8	28	5.9
101–1,000	4.8	25	5.2
1,001–4,100	2.5	17	6.9
NTNCWS undisinfected GW:			
< 101	3.7	26	7.0
101–1,000	2.7	26	9.6
1,001–4,100	2.7	26	9.6
CWS undisinfected GW:			
< 101	3.1	19	6.0
101–1,000	2.7	19	7.1
1,001–4,100	2.7	13	4.9
TNCWS disinfected GW:			
< 101	2.3	14	6.2
101–1,000	2.3	14	6.2
1,001–4,100	2.3	14	6.2
NTNCWS disinfected GW:			
< 101	1.6	11	6.7
101–1,000	1.1	11	9.4
1,001–4,100	1.1	11	9.4
CWS disinfected GW:			
< 101	1.6	9.4	5.9
101–1,000	1.2	9.4	7.6
1,001–4,100	0.78	5.2	6.7
TNCWS SW:			
< 101	2.3	14	6.2
101–1,000	2.3	14	6.2
1,001–4,100	2.3	14	6.2
NTNCWS SW:			
< 101	1.6	11	6.7

EXHIBIT III–1—RELATIVE PROBABILITY OF TOTAL COLIFORM-POSITIVE SAMPLES IN ROUTINE COMPARED TO REPEAT SAMPLES—Continued

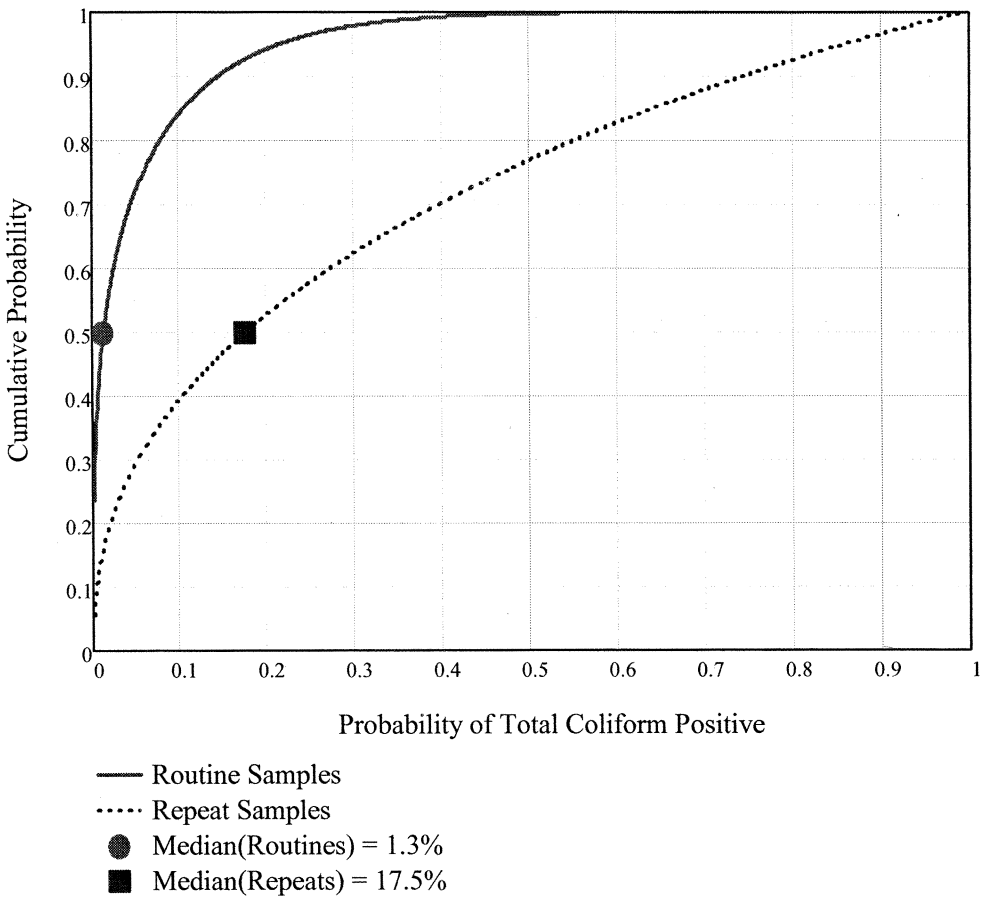
System type [1]	Average pRTTC [2] (percent)	Average pRPTC [3] (percent)	Ratio pRPTC/ pRTTC
101–1,000	1.1	11	9.4
1,001–4,100	1.1	11	9.4
CWS SW:			
< 101	1.5	6.5	4.3
101–1,000	0.95	6.5	6.8
1,001–4,100	0.59	3.4	5.8

[1] The following acronyms are used: (1) TNCWS Transient Non-Community Water System; (2) NTNCWS Non-Transient Non-Community Water System; (3) CWS Community Water System; (4) GW Ground Water; (5) SW Surface Water.
[2] Average probability of a total coliform-positive from a routine total coliform sample.
[3] Average probability of a total coliform-positive from a repeat total coliform sample.

Exhibit III–1 shows that for any type and size of system, regardless of source water and disinfection practice, repeat total coliform samples (triggered by positive routine samples) are much more likely to be positive than are routine samples. For small (serving 100 or fewer people) CWSs that provide undisinfected ground water, the average repeat total coliform-positive rate (19 percent) is about six times as great as the average routine total coliform-positive rate (3.1 percent) for these systems. The ratio of repeat to routine total coliform-positive rates is greater for some sets of systems and smaller for others, but a ratio of at least six to one is common. Similar ratios of repeat to routine monitoring total coliform-positive rates were found for disinfected systems (ground water and surface water systems).

Exhibit III–2 shows maximum likelihood distributions for the positive rates in routine and repeat samples of small TNCWSs (serving 100 people or fewer) serving undisinfected ground water. The vertical axis shows cumulative probability, which is the fraction of systems having at most the corresponding horizontal axis value. Corresponding to 0.5 on the vertical axis is the median probability of a total coliform-positive. For example, for half of the systems, the probability of getting a total coliform-positive is 1.3 percent (*i.e.,* 0.013 probability of total coliform-positive on horizontal axis) for routine samples. This is the median probability of total coliform-positive in routine samples. For repeat samples, the median probability of a positive is 17.5 percent (*i.e.,* 0.175 probability of total coliform-positive on horizontal axis), which is about 13 times greater than that of the routine samples.

Exhibit III-2 Maximum Likelihood Distribution for TNCWS Serving Undisinfected GW to <101 People



ii. Frequency of repeat samples. The advisory committee recommended that the current TCR requirement for systems serving more than 1,000 people to take three repeat samples subsequent to a routine total coliform-positive be retained. The advisory committee recommended that systems serving 1,000 or fewer people also be required to take three repeat samples rather than the four required under the current TCR. This view is supported by analysis of repeat sample records from the Six-Year Review 2 data (USEPA 2010e).

Repeat sampling helps utility operators to better understand the extent and duration of potential pathways of contamination into the distribution system. The Six-Year Review 2 data (USEPA 2010e) show that the average percentage of samples that are positive among repeat samples is much higher than that of routine samples, demonstrating that when operators are required to take a second look at their systems following the positive routine sample, they find, on average, a higher rate of coliform presence than during routine sampling. In other words, the high repeat total coliform-positive rate indicates the persistence of total coliforms at such locations in the distribution system.

Further analysis of the data shows that for all PWSs serving 1,000 or fewer people, two or more of the repeat samples are positive in 75 percent of those instances in which there are any positive repeat samples, as shown in Exhibit III–3. For those 75 percent of instances, reducing the number of repeat samples from four to three would have no effect on the number of systems that would be triggered to conduct an assessment of the system under the proposed RTCR. In these cases, at least one of the remaining repeat samples would still be total coliform-positive, and only one positive repeat sample is required to trigger an assessment.

The data show that one repeat sample is positive in 25 percent of the instances in which any of the four repeat samples is positive. For these instances, EPA estimates that if only three repeat samples had been taken instead of four, three out of four (or 75 percent) of these positive samples would still have been encountered.

EXHIBIT III–3—PERCENTAGE OF INSTANCES WITH 1 OR >1 POSITIVE REPEAT SAMPLES AMONG THOSE INSTANCES IN WHICH ≥1 REPEAT SAMPLES IS POSITIVE

System category	Number of positive repeat samples	
	1	> 1
Undisinfected GWSs Serving ≤1000	23%	77%
All PWSs Serving ≤1000	25	75

Note: Based on the analysis of Six-Year Review 2 dataset (USEPA 2010e) (described in chapter 4 of the Proposed RTCR EA (USEPA 2010a)). The total number of instances of positive repeat samples for undisinfected GWSs ≤1000 is 2953, while all PWSs ≤1000 have 3537 positive repeat samples.
Source: Proposed RTCR EA Appendix H (USEPA 2010a).

When both of the two situations in which at least one repeat sample is positive (either one positive repeat sample or more than one positive repeat sample) are considered together, it is possible to estimate the overall effect of reducing the number of repeats from four to three, as presented in Exhibit III–4. The estimates in the table indicate that if the number of required repeats were reduced from four to three, there would still be almost as many (approximately 94 percent) situations leading to an assessment being triggered for the system.

EXHIBIT III–4—ESTIMATED EFFECTS OF REDUCING NUMBER OF REQUIRED REPEAT SAMPLES FOR PWSS SERVING >1000 FROM 4 TO 3

	Percentage of events [1] with exactly 1 total coliform-positive (TC+) repeat sample	Estimated percentage of events that would still have 1 TC+ if 1 out of 4 repeat samples were not taken	Percentage of events [1] with >1 TC+ repeat sample	Estimated overall percentage of events that would still have ≥1 TC+ repeat sample if 1 out of 4 repeat samples were not taken
	A	B = A*0.75	C	D = B+C
Undisinfected GWSs Serving ≤1000	23%	18%	77%	94.2%
All PWSs Serving ≤1000	25%	19%	75%	93.8%

[1] Based on the analysis of the Six-Year Review 2 dataset (USEPA 2010e) (described in chapter 4 of the Proposed RTCR EA (USEPA 2010a)). The total number of events for undisinfected GWSs ≤1000 is 2953, while all PWSs ≤1000 have 3537 events.
Source: Proposed RTCR EA Appendix H (USEPA 2010a).

Although dropping the required number of repeat samples from four to three means that some fraction of triggers may be missed, the other provisions of the proposed RTCR compensate for that change and, taken as a whole, the provisions of the proposed RTCR provide for greater protection of public health. One such provision includes enhanced consequences for monitoring violations. For example, systems that do not take all of their repeat samples under the proposed RTCR are triggered to conduct a Level 1 assessment. This permits an increase in public health protection over the current TCR because PWSs are required to assess their systems when monitoring results show that the PWS may be vulnerable to contamination (indicated by exceeding the trigger). Moreover, because of the substantial cost of this potential consequence, systems would be more likely to take all of their required repeat samples in the first place.

It is important to point out that the majority of systems in this category are ground water systems treating to less than 4-log inactivation for viruses (*see* Exhibit 4.1 of the Proposed RTCR EA (USEPA 2010a)). Because of the triggered source monitoring provision under the GWR, these systems are required to collect a fecal indicator sample from the source water following a total coliform-positive sample in the distribution system in addition to the repeat samples. Under the existing GWR and TCR, systems taking four repeat samples are permitted to take the fourth repeat sample at the source water if they measure for *E. coli* as the fecal indicator and if they have State approval. Under the proposed RTCR, systems would continue to take this source water sample to comply with the GWR in addition to the required repeat samples in the distribution system to comply with the TCR. A positive sample at the source that is not also considered a repeat sample would not trigger an assessment under the proposed RTCR, but it would provide diagnostic value to the system in addition to triggering additional requirements under the GWR (*i.e.,* corrective action or five additional source water fecal indicator samples).

As under the existing GWR and current TCR, with State approval, ground water systems serving 1,000 or fewer people may use the sample taken at the location required for triggered source monitoring to also count toward the repeat monitoring requirements of the proposed RTCR. In this case, the State must also approve the use of *E. coli* as the fecal indicator under the GWR, and the system would comply with both GWR and the proposed RTCR when a total coliform-positive or *E. coli*-positive sample occurs. The advisory committee recommended this flexibility to reduce the burden on small ground water systems that in most cases will have a very limited distribution system and only one source, consistent with the GWR.

iii. Location of repeat samples. The advisory committee believed that

requiring repeat samples to be taken within five service connections up and downstream of the original total coliform-positive location can be difficult for systems to implement within the required 24 hours for a repeat sample because of issues such as access to the site. Therefore, the advisory committee recommended that systems be allowed to develop standard operating procedures (SOPs) as part of their sample siting plan to identify alternative monitoring sites and facilitate the identification of the source and extent of any problem. EPA is not requiring prior State approval for this provision since there is no reduction in monitoring and the SOP is expected to be used only by larger systems with the technical resources to justify alternative monitoring sites.

The advisory committee also recommended that ground water systems have the flexibility to propose repeat sampling locations that differentiate potential source water and distribution system contamination (*e.g.,* by sampling at entry points to the distribution system). *See* section III.A.3 of this preamble for additional discussion on this topic. Consistent with its understanding of the intent of the TCRDSAC, EPA has proposed that systems be allowed to exercise this flexibility only with prior State approval. State approval is required because this constitutes a reduction in monitoring (no separate triggered source water samples). EPA believes that this reduction in monitoring is appropriate only if the State determines that the dual purpose sample provides public health protection equivalent to that provided by separate repeat and source water samples. EPA believes that many ground water systems serving 1,000 or fewer people, such as systems with extensive distribution systems, will not be able to show that this reduction in monitoring (*i.e.,* a loss of repeat sample that is near the total coliform-positive routine sample site, but not near the source water sample site) will provide public health protection equivalent to separate samples. EPA believes that systems with limited or no distribution systems are the best candidate for approval.

c. *Request for comment.* EPA requests comment on the foregoing proposed repeat sampling requirements. Specifically, EPA requests comment on the proposal to allow samples taken at the ground water source to serve both as a triggered source sample under the GWR and as one of the repeat samples under the proposed RTCR. EPA is also requesting comment on whether systems should be allowed to use a dual purpose sample simply by including that in the sample siting plan, without prior State approval. Also, should systems using repeat monitoring sites more than five connections upstream or downstream from the routine total coliform-positive site be required to get prior State approval?

5. Treatment Technique Requirements

a. *Provisions.* i. Coliform treatment technique triggers. The non-acute MCL violation for total coliforms under the current TCR is effectively replaced by a coliform treatment technique involving monitoring for total coliforms under the proposed RTCR. Under the proposed treatment technique framework, the presence of total coliforms is used as an indicator of a potential pathway of contamination into the distribution system. As discussed in section III.A.2 of this preamble, the proposed RTCR eliminates the associated MCLG and MCL for total coliforms. The proposed revision specifies two levels of treatment technique triggers, Level 1 and Level 2, and their corresponding levels of response. Whether systems are required to conduct either a Level 1 or Level 2 assessment is based on the degree of potential pathway for contamination. The proposed rule further lays out an additional trigger for a Level 1 assessment and defines Level 2 triggers that require a more in-depth examination of the system and its monitoring and operational practices.

The system has exceeded the trigger immediately once any of the following conditions have been met:

Level 1 treatment technique triggers:

- For systems taking 40 or more samples per month, the PWS exceeds 5.0 percent total coliform-positive samples for the month; or
- For systems taking fewer than 40 samples per month, the PWS has two or more total coliform-positive samples in the same month; or
- The PWS fails to take every required repeat sample after any single routine total coliform-positive sample.

Level 2 treatment technique triggers:

- The PWS has an *E. coli* MCL violation (*see* section III.A.6 of this preamble for description of what constitutes an *E. coli* MCL violation); or
- The PWS has a second Level 1 treatment technique trigger within a rolling 12-month period, unless the first Level 1 treatment technique trigger was based on exceeding the allowable number of total coliform-positive samples, the State has determined a likely reason for the total coliform-positive samples that caused the initial Level 1 treatment technique trigger, and the State establishes that the system has fully corrected the problem.
- For PWSs with approved reduced annual monitoring, a Level 1 treatment technique trigger in two consecutive years.

ii. Assessment. EPA is proposing an assessment process in the RTCR to strengthen public health protection. Under the current TCR, a system is not required to perform an assessment following a monthly/non-acute MCL violation or an acute MCL violation. In contrast, the proposed RTCR requires systems to conduct assessments following the triggers specified above.

EPA is proposing two levels of assessment based on the associated treatment technique trigger: Level 1 assessment for a Level 1 treatment technique trigger and Level 2 assessment for a Level 2 treatment technique trigger. At a minimum, both Level 1 and 2 assessments must include review and identification of the following elements:

- Inadequacies in sample sites, sampling protocol, and sample processing,
- Atypical events that may affect distributed water quality or indicate that distributed water quality was impaired,
- Changes in distribution system maintenance and operation that may affect distributed water quality, including water storage,
- Source and treatment considerations that bear on distributed water quality, where appropriate, and
- Existing water quality monitoring data.

EPA expects that States will tailor specific assessment elements to the size and type of the system and that each public water system in turn will tailor its assessment activities based on the characteristics of its distribution system.

Level 1 assessment:

A Level 1 assessment must be conducted when a PWS exceeds one or more of the Level 1 treatment technique triggers specified above. Under the proposed rule, this self-assessment shall consist of a basic examination of the source water, treatment, distribution system and relevant operational practices. The PWS might look at conditions that could have occurred prior to and caused the total coliform-positive sample. Example conditions include treatment process interruptions, loss of pressure, maintenance and operation activities, recent operational changes, etc. In addition, the PWS might check the conditions of the following elements: sample sites, distribution system, storage tanks, source water, etc.

The PWS must complete the Level 1 assessment as soon as practical after

notification of its monitoring results or failure to take repeat samples. The PWS must submit the completed assessment form to the State for review within 30 days after determination that the PWS has exceeded the trigger. Failure to submit the completed assessment form within 30 days is a reporting violation. If the State determines that the assessment is insufficient, the State will consult with the PWS. If necessary after consultation, the PWS must submit a revised assessment to the State on an agreed upon schedule not to exceed 30 days from the date of the initial consultation.

The completed assessment form must include assessments conducted, all sanitary defects identified (or a statement that no sanitary defects were identified), corrective actions completed, and a timetable for any corrective actions not already completed. Upon completion and submission of the assessment form by the PWS to the State, the State shall determine if the system has identified the likely cause(s) for the Level 1 treatment technique trigger and establish whether the system has corrected the problem(s).

Level 2 assessment:

A Level 2 assessment must be conducted when a PWS exceeds one or more of the Level 2 treatment technique triggers specified previously.

A Level 2 assessment is a more comprehensive examination of the system, its monitoring and operational practices than the Level 1 assessment. The level of effort and resources committed to undertaking a Level 2 assessment will be commensurate with the more comprehensive investigation and review of available information, and engage additional parties and expertise relative to the Level 1 assessment (*see* Appendix X of the AIP) (USEPA 2008c). Level 2 assessments must be conducted by a party approved by the State: The State itself, a third party, or the PWS where the system has staff or management with the required certification or qualifications specified by the State. If the PWS or a third party conducts the Level 2 assessment, the PWS or third party must follow the State requirements for conducting the Level 2 assessment.

The PWS must complete the Level 2 assessment as soon as practical after notification that the PWS has exceeded a Level 2 treatment technique trigger. The PWS must submit the completed assessment form to the State for review within 30 days after determination that the PWS has exceeded the trigger. Failure to submit the completed assessment form after the PWS properly conducts the assessment is a reporting violation. The State may direct expedited action or additional actions such as in the case of an *E. coli* MCL violation. If the State determines that the assessment is insufficient, the State will consult with the PWS. If necessary after consultation, the PWS must submit a revised assessment to the State on an agreed upon schedule not to exceed 30 days from the date of the initial consultation.

The completed assessment form must include assessments conducted, all sanitary defects (or a statement that no sanitary defects were identified), corrective actions completed, and a timetable for any corrective actions not already completed. Upon completion and submission of the assessment form by the PWS to the State, the State shall determine if the system has identified the likely cause(s) for the Level 2 treatment technique trigger and, if so, establish that the system has corrected the problem(s).

iii. Corrective action. The current TCR does not require systems that have MCL violations to perform corrective actions. Under this proposal, EPA is requiring PWSs to correct sanitary defects found through either a Level 1 or Level 2 assessment. Ideally, systems will be able to correct any sanitary defects found in the assessment within 30 days and report that correction on the assessment form. When the correction of sanitary defects is not completed by the time the PWS submits the completed assessment form to the State, the PWS must complete the corrective action(s) on a schedule determined by the State. This schedule may be developed in consultation with the PWS. The schedule must include when the corrective action will be completed and any necessary milestones and temporary public health protection measures. The PWS must notify the State when each scheduled corrective action is completed.

At any time during the assessment or corrective action phase, either the PWS or the State may request a consultation with the other entity to discuss and determine the appropriate actions to be taken. The system may consult with the State on all relevant steps that the system is considering to complete the corrective action, including the method of accomplishment, an appropriate timeframe, and other relevant information.

E. coli detection in the distribution system indicates a public health hazard and can result in an *E. coli* MCL violation. Under the proposed rule, when an *E. coli* MCL violation has occurred, the system must complete a Level 2 assessment and corrective action must be implemented as soon as practical. The Agency encourages systems to promptly find the source of *E. coli* and fix the problem before the completed assessment form is due to the State.

b. *EPA's rationale.* i. Coliform treatment technique. The advisory committee indicated that the conditions leading to a monthly/non-acute MCL under the current TCR should trigger an assessment under the RTCR for several reasons. First, the advisory committee recognized that presence of total coliform indicates the potential presence of a pathway for contamination from external sources such as source water or through a loss of distribution system integrity. The change to a coliform treatment technique construct that uses total coliforms as an indicator of distribution system integrity places the emphasis on systems to take more preventive actions to address problems. These actions would better protect public health than the additional monitoring with no corrective action that is required under the current TCR. To address the high and constant number of PWSs with violations over the years under the current TCR, the proposed changes would be more protective by requiring systems to correct deficiencies associated with the non-acute MCL (*see* Exhibit VI.1 in section VI.C.1 of this preamble). Second, the advisory committee indicated that the public notice associated with non-acute violations is confusing because the presence of total coliforms is not necessarily an indication of a potential public health threat; however, it is an indicator of a potential pathway for fecal contamination to enter into the distribution system. Under the treatment technique requirement, the presence of total coliforms (at the level equivalent to a non-acute violation) indicates a need to assess whether a problem exists. When a system fails to conduct the assessment, the system will then incur a violation and be required to issue public notification. If the system does conduct the assessment and satisfies the requirements of the treatment technique (including corrective action when a sanitary defect is identified), no public notification is required. Third, the occurrence of total coliforms in the context of the coliform treatment technique requirement continues to inform and further the original objectives of the TCR: to evaluate the effectiveness of treatment, determine the integrity of the distribution system, and signal the

possible presence of fecal contamination. Finally, total coliform presence indicates the potential presence of a pathway for contaminants from external sources such as source water or through a loss of distribution system integrity.

ii. Assessment. The proposed rule requires assessments to ensure that specific action is taken to identify whether potential pathways of contamination into the distribution system exist. The advisory committee indicated that assessments are significant actions that protect public health. Under the current rule, when a system has a non-acute MCL violation and if any subsequent sampling did not detect total coliform, the problem may persist due to the intermittent nature of total coliform and remain unaddressed. However, the absence of total coliform-positive samples subsequent to an initial positive finding is not a reliable indicator that a contamination pathway no longer exists. In contrast, the proposed revisions would ensure that systems examine and assess the cause of the total coliform occurrence (that is equivalent to the current non-acute MCL level) and take any corrective action if necessary.

Under the proposed rule, the system will also be required to conduct an assessment if it fails to conduct repeat monitoring following an initial total coliform-positive sample result. As discussed in section III.A.4 of this preamble, repeat monitoring is critical in identifying the extent, source, and characteristics of fecal contamination in a timely manner. Since the revised rule proposes to eliminate additional routine monitoring for systems that monitor at least monthly and decrease the number of additional routine monitoring and repeat monitoring samples for the smallest systems, the need to conduct repeat monitoring is more crucial than ever in providing immediate and useful information needed to protect public health. The cost for collecting and analyzing a repeat sample would be considerably less than the cost for conducting a Level 1 assessment. EPA expects that systems will want to ensure that assessments are conducted only when potential problems may exist rather than for failure to take repeat samples.

The proposed rule specifies two different levels of assessments—Level 1 and Level 2—to recognize that a higher level of effort to diagnose a problem applies to situations of greater potential of public health concern such as repeated Level 1 triggers or an *E. coli* MCL violation. Level 2 assessments are conducted by a party approved by the State, which may be the PWS where it has staff or management with the certification or qualifications as determined by the State. The Level 2 assessments may also be conducted by the State or a third party approved by the State.

To make more transparent what the Level 1 and Level 2 assessments entail and to facilitate consistent implementation among States, the proposed rule specifies minimum elements for these assessments. The advisory committee recommended that the minimum elements identified previously in this preamble be included in the Level 1 and Level 2 assessments to identify potential flaws in monitoring or specific pathways of contamination. Although the proposed RTCR specifies the same minimum elements for both the Level 1 and Level 2 assessments, the Level 2 assessment involves a more in-depth examination of these elements compared to a Level 1 assessment. Specific examples of how the Level 2 assessments are more in-depth than Level 1 assessments may be found in Appendix X of the AIP (USEPA 2008c).

EPA recognizes that not every assessment will identify a sanitary defect or find a reason or cause for the presence of total coliforms. If no sanitary defect is identified, the system must document that fact in the completed assessment form and provide supporting evidence for this conclusion. EPA expects that only systems that adhere to proper procedures and standards set by the State are eligible to arrive at this determination, and only after providing sufficient supporting evidence.

The advisory committee recommended that the Level 1 and Level 2 assessments be conducted as soon as practical after the PWS receives notice that the system has exceeded the treatment technique trigger. The advisory committee also recommended that systems submit the completed assessment forms to the State within 30 days after determination that the PWS has exceeded the trigger. The rationale for the 30-day interval is to allow sufficient time for problem identification and potential remediation of the problem in conjunction with the follow-up assessment, in most cases.

To help States and PWSs conduct assessments, EPA intends to develop a draft assessment and corrective action guidance manual and to make it available for public comment prior to promulgation of the final rule and to finalize the guidance manual after the rule is finalized.

iii. Corrective action. The advisory committee recognized that not every assessment will identify a sanitary defect. However, the advisory committee recommended that the RTCR require all sanitary defects be corrected by the system in a timely manner. The system, in consultation with the State as needed, identifies and determines the specific corrective action.

Under the proposed rule, the State may allow the PWS additional time to conduct the corrective action if needed. EPA recognizes that some systems may not be able to fix sanitary defects before submitting the completed assessment form within the 30-day interval due to the extent and cost of the corrective action. In such situations, EPA encourages the State and PWS to work together to determine the appropriate schedule for corrective actions (which may include additional or more detailed assessment or engineering studies) to be completed as soon as possible. The system must comply with the agreed upon schedule and notify the State when each scheduled corrective action is completed.

Either the PWS or the State may request consultation with the other party to determine the appropriate actions to be taken. EPA is not requiring this to be a mandatory consultation to provide ease of implementation for States. In many cases, consultation may not be necessary because the type of corrective action for the sanitary defect will be clear and can be fixed right away (for example, replacement of a missing screen).

c. *Request for comment.* EPA requests comment on the: (1) Proposed change from the non-acute MCL for total coliforms to a coliform treatment technique requirement that uses total coliforms as an indicator of a pathway of contamination; (2) proposed requirement for systems to conduct an assessment following a trigger condition; (3) proposed levels of assessment required; and (4) proposed requirement for systems to correct all sanitary defects found during an assessment. In addition, EPA requests comment on how to ensure that a Level 2 assessment is more comprehensive than a Level 1 assessment (*e.g.,* should a Level 2 assessment include additional elements such as asset management and capacity development?). Should EPA provide more detail, either in guidance or rule language, on the elements and differences between a Level 1 and Level 2 assessments? If in rule language, how should the rule language distinguish the two levels of assessments? Please provide examples. Additionally, should EPA provide additional guidance on how systems might address the situation where a Level 1 or Level 2 assessment

fails to identify any sanitary defects (*i.e.,* the trigger event remains unexplained). If so, what should such guidance say?

6. Violations

a. *Provisions.* EPA is proposing to modify the definition of the existing MCL violation, establish a treatment technique violation, and revise the monitoring and reporting violations. EPA is proposing that public notice be required for each type of violation (*see* section III.A.7 of this preamble for detail information on public notification).

i. *E. coli* MCL violation. A violation of the *E. coli* MCL occurs when:

- A routine sample is total coliform-positive and one of its associated repeat samples is *E. coli*-positive; or
- A routine sample is *E. coli*-positive and one of its associated repeat samples is total coliform-positive; or
- A system fails to take all required repeat samples following a routine sample that is positive for *E. coli;* or
- A system fails to test for *E. coli* when any repeat sample tests positive for total coliforms.

ii. Coliform treatment technique violation. A coliform treatment technique violation occurs when:

- A system fails to conduct a required assessment within 30 days of notification of the system exceeding the trigger (*see* section III.A.5 of this preamble for conditions under which monitoring results trigger a required assessment); or
- A system fails to correct any sanitary defect found through either a Level 1 or 2 assessment within 30 days (*see* also section III.A.6 of this preamble) or in accordance with State-derived schedule.

There would be no treatment technique violation associated solely with a system exceeding one or more action triggers (Level 1 or Level 2 triggers).

iii. Monitoring violation. Under the current TCR, a monitoring violation occurs when a system fails to comply with the total coliform monitoring requirements, including the sanitary survey requirement. Under the proposed RTCR, a monitoring violation occurs when a system fails to take every required routine or additional routine sample in a compliance period, or when it fails to test for *E. coli* following a routine sample that is total coliform-positive.

In addition, if a system on quarterly monitoring has a monitoring violation in two or more quarters, or if a system on annual monitoring misses its annual monitoring, it must begin monthly monitoring until it meets criteria for less frequent monitoring. *See* section III.A.3 of this preamble for a detailed discussion on monitoring frequency.

iv. Reporting violation. A reporting violation occurs when a system that properly conducts monitoring or an assessment fails to submit a monitoring report or a correctly completed assessment form by the required deadline. The PWS is responsible for reporting this information to the State regardless of any arrangement with a laboratory. A reporting violation also occurs when a system fails to notify the State following an *E. coli*-positive sample.

b. *EPA's rationale.* To define violations, the advisory committee built upon the principles underlying the current TCR violations and current TCR public notification and suggested changes to improve public health protection where they saw a specific need. This proposal specifies responses to different degrees of potential public health concern. As described in the next section on providing information and notification to the public, Tier 1, Tier 2, and Tier 3 public notices are required following violations corresponding to the severity of each violation type.

i. *E. coli* MCL violation. An *E. coli* MCL violation (which includes failure to take all required repeat samples following an *E. coli*-positive sample) creates concern of an immediate potential public health threat. For this reason, an *E. coli* MCL violation is considered an acute violation requiring immediate response by the system. Including an *E. coli* MCL violation condition for systems failing to collect all repeat samples following an initial *E. coli*-positive sample enhances public health protection by preventing a system from incurring only a monitoring violation when there is an indication of fecal contamination. As discussed previously in section II.D of this preamble, the presence of *E. coli* indicates a pathway of fecal contamination and should be taken seriously. Systems need to follow up with repeat samples to characterize the extent and source of such contamination. Failure to take the required repeat samples following an initial *E. coli*-positive sample is not protective of public health and is a serious violation.

ii. Coliform treatment technique violation. A coliform treatment technique violation occurs when a potential pathway of contamination in the distribution system is unexplored and/or uncorrected. Performing the Level 1 and 2 assessments and taking corrective action are essential aspects of compliance with the treatment technique. A system which neglects to perform the prescribed assessment or corrective action is in violation of the proposed RTCR's treatment technique requirements.

iii. Monitoring violation and reporting violation. Monitoring and reporting violations occur when a system fails to comply with the routine monitoring requirements or when a system fails to submit monitoring reports or completed assessment forms. EPA believes that monitoring violations and reporting violations need to be addressed so that a system is held accountable to take actions to reduce public health risk, including regular monitoring of water quality.

c. *Request for comment.* EPA requests comment on the proposed violation determinations.

7. Providing Notification and Information to the Public

a. *Provisions.* To correspond to the changes in the proposed revised rule, EPA is proposing some modifications to the public notice (PN) requirements contained in 40 CFR part 141 subpart Q. Tier 1 PN is required for an *E. coli* MCL violation. Tier 2 PN is required for a treatment technique violation for failure to conduct assessments or corrective actions. Tier 3 PN is required for a monitoring violation or a reporting violation.

In the current TCR, if a system has an acute MCL violation which is based on the presence of fecal coliforms or *E. coli,* or which is based on the system's failure to test for fecal coliforms or *E. coli* following a total coliform-positive repeat sample, the system is required to publish Tier 1 PN. Under the proposed RTCR, a system is required to publish Tier 1 PN when it has an *E. coli* MCL violation (*see* section III.A.6 of this preamble for what constitutes an *E. coli* MCL violation). In addition, the system will continue to be required to notify the State after learning of an *E. coli*-positive sample, as currently is required under the TCR. As mentioned earlier in section III.A.2 of this preamble, EPA is proposing to eliminate the MCL for fecal coliforms. Under the proposed rule, the standard health effects language, which is required to be included in all public notification actions, is modified to delete the reference to the fecal coliform MCL and fecal coliforms. The language for a non-acute violation under the current TCR is modified to apply to a violation of the assessments and corrective action requirements of the coliform treatment technique.

In the current TCR, a system is required to publish a Tier 2 PN when the system has a non-acute MCL violation, which is based on total

coliform presence. Under the proposed rule, a system is required to publish a Tier 2 PN if the system violates the coliform treatment technique requirements. Also, EPA is proposing to modify the standard health effects language for coliform to emphasize the assessment and corrective action requirements of the proposed rule.

In the current TCR, a system is required to publish a Tier 3 PN when the system has a monitoring or reporting violation. In the proposed rule, the Tier 3 PN requirements are changed to incorporate the recommendation in the AIP that monitoring violations be considered distinct from reporting violations under the proposed RTCR. Both types of violations require Tier 3 PN.

Consumer confidence report (CCR) requirements are also modified. Health effects language for the CCR, which is identical to the health effects language required for PN, is updated in the same way as described for PN. In addition, the proposed RTCR removes the CCR requirements that require the inclusion of total numbers of positive samples, or highest monthly percentage of positive samples for total coliforms as well as total number of positive samples for fecal coliforms. These provisions are replaced by requirements to include the number of Level 1 and Level 2 assessments required and completed, the corrective actions required and completed, and the total number of positive samples for *E. coli.* Unchanged and consistent with existing provisions under the current TCR, a CWS may provide Tier 3 PN using the annual CCR.

b. *EPA's rationale.* The proposed public notification requirements are consistent with the AIP language as well as with the tier system described in 40 CFR part 141 subpart Q. These changes are appropriate because some of the types of violations in the proposed RTCR are different from the current TCR. The standard health effects language for the public notification is also revised as appropriate given the changes to what constitutes a violation under the proposed RTCR.

The proposed Tier 1 PN requirement for an *E. coli MCL* violation is consistent with the current TCR. Tier 1 PN is required for NPDWR violations and situations with significant potential to have serious adverse effects on human health as a result of short term exposure. The existing Tier 1 PN requires public notice as soon as possible but no later than 24 hours after the system learns of the violation. Exposure to *E. coli* in drinking water can possibly result in serious, acute health effects, such as diarrhea, cramps, nausea, headaches, or other symptoms and possible greater health risks for infants, young children, some of the elderly, and people with severely compromised immune systems.

Tier 2 PN is required for all NPDWR violations and situations with potential to have serious adverse effects on human health not requiring Tier 1 PN. The system must provide public notice as soon as practical, but no later than 30 days after the system learns of the violation. A treatment technique violation under the proposed RTCR meets these criteria because it is an indication that the public water system failed to conduct an assessment or complete corrective action following identification of sanitary defects. Identification of a sanitary defect indicates that a problem may exist in the distribution system that has potential to cause public health concern.

Tier 3 PN is required for all other NPDWR violations and situations not included in Tier 1 or Tier 2. The existing Tier 3 PN requires a system to provide public notice no later than one year after the system learns of the violation or situation or begins operating under a variance or exemption. Monitoring violations and reporting violations meet these criteria because, while they do represent a violation of the proposed RTCR, the risk to public health is not as clearly linked as those that are Tier 1 or 2. Therefore, EPA believes that a public notice given at least annually fulfills the public's right-to-know about these violations.

Consumer confidence report requirements are updated to reflect the advisory committee's recommendations that total coliforms be used as an indicator to start an evaluation process that, where necessary, will require the PWS to correct sanitary defects. EPA believes it is most appropriate to inform the public about actions taken, in the form of assessments and corrective actions, since failure to conduct these activities lead to treatment technique violations under the proposed RTCR. Because the proposed RTCR no longer includes the total coliform MCL but now includes a trigger, EPA believes that systems no longer need to report the number of total coliform-positive samples via the CCR, since that could cause confusion or inappropriate changes in behavior among consumers. In addition, the CCR requirements will also reflect the removal of fecal coliform provisions under the proposed RTCR.

c. *Request for comment.* EPA requests comment on whether the PN and CCR language revisions are consistent with the provisions of the proposed RTCR that reflect the use of total coliforms as an indicator within a coliform treatment technique. Since EPA is not aware of health effects resulting solely from exposure to total coliforms, the proposed RTCR eliminates the public notification requirement for detection of total coliforms, but provides for public notification upon detection of *E. coli,* and for violation of the coliform treatment technique. The Agency does request comment, however, on the loss of information to consumers resulting from elimination of public notification requirements following positive sample results for total coliforms. EPA also requests comment on whether the proposed RTCR should require special notice to the public of sanitary defects, in addition to the PN requirements, similar to the GWR special notice requirements. This would be consistent with current requirements for other regulations that limit pathogens in ground water systems. Under 40 CFR 141.403(a)(7)(i), a CWS must inform the public of the significant deficiency and/or fecal indicator-positive sample. The CWS must continue to inform the public annually until the significant deficiency is corrected or the fecal contamination in the ground water source has been determined by the State to be corrected. Under 40 CFR 141.403(a)(7)(ii), an NCWS that receives notice from the State of a significant deficiency must inform the public of any significant deficiency that has not been corrected within 12 months of being notified by the State, or earlier if directed by the State. The NCWS must continue to inform the public annually until the significant deficiency is corrected.

8. Reporting and Recordkeeping Requirements for Systems

a. *Provisions.* i. Reporting. In addition to the existing general reporting requirements provided in 40 CFR 141.31, the proposed RTCR requires a PWS to:

- Notify the State no later than the end of the next business day after it learns of an *E. coli*-positive sample.
- Report to the State an *E. coli* MCL violation no later than the end of the next business day after learning of the violation. The PWS is also required to notify the public according to the provisions laid out in 40 CFR part 141 subpart Q.
- Report to the State a treatment technique violation no later than the end of the next business day after it learns of the violation. The PWS must also notify the public in accordance with 40 CFR part 141 subpart Q.

• Report to the State monitoring violations within ten days after the system discovers the violation, and notify the public in accordance with 40 CFR part 141 subpart Q.

• Notify the State when each scheduled corrective action is completed for corrections not completed by the time of the submission of the assessment form.

In addition, systems triggered into conducting an assessment are required to submit the completed assessment form within 30 days after determination that the coliform treatment technique trigger has been exceeded (*see* section III.A.3 of this preamble for additional discussion).

ii. Recordkeeping. EPA is proposing to maintain the current TCR requirements regarding retention of sample results and records of decisions related to monitoring schedules found in 40 CFR 141.33, including provisions that address the new requirements of the proposed RTCR pertaining to reduced and increased monitoring, treatment technique, etc. In addition, systems are required to maintain on file for State review the assessment form or other available summary documentation of the sanitary defects and corrective actions taken. Systems are required to maintain these documents for a period not less than five years after completion of the assessment or corrective action.

b. *EPA's rationale.* In the case of an *E. coli*-positive sample, the proposed RTCR maintains the current TCR requirement that systems must notify the State by the end of the day when they are notified of the *E. coli*-positive result or by the end of the next business day if the State office is already closed. The advisory committee believed that this requirement is important to maintain because of the potential for immediate public health risk associated with *E. coli* presence and the desire for States to consider quickly whether additional actions might be appropriate. The same rationale applies to *E. coli* MCL violations.

Since there are new requirements for conducting assessments and corrective actions, and new conditions for obtaining increased or reduced monitoring provisions, the proposed rule includes reporting and recordkeeping requirements to facilitate tracking of Level 1 and Level 2 triggers and compliance with treatment technique requirements. Systems are required to maintain these files no less than five years. Since systems have to maintain these files no shorter than the maximum period allowed between sanitary surveys (*i.e.,* five years; *see* 40 CFR 142.16(b)(3) and 40 CFR 142.16(o)(2)), States have the opportunity to look at and review these files during sanitary surveys and/or annual visits. The five year period is also consistent with the recordkeeping requirements for microbiological analyses under 40 CFR 141.33(a).

The timeframe by which reporting and recordkeeping are required under the proposed rule is consistent with EPA's practice regarding reporting and recordkeeping requirements in other regulations under SDWA.

c. *Request for comment.* EPA requests comment on whether the timeframe required for reporting and recordkeeping requirements are appropriate.

9. Analytical Methods

a. *AIP-related method issues.* i. Evaluation of currently-approved methods. The AIP contains several recommendations by the advisory committee regarding the analytical methods approved under the proposed RTCR. The advisory committee noted that the methods currently approved under the current TCR have varying sensitivities and specificities, and recommended that " * * * the Agency evaluate all currently approved coliform analytical methods to determine whether these methods continue to be appropriate for use in drinking water compliance monitoring" (USEPA 2008c, AIP p. 7).

In the twenty years since the current TCR was promulgated, many methods have been developed and approved for use. Most of the approved methods that are used to support the current TCR were evaluated under EPA's Alternate Test Procedure (ATP) process. Under this process, a proposed method is evaluated in comparison to a reference method. A favorable comparison serves as the basis for subsequent approval of the method for use in regulatory compliance monitoring.

The ATP evaluations are designed based on the ATP Microbiology Protocol (USEPA 2004), an EPA guidance document that outlines how the evaluation study should be conducted. In the years the ATP program has been in place, the ATP guidance document has been revised several times. As a result of different protocols being used over time, the current set of approved methods have not all been evaluated under identical conditions.

In addition to the concerns expressed by the advisory committee that the approved methods may not be equivalent to each other, EPA notes that there have been additional concerns with some of the methods currently approved. This includes allegations that some of the approved methods may have been modified since approval without EPA's knowledge. EPA is also aware of reports of varying performance of some enzyme-based methods (Oldstadt *et al.* 2007; Fricker *et al.* 2003). Lastly, EPA is aware of at least one circumstance where the manufacturer of an approved method placed a "product hold" and recall on the medium after the product was reported to be experiencing reduced recovery of *E. coli.*

For these reasons, EPA believes that additional information may be needed regarding the performance of the currently approved methods in order to justify their continued approval. Among the options, EPA is considering a complete, side-by-side method evaluation study, whereby all the methods are compared to each other under identical conditions, according to the same protocol.

EPA is considering an approach under which vendors of all currently approved methods would have the option of voluntarily participating in an independent, third-party laboratory evaluation through EPA's Environmental Technology Verification (ETV) Program. The goal of the ETV Program is to provide independent, objective, and credible performance data for commercial-ready environmental technologies. More information on this program is available on EPA's Web site at *www.epa.gov/etv/index.*

Under the ETV approach, EPA anticipates that participating vendors would generally fund the majority of the cost of their method evaluation. Based on the results of the ETV study, as documented in the verification report, EPA would judge the appropriateness of each analytical method and would determine which should continue to be approved for future monitoring. EPA would then make any changes to the analytical methods approved under the RTCR through later rulemaking.

If a vendor chooses not to participate in the ETV study, EPA would allow the vendor to propose, for EPA's consideration, an equivalent alternative approach for method evaluation. EPA will determine whether the proposed approach will provide an independent, effective, and credible evaluation. EPA emphasizes that any alternative approach would need to be equivalent in scope and rigor to the ETV program. As with the ETV study, EPA would use the results from an alternative study to judge the appropriateness of each analytical method and would determine which methods warrant approval for future monitoring under this regulation.

As described at EPA's April 2009 stakeholder meeting, the time required to plan and conduct a proper method evaluation, and to assess the results, is such that EPA does not expect to be able to complete this effort and to take action on the method evaluation in time for the results to be included in the final RTCR. Instead, and to the extent necessary, EPA would address the disapproval of any of the current methods, or restrictions on any methods, in independent regulatory actions.

ii. Review of ATP protocol. The AIP further recommends that EPA "engage stakeholders in a technical dialogue in its review of the Alternative Test Procedure (ATP) microbial protocol for TC/*E. coli* methods for drinking water to determine if the criteria for acceptance of methods are consistent with the intent and objectives of the TCR * * *" (USEPA 2008c, AIP p. 7). In response, EPA notes that the study plan developed for the re-evaluation of current methods (under an ETV or alternative approach) could serve as a starting point for discussions with stakeholders regarding the basis for evaluating new methods. The study plan could be used as a model for a revised ATP protocol; lessons learned from the re-evaluation could also inform EPA's future assessment of new methods.

iii. Approval of "24-hour" methods. The AIP also recommends that EPA "consider approving methods that allow the timely (*e.g.* on the order of 24 hours) analytical results for *E. coli* and TC and that provide relatively concurrent analyses, without significantly sacrificing accuracy, precision and specificity" (USEPA 2008c, AIP p. 7). EPA notes that many of the approved methods that may be used in compliance with the proposed rule can be completed in approximately 24 hours. However, the methods that detect lactose fermentation include a confirmation step that involves transfer of a presumptively positive culture into a more inhibitory confirmation medium which serves to ensure the initial positive was correct. As a result of this confirmatory step, lactose fermentation methods can take up to 96 hours to obtain a result. The enzyme based methods do not require this confirmation step, and their results can be obtained in a 24 to 48 hour time period.

EPA is aware of some concerns that methods with a 24 hour incubation time may not be able to detect as many coliform bacteria as methods with a 48 hour incubation period. Since many of the coliform bacteria found in a distribution system are injured or stressed due to disinfection practices, and since injured/stressed organisms may take longer to detect than 24 hours, this concern is of interest to EPA. As part of, or in addition to, the method evaluation previously described, EPA may therefore further investigate the impact of incubation time on the recovery of stressed/injured organisms in drinking water using approved media. At this time, EPA believes that it is premature to conclude that either enzyme-based or lactose-based methods are inherently preferable.

As discussed during the advisory committee meetings, the analysis time of the analytical methods is just one aspect in the overall amount of time it takes before a PWS obtains sample results from the laboratory and subsequently collects repeat samples. Factors that can impact how quickly the PWS receives notification of a positive result include whether the PWS uses an in-house laboratory or must ship the sample to a distant contract laboratory, and whether the sample results are reported via an electronic means or via traditional mail. In addition, the turnaround time for repeat sampling can be affected by such factors as the laboratory daily hours of operation. The current TCR specifies that repeat samples be collected within 24 hours, but States currently have the flexibility to extend this timeline. The current TCR does not contain provisions for how quickly the laboratory must notify the PWS when a positive result is obtained. This proposal does not change these provisions.

iv. Elimination of fecal coliforms under the proposed RTCR. The AIP also contains a recommendation that EPA remove all provisions related to fecal coliforms under the proposed RTCR. Consistent with this recommendation, and for the following reasons, EPA is proposing to eliminate all fecal coliform provisions in the RTCR.

First, the fecal coliform group can contain bacteria not associated with fecal contamination. *E. coli* is the most prominent member of the fecal coliform group. However, other coliform bacteria, such as thermotolerant strains of *Klebsiella spp.,* have been shown to occur in the fecal coliform group (Warren *et al.* 1978). These non-*E. coli* bacteria are often found in environmental sources (for example, soil, vegetation, water) and, therefore, are not exclusively associated with feces. Due to the presence of these non-fecal bacteria, the fecal coliform group may not always provide the public water system with meaningful data regarding the vulnerability of their distribution system to fecal contamination.

Secondly, when the current TCR was developed, there were few *E. coli* methods available. Many public water systems were familiar with and preferred to use the fecal coliform methods. However, since the current TCR was promulgated, many *E. coli* methods have been developed and approved for use. EPA believes that most systems nationwide currently test for *E. coli,* while few test for fecal coliform bacteria. Since the methods used to test for *E. coli* have approximately the same cost as those used to test for fecal coliform bacteria, this proposed change is not expected to create an additional burden on PWSs.

EPA is proposing to eliminate all analytical method provisions for fecal coliforms that are included in the current TCR. EPA proposes instead to allow testing only for *E. coli* following a total coliform-positive sample. This change will provide the water system with more meaningful information regarding potential fecal contamination of the distribution system.

The current TCR specifies a number of analytical methods that can be used for compliance sample analysis (in 40 CFR 141.21(f)). Since fecal coliform bacteria are not regulated contaminants under this proposed rule, the analytical methods for fecal coliforms are no longer applicable and are removed from the list of analytical methods. All other methods used for compliance with the current TCR are maintained for compliance sample analysis under the proposed RTCR.

v. Request for comment on AIP-related method issues. EPA is requesting comment on the following RTCR analytical method issues related to recommendations from the TCRDSAC in its AIP:

- The use of an ETV approach for a reevaluation of analytical methods.
- Whether the RTCR should include provisions to ensure a more expedited results notification process. The RTCR could, for example, include language requiring that PWSs arrange to be notified of a positive result by their laboratory within 24 hours.
- Whether the RTCR should require repeat samples be taken within 24 hours of a total coliform-positive with no (or limited) exceptions.

b. *Other method issues.* In addition to addressing the recommendations of the advisory committee, EPA is proposing some minor technical changes related to analytical methods. Many of these changes document practices that are already followed by PWSs and laboratories, and are consistent with the

Manual for the Certification of Laboratories Analyzing Drinking Water (referred to as the "Laboratory Certification Manual") (USEPA 2005), an EPA document that outlines method requirements and good laboratory practices for certified laboratories conducting drinking water compliance sample analyses.

Some of these changes were brought to the attention of EPA by EPA Regions and States involved in the implementation of the drinking water certification program. Other minor changes have been proposed to make the analytical methods section of this regulation easier to understand and implement. Each proposed change is described as follows with a discussion of the rationale for the change.

i. Holding time. The proposed RTCR continues to provide a 30-hour holding time limit for the samples collected in compliance with this regulation (40 CFR 141.21(f)(3)). However, EPA is proposing to change the definition for holding time from "the time from sample collection to initiation of analysis may not exceed 30 hours" to "the time from sample collection to initiation of test medium incubation may not exceed 30 hours."

ii. Dechlorinating agent for sample preservation of chlorinated water supplies. The proposed RTCR establishes the following provision: "If chlorinated water is to be analyzed, sufficient sodium thiosulfate ($Na_2S_2O_3$) must be added to the sample bottle before sterilization to neutralize any residual chlorine in the water sample." Dechlorination procedures are addressed in section 9060A.2 of *Standard Methods for the Examination of Water and Wastewater* (20th and 21st editions) (Clesceri *et al.* 1998; Eaton *et al.* 2005).

iii. Filtration funnels. EPA is proposing to add the following footnote to the analytical methods table (§ 141.852) under the revised rule:

> All filtration series must begin with membrane filtration equipment that has been sterilized by autoclaving. Exposure of membrane filtration equipment to UV light is not adequate to ensure sterilization. Subsequent to the initial autoclaving, exposure of the filtration equipment to UV light may be used to sanitize the funnels between filtrations within a filtration series.

iv. Analytical methods table changes. EPA is proposing the following changes to the analytical methods table:

- The table is organized by methodology (*e.g.,* lactose-fermentation methods vs. enzyme-substrate methods).
- *E. coli* methods are included in the table.
- 18th and 19th editions of *Standard Methods for the Examination of Water and Wastewater* are no longer approved and have been removed.
- The references to Standard Methods 9221A and 9222A are removed.
- The reference to Standard Methods 9221B is changed to 9221B.1, B.2.
- The reference to Standard Methods 9221D is changed to 9221D.1, D.2.
- The table proposes to allow Standard Methods 9221D in the multiple tube format as described in Standard Methods 9221B.
- The citation for MI agar is changed to EPA Method 1604 for clarity and consistency.
- The table clarifies that Standard Methods 9221 F.1 and 9222 G.1*a* (1), (2) may be used for *E. coli* analysis.
- The table clarifies the correct formulation for EC–MUG broth, when used in conjunction with Standard Methods 9222G.1*a*(2), through the addition of the following footnote:

> The following changes must be made to the EC broth with MUG (EC–MUG) formulation: Potassium dihydrogen phosphate, KH_2PO_4 must be 1.5g and 4-methylumbelliferyl-Beta-D-glucuronide must be 0.05 g.

- The table reflects the approval of a modified Colitag method for the simultaneous detection of *E. coli* and other total coliforms.

v. EPA's rationale for proposed changes related to other method issues. *(a). Holding time.*

The current rule states "The time from sample collection to initiation of analysis may not exceed 30 hours" (40 CFR 141.21 (f)(3)). Since promulgation of the current TCR, some States and EPA Regions have commented that "initiation of analysis" may be interpreted several different ways, which can lead to the sample being held longer than the 30 hours intended by the rule. The proposed language more clearly defines the amount of time that the sample may be held and is consistent with section 6.4.1 of the *Manual for the Certification of Laboratories Analyzing Drinking Water* which states: "For the analysis of total coliform in drinking water, the time between sample collection and the placement of sample in the incubator must not exceed 30 hours."

EPA believes that changing the definition of holding time from "the time from sample collection to initiation of analysis" to "the time from sample collection to initiation of test medium incubation" may slightly decrease the amount of time a PWS has to get the sample to a laboratory. EPA does not believe that this change will significantly reduce the amount of time a water system has to get a sample to the laboratory, as most of the methods approved under this rule require 30 minutes or less to process and prepare the sample for the incubation step. Thus, the initial analytical steps should not constitute a large portion of the holding time as a whole. EPA recommends that PWSs that have difficulty meeting the holding time notify the laboratory that the samples are in transit and need to be given priority. The laboratory could begin analysis immediately upon sample arrival so that the samples could be placed in the incubator in time to meet the 30 hour holding time. EPA notes that a laboratory may have to make specific accommodations in their processes in order to properly analyze a sample received close to the end of the holding time. EPA believes that this is feasible with proper planning.

(b). *Dechlorinating agent for sample preservation of chlorinated water supplies.* Under this proposal, EPA would require that chlorinated water samples be collected in bottles that contain the dechlorinating agent sodium thiosulfate. This is consistent with section 3.15.4 of the Laboratory Certification Manual, which states "If chlorinated water is to be analyzed, sufficient sodium thiosulfate ($Na_2S_2O_3$) must be added to the sample bottle before sterilization to neutralize any residual chlorine in the water sample." Neutralization ceases the bactericidal action of the chlorine during sample transit, thus allowing a more accurate assessment of what the true microbial content of the water sample was at the time of sample collection. Implementation of this new requirement should be straightforward since PWSs need only ask the laboratory for pre-treated sample containers. EPA does not believe this provision will cause an increase in cost to PWSs, as the cost of the bottles with the sodium thiosulfate is essentially the same as the cost of the bottles without the sodium thiosulfate.

(c). *Filtration funnels.* Under this proposal, EPA is requiring that membrane filtration equipment be autoclaved before beginning a filtration series. This requirement is consistent with section 4.1.3 of the Laboratory Certification Manual, which states: "Membrane filter equipment must be autoclaved before the beginning of a filtration series."

Under the current TCR, not all of the approved membrane filtration methods require that a filtration series begin with membrane filtration units that have been sterilized by autoclave. Some of the approved methods allow the laboratory to use ultraviolet (UV)

radiation exposure in lieu of autoclaving to sterilize filtration units between filtration series. EPA does not believe that ultraviolet radiation is sufficient to properly sterilize the membrane filtration equipment. Additionally, EPA believes that when ultraviolet radiation is used, not all areas of the membrane filtration equipment are exposed, and therefore microorganisms may persist and contaminate other water samples and the laboratory. For these reasons, EPA is proposing to include a footnote to the analytical methods table in order to ensure proper sterilization.

EPA does, however, believe that ultraviolet light can be used to sanitize the filtration equipment between filtrations within a filtration series, as stated in section 4.1.4 of the Laboratory Certification Manual: "Ultraviolet light (254 nm) may be used to sanitize equipment (after initial autoclaving for sterilization), if all supplies are pre-sterilized. Ultraviolet light may be used to reduce bacterial carry-over between samples during a filtration series."

(d). *Analytical methods table.* In this proposal, EPA is identifying a number of changes to the analytical methods table for clarity and accuracy.

In the current TCR, the methods are listed by date approved and the *E. coli* methods are listed in a text format. In this proposal, the analytical methods table is organized by methodology (*e.g.,* lactose-fermentation methods vs. enzyme-substrate methods), and the *E. coli* methods are included in the table.

Standard Methods for the Examination of Water and Wastewater is a reference document designed to represent "the best current practice of American water analysts." Periodically, new editions are published in order to incorporate improvements in the methods contained within this manual. Thus, new editions of this publication contain more current and improved versions of the methods. Under the current TCR, four editions of this publication are approved, resulting in different, oftentimes outdated, versions of the same method being approved. Having multiple editions of this manual approved under this regulation also creates a burden for the laboratory certification officers who must understand the differences between the versions of the method for which the laboratory may be seeking certification. For these reasons, EPA is proposing to remove the 18th and 19th editions of *Standard Methods for the Examination of Water and Wastewater* for use in compliance sample analysis under the RTCR. EPA expects that the burden associated with this change will be minimal as most laboratories have already procured the newer editions or have arranged for access to the online publication.

In this proposed regulation, the reference to Standard Methods 9221A and 9222A are removed. These sections of the methods contain only introductory information, not any actual methodology. They do not represent methods approved for use under this regulation.

The references to Standard Methods 9221B and 9221D are modified in this proposed regulation. In the current TCR, the methods are referenced as 9221B and 9221D with footnote 5 denoting that the "completed phase" called for in the methods is not required. By more specifically citing Standard Methods 9221 B.1, B.2, and 9221 D.1, D.2 (which contain the applicable, required steps of these methods) EPA is able to eliminate the original footnote and improve clarity.

EPA is proposing to allow Standard Methods 9221D (Presence-Absence broth) to be used in a multiple tube format. This method has traditionally been used in a single bottle, allowing only the qualitative detection of total coliforms. However, there are published reports showing this method can be used in a multiple tube format for the quantitative detection of total coliforms (Rice *et al.* 1987; Rice *et al.* 1993). This medium would be used in the same manner that Lauryl Tryptose Broth (LTB) is described as being used in Standard Methods 9221B. Allowing the use of this method in a multiple tube format would allow PWSs that use this method to quantitate any total coliforms that may occur in the water sample.

EPA is proposing to change the citation for MI Agar. Under the current TCR, this method is cited as Standard Methods 9222, with a footnote citing the *Applied and Environmental Microbiology* article where the method was initially described. In this proposal, the method is now cited as EPA Method 1604, consistent with section 5.4.2.1.3 of the Laboratory Certification Manual. EPA Method 1604 is identical to the citation in the TCR and does not require the use of the original footnote. This change is also consistent with the citation of this method as listed in the Ground Water Rule (*see* 40 CFR 141.402).

The current TCR describes the use of "EC medium supplemented with 50 µg/mL of 4-methylumbelliferyl-Beta-D-glucuronide (MUG)" (*see* 40 CFR 141.21(f)(6)(i)). This proposal clarifies that this medium, included in both Standard Methods 9221F and Standard Methods 9222G.1*a*(2), is approved for use under this regulation. This is consistent with the Laboratory Certification Manual, particularly section 5.1.8, which describes both of these methods as approved for use in the detection of *E. coli* under this regulation.

Lastly, EPA is clarifying the formulation for EC broth with MUG (EC–MUG) given in Standard Methods 9222G.1*a*(2) to correct an error in the publication. The Standard Methods 9222G.1*a*(2) formulation calls for 0.1 g of 4-methylumbelliferyl-Beta-D-glucuronide, and 1.4g KH_2PO_4. This formulation differs from that given in Standard Methods 9221F.1, which calls for 0.05 g and 1.5 g, respectively. EPA believes that the correct formulation is given in Standard Methods 9221F and has confirmed this with Standard Methods committee members (Rice 2009). Accordingly, EPA has added a footnote to the 9222G.1*a*(2) stating the proper formulation.

EPA anticipates that these changes to the analytical methods table will not cause any additional burden to the PWSs.

vi. Request for comment regarding holding temperature. The current TCR states the following regarding sample shipment: "Systems are encouraged but not required to hold samples below 10 deg. C during transit." Other national primary drinking water regulations requiring microbial sampling require that the samples be shipped in cold conditions, and require the sample be maintained at a temperature of 10 degrees Celsius (C) or less. Maintaining the sample temperature below 10 degrees C serves to preserve the bacterial population by minimizing both bacterial cell death and cell multiplication, thus allowing for a more accurate representation of the microbial population in the sample at the time of sample collection. Also, *Standard Methods for Examination of Water and Wastewater,* 21st edition (Eaton *et al.* 2005) recommends that samples be shipped at less than 8 degrees C but not frozen.

In the years since the promulgation of the current TCR, EPA has heard concern that at times, samples collected under the TCR may reach high temperatures during transit to the laboratory due to the lack of a requirement to ship samples on ice. High temperatures that may be reached during transit could have a deleterious or prolific effect on the bacterial cells present in the samples such that the samples may no longer represent the microbial content of the water at the time of sample collection.

EPA recognizes that requiring the samples under the proposed RTCR to be held at 10 degrees C or less, but above

freezing, would result in an increased cost to the water systems (for shipping, supplies, etc.), but believes the extra burden may be warranted. EPA is seeking public comment on whether this passage should remain as is in the current TCR or whether the RTCR should require that the samples collected for compliance with this regulation be shipped in cold conditions, *i.e.,* requiring a temperature of 10 degrees C or less, but above freezing to be maintained for better sample preservation. EPA also welcomes comments and supporting data on what the acceptable temperature range should be when samples are in transit.

B. Proposed Compliance Date

Consistent with SDWA section 1412(b)(10), EPA proposes that the compliance date of the final RTCR be three years from the date on which the regulation is promulgated (*i.e.,* the publication date of the final rule in the **Federal Register**). PWSs must comply with the requirements of the rule by the compliance date.

EPA believes that capital improvements generally are not necessary to ensure compliance with the proposed RTCR. However, a State may allow individual systems up to two additional years to comply with the RTCR if the State determines that additional time is necessary for capital improvements, in accordance with SDWA section 1412(b)(10).

EPA requests comment on the proposed compliance date of the proposed RTCR.

C. Links to Other Drinking Water Rule Requirements

The proposed RTCR recognizes that existing NPDWRs contain linkages among monitoring requirements in different rules. The current residual disinfectant monitoring must be conducted at the same time and location at which TCR samples are taken, as provided for in the Surface Water Treatment Rule (SWTR) (USEPA 1989b, 54 FR 27486, June 29, 1989) and the Stage 1 Disinfectants and Disinfection Byproducts Rule (Stage 1 DBPR) (USEPA 1998a, 63 FR 69389, December 16, 1998). Under the GWR, TCR distribution system monitoring results determine whether a system is required to conduct source water monitoring. Under the SWTR, high measurements of turbidity in an unfiltered subpart H system of this part trigger additional total coliform samples. Sanitary survey provisions exist in surface water and ground water drinking water regulations. The proposed RTCR does not change the existing sanitary survey requirements except to add the special monitoring evaluation that States must conduct at systems serving 4,100 or fewer people. These evaluations do not increase the burden to conduct sanitary surveys because of the relatively simple nature of these systems and their monitoring requirements.

1. SWTR, Stage 1 and Stage 2 DBPRs, ADWR

After considering the possible linkages among the proposed RTCR and the SWTR, Stage 1 DBPR, Stage 2 DBPR (USEPA 2006e, 71 FR 388, January 4, 2006), and Airline Drinking Water Rule (ADWR) (USEPA 2009), EPA has concluded that the only necessary revision is to update the reference to the current TCR at 40 CFR 141.21, which is superseded by 40 CFR part 141 subpart Y beginning three years following publication of the final rule. EPA is also proposing several revisions to other NPDWRs, discussed below, that are not necessary but would facilitate implementation of all applicable NPDWRs.

2. GWR

As with the other drinking water rules mentioned above, EPA is proposing to update the references in the GWR to the current TCR at 40 CFR 141.21, which will be superseded by 40 CFR part 141 subpart Y.

3. Sanitary Surveys

Sanitary survey requirements are not included in the proposed RTCR. Under the current TCR, community water systems and non-community water systems that serve 4,100 or fewer people are required to conduct periodic sanitary surveys. Since the promulgation of the TCR in 1989, new sanitary survey requirements for surface water systems and ground water systems have been established for all system sizes and types under the Interim Enhanced Surface Water Treatment Rule (IESWTR) (USEPA 1998b, 63 FR 69477, December 16, 1998) (40 CFR 142.16(b)(3)), and the Ground Water Rule (GWR) (40 CFR 142.16(o)(2)(i)). Public water systems began implementing the IESWTR sanitary survey requirements in 2001. Therefore, for surface water systems, the current TCR sanitary survey requirements have phased out since that time. Implementation of the GWR sanitary survey requirements began in December 2009 for ground water systems. Therefore, for ground water systems, the GWR sanitary survey requirements will be in effect by the time the RTCR is finalized.

D. Best Available Technology (BAT)

1. Provisions

The proposed RTCR would maintain the provisions set forth in 40 CFR 141.63(d) (proposed to be in § 141.63(e)), regarding the best technology, treatment techniques, or other means available for achieving compliance with the MCL of either total coliforms or *E. coli.* EPA is proposing the following modifications:

- 40 CFR 141.63(d)(1) (proposed § 141.63(e)(1)) would be modified by replacing "coliforms" with "fecal contaminants."
- 40 CFR 141.63(d)(3) (proposed § 141.63(e)(3)) would be modified by including "cross connection control" in the list of proper maintenance practices for the distribution system.
- 40 CFR 141.63(d)(4) (proposed § 141.63(e)(4)) would be modified by including the subparts P, T, and W that describe filtration and/or disinfection of surface water, and subpart S for disinfection of ground water.

2. EPA's Rationale

a. *Change "coliform" to "fecal contaminants."* This change reflects the approach of the proposed RTCR that the presence of total coliforms does not necessarily have a direct public health implication. Instead, total coliform is used as an indicator of a potential pathway of contamination within a treatment technique requirement. For additional discussion on this topic, *see* section III.A.2 of this preamble.

b. *Inclusion of cross connection control.* EPA believes that adding cross connection control to the list of proper maintenance practices for distribution systems is appropriate because of the significant contribution of cross connections and backflow to waterborne disease outbreaks. From 1981 to 1998, the CDC documented 9, 734 detected and reported illnesses from 57 waterborne outbreaks related to cross connections (NRC 2006). From 1970 to 2001, approximately 12,000 illnesses resulted from 459 incidents of waterborne outbreaks from backflow events (NRC 2006).

c. *Addition of other relevant subparts of 141.* This change adds references to subparts that contain provisions for the other drinking water rules promulgated since 1989 when the TCR was promulgated (in particular, subpart P for the IESWTR, subpart S for the GWR, subpart T for the Long Term Enhanced Surface Water Treatment Rule (USEPA 2002, 67 FR 1812, January 14, 2002, and subpart W for the Long Term 2 Enhanced Surface Water Treatment Rule (USEPA 2006d, 71 FR 654, January 5,

2006)). These drinking water rules contain updated filtration and disinfection standards that were not part of the current TCR when it was promulgated in 1989.

3. Request for Comment

EPA requests comment on the modifications to the existing BATs and whether there is a need to add or otherwise update the list of BATs.

E. Variances and Exemptions

1. Provisions

EPA is proposing to not allow variances or exemptions to the *E. coli* MCL. EPA is also proposing to eliminate the variance provisions in 40 CFR 141.4(b) that allow systems to demonstrate to the State that the violation of the monthly/non-acute total coliform MCL is due to biofilm and not fecal or pathogenic contamination. This change will also result in a parallel change in 40 CFR 142.63(b).

2. EPA's Rationale

Under the proposed RTCR, *E. coli* is used as an indicator of fecal contamination that may contain waterborne pathogens. To the extent a variance or exemption would permit the continued presence of *E. coli,* the potential for pathogens to be present also would remain. EPA believes that water which exceeds the MCL for *E. coli* poses an unreasonable risk to public health. Therefore, EPA is not allowing any variances or exemptions to the *E. coli* MCL. This provision is consistent with the existing requirement, since the provision that allows variances applies only to the monthly/non-acute total coliform MCL violation and not to the acute violation associated with the presence of *E. coli.*

Under the current TCR, EPA allows variances to the MCL for total coliforms when a system has demonstrated to the State that the violation of the total coliform MCL is due to a persistent growth of total coliforms in the distribution system (*i.e.,* biofilm) rather than fecal or pathogenic contamination, a treatment lapse or deficiency, or a problem in the operation or maintenance of the distribution system.

EPA is proposing to eliminate the variance in 40 CFR 141.4(b) because under the proposed RTCR, there would no longer be an MCL for total coliforms (*see* section III.A.2 of this preamble). The current TCR MCL for total coliforms was based on the presence or absence of total coliforms in a sample (*see* 40 CFR 141.63 for details). In the proposed RTCR, the presence of total coliforms at a certain level requires the system to comply with the coliform treatment technique requirements (*see* section III.A.5 of this preamble). The assessment and corrective action requirements under this proposed rule include the possibility of recognizing that the total coliform presence is associated with biofilm. EPA plans to include this information in a new assessment and corrective action guidance manual related to the RTCR.

3. Request for Comment

EPA requests comment on its proposal to allow no variance or exemption to the *E. coli* MCL and to eliminate the variance provisions associated with the monthly/non-acute total coliform MCL.

F. Request for Comment on Other Issues Related to the Proposed RTCR

1. Consistency Between the Proposed RTCR and the GWR

EPA requests comment on the need for general consistency between the proposed RTCR and the GWR. Please provide specific examples. For example, under the current TCR, States are required to keep records of their decision to either waive or extend the 24-hour limit for collecting samples (that is, for repeat samples following a total coliform-positive sample, or for follow-up samples after high levels of turbidity) (*see* 40 CFR 142.14(a)(5)(i)(A) and 142.14(a)(5)(ii)(D)). The proposed RTCR also requires States to keep records of decisions to either waive or extend the 24-hour limit for repeat samples following a total coliform-positive sample, for samples following invalidation, or for follow-up samples after high levels of turbidity (*see* §§ 142.14(a)(10)(i)(A) and 142.14(a)(10)(ii)(D) of the proposed RTCR). Under the GWR, there are no recordkeeping requirements for the decision to waive or extend the 24-hour limit. Instead, the GWR includes special primacy requirements to describe criteria the State will use to extend the 24-hour limit (*see* 40 CFR 142.16(o)(3)(i)). EPA requests comment on whether it is appropriate to have States describe their criteria for waiving or extending the 24-hour limit as a primacy condition, or instead have States keep records of decisions to waive and/or extend the 24-hour limit.

2. Storage Tank Inspection and Cleaning

EPA requests comment on the value and cost of periodic storage tank inspection and cleaning. There are instances of storage tanks being the source of waterborne disease outbreaks at PWSs. In December 1993, a *Salmonella typhimurium* outbreak in Gideon, Missouri resulted in over 600 people affected by diarrhea, 31 cases of laboratory-confirmed salmonellosis and seven deaths of nursing home residents who had exhibited diarrheal illness (four deaths were confirmed by culture). The larger of the two storage tanks had a breach in the roof hatch that allowed pigeon droppings to be carried into the tank and likely accumulated in the several inches of sediment. This contaminated sediment, more than likely, was pulled into the distribution system by a flushing program that drained the tank (Clark *et al.* 1996). *Salmonella typhimurium* was isolated from the sediment of one of the towers, and tap water tested positive for fecal coliforms (CDC 1996).

In March 2008, Alamosa, Colorado (with a population of about 9,000 people) experienced a waterborne disease outbreak associated with *Salmonella.* The report released by the Colorado Department of Public Health and Environment (Falco and Williams 2009) indicated that the outbreak resulted in 442 reported cases of illnesses, 122 of which were laboratory confirmed, and one fatality. The State epidemiologist estimated that a total of 1,300 people may have been ill. Two storage tanks in Alamosa had several inches of sediment and breaches; one tank had breaches large enough for birds and animals to enter. Some of the key factors that contributed to these two outbreaks include significant levels of sediment (several inches to feet) and the presence of breaches of the integrity of the storage tank.

Sediment accumulation occurs within storage facilities due to quiescent conditions which promote particle setting. Over time sediment continues to accumulate in a tank, even if the finished water is consistently treated to below 0.1 nephelometric turbidity unit (NTU). For surface water systems, it is not uncommon to have ¼ to ½ inch or more of sediment accumulate after two to three years (Kirmeyer *et al.* 1999). While there are no turbidity regulations for ground water systems (except for ground water under the direct influence of surface water (GWUDI)), the levels of turbidity can be significant in the water pumped from an aquifer. Sand particles, if allowed to accumulate, provide pore spaces that house diverse populations of biota (which may include pathogenic microorganisms) (Kirmeyer *et al.* 1999; van der Kooij 2003). Periodic high flows in the storage tank may scour, stir up, and suspend the sediment (along with entrapped bacteria and pathogens) and carry it into the distribution system, with greater accumulation of sediment

being a more significant concern. Other water quality problems associated with sediment accumulation include increased disinfectant demand and disinfection byproduct formation.

The storage tank's vulnerability to contamination increases when breaches of the storage tank allow insects, animals, and birds and their associated diseases to enter. Contamination from bird and other animal excrement can potentially transmit disease-causing organisms to the finished water. Waterfowl, for example, are known carriers of many different waterborne pathogens including *Vibrio cholerae* (Ogg *et al.* 1989).

Based on the potential public health implications associated with poorly maintained storage tanks (*e.g.,* as indicated by significant sediment accumulation and breaches), EPA is interested in receiving comments and supporting information regarding the state and condition of tanks that have been cleaned and inspected, costs of storage tank inspection and cleaning, and how public health can be better protected. EPA requests information on whether there are States that recommend or require periodic inspection and cleaning of storage tanks. If so, what are the requirements, the frequency of inspection and cleaning, and how successful are they? Are inspections and cleaning done by individual PWSs or by contractors?

3. States Under EPA Direct Implementation

EPA does not have the authorities provided to other primacy agencies under 40 CFR part 142 to use in implementing rules in direct implementation entities (*e.g.,* Tribal systems and Wyoming). To provide EPA the flexibility of other primacy agencies to modify monitoring requirements as necessary to protect public health (*e.g.,* to require more stringent monitoring or to develop criteria such as those that primacy States develop under the special primacy conditions requirement in 40 CFR 142.16) and facilitate implementation of this rule. EPA is requesting comment on whether the Agency should have the same authorities specified in subpart Y, as States have in 40 CFR 142.16, for PWSs for which the Agency has direct implementation responsibilities. EPA is requesting comment on whether this authority should be added to subpart Y specifically.

G. Limitations to the Public Comment on the Proposed RTCR

The proposed revisions to other drinking water regulations (SWTR, Stage 1 DBPR, Stage 2 DBPR, and ADWR) are made solely to update the reference to the current TCR at 40 CFR 141.21, which will be superseded by 40 CFR part 141 subpart Y beginning three years following publication of the final rule. This proposed rule would not change any substantive requirements of those rules and EPA is not soliciting public comments on those rules other than their proposed revised references to the current TCR or any other references to the current TCR that EPA may need to revise.

IV. State Implementation

The proposed RTCR provides States with flexibility to implement the requirements of the rule in a manner that maximizes the efficiency of the rule for the States and water systems while increasing the effectiveness of the rule to protect public health. While the proposed rule provides some reduction in monitoring relative to the current TCR, overall, the proposed rule is more stringent and better protects public health. As a result, States must adopt these revisions, when final, or adopt or maintain more stringent requirements, in order to maintain primacy. This section describes the regulations and other procedures and policies States must adopt in order to obtain primacy to implement the RTCR, if finalized as proposed today.

SDWA section 1413 establishes requirements that States or eligible Indian Tribes must meet to assume and maintain primary enforcement responsibility (primacy) for its PWSs. These requirements include:

- Adopting drinking water regulations that are no less stringent than Federal drinking water regulations;
- Adopting and implementing adequate procedures for enforcement;
- Keeping records and making reports available on activities that EPA requires by regulation;
- Issuing variances and exemptions (if allowed by the State), under conditions no less stringent than allowed under SDWA; and
- Adopting and being capable of implementing an adequate plan for the provisions of safe drinking water under emergency situations.

States may adopt more stringent requirements (*e.g.,* requiring all systems to conduct routine monthly monitoring). Many States have used this authority in the past to improve public health protection and/or simplify implementation.

Section 1413(a)(1) of SDWA provides two years (plus up to two more years if the Administrator approves) after promulgation of the final RTCR for the State to adopt corresponding drinking water regulations in order to obtain primacy for the final RTCR. To implement the final RTCR, States would be required to adopt or maintain requirements that are at least as stringent as the following revisions to 41 CFR part 141:

- Section 141.4—Variances and exemptions (if allowed by the State).
- Section 141.21—Coliform sampling.
- Section 141.52—Maximum contaminant level goals for microbiological contaminants.
- Section 141.63—Maximum contaminant levels (MCLs) for microbiological contaminants.
- Section 141.74—Analytical and monitoring requirements.
- Section 141.132—Monitoring requirements.
- Subpart 141.153—Content of the reports.
- Subpart 141.202—Tier 1 Public Notice—Form, manner, and frequency of notice.
- Subpart 141.203—Tier 2 Public Notice—Form, manner, and frequency of notice.
- Subpart 141.204—Tier 3 Public Notice—Form, manner, and frequency of notice.
- Subpart O—Consumer Confidence Reports, Appendix A, Regulated Contaminants.
- Subpart Q—Public Notification of Drinking Water Violations, Appendix A, NPDWR Violations and Other Situations.
- Subpart Q—Public Notification of Drinking Water Violations, Appendix B, NPDWR Violations and Other Situations.
- Subpart Y—Revised Total Coliform Rule.

EPA's regulation at 40 CFR part 142 sets out the specific program implementation requirements for States to obtain primacy for the public water supply supervision program as authorized under SDWA section 1413. In addition to adopting basic primacy requirements specified in 40 CFR part 142, States may be required to adopt special primacy provisions pertaining to specific regulations where implementation of the rule involves activities beyond general primacy provisions. States must include these regulation-specific provisions in their application for approval of their program revision. States must continue to meet all other conditions of primacy for all other rules in 40 CFR part 142. Primacy requirements for the proposed RTCR are described below.

The advisory committee recognized that this rule will require more tracking to ensure effective implementation.

Therefore, EPA plans to release an upgrade to SDWIS/State and SDWIS/FED (the State and Federal versions of the Safe Drinking Water Information System, respectively) within 18 months of final rule promulgation to accommodate monitoring data, tracking, compliance determinations and reporting of all rule related requirements, as appropriate.

A. State Special Primacy Requirements

To ensure that a State program includes all the elements necessary for an effective and enforceable program under the proposed RTCR, a State primacy application must include a description of how the State will perform the following:

- Sample Siting Plans—States must describe the frequency and process used to review and revise sample siting plans in accordance with 40 CFR 141, subpart Y to determine adequacy.
- Reduced Monitoring Criteria—The primacy application must indicate whether the State will adopt the reduced monitoring provisions of subpart Y. If the State adopts the reduced monitoring provisions, it must describe the specific types or categories of water systems that will be covered by reduced monitoring and whether the State will use all or a reduced set of the optional criteria. For each of the reduced monitoring criteria, both mandatory and optional, the State must describe how the criteria will be evaluated to determine when systems qualify.
- Assessments and Corrective Actions—States must describe their process to implement the new assessment and corrective action phase of the rule. The description must include examples of sanitary defects, examples of assessment forms or formats, and methods that systems may use to consult with the State on appropriate corrective actions.
- Invalidation of routine and repeat samples collected under subpart Y—States must describe their criteria and process to invalidate total coliform-positive and *E. coli*-positive samples under subpart Y. This includes criteria to determine if a sample was improperly processed by the laboratory, reflects a domestic or other non-distribution system plumbing problem or reflects circumstances or condition that does not reflect water quality in the distribution system.
- Approval of individuals allowed to conduct subpart Y Level 2 assessments—States must describe their criteria and process for approval of individuals allowed to conduct subpart Y Level 2 assessments.
- Special monitoring evaluation—States must describe how they will perform special monitoring evaluations during sanitary surveys for ground water systems serving 1,000 or fewer people to determine whether systems are on an appropriate monitoring schedule.
- Seasonal systems—States must describe how they will identify seasonal systems, how they will determine when systems on less than monthly monitoring must monitor, and what will be the seasonal system start-up provisions.
- Additional criteria for reduced monitoring—States must describe how they will require systems on reduced monitoring to demonstrate:

—Continuous disinfection entering the distribution system and a residual in the distribution system;

—Cross connection control;

—Other enhancements to water system barriers; and

—Procedures for seasonal systems to start up operations at the beginning of each season.

B. State Recordkeeping Requirements

The current regulations in 40 CFR 142.14 require States with primacy to keep records, including: Analytical results to determine compliance with MCLs, MRDLs, and treatment technique requirements; PWS inventories; State approvals; enforcement actions; and the issuance of variances and exemptions. The proposed RTCR requires States to keep additional records, including all supporting information and an explanation of the technical basis for each decision as follows. Records of the following decisions or activities must be retained for five years, consistent with recordkeeping requirements for existing regulations:

- Any decision to waive the 24-hour time limit for collecting repeat samples after a total coliform-positive routine sample, or to extend the 24-hour limit for collection of samples following invalidation, or for an unfiltered subpart H system of this part to collect a total coliform sample following a turbidity measurement exceeding 1 NTU.
- Any decision to allow a system to waive the requirement for three routine samples the month following a total coliform-positive sample. The record of the waiver decision must contain all the items listed in §§ 141.854(j) and 141.855(f) of the proposed RTCR.
- Any decision to invalidate a total coliform-positive sample. If the State decides to invalidate a total coliform-positive sample as provided in § 141.853(c)(1) of the proposed RTCR, the record of the decision must contain all the items listed in that paragraph.
- Completed and approved 40 CFR part 141 subpart Y assessments, including reports from the system that corrective action has been completed.

States must retain records of each of the following decisions in such a manner so that each system's current status may be determined at any time:

- Any decision to reduce the total coliform monitoring frequency for a community water system serving 1,000 or fewer people to less than once per month, as provided in § 141.855(d) of the proposed RTCR; and what the reduced monitoring frequency is. A copy of the reduced monitoring frequency must be provided to the system.
- Any decision to reduce the total coliform monitoring frequency for a non-community water system using only ground water and serving 1,000 or fewer people to less than once per quarter, as provided in § 141.854(e) of the proposed RTCR, and what the reduced monitoring frequency is. A copy of the reduced monitoring frequency must be provided to the system.
- Any decision to reduce the total coliform monitoring frequency for a non-community water system using only ground water and serving more than 1,000 persons during any month the system serves 1,000 or fewer people, as provided in § 141.857(d) of the proposed RTCR. A copy of the reduced monitoring frequency must be provided to the system.
- Any decision to waive the 24-hour limit for taking a total coliform sample for a public water system that uses surface water, or ground water under the direct influence of surface water, and that does not practice filtration in accordance with part 141, subparts H, P, T, and W, and that measures a source water turbidity level exceeding 1 NTU near the first service connection.
- Any decision to allow a public water system to forgo *E. coli* testing on a total coliform-positive sample if that system assumes that the total coliform-positive sample is *E. coli*- positive.

C. State Reporting Requirements

EPA currently requires at 40 CFR 142.15 that States report to EPA information such as violations, variance and exemption status, and enforcement actions. The proposed RTCR requires States to develop and maintain a list of public water systems that the State is allowing to monitor less frequently than once per month for community water systems or less frequently than once per quarter for non-community water

systems, including the compliance date (the date that reduced monitoring was approved) of the reduced monitoring requirement for each system.

D. Interim Primacy

On April 28, 1998, EPA amended its State primacy regulations at 40 CFR 142.12 to incorporate the new process identified in the 1996 SDWA Amendments for granting primary enforcement authority to States while their applications to modify their primacy programs are under review (USEPA 1998c, 63 FR 23361, April 28, 1998). The new process grants interim primary enforcement authority for a new or revised regulation during the period in which EPA is making a determination with regard to primacy for that new or revised regulation. This interim enforcement authority begins on the date of the primacy application submission or the effective date of the new or revised State regulation, whichever is later, and ends when EPA makes a final determination. However, this interim primacy authority is only available to a State that has primacy (including interim primacy) for every existing NPDWR in effect when the new regulation is promulgated.

As a result, States that have primacy (including interim primacy) for every existing NPDWR already in effect may obtain interim primacy for the RTCR, beginning on the date that the State submits the application for this rule to EPA, or the effective date of its revised regulations, whichever is later. A State that wishes to obtain interim primacy for future NPDWRs must obtain primacy for this rule.

E. Request for Comment

EPA requests comment on the adequacy of the proposed RTCR requirements for State implementation, including but not limited to State special primacy requirements and State reporting and recordkeeping requirements. Specifically, EPA requests comment on whether there are any requirements that should be added to assure proper State oversight, or any that can be removed without detriment to implementation of the rule.

V. Distribution System Research and Information Collection Activities

A. Research and Information Collection Partnership

The advisory committee recommended that a Research and Information Collection Partnership (RICP) be formed to inform and support the drinking water community in developing future national risk management decisions pertaining to drinking water distribution systems. The advisory committee recommended seven priority areas for research and information collection. These seven priority areas are: (1) Cross-connection and backflow of contaminated water; (2) contamination due to storage facility design, operation, or maintenance; (3) contamination due to main installation, repair, or rehabilitation practices; (4) contaminant intrusion due to pressure conditions and physical gaps in distribution system infrastructure; (5) significance and control of biofilm and microbial growth; (6) nitrification issues that lead to public health effects; and (7) accumulation and release of contaminants from distribution system scales and sediments (USEPA 2008c, AIP p. 30).

In January 2009, EPA and the Water Research Foundation (WRF or the Foundation) signed a memorandum of understanding (MOU) to form the RICP in response to recommendations from the advisory committee contained in the AIP (USEPA and WRF 2009). The MOU conveys the partners' agreement to collaborate and identify, define, prioritize, coordinate, and communicate critical decision-relevant distribution system research and information collection needs of the drinking water community. The RICP is directed by a steering committee comprised of nine members: Three members from EPA, three members from water utilities, and three additional members representing the public health, environmental advocate, and State regulator perspectives.

The partners are developing a distribution system research and information collection agenda that focuses on characterizing and reducing public health risks. The identified priority information and research will allow better understanding and management of potential public health risks from drinking water distribution systems. *See http://www.epa.gov/safewater/disinfection/tcr/regulation_revisions_tcrdsac.html* for further information on this effort.

B. Distribution System Optimization Activities

As part of the AIP, the advisory committee encouraged "the development of national and regional distribution system optimization partnerships that focus on protecting the integrity of drinking water quality once it is delivered to the distribution system. The purpose of the partnerships should be to inform and inspire proactive systems to implement best management practices that emphasize protection of public health. These partnerships, comprised, for example, of representatives from utilities, communities, academia, and regulatory organizations could develop continuous improvement programs that encompass water distribution optimization principles and practices for system design, operations, and maintenance. These partnerships should foster continuous review of distribution system issues and should define excellence in distribution system operation in terms of processes, systems, procedures, as well as measures. The optimization partnerships should encourage voluntary program participation of all drinking water utilities regardless of system size" (USEPA 2008c, AIP p. 25).

EPA is aware of two distribution system optimization programs that are currently being developed. EPA and the Foundation are concurrently developing distribution system optimization programs that focus on protecting public health in the distribution system. Developmental activities to support these efforts are occurring through the EPA's National Area Wide Optimization Program (AWOP) and the Foundation's project #4109. While these programs are being developed independently with differing measures of performance, both are founded on the optimization principles of improving water systems, and go beyond the regulatory requirements, while using existing staff and facilities. These principles and practices are currently being used through the in-plant treatment optimization programs operated through AWOP and the American Water Works Association's (AWWA) Partnership for Safe Water (the Partnership). For more information on the Partnership for Safe Water, *see (http://www.awwa.org/Resources/PartnershipforSafeWater.cfm?ItemNumber=3787&navItemNumber=33969).*

The goal of EPA's optimization program is to protect public health by addressing both the technical and management issues that limit the water system's ability to meet water quality performance goals. EPA has started developing a distribution system optimization program, which is currently focused on improving water treatment plant finished water quality while maintaining disinfectant residual and minimizing disinfection byproduct formation in the distribution system. Future work may focus on other water quality parameters or issues of concern. An outcome of this effort will be the identification of the key technical and management skills, practices, and tools

that a water system should implement to achieve long-term distribution system optimization. Ultimately, participating AWOP States will be introduced to distribution system optimization methods developed by EPA. At this time, additional development activities are needed before a distribution system optimization program will be available for State implementation.

In 2007, the Foundation initiated project #4109 to identify a limited number of straightforward criteria that can be used by water utilities to measure distribution system optimization performance and to develop a self-assessment approach using standards of excellence. The results from this project will also be used to expand the Partnership for Safe Water Program treatment plant optimization program into distribution system optimization. The Foundation anticipates project #4109 to be completed by early 2010. With the results of project #4109, the Partnership anticipates finalizing a preliminary set of optimization goals and a model assessment process in calendar year 2010. Prior to finalizing the goals and assessment process, the Partnership will conduct trials at several volunteer utilities. The optimization goals and assessment process will be evaluated and refined based on those trials prior to consideration by the Partnership for adoption and implementation. AWWA anticipates that applications for the Partnership's Distribution System Optimization Program will be available in calendar year 2011.

C. Request for Comment

EPA requests comment about these distribution system optimization projects and information about or suggestions for other possible approaches to distribution system optimization.

VI. Economic Analysis (Health Risk Reduction and Cost Analysis)

This section summarizes the Health Risk Reduction and Cost Analysis (HRRCA) in support of the proposed RTCR as required by section 1412(b)(3)(C) of the SDWA. EPA has prepared the RTCR Economic Analysis (EA) (USEPA 2010a) to comply with this requirement. The EA document for the proposed RTCR is available in the docket and is also published on the government's Web site at *http://www.regulations.gov.*

The HRRCA consists of seven elements: (1) quantifiable and nonquantifiable health risk reduction benefits; (2) quantifiable and nonquantifiable health risk reduction benefits from reductions in co-occurring contaminants; (3) quantifiable and nonquantifiable costs that are likely to occur solely as a result of compliance; (4) incremental costs and benefits of rule options; (5) effects of the contaminant on the general population and sensitive subpopulations including infants, children, pregnant women, elderly, and individuals with a history of serious illness; (6) any increased health risks that may occur as a result of compliance, including risks associated with co-occurring contaminants; and (7) other relevant factors such as uncertainties in the analysis and factors with respect to the degree and nature of risk. *See* SDWA section 1412(b)(3)(C). A summary of these elements is provided in this section of the preamble, and a complete discussion can be found in the Proposed RTCR EA (USEPA 2010a).

The benefits described in this section are discussed qualitatively, and reductions in detection of total coliforms and *E. coli* and in Level 2 assessments are used to describe the benefits, as described later in this section. The costs discussed in this section are presented as annualized present values in 2007 dollars. Both benefit and cost measures are adjusted using social discounting. In social discounting, future values of a rule's or policy's effects are multiplied by discount factors. The discount factors reflect both the amount of time between the present and the point at which these events occur and the degree to which current consumption is more highly valued than future consumption (USEPA 2000c). This process allows comparison of cost and benefit streams that are variable over a given time period. EPA uses social discount rates of both three percent and seven percent to calculate present values from the stream of benefits and costs and also to annualize the present value estimates. Historically, the use of three percent is based on rates of return on relatively risk-free financial instruments, while seven percent is generally an estimate of before-tax rate of return to incremental private investment. For further information, *see* USEPA 2000c and OMB 1996.

In the Proposed RTCR EA (USEPA 2010a), EPA also presents the undiscounted stream of benefits and costs over the 25-year time frame (*i.e.,* the year-to-year realization of benefits and costs presented in constant terms).

The time frame used for both benefit and cost comparisons in this rule is 25 years. This time interval accounts for rule implementation activities occurring soon after promulgation (*e.g.,* States adopting the criteria of the regulation) and the time for different types of compliance actions (*e.g.,* assessments and corrective actions) to be realized up through the 25th year following rule promulgation.

EPA was unable to quantify health benefits for the proposed RTCR because there are insufficient data reporting the co-occurrence in a single sample of fecal indicator *E. coli* and pathogenic organisms. In addition, the available fecal indicator *E. coli* data from the Six-Year Review 2 dataset (USEPA 2010e) described in this preamble were limited to presence-absence data because the current TCR requires only the reporting of presence or absence of fecal indicator *E. coli* using EPA-approved standard methods. However, as discussed in chapter 6 of the Proposed RTCR EA (USEPA 2010a), even though health benefits could not be directly quantified, the potential benefits from the proposed RTCR include avoidance of a full range of health effects from the consumption of fecally contaminated drinking water, including the following: acute and chronic illness, endemic and epidemic disease, waterborne disease outbreaks, and death. Also, since fecal contamination may contain waterborne pathogens including bacteria, viruses, and parasitic protozoa, in general, a reduction in fecal contamination should reduce the risk from these other contaminants.

The net costs of the rule stem mostly from the new assessment and corrective action requirements as well as the revised monitoring provisions described earlier in this preamble.

This section of the preamble includes elements as follows: (A) Regulatory Options Considered, (B) Major Sources of Data and Information used in Supporting Analyses, (C) Occurrence and Predictive Modeling, (D) Baseline Profiles, (E) Anticipated Benefits of the Proposed RTCR, (F) Anticipated Costs of the Proposed RTCR, (G) Potential Impact of the Proposed RTCR on Households, (H) Incremental Costs and Benefits, (I) Benefits from Simultaneous Reduction of Co-occurring Contaminants, (J) Change in Risk from Other Contaminants, (K) Effects of Fecal Contamination and/or Waterborne Pathogens on the General Population and Sensitive Subpopulations, (L) Uncertainties in the Benefit and Cost Estimates for the Proposed RTCR, (M) Benefit Cost Determination for the Proposed RTCR, and (N) Request for Comment.

A. Regulatory Options Considered

EPA evaluated the following three regulatory options as part of this revised

rule proposal: (1) The current TCR option, (2) the AIP option, and (3) an Alternative option. EPA discusses the three regulatory options briefly in this preamble and in greater detail in chapter 3 of the Proposed RTCR EA (USEPA 2010a).

First, the current TCR option reflects EPA's understanding of how the current TCR (USEPA 1989a, 54 FR 27544, June 29, 1989) is currently being implemented. That is, the current TCR option is assumed to include "status quo" PWS and State implementation practices. Next, the AIP option is a revised TCR based on the recommendations of the advisory committee. The provisions of this proposed rule are based on the AIP option and are described in detail in section III of this preamble. Third, the Alternative option parallels the AIP in most ways but includes variations of some of the provisions that were discussed by the advisory committee before consensus was reached on the AIP.

The Alternative option differs from the AIP option in two ways. First, under the Alternative option, at the compliance date all PWSs are required to sample monthly for an initial period until they meet the eligibility criteria for reduced monitoring. EPA assumes that eligibility for reduced monitoring is determined during the next sanitary survey following the RTCR compliance date. This more stringent approach differs from the AIP option that allows PWSs to continue to monitor at their current frequencies (with an additional annual site visit or voluntary Level 2 assessment requirement for PWSs wishing to remain on annual monitoring) until they are triggered into an increased sampling frequency. Second, under the Alternative option, no PWSs are allowed to reduce monitoring to an annual basis. EPA defined the Alternative option this way and included it in the Proposed RTCR EA (USEPA 2010a) to assess the relative impacts of a more stringent rule and to better understand the balance between costs and public health protection.

To understand the relative impacts of the options, EPA gathered available data and information to develop and provide input into an occurrence and predictive model. EPA estimated both baseline conditions and changes to these conditions anticipated to occur over time as a result of these revised rule options. The analysis is described in more detail in the Proposed RTCR EA (USEPA 2010a).

B. Major Sources of Data and Information Used in Supporting Analyses

This section of the preamble briefly discusses the data sources that EPA used in its supporting analyses for the proposed RTCR. For a more detailed discussion, *see* chapter 4 of the Proposed RTCR EA (USEPA 2010a).

1. Safe Drinking Water Information System Federal Version Data

Safe Drinking Water Information System Federal Version (SDWIS/FED) is EPA's national regulatory compliance database for the drinking water program and is the main source of PWS inventory and violation data for the proposed RTCR baseline. SDWIS/FED contains information on each of the approximately 155,000 active PWSs as reported by primacy agencies, EPA Regions, and EPA headquarters personnel. SDWIS/FED includes records of MCL violations and monitoring and reporting (MR) violations (both routine and repeat and minor and major). It does not include sample results. It also contains information to characterize the US inventory of PWSs including system name and location, retail population served, source water type (ground water (GW), surface water (SW), or ground water under the direct influence of surface water (GWUDI)), disinfection status, and PWS type (community water system (CWS), transient non-community water system (TNCWS), and non-transient non-community water system (NTNCWS)).

To create the PWS and population baseline, EPA used the fourth quarter of SDWIS/FED 2007 (USEPA 2007b), which was the most current PWS inventory data available when EPA began developing the Proposed RTCR EA. These data represent all current, active PWSs and the population served by these systems.

EPA also used the MCL violation data from SDWIS/FED to validate model predictions for systems serving 4,100 or fewer people and to predict *E. coli* (acute)_–MCL violations (current TCR, AIP, and Alternative option), total coliform (non-acute or monthly) MCL violations (current TCR), and Level 1 and Level 2 assessment triggers (AIP and Alternative option) for systems serving more than 4,100 people.

2. Six-Year Review 2 Data

Through an Information Collection Request (USEPA 2006b), States voluntarily submitted electronically available TCR monitoring data (sample results) that were collected between January 1998 and December 2005. EPA requested the TCR monitoring results with the intent of conducting analyses and developing models to assess the potential impacts of changes to the current TCR. EPA received data from 46 States, Tribes, and territories. A Data Quality Report (USEPA 2010c) describes how TCR monitoring data were obtained, evaluated, and modified where necessary to make the database internally consistent and usable for analysis. Exhibit 2.1 in the Data Quality Report provides a complete list of States or territories that submitted data and a description of the use of these data.

In this EA, EPA included data from 37 primacy agencies (35 States and 2 Tribes). Records included data for:

- PWS information (system type, population served, source water type)
- Sample type (routine, repeat, special purpose)
- Analytical result
- Sampling location—entry point, distribution system and, for repeat samples, original location, downstream, upstream, and other
- Analytical method
- Disinfectant residual data collected at TCR monitoring sites

As discussed in greater detail in section 4.2.2.1 of the Proposed RTCR EA (USEPA 2010a), EPA used 2005 data exclusively in the analyses supporting the proposed RTCR because the 2005 data set was the most complete year of data among the Six-Year Review 2 data (USEPA 2010e). The 2005 data was also the most recent data available suggesting that it may be the most representative of present conditions.

The Six-Year Review 2 data (USEPA 2010e) also informed EPA's assumptions regarding the proportions of GWSs serving 1,000 or fewer people that sample monthly, quarterly, or annually.

3. Other Information Sources

Additional data and information sources included the Economic Analysis for the Ground Water Rule (GWR EA) (USEPA 2006a), the *Technology and Cost Document for the Proposed Revised Total Coliform Rule* (proposed RTCR T&C document) (USEPA 2010b), the U.S. Census data, and the knowledge and experience of stakeholders representing industry, States, small systems, and the public.

The GWR EA provided occurrence information on *E. coli* in the source water of ground water PWSs for modeling the triggered monitoring component of GWR and informed the assumptions on the distribution of corrective actions taken in response to the presence of *E. coli* in the source water. As discussed in section VI.C.1 of

this preamble, the model developed for this economic analysis considers the effect of GWR both before and during implementation of the proposed revised rule. The proposed RTCR T&C document included estimates of unit costs for the major components of the proposed RTCR including labor, monitoring, assessments, and corrective actions. U.S. Census data were used to estimate population per household and to characterize sensitive subpopulations. Lastly, knowledge and experience from stakeholders helped to inform the assumptions that were made for the analysis.

A more detailed discussion of these data sources and how EPA used them are included in the Proposed RTCR EA (USEPA 2010a).

C. Occurrence and Predictive Modeling

EPA used the data to develop an occurrence and predictive model for PWSs serving 4,100 or fewer people based primarily on the 2005 Six-Year Review 2 data (USEPA 2010e). The model predicts changes in total coliform and *E. coli* occurrence, Level 1 and Level 2 assessments (based on simulated monitoring results), corrective actions, and violations over time. EPA developed another, simpler, predictive model, for PWSs serving more than 4,100 people, that predicts Level 1 and Level 2 assessments (based on 2005 violation data from SDWIS/FED), corrective actions, and violations over time, but not total coliform and *E. coli* occurrence. EPA modeled systems serving more than 4,100 people separately because the Six-Year Review 2 data (USEPA 2010e) for larger PWSs were not as robust as the data for the smaller systems. In addition, while EPA is proposing new monitoring requirements for PWSs serving 4,100 people or fewer, proposed monitoring requirements for systems serving greater than 4,100 people remain essentially unchanged. This section briefly discusses the structures of each of the two models and how they used available data, information, and assumptions to make predictions over time resulting from the proposed regulatory options.

Chapter 5 of the Proposed RTCR EA (USEPA 2010a) includes a more detailed description of the occurrence and predictive model used for PWSs serving 4,100 or fewer people, and the other simpler predictive model used for PWSs serving greater than 4,100 people.

1. Model Used for Public Water Systems Serving 4,100 or Fewer People

The occurrence and predictive model used for PWSs serving 4,100 or fewer people has two components. The first component of the model characterized how the presence or positive rates of total coliform and *E. coli* detections vary across the population of small (serving 4,100 or fewer people) public water systems in the U.S. These rates vary by the type of sample (routine or repeat), by analyte (total coliforms or *E. coli*), and by system type (CWS, NCWS, or TNCWS) and size. The second component of the model used the total coliform and *E. coli* occurrence distributions to simulate a set of nationally-representative systems within the context of the three regulatory options (TCR, AIP, and Alternative) to predict changes in total coliform and *E. coli* occurrence, triggers, assessments, corrective actions over time, and violations.

The model assumed that the national occurrence of total coliforms and *E. coli* has reached a steady state in recent years under the current TCR. It assumed that cycles of normal deterioration and repair/replacement are occurring at the individual system level. However, the numbers of violations at the national level have remained relatively unchanged. This assumption is based on evaluation of SDWIS/FED violation data. Exhibit VI–1 presents the number of PWSs with TCR violations over the last several years which shows that national violation rates have remained relatively steady over the past several years. Revisions to the TCR affect this steady state, likely resulting in a reduction of the underlying occurrence and associated violations. However, before the RTCR goes into effect, GWR implementation begins which is also expected to affect the steady state.

Exhibit VI-1 Number of PWSs with Violations by System Type (2001 – 2007)

PWS Type	Year						
	2001	2002	2003	2004	2005	2006	2007
Acute MCL Violations							
CWS	143	144	185	171	151	171	171
NTNCWS	51	53	70	58	65	68	45
TNCWS	261	278	322	351	349	361	295
All	455	475	577	580	565	600	511
Non-Acute MCL Violations							
CWS	2,074	2,110	2,204	2,314	2,196	2,095	1,996
NTNCWS	601	679	725	750	753	735	655
TNCWS	2,707	2,934	3,036	3,132	3,039	3,244	3,209
All	5,382	5,723	5,965	6,196	5,988	6,074	5,860

Note: PWSs counts are of systems that had at least one violation during the year.
Source: SDWIS/FED annual data for period ending 3rd quarter 2001 – 2007. OH, US territories, Tribal PWS data excluded.

To estimate the effects that GWR implementation is expected to have on present steady state conditions, EPA used the occurrence and predictive model to simulate five years of implementation of the current TCR with the GWR, which became effective in December 2009. EPA assumed these five years to account for the approximately two years before the expected promulgation date of the final RTCR and an additional three years after that until the RTCR effective date. The assumptions made to account for the GWR are described in detail in the Proposed RTCR EA (USEPA 2010a) and summarized in Exhibit VI–2.

EXHIBIT VI–2—SUMMARY OF MAJOR ASSUMPTIONS FOR SIMULATING GWR IMPLEMENTATION

GWR provision	Modeling approach/ assumption
Triggered Monitoring: GWSs not providing 4-log treatment for viruses that have total coliform-positive samples under current TCR are required to take source water samples and test for fecal indicator. If the sample is positive, they must take an additional 5 source water samples (unless the State requires corrective action). If any of these is positive, they must conduct corrective action.	Current model used same probabilities used in GWR EA (USEPA 2006a) to predict whether source water samples will be *E. coli*-positive. GWSs required to conduct corrective action due to monitoring results will either install disinfection or implement a nondisinfecting corrective action as described in Proposed RTCR EA (USEPA 2010a). GWSs installing disinfection will draw from the probability distributions for total coliforms and *E. coli* for disinfected systems for the remainder of analysis. GWSs implementing a nondisinfecting corrective action will experience no positive samples for the remainder of the year plus two additional years and will experience a 75[1] percent reduction in occurrence for five additional years.
Sanitary Surveys: GWR includes Federal sanitary survey requirements for all GWSs, and requires States to perform regular comprehensive sanitary surveys including eight critical elements.	Model did not explicitly simulate sanitary surveys or their results. Rather, it assumed that the new sanitary survey provisions will result in 10 percent[2] reduced occurrence of total coliforms universally for entire analysis.
Compliance Monitoring: GWSs that provide 4-log treatment for viruses must demonstrate that they are providing this level of treatment by conducting compliance monitoring..	Model did not explicitly simulate compliance monitoring. Rather, it assumed that the provision will result in 10 percent[3] reduced occurrence of total coliforms for those GWSs that are conducting compliance monitoring once assumed 4-log treatment for viruses begins

[1, 2, 3] Assumption reflects EPA best professional judgment.
Source: Proposed RTCR EA (USEPA 2010a) as informed by GWR EA (USEPA 2006a).

Actual reductions in occurrence that are expected to result from the implementation of GWR requirements may differ from what is presented here. However, based on assumptions used in this model, the analysis of how the AIP and Alternative option perform relative to each other are not affected.

In addition to capturing the effect of implementation of GWR requirements with the current TCR for a five-year period of analysis, the model captures an additional 25 years with the current TCR, the AIP option, and the Alternative option. Along with changes in total coliform and *E. coli* occurrence, the model predicts behavioral changes: The number of Level 1 and Level 2 assessments (and associated Level 1 or Level 2 corrective actions) to be performed, further resulting adjustments to occurrence, and changes in sampling regimens as systems qualify for reduced monitoring requirements. The assumptions used to simulate RTCR implementation are detailed in the Proposed RTCR EA (USEPA 2010a) and summarized in Exhibit VI–3.

EXHIBIT VI–3—SUMMARY OF MAJOR ASSUMPTIONS FOR SIMULATING PROPOSED RTCR IMPLEMENTATION

Proposed RTCR provision	Modeling approach/assumption
Level 1 Assessment	Model simulates sampling and sampling results and determines which PWSs will be triggered to conduct an assessment. Sanitary defects are found in 10 percent[1] of assessments (represents net increase over current TCR). All sanitary defects are corrected. Model selects from distribution of potential corrective actions as explained in chapter 7 of the Proposed RTCR EA (USEPA 2010a). PWSs implementing a corrective action as a result of a Level 1 assessment experience no positive samples for the remainder of the year plus one additional year and will experience 50 percent[2] reduction in occurrence for three additional years.
Level 2 Assessment	Model simulates sampling and sampling results and determines which PWSs will be triggered to conduct an assessment. Sanitary defects will be found in 10 percent[3] of assessments (represents net increase over current TCR). All sanitary defects are corrected. Model selects from distribution of potential corrective actions as explained in chapter 7 of the Proposed RTCR EA (USEPA 2010a). PWSs implementing a corrective action as a result of a Level 2 assessment will experience no positive samples for the remainder of the year plus two additional years and will experience 75 percent[4] reduction in occurrence for five additional years.

[1 3] Assumption based on conversation with State representatives with on-the-ground experience.
[2 4] Assumption reflects EPA best professional judgment.

Note: EPA recognizes that there is a large uncertainty with the assumptions. Sensitivity analyses showed that the fundamental conclusions of the economic analysis do not change over a wide range of assumptions tested.
Source: Proposed RTCR EA (USEPA 2010a).

EPA made different assumptions for the effectiveness of assessments and subsequent corrective actions to account for the differences between the two types of assessments. The Level 2 assessment is a more comprehensive investigation that may result in finding more substantial problems than what may be found during a Level 1 assessment, and for that reason the corrective actions that result from a Level 2 assessment were modeled to have bigger and longer lasting effects than those of the Level 1 assessments. EPA conducted sensitivity analyses around the key assumptions summarized in Exhibit VI–2 as discussed in section VI.L of this preamble.

2. Model Used for Public Water Systems Serving More Than 4,100 People

For systems serving more than 4,100 people, EPA estimated violation and trigger rates using SDWIS/FED because the Six-Year Review 2 data (USEPA 2010e) for PWSs serving more than 4,100 people were not as robust as the Six-Year Review 2 data (USEPA 2010e) for systems serving 4,100 or fewer people. EPA did not quantify changes in violation or trigger rates for systems serving more than 4,100 people among the current TCR, AIP, and Alternative options because of: (1) Limited Six-Year Review 2 data (USEPA 2010e) to characterize these systems, (2) the essentially unchanged monitoring requirements across options for these systems, and (3) the level of effort already occurring to implement the TCR.

D. Baseline Profiles

The estimate of baseline conditions that EPA developed provides a reference point for understanding net impacts of the proposed rule revisions.

Compliance with the GWR begins in December 2009, and the expected compliance date of the RTCR is approximately five years following commencement of the GWR implementation. The majority of PWSs are GWSs and these systems are expected to be affected by the GWR. Because GWR implementation prior to the effective date of RTCR is expected to cause changes to GWSs, the baseline conditions that EPA developed for GWSs account for the expected effects of the GWR.

For PWSs serving more than 4,100 people, EPA assumed that present conditions, as reflected in 2005 SDWIS/FED data, are an appropriate representation of the conditions that are likely to exist when the RTCR becomes effective. EPA assumed that a steady state exists at the national level.

The number of GW PWSs that disinfect is expected to change during implementation of the GWR before the expected rule compliance date of the proposed RTCR. Exhibit VI–4 shows the estimated baseline number of the GW PWSs at the proposed RTCR compliance date.

Exhibit VI-4 Estimated Baseline Number of GW Systems and Disinfection Status at compliance date (3 years post RTCR promulgation)

PWS Size	Number of GW PWSs (Post-GWR)					
	CWS		NTNCWS		TNCWS	
	Disinfecting	Non-Disinfecting	Disinfecting	Non-Disinfecting	Disinfecting	Non-Disinfecting
≤100	6,308	5,630	2,937	5,889	13,781	46,419
101 - 500	9,326	4,566	2,777	3,836	5,459	13,816
501-1,000	3,516	951	873	845	685	1,278
1,001-4,100	5,423	1,020	547	265	274	343
4,101-33,000	2,798	358	56	14	27	40
33,001-96,000	307	28	2	-	-	2
96,001-500,000	62	1	-	-	-	1
500,001-1 Million	4	-	-	-	-	1
> 1 Million	3	-	-	-	-	-
Total	**27,746**	**12,555**	**7,192**	**10,849**	**20,226**	**61,900**
Combined Total	**40,301**		**18,041**		**82,126**	

Source: Proposed RTCR Occurrence and Predictive Model Output as detailed in the Proposed RTCR EA (USEPA 2010a)

EPA estimated the numbers of GW PWSs that monitor monthly, quarterly, and annually under the current TCR based on an analysis of the Six-Year Review 2 data (USEPA 2010e) and individual State statutes conducted by EPA and the advisory committee Technical Work Group (TWG). Of the GW PWSs serving 1,000 or fewer people, EPA estimated that approximately 34,000 monitor monthly, 67,000 monitor quarterly, and 27,000 monitor annually. EPA assumed that the numbers of systems on monthly, quarterly, and annual monitoring remain unchanged at the rule effective date for either a continuation of the current TCR or for the AIP option. Under the Alternative option, all PWSs, regardless of size or type, start at monthly monitoring at the rule effective date.

The following two tables provide an overview of summary statistics relating to baseline water quality. Exhibit VI–5 shows the percentage of total coliform- and *E. coli*-positive samples based on PWS type and size. The percentages of samples that are total coliform-positive are generally higher in ground water

systems than in surface water systems; in smaller systems than in larger systems; and in NCWSs than in CWSs.

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Exhibit VI-5 Total Coliform and *E. coli* Percent Positive by System Size and Type

PWS Type	Source Water	Population Served	TC (# Samples)	TC (+ Samples)	TC (% Positive)	EC (# Samples) [1]	EC (+ Samples)	EC (% Positive)[2]
CWS	GW	≤100	93,105	2,479	2.66%	1,172	72	0.08%
		101 - 500	125,490	2,500	1.99%	1,639	61	0.05%
		501-1,000	48,265	736	1.52%	483	20	0.04%
		1,001-4,100	110,391	1,176	1.07%	732	21	0.02%
		4,101-33,000	183,721	877	0.48%	458	22	0.01%
		33,001-100,000	96,361	214	0.22%	44	2	0.00%
		>100,000	64,965	289	0.44%	34	1	0.00%
		Total GW	722,298	8,271	1.15%	4,562	199	0.03%
	SW	≤100	6,735	95	1.41%	64	6	0.09%
		101 - 500	19,716	227	1.15%	159	10	0.05%
		501-1,000	12,828	90	0.70%	70	7	0.05%
		1,001-4,100	55,310	314	0.57%	233	17	0.03%
		4,101-33,000	175,758	525	0.30%	399	41	0.02%
		33,001-100,000	112,894	157	0.14%	106	5	0.00%
		>100,000	112,143	235	0.21%	99	2	0.00%
		Total SW	495,384	1,643	0.33%	1,130	88	0.02%
	GW & SW	**Total CWS**	1,217,682	9,914	0.81%	5,692	287	0.02%
TNCWS	GW	≤100	163,730	7,820	4.78%	5,820	316	0.20%
		101 - 500	52,891	2,418	4.57%	1,869	99	0.19%
		501-1,000	6,952	299	4.30%	217	4	0.06%
		>1,000	7,062	143	2.02%	85	2	0.03%
		Total GW	230,635	10,680	4.63%	7,991	421	0.18%
	SW	≤100	6,723	150	2.23%	141	17	0.25%
		101 - 500	2,854	75	2.63%	69	13	0.46%
		501-1,000	523	19	3.63%	19	-	0.00%
		>1,000	988	6	0.61%	37	-	0.00%
		Total SW	11,088	250	2.25%	266	30	0.27%
	GW & SW	**Total TNCWS**	241,723	10,930	4.52%	8,257	451	0.19%
NTNCWS	GW	≤100	46,505	1,476	3.17%	1,061	34	0.07%
		101 - 500	33,084	893	2.70%	628	19	0.06%
		501-1,000	9,531	166	1.74%	103	2	0.02%
		>1,000	13,138	177	1.35%	103	5	0.04%
		Total GW	102,258	2,712	2.65%	1,895	60	0.06%
	SW	≤100	1,668	32	1.92%	30	4	0.24%
		101 - 500	2,304	9	0.39%	9	2	0.09%
		501-1,000	932	6	0.64%	5	-	0.00%
		>1,000	1,316	1	0.08%	1	-	0.00%
		Total SW	6,220	48	0.77%	45	6	0.10%
	GW & SW	**Total NTNCWS**	108,478	2,760	2.54%	1,940	66	0.06%

[1] Number of *E. coli* samples is the denominator of the *E. coli* percent positive calculation, and includes the number of total coliform negative samples plus the number of total coliform-positive samples that were tested for *E. coli*.

[2] Percent *E. coli*-positive was calculated as (number of *E. coli*-positive samples)/(number of *E. coli* samples taken).

Source: Derived using Six-Year Review 2 Data (USEPA 2010e), which was filtered by including a State only if the State's PWSs as a group had submitted at least 50 percent of the expected sample-months of usable data. The Total Coliform Rule Compliance Monitoring Data Quality and Completion Report (USEPA 2010c) includes a detailed description of this data cleaning process.

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Exhibit VI–6 presents the number of acute and non-acute violations received by PWSs. The number of violations is also an indicator of baseline water quality prior to implementation of the proposed RTCR. As discussed in detail in chapter 5 of the Proposed RTCR EA (USEPA 2010a), EPA used these data to estimate the numbers of MCL violations and triggers for PWSs serving more than 4,100 people for the three options. Under the current TCR, larger systems incur a relatively small number of violations annually, while smaller systems incur the majority.

EXHIBIT VI–6—BASELINE NUMBER OF TCR VIOLATIONS BY SYSTEM SIZE AND TYPE (2005)

	GW PWSs			SW PWSs			All PWSs total
	Non-acute	Acute	Total	Non-acute	Acute	Total	
CWSs							
≤100	905	52	957	16	3	19	976
101–500	809	34	843	50	7	57	900
501–1,000	203	13	216	16	3	19	235
1,001–3,300	272	8	280	55	7	62	342
3,301–10,000	171	8	179	75	3	78	257
10,001–50,000	125	8	133	78	4	82	215
50,001–100,000	11	2	13	5	4	9	22
100,001–1 Million	1	1	2	3	1	4	6
>1 Million	.....	.....	.....	1	.....	1	1
Totals	2,497	126	2,623	299	32	331	2,954
NTNCWSs							
≤100	514	34	548	7	2	9	557
101–500	346	20	366	4	.....	4	370
501–1,000	57	6	63	2	.....	2	65
1,001–3,300	58	4	62	.....	.....	.....	62
3,301–10,000	9	2	11	1	.....	1	12
10,001–50,000	1	.....	1	.....	.....	.....	1
50,001–100,000	.....	.....	.....	.....	.....	.....	.....
100,001–1 Million	.....	.....	.....	.....	.....	.....	.....
>1 Million	.....	.....	.....	.....	.....	.....	.....
Totals	985	66	1,051	14	2	16	1,067
TNCWSs							
≤100	2,665	278	2,943	19	5	24	2,967
101–500	833	76	909	11	1	12	921
501–1,000	133	11	144	4	.....	4	148
1,001–3,300	58	2	60	1	.....	1	61
3,301–10,000	5	.....	5	1	.....	1	6
10,001–50,000	.....	.....	.....	.....	.....	.....	.....
50,001–100,000	.....	.....	.....	.....	.....	.....	.....
100,001–1 Million	.....	.....	.....	.....	.....	.....	.....
>1 Million	.....	.....	.....	.....	.....	.....	.....
Totals	3,694	367	4,061	36	6	42	4,103
Grand Total	7,176	559	7,735	349	40	389	8,124

Note: The proposed RTCR EA uses violations data for PWSs serving greater than 4,100 people to estimate triggers for these systems. Data for other system sizes is provided for reference.

Source: SDWIS/FED 2005 3rd quarter data. OH, U.S. territories, Tribal PWS data excluded. *See* the Proposed RTCR EA (USEPA 2010a) for additional details.

E. Anticipated Benefits of the Proposed RTCR

In promulgating the RTCR, EPA expects to further reduce the risk of contamination of public drinking water supplies from the current baseline risk under the current TCR. The options considered during development of this proposed rule and analyzed as part of the Proposed RTCR EA (USEPA 2010a) are designed to achieve this reduction while maintaining public health protection in a cost-effective manner.

This section examines the benefits in terms of trade-offs among compliance with the current TCR option, the AIP option, and the Alternative option. Because there are insufficient data reporting the co-occurrence in a single sample of fecal indicator *E. coli* and pathogenic organisms and because the available fecal indicator *E. coli* data from the Six-Year Review 2 dataset (USEPA 2010e) were limited to presence-absence data, EPA was unable to quantify health benefits for the proposed RTCR. EPA used several methods to qualitatively evaluate the benefits of the proposed RTCR options. The qualitative evaluation uses both the judgment of EPA as informed by the TCRDSAC deliberations as well as quantitative estimates of changes in total coliform occurrence and counts of systems implementing corrective actions. The evaluation characterizes, in relative terms, the reduction in risk for each regulatory scenario as compared to baseline conditions.

Since *E. coli* is an indicator of fecal contamination, EPA assumed that a decrease in *E. coli* occurrence in the distribution system would be associated with a decrease in fecal contamination in the distribution system. In general, this decrease in fecal contamination should reduce the potential risk to human health for PWS customers. Thus, any reduction in *E. coli* occurrence is considered a benefit of the proposed RTCR. Also, since fecal contamination may contain waterborne pathogens including bacteria, viruses, and parasitic protozoa, in general, a reduction in fecal contamination should also reduce the risk from these other contaminants.

As presented in Exhibit VI–5, the percentages of samples that are positive for total coliforms and *E. coli* are generally higher for PWSs serving 4,100 or fewer people than those serving more than 4,100 people. PWSs with higher total coliform and *E. coli* occurrence are more likely to be triggered into assessments and corrective action. As discussed previously, the assessments and corrective action lead to a decrease in total coliform and *E. coli* occurrence. Because the PWSs serving 4,100 or fewer people have a higher initial *E. coli* occurrence and are likely triggered into more assessments and corrective actions than larger PWSs, the increase in benefits for these small systems are likely more evident as compared to the larger systems. In particular, model results suggest that customers of small ground water TNCWSs serving 100 or fewer people, which constitute approximately 40 percent of PWSs, experience the most improvement in water quality under the proposed RTCR. That is, the occurrence of *E. coli* is predicted to decrease more for these systems than for other systems types.

1. Relative Risk Analysis

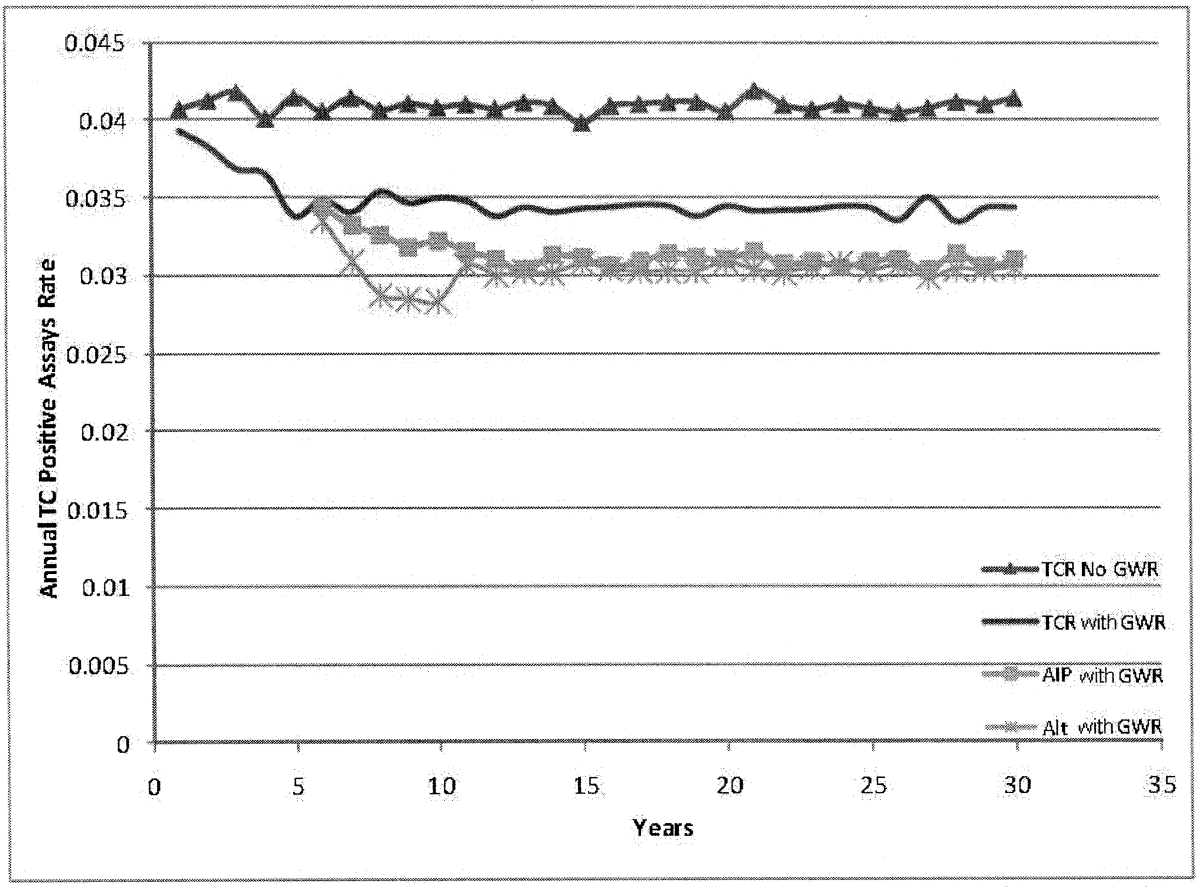
When revising an existing drinking water regulation, one of the main concerns is to ensure that backsliding on water quality and public health protection does not occur. SDWA requires that EPA at least maintain or improve public health protection for any rule revision. The proposed RTCR is more stringent that the current TCR with regard to protecting public health. The basis for this perspective is provided in this subsection and the following subsections (sections V*I.E.*1–3) of this preamble.

Risk reduction for the proposed RTCR is characterized by the activities performed that are presumed to reduce risk of exposing the public to contaminated water. These activities are considered under each rule component presented in Exhibit VI–8.

More frequent monitoring has the potential to decrease the risk of contamination in PWSs based on an enhanced ability to diagnose and mitigate system issues in a more timely fashion. Conversely, less frequent monitoring has the potential to increase risk. Real-time continuous sampling would mitigate the most risk possible based on sampling schedule; however, it would cost prohibitively more than the periodic sampling practiced under the current TCR and included in the AIP and the Alternative options. EPA's objective in proposing the sampling schedules included in the AIP and Alternative options was to find an appropriate balance between the factors of risk mitigation and cost management.

Under the AIP and Alternative options, the reduction in the number of repeat samples and additional routine samples for some PWSs has the potential to contribute to increased risk for PWS customers (*see* also sections III.A.3 and III.A.4 of this preamble for discussions on the repeat sample and additional routine sample provisions respectively). However, this increase in risk is expected to be more than offset by potential decreases in risk from increased routine monitoring (*see* section III.A.3 of this preamble) and the addition of the assessments and corrective action provisions (*see* section III.A.5 of this preamble) that find and fix problems indicated by monitoring. Exhibit VI–7 illustrates the predicted reduced frequency at which total coliforms occur subsequent to the implementation of the AIP and Alternative options. As discussed previously, the proposed RTCR uses total coliform occurrence as an indicator of potential pathways for possible contamination to enter the distribution system (*see* section III.A.2 of this preamble). Exhibit VI–7 illustrates the combined effects on total coliform occurrence resulting from changes in monitoring and the effects of assessments and corrective actions for the different rule options illustrated. The relative trends indicated in Exhibit VI–7 for transient non-community water systems also pertain to other PWS categories as illustrated in chapter 5 of the Proposed RTCR EA (USEPA 2010a). EPA chose to include the characterization for TNCWSs because they represent the system category of largest influence on the national impacts.

Exhibit VI-7 GW Transient Non-community Water System Total Coliform Occurrence



Source: Proposed RTCR occurrence model as described in the Proposed RTCR EA (USEPA 2010a).

The effect that the proposed changes to public notification requirements for monthly/non-acute MCL violations have on risk is difficult to predict. Some factors, such as reduction in available public information and possible PWS complacency, lead to a potential increase in risk and other factors, such as less confusion (PN more in line with potential health risks) and PWSs resources used more efficiently, lead to a potential decrease, as discussed in Exhibit VI–8. This change to PN is addressing a key concern expressed by various stakeholders in the advisory committee and during the Six-Year Review 1 comment solicitation process. By eliminating the requirement and replacing it with assessment and corrective action requirements, the Agency expects less public confusion, more effective use of resources, and increased transparency. Other proposed rule components are expected to have a negligible effect on risk. However, the overall effect of the proposed RTCR is expected to be a further reduction in risk from the current baseline risk under the current TCR. Chapter 6 of the Proposed RTCR EA (USEPA 2010a) presents a detailed discussion of the potential influence on health risk for each proposed rule component.

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Exhibit VI-8 Potential Changes in Risk under the AIP and Alternative Options Relative to the Current TCR

Proposed Rule Component	Factors Leading to a Potential Increase in Risk		Factors Leading to a Potential Decrease in Risk		Overall Predicted Change in Risk	
	AIP	Alternative	AIP	Alternative	AIP	Alternative
Implementation Activities	None	None	None	None	No change	No change
Routine Monitoring (Including Reduced Monitoring)	None	None	Increased stringency in requirements to qualify for reduced monitoring along with requirement to return to baseline monitoring upon loss of these criteria is expected to result in decreased risk (That is, fewer PWSs will qualify and therefore monitor more frequently than under the baseline for reduced monitoring)	PWSs all monitor monthly in the first few years of implementation of the RTCR, which is an increase in sampling frequency for systems that monitor quarterly or annually under the current TCR. After the first few years, systems may reduce to quarterly, but none may reduce to annual monitoring, creating a decrease in risk for systems on annual monitoring under the current TCR	Decrease	Decrease
Repeat Monitoring	Required repeat samples reduced from 4 to 3 for systems serving <1,000 people	Same as AIP option	None	None	Increase	Increase
Additional Routine Monitoring	Additional routine samples are no longer required for PWSs monitoring monthly. Ground water PWSs serving 1,000 or fewer people reduce additional routine samples from 5 to 3.	Same as AIP option	None	None	Increase	Increase
Annual Site Visits	None (only States currently performing annual site visits are expected to continue)	Based on discussions with stakeholders, States that currently conduct	None (only States currently performing annual site visits are expected to continue)	None	No change	Increase

	. . .	annual site visits under the current TCR may no longer have the resources to continue the site visits and conduct quarterly monitoring under the Alternative option				
Assessments	None	None	Mandatory assessments are a new requirement	Same as AIP option	Decrease	Decrease
Corrective Actions	None	None	Mandatory corrective actions are a new requirement	Same as AIP option	Decrease	Decrease
Public Notification – Monthly/Non-Acute MCL Violations	Reduction in available public information Possible PWS complacency	Same as AIP option	Less confusion (PN more in line with potential health risks) PWSs resources used more efficiently	Same as AIP option	Unknown	Unknown
Public Notification – Monitoring and Reporting Violations	None	None	Increased stringency of PNs motivates PWSs to conduct required sampling	Same as AIP option	Decrease	Decrease
Overall					Decrease	Decrease

Notes: Detailed discussion of the rationale for determinations of potential risk for each rule component is presented in chapter 6 (section 6.2) of the Proposed RTCR EA (USEPA 2010a). Implementation activities consist of administrative activities by PWSs and States to implement the rule. Assessment of potential changes in risk for monitoring components is an *overall* assessment. Potential changes (or static state) of risk for particular system sizes and types differ according to individual regulatory requirements and are discussed in section 6.2 of the Proposed RTCR EA. Chapter 3 of the Proposed RTCR EA provides a detailed description of the regulatory components for all three regulatory scenarios, and this preamble provides additional discussion of the TCRDSAC process and the rationale underlying the structure of the regulatory options considered.

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2. Changes in Violation Rates and Corrective Actions

The quantified portion of the benefits analysis focuses on several measures that contribute to the changes in risk expected under the proposed RTCR. Specifically, EPA modeled the predicted outcomes based on each regulatory option considered—baseline (current TCR), the AIP, and the Alternative option—in the form of estimates of non-acute violations for the current TCR and assessment triggers for the AIP and Alternative option; *E. coli* violations; and the number of corrective actions implemented under each option. This section of the preamble includes six graphs (Exhibit VI–9 through Exhibit VI–14) that help to illustrate these endpoints.

Evaluation of each of these endpoints informed EPA's understanding of potential changes to the underlying quality of drinking water. In particular, the number of corrective actions performed has a strong relationship to potential improvements in water quality and public health. For a given rate of total coliform and *E. coli* occurrence, an increase in the number of corrective actions implemented leads to improved water quality. However, a reduction in sampling likely leads to a reduction in total coliform and *E. coli* positives being found, which in turn likely leads to a reduction in assessments and corrective actions being implemented. The number of total coliform and *E. coli* positives that are prevented, missed, or found under each regulatory option considered in comparison to those predicted under the current TCR results in estimates of annual non-acute and acute violations (current TCR) and assessment triggers (AIP and Alternative options). Section 6.4 of the Proposed RTCR EA (USEPA 2010a) presents a step-wise sensitivity analysis of the competing effects of additional protective activity (*e.g.,* assessments and corrective actions) and decreased additional routine and repeat sampling of the regulatory alternatives compared to the current TCR. The results of this sensitivity analysis showed that for all categories of systems, more total coliform and *E. coli* positives are prevented than missed under both regulatory options.

For each of the graphs presented in Exhibit VI–9 through Exhibit VI–14, there are two main model drivers that affect the endpoints depicted: The total

number of samples taken over time (including routine, additional routine, and repeat samples) and the effect of corrective actions taken. When looking at the comparisons between the TCR with the AIP across all PWSs, the overall effect of the total numbers of samples taken is negligible because the total number of samples predicted to be taken throughout the period of analysis is almost the same (approximately 82 million samples) under both the TCR and AIP. For the Alternative option, the analysis predicts that approximately 87 million total samples are taken over the period of analysis. Exhibit VI–18 of this preamble presents estimated total numbers of samples taken over the 25-year period of analysis. Based on the relationships of total samples taken among the TCR, AIP, and Alternative options, the best way to interpret the graphs presented in this section is in a step-wise manner.

The first comparison that should be made is between the current TCR and AIP options. Because similar total numbers of samples are taken under each option, the major effect seen in the graphs can be isolated to the effects that implementation of corrective actions has on underlying occurrence and how that occurrence influences the endpoint in question (assessments, *E. coli* MCL violations, and corrective actions). In each graph, this is depicted by a marked reduction in the endpoint under the AIP option compared to the current TCR option and is a reflection of overall better water quality. The second comparison can then be made of the Alternative option against the AIP option. In each graph, the predicted results (assessments, *E. coli* MCL violations, and corrective actions) for the Alternative option are above those for the AIP option and represent an additional benefit over the AIP option. This additional benefit is primarily a function of the additional diagnostic abilities gained through increased monitoring under the Alternative option, and is especially prominent in the early years of the analysis when all systems are required to monitor at least monthly.

More detailed descriptions of each endpoint considered in terms of the evaluation process described previously are provided in this section as they apply to the individual graphs in Exhibit VI–9 through VI–14. Each of the graphs shown in this section is presented first in nondiscounted terms, and then based on a discount rate of three percent to reflect the reduced valuation of potential benefits over time, consistent with the presentation of costs in the section that follows. Graphs of benefits discounted using seven percent discounted rates are presented in Appendix B of the Proposed RTCR EA (USEPA 2010a).

Exhibit VI–9 shows the effect (on average across all PWSs) of the AIP and the Alternative options on the annual number of non-acute violations (TCR) and assessment triggers (AIP and Alternative options) over time. The estimated reduction of annual assessment triggers (from the current TCR estimates of non-acute violations) by approximately 1,000 events under the AIP option is a reflection of the improved water quality expected under the AIP option. A similar but smaller reduction in non-acute violations (Level 1 triggers) from the current TCR is seen under the Alternative option. The larger initial estimate of assessment triggers followed by a higher steady state number for the Alternative option than seen under the AIP option reflects the diagnostic abilities provided by increased sampling under the Alternative option. The additional triggers identified by increased sampling under the Alternative option translate into greater potential benefits than under the AIP option.

Exhibit VI–10 shows the effect (on average across all PWSs) of the AIP and the Alternative option with respect to *E. coli* violations found over the 25-year period of analysis in comparison to the current TCR. The overall reduction in annual *E. coli* violations under the AIP option of more than 100 events is a measure that should correlate more closely with expected benefits (that is, reductions in adverse health outcomes) than non-acute events (as presented in Exhibit VI–9) because *E. coli* violations are a direct result of measurement of fecal contamination in water. A similar but smaller reduction is seen under the Alternative option after steady state is achieved. This is the result of two off-setting effects. The "true" number of steady state violations under the Alternative option is lower because there is a greater likelihood that violations will be found and fixed. However, the additional monitoring leads to a higher percentage of violations being detected. This second effect outweighs the first, so that the total number of detected violations in the steady state is higher than for the AIP, even though the underlying "true" number of violations is lower. This lower number of "true" violations means that the Alternative option is more protective of public health, even though more violations are detected.

Exhibit VI–11 presents estimates over the 25-year period of analysis of the increase in corrective actions (on average across all PWSs) attributable to the regulatory options considered. Performance of these additional corrective actions is expected to result in the most direct benefits under the proposed RTCR. Because only the incremental numbers of corrective actions estimated under the AIP and Alternative options were modeled, the reference point for comparison to the current TCR is the base (zero) line in the graph. The Proposed RTCR EA (USEPA 2010a) assumes that corrective actions are already being performed under the current TCR. Baseline corrective actions are taken into account by assuming only a modest incremental increase of 10 percent in implementation of effective corrective actions under both regulatory options considered.

Exhibit VI–11 indicates that more corrective actions are implemented under the Alternative option than under the AIP option. This is driven, again, by the increased diagnostic power of more sampling and reflects additional potential benefits beyond those gained under the AIP option.

Taken together, Exhibit VI–9 through Exhibit VI–11 indicate that the modeled endpoints for the AIP and Alternative options predict positive benefits in comparison to the current TCR; in particular, the Alternative option captures more benefits than the AIP option. Similar to the patterns seen in Exhibits VI–9 through VI–11, for each of the discounted endpoints presented over time in Exhibits VI–12 though VI–14, the graphs show that (on average across all PWSs) the Alternative option provides more benefit than the AIP, and both provide more benefit than the current TCR. These outcomes are consistent with the qualitative assessment of the benefits summarized in section VI.E.1.

The major difference between the AIP option and Alternative option is the increased monitoring that is required under the Alternative option. The increased diagnostic ability of the extra samples taken under the Alternative option is seen in the large difference in the endpoint counts through the first several years in Exhibit VI–9 through Exhibit VI–14. Absent this effect, the Alternative option essentially mirrors the AIP option in the exhibits. Even though the predicted results (assessments, *E. coli* MCL violations, and corrective actions) under the Alternative option are greater than the current TCR at first, the trend is due to initially finding more problems through monitoring. The increased monitoring during the first several years under the Alternative option results in a frontloading of benefits at the beginning

of the implementation period. The benefits, however, tend to even out over time between the AIP and Alternative option as eligible systems qualify for less intense (quarterly) monitoring under the Alternative option. However, the Alternative option leads to a greater number of assessments, *E. coli* MCL violations, and corrective actions than the AIP option because all PWSs are required to sample no less than quarterly under the Alternative option while under the AIP option qualifying PWSs are permitted to sample at a minimum of once per year (more monitoring has the potential for more triggered assessments, corrective actions, and/or violations than less monitoring).

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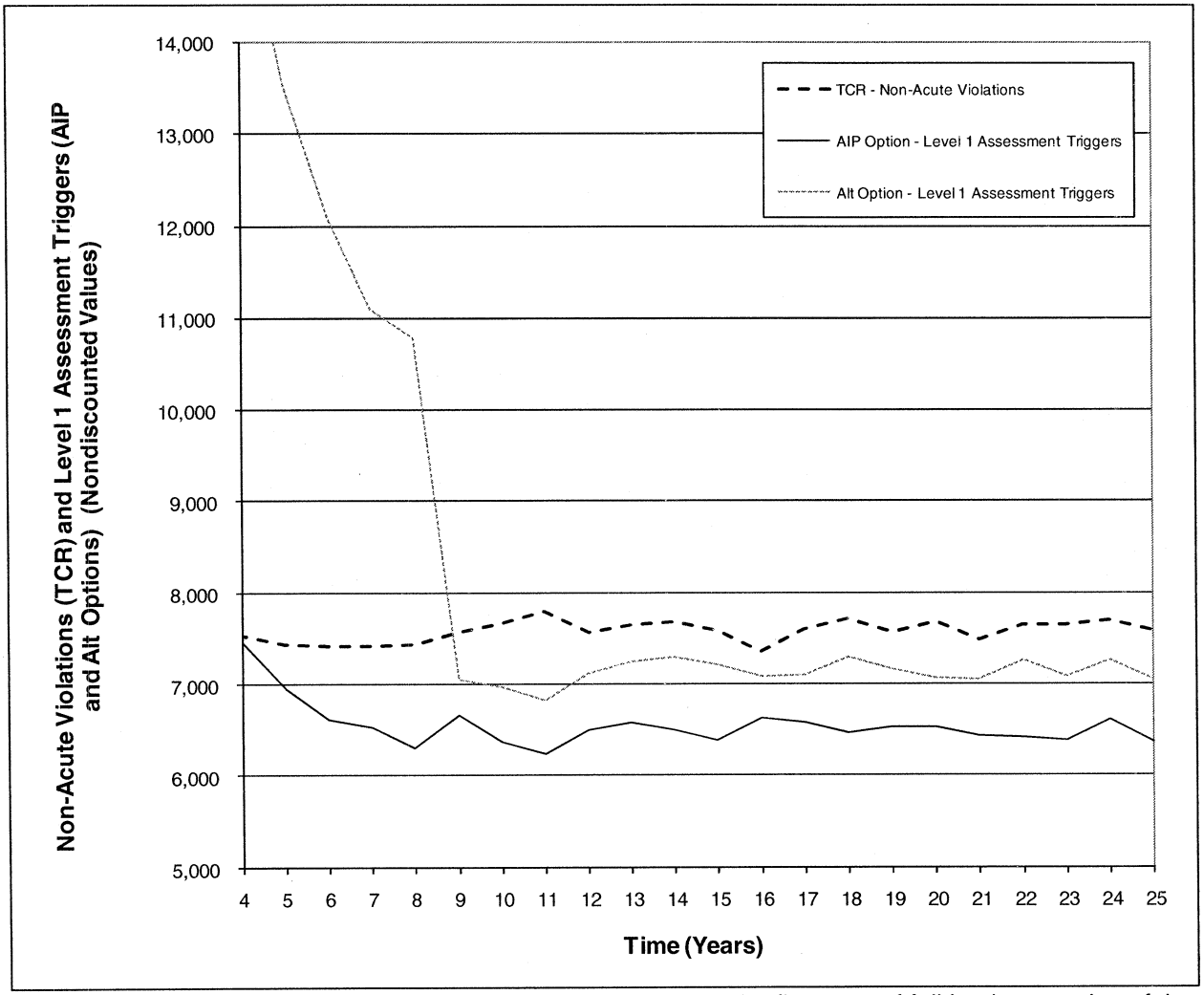
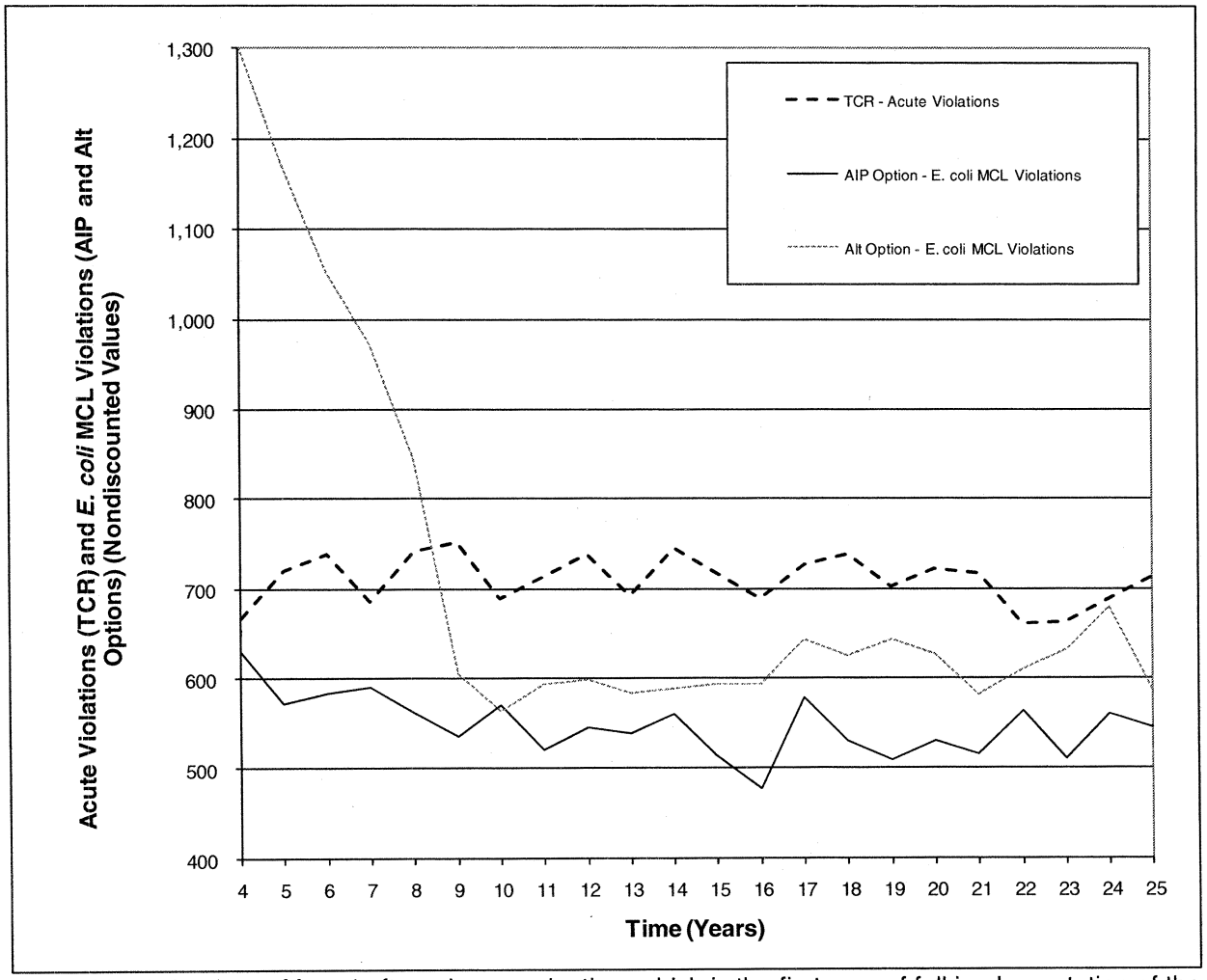
Exhibit VI-9 Estimates of Non-Acute Violations (TCR) and Level 1 Assessment Triggers (AIP and Alternative Option)



Notes: X-axis begins at Year 4 after rule promulgation, which is the first year of full implementation of the proposed RTCR (AIP option) or Alternative option. The annual rates of non-acute violations (TCR) and Level 1 assessment triggers (AIP and Alternative option) as predicted by the model reach a steady state beginning in approximately Year 9, by which time PWSs that are expected to meet the criteria for reduced monitoring begin reduced monitoring, and the distribution of PWSs the monitor monthly, quarterly, and annually is assumed to remain relatively constant. Estimates represent the annual number of assessment triggers found by each option and the non-acute violations found under the TCR.
Source: Proposed RTCR occurrence model output.

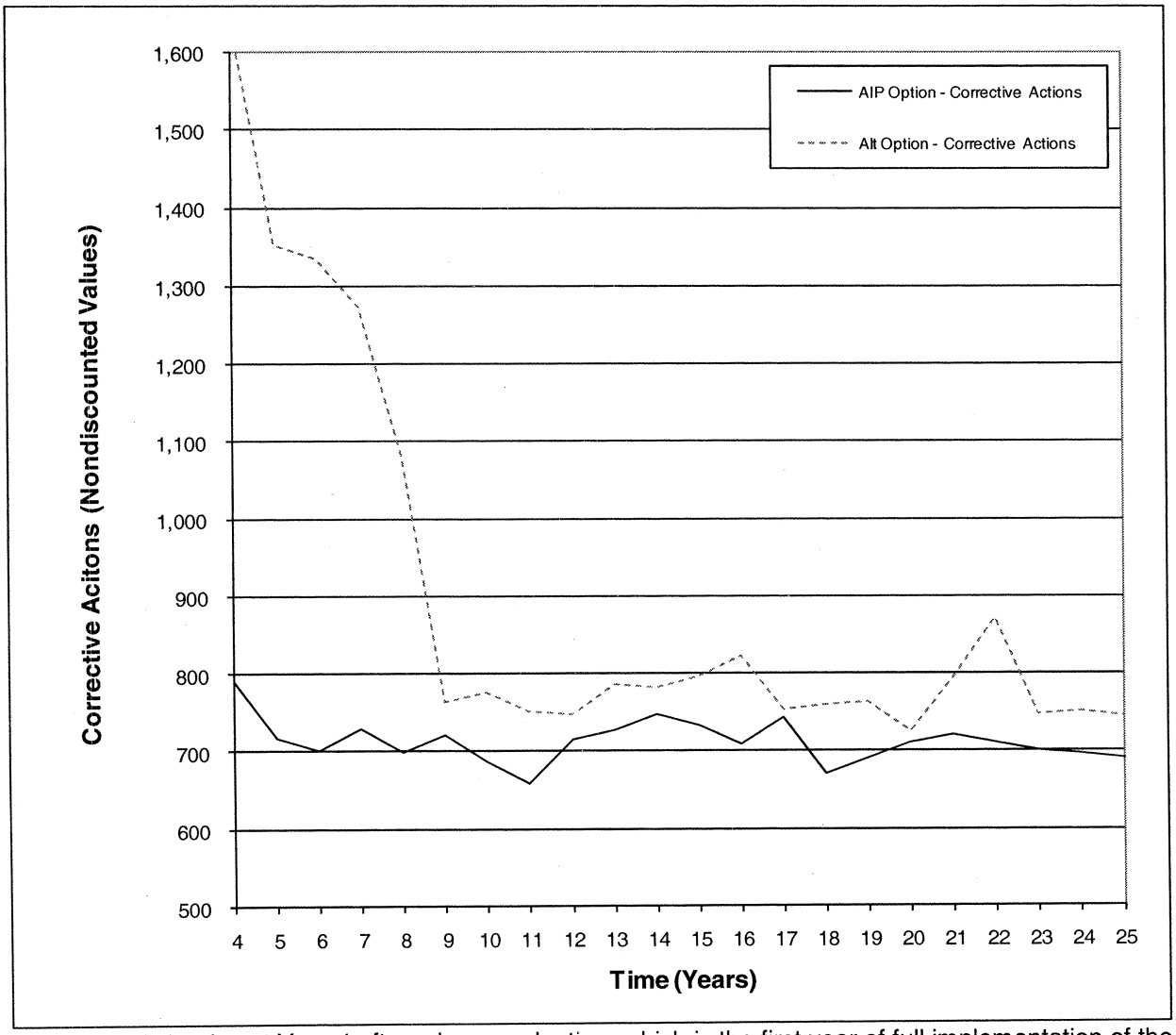
Exhibit VI-10 Estimates of Acute Violations (TCR) and *E. coli* MCL Violations (AIP and Alternative Options)



Notes: X-axis begins at Year 4 after rule promulgation, which is the first year of full implementation of the proposed RTCR (AIP option) or Alternative option. The annual rates of acute violations (TCR) and *E. coli* MCL violations (AIP and Alternative option) as predicted by the model reach steady state in approximately Year 9, by which time PWSs that are expected to meet the criteria for reduced monitoring begin reduced monitoring, and the distribution of PWSs the monitor monthly, quarterly, and annually is assumed to remain relatively constant. Estimates represent the annual number of acute violations found by each option and the TCR.

Source: Proposed RTCR occurrence model output.

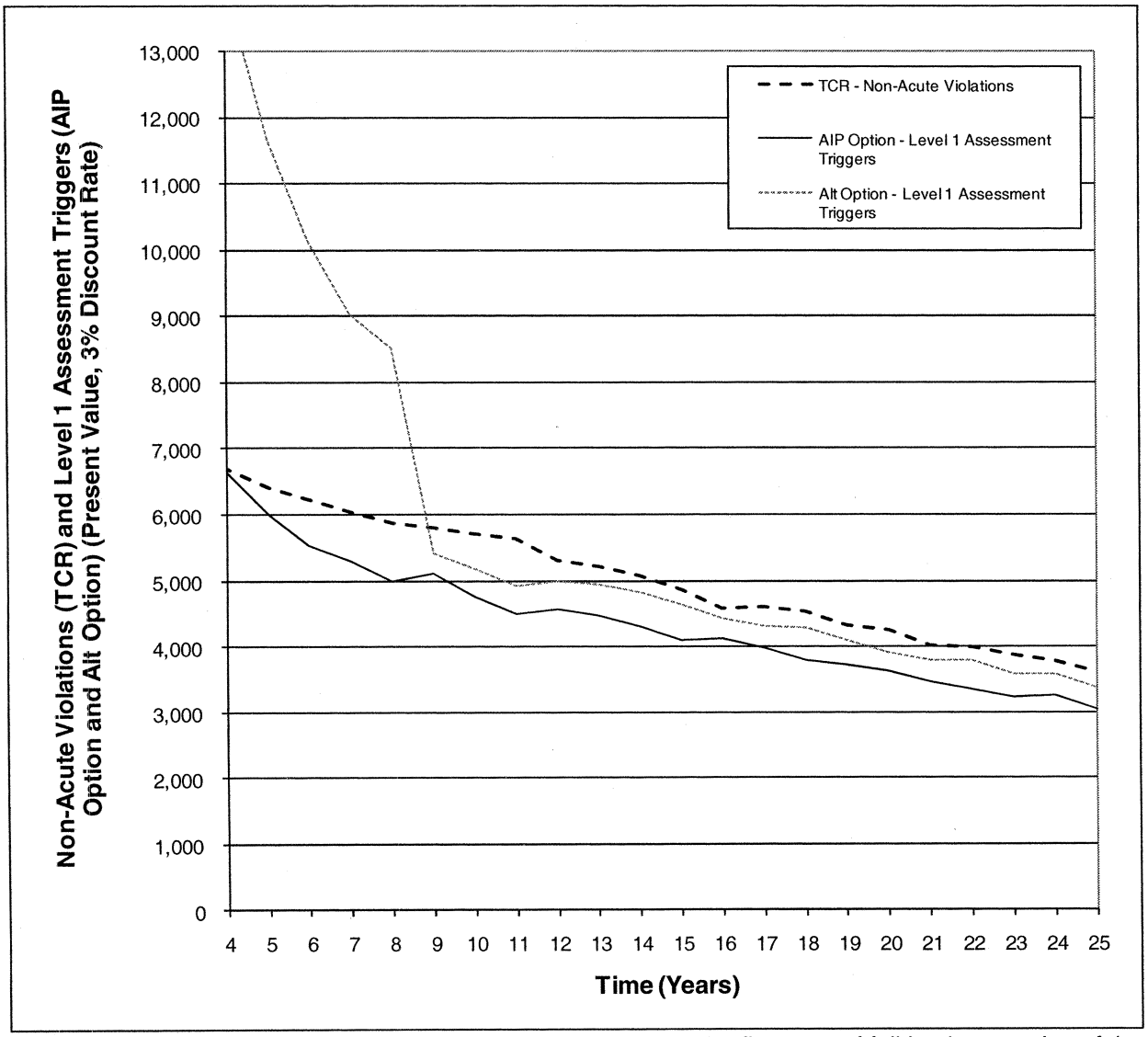
Exhibit VI-11 Estimates of Corrective Actions



Notes: X-axis begins at Year 4 after rule promulgation, which is the first year of full implementation of the proposed RTCR (AIP option) or Alternative option. The annual rates of corrective actions as predicted by the model reach a steady state beginning approximately in Year 9, by which time PWSs that are expected to meet the criteria for reduced monitoring begin reduced monitoring, and the distribution of PWSs the monitor monthly, quarterly, and annually is assumed to remain relatively constant. All corrective actions performed are in addition to activity under the current TCR, which does not require corrective actions. Therefore the current TCR is not included in this graph.

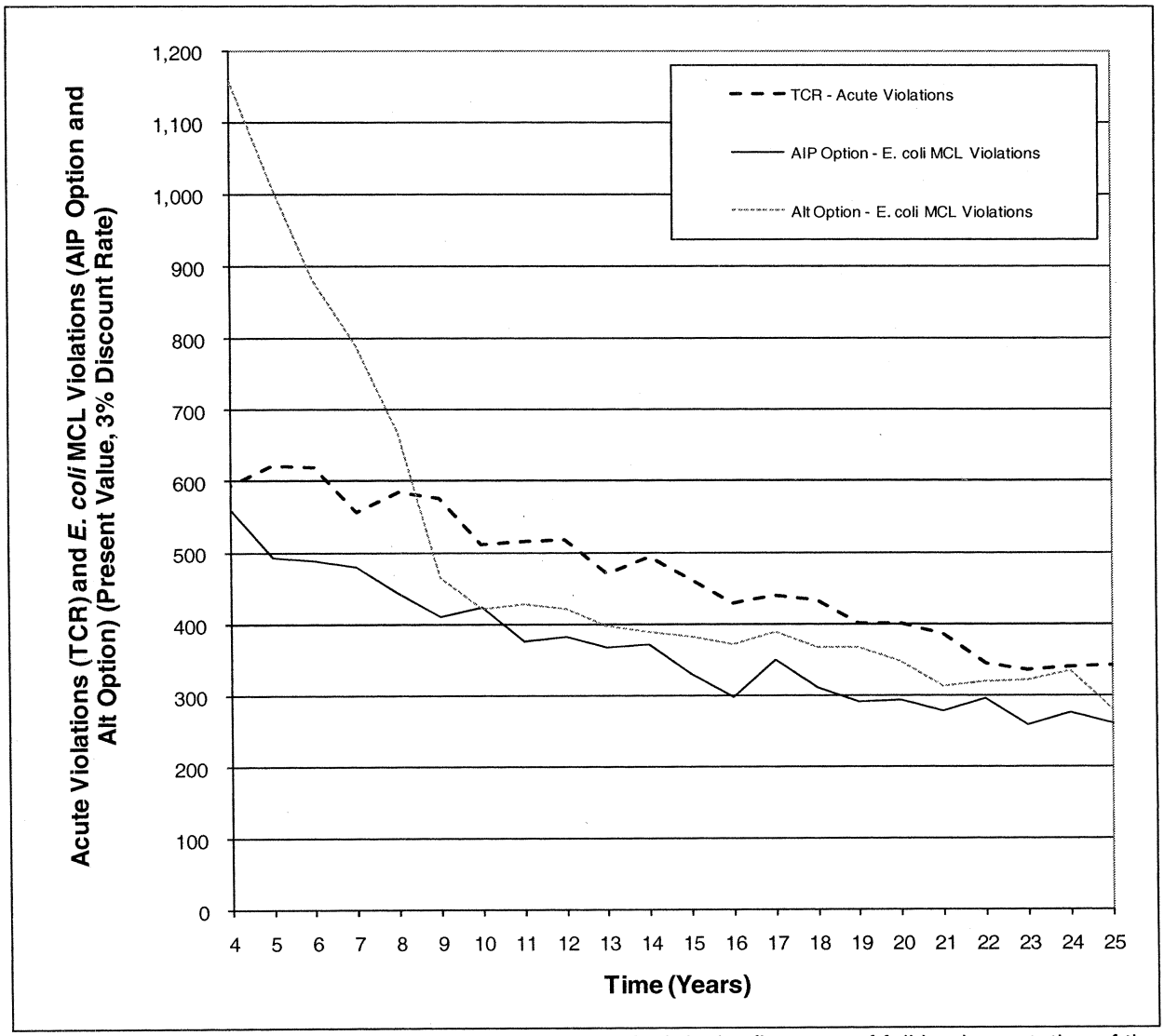
Source: Proposed RTCR occurrence model output.

Exhibit VI-12 Discounted Estimates of Non-Acute Violations (TCR) and Level 1 Assessment Triggers (AIP and Alternative Options) (three percent discount rate)



Notes: X-axis begins at Year 4 after rule promulgation, which is the first year of full implementation of the proposed RTCR (AIP option) or Alternative option. The annual rates of non-acute violations (TCR) and Level 1 assessment triggers (AIP and Alternative option) as predicted by the model reach a steady state beginning in approximately Year 9, by which time PWSs that are expected to meet the criteria for reduced monitoring begin reduced monitoring, and the distribution of PWSs the monitor monthly, quarterly, and annually is assumed to remain relatively constant. Estimates represent the annual number of assessment triggers found by each option and the non-acute violations found under the TCR.
Source: Proposed RTCR occurrence model output.

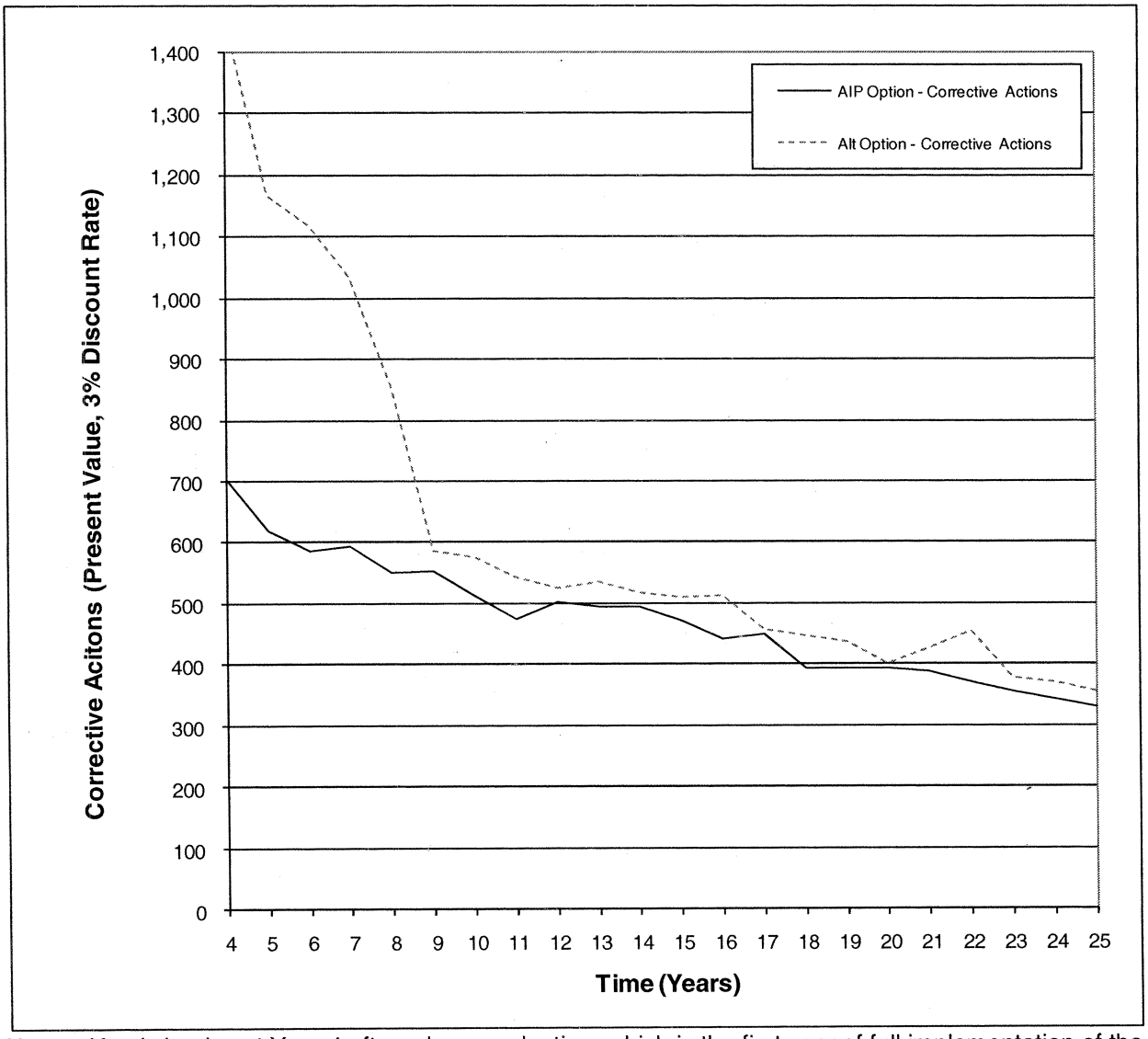
Exhibit VI-13 Discounted Estimates of Acute Violations (TCR) and *E. coli* Violations (AIP and Alternative Options) (three percent discount rate)



Notes: X-axis begins at Year 4 after rule promulgation, which is the first year of full implementation of the proposed RTCR (AIP option) or Alternative option. The annual rates of acute violations (TCR) and *E. coli* MCL violations (AIP and Alternative option) as predicted by the model reach steady state in approximately Year 9, by which time PWSs that are expected to meet the criteria for reduced monitoring begin reduced monitoring, and the distribution of PWSs the monitor monthly, quarterly, and annually is assumed to remain relatively constant. Estimates represent the annual number of acute violations found by each option and the TCR.

Source: Proposed RTCR occurrence model output.

Exhibit VI-14 Discounted Estimates of Corrective Actions (three percent discount rate)



Notes: X-axis begins at Year 4 after rule promulgation, which is the first year of full implementation of the proposed RTCR (AIP option) or Alternative option. The annual rates of corrective actions as predicted by the model reach a steady state beginning in approximately Year 9, by which time PWSs that are expected to meet the criteria for reduced monitoring begin reduced monitoring, and the distribution of PWSs the monitor monthly, quarterly, and annually is assumed to remain relatively constant. All corrective actions performed are in addition to activity under the current TCR, which does not require corrective actions. Therefore the current TCR is not included in this graph.
Source: Proposed RTCR occurrence model output.

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3. Nonquantifiable Benefits

a. *Potential decreased incidence of endemic illness from fecal contamination, waterborne pathogens, and associated outbreaks.* As discussed in section VI of this preamble and chapter 2 of the Proposed RTCR EA (USEPA 2010a), benefits from the proposed RTCR may include avoidance of a full range of health effects from the consumption of fecally contaminated drinking water, including the following: Acute and chronic illness, endemic and epidemic disease, waterborne disease outbreaks, and death. EPA recognizes that the EPA-approved standard methods available for *E. coli* do not typically identify the presence of the pathogenic *E. coli* strains, such as *E. coli* O157:H7. Thus, *E. coli* occurrence, as used in this EA, serves as an indication of fecal contamination but not necessarily pathogenic contamination. *See* also discussion in sections III.A.2 and III.A.9 of this preamble.

EPA was unable to quantify the cases of morbidity or mortality avoided because there are insufficient data reporting the co-occurrence of fecal indicator *E. coli* and pathogenic organisms in a single water sample, and because the available fecal indicator *E. coli* data from the Six-Year Review 2 dataset (USEPA 2010e) were limited to presence-absence data. Instead, EPA estimated changes in total coliform and fecal indicator *E. coli* occurrence (for systems serving 4,100 or fewer people) and changes in number of corrective actions (for systems serving greater than 4,100 people) as measures of reduced risk. As discussed previously, the assessments and corrective actions required under the RTCR will help lead to a decrease in total coliform and *E. coli* occurrence in drinking water. Since fecal contamination can contain waterborne pathogens including bacteria, viruses, and parasitic protozoa, in general, a reduction in fecal contamination should also reduce the potential risk from these other contaminants and the associated primary and secondary endemic disease burden, both acute and chronic.

b. *Other nonquantifiable benefits.* Other nonquantified benefits may include those associated with increased knowledge regarding system operation, accelerated maintenance and repair, avoided costs of outbreaks, and reductions in averting behavior.

By requiring PWSs to conduct assessments that meet minimum elements focused on identifying sanitary defects in response to triggers for total coliform- or *E. coli*-positive samples, the proposed RTCR increases the likelihood that PWS operators, in particular those of systems triggered to conduct assessments and corrective action, will develop further understanding of system operations and improve and practice preventive maintenance compared to the current TCR, which does not require PWSs to perform assessments and corrective action.

Another non-quantified benefit is that systems may choose corrective actions that also address other drinking water contaminants. For example, correcting for a pathway of potential contamination into the distribution system can possibly also mitigate a variety of other potential contaminants. Due to the lack of data available on the effect of corrective action on contamination entering through distribution system pathways, EPA has not quantified such potential benefits.

Some systems may *see* additional nonquantified benefits associated with the acceleration of their capital replacement fund investments in response to early identification of impending problems with large capital components. Although such capital investment will eventually occur anyway, earlier investment may ensure that problems are addressed in a preventive manner and may preclude some decrease in protection that might have occurred otherwise. At the very least, the increased operator awareness is expected to reduce the occurrence of unplanned capital expenditures in any given year. However, because of the difficulty of projecting when capital replacements would occur, EPA has not costed this acceleration of capital replacement, so there would also be a nonquantified cost of making such investments sooner.

Another major non-health benefit is the avoided costs associated with outbreak response. Outbreaks can be very costly for both the PWS and the community in which they occur. Avoided outbreak response costs include such costs as issuing public health warnings, boiling drinking water and providing alternative supplies, remediation and repair, and testing and laboratory costs. Reduced total coliform occurrence resulting from the proposed RTCR may also lead to a reduction of costs associated with boil-water orders, which some States require following non-acute violations under the current TCR. Taken together, these expenses can be quite significant. For example, an analysis of the economic impacts of a waterborne disease outbreak in Walkerton, Ontario (population 5,000) estimated the economic impact, excluding medically related costs, to be over $45.9 million in 2007 Canadian dollars (approximately 42.8 million 2007 US dollars) (Livernois 2002). The author of the study believed that this was a conservative estimate.

In addition, the proposed RTCR may also reduce uncertainty regarding drinking water safety, which may lead to reduced costs for averting behaviors. Averting behaviors include the use of bottled water and point-of-use devices. This benefit also includes the reductions in time spent on averting behavior such as the time spent obtaining alternative water supplies.

F. Anticipated Costs of the Proposed RTCR

To understand the net impacts of the proposed RTCR on public water systems and States in terms of costs, EPA first used available data, information, and best professional judgment to characterize how PWSs and States are currently implementing the current TCR, and to estimate cost relative to a baseline of no RTCR. Then, EPA considered the net change in costs that results from implementing the AIP or Alternative options as compared to the costs of continuing with the current TCR. The objective was to present the net change in costs resulting from revisions to the current TCR rather than absolute totals. More detailed information on cost estimates is provided in the sections that follow and a complete discussion can be found in chapter 7 of the Proposed RTCR EA (USEPA 2010a). A detailed discussion of the proposed revisions is located in section III of this preamble.

1. Total Annualized Present Value Costs

To compare cost of compliance activities for the three regulatory scenarios, the year or years in which all costs are expended are determined and the costs are then calculated as a net present value. For the purposes of this EA, one-time and yearly costs were projected over a 25-year time period to allow comparison with other drinking water regulations using the same analysis period. For this analysis, the net present values of costs in 2007 dollars are calculated using discount rates of three percent and seven percent. These present value costs are then annualized over the 25-year period using the two discount rates.

Exhibit VI–15 summarizes the comparison of total and net change in annualized present value of the AIP and Alternative options relative to the current TCR baseline. A continuation of the current TCR will result in no net change in costs. The net change in mean annualized present value national costs of the AIP option is estimated to be

approximately $14 million (M) using either a three percent or seven percent discount rate. The net change in mean annualized present value national costs for the Alternative option are estimated to be approximately $27M using a three percent discount rate and $30M using a seven percent discount rate.

Under the AIP option, public water systems are estimated to incur greater than 90 percent of the proposed revised rule's net annualized present value costs. States are expected to incur the remaining costs.

Exhibit VI–16 presents the comparison of total and net change in annualized present value costs by rule component. The table shows that routine monitoring and corrective action costs are the most significant contributors to the net increase in costs for PWSs under both the AIP and Alternative options. For States, revising sampling plans contribute most to the cost increase. For both PWSs and States, a net decrease in costs associated with PN requirements helps to offset the total net cost increase.

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Exhibit VI-15 Comparison of Total and Net Change from Current TCR in Annualized Present Value Costs ($Millions, 2007$)

	PWSs	State	Total	PWSs	State	Total
	3% Discount Rate			7% Discount Rate		
TCR – Baseline [1]	$ 185	$ 0.9	$ 186	$ 178	$ 0.9	$ 179
AIP – Baseline + Incremental [2]	$ 199	$ 1.1	$ 200	$ 191	$ 1.3	$ 192
AIP - Net Change	$ 14	$ 0.1	$ 14	$ 13	$ 0.4	$ 14
AIP - Percent Change	7%	16%	7%	7%	48%	8%
Alternative option – Baseline + Incremental [2]	$ 212	$ 1.2	$ 213	$ 207	$ 1.5	$ 209
Alternative option - Net Change	$ 27	$ 0.3	$ 27	$ 29	$ 0.6	$ 30
Alternative option - Percent Change	15%	32%	15%	16%	67%	17%

Note: Detail may not add due to independent rounding.

Source: Proposed RTCR EA (USEPA 2010a).

[1] Does not quantify all TCR components.

[2] For components not quantified for the TCR, the AIP and Alternative option totals include only an estimate of the net increase for those same rule components (*e.g.*, corrective action costs).

Exhibit VI-16 Comparison of Total and Net Change in Annualized Present Value Costs by Rule Component ($Millions, 2007$)

	PWSs	State	Total	PWSs	State	Total
	3% Discount Rate			7% Discount Rate		
Rule Implementation						
TCR - Total	$ -	$ -	$ -	$ -	$ -	$ -
AIP - Total	$ 2.77	$ 0.18	$ 2.95	$ 4.00	$ 0.26	$ 4.26
AIP - Net Change	$ 2.77	$ 0.18	$ 2.95	$ 4.00	$ 0.26	$ 4.26
Alternative Option - Total	$ 2.77	$ 0.18	$ 2.95	$ 4.00	$ 0.26	$ 4.26
Alternative Option - Net Change	$ 2.77	$ 0.18	$ 2.95	$ 4.00	$ 0.26	$ 4.26
Revising Sampling Plans						
TCR - Total	$ -	$ -	$ -	$ -	$ -	$ -
AIP - Total	$ 0.59	$ 0.42	$ 1.01	$ 0.84	$ 0.59	$ 1.42
AIP - Net Change	$ 0.59	$ 0.42	$ 1.01	$ 0.84	$ 0.59	$ 1.42
Alternative Option - Total	$ 0.59	$ 0.42	$ 1.01	$ 0.84	$ 0.59	$ 1.42
Alternative Option - Net Change	$ 0.59	$ 0.42	$ 1.01	$ 0.84	$ 0.59	$ 1.42
Routine Monitoring						
TCR - Total	$ 170.59	$ -	$ 170.59	$ 163.94	$ -	$ 163.94
AIP - Total	$ 174.71	$ -	$ 174.71	$ 167.74	$ -	$ 167.74
AIP - Net Change	$ 4.12	$ -	$ 4.12	$ 3.80	$ -	$ 3.80
Alternative Option - Total	$ 186.34	$ -	$ 186.34	$ 181.49	$ -	$ 181.49
Alternative Option - Net Change	$ 15.75	$ -	$ 15.75	$ 17.56	$ -	$ 17.56
Additional Routine Monitoring						
TCR - Total	$ 3.87	$ -	$ 3.87	$ 3.72	$ -	$ 3.72
AIP - Total	$ 1.12	$ -	$ 1.12	$ 1.09	$ -	$ 1.09
AIP - Net Change	$ (2.75)	$ -	$ (2.75)	$ (2.63)	$ -	$ (2.63)
Alternative Option - Total	$ 0.68	$ -	$ 0.68	$ 0.58	$ -	$ 0.58
Alternative Option - Net Change	$ (3.18)	$ -	$ (3.18)	$ (3.14)	$ -	$ (3.14)
Repeat Monitoring						
TCR - Total	$ 5.11	$ -	$ 5.11	$ 4.91	$ -	$ 4.91
AIP - Total	$ 4.82	$ -	$ 4.82	$ 4.64	$ -	$ 4.64
AIP - Net Change	$ (0.29)	$ -	$ (0.29)	$ (0.27)	$ -	$ (0.27)
Alternative Option - Total	$ 5.50	$ -	$ 5.50	$ 5.45	$ -	$ 5.45
Alternative Option - Net Change	$ 0.39	$ -	$ 0.39	$ 0.54	$ -	$ 0.54
Site Inspections						
TCR - Total	$ -	$ -	$ -	$ -	$ -	$ -
AIP - Total	$ -	$ -	$ -	$ -	$ -	$ -
AIP - Net Change	$ -	$ -	$ -	$ -	$ -	$ -
Alternative Option - Total	$ -	$ -	$ -	$ -	$ -	$ -
Alternative Option - Net Change	$ -	$ -	$ -	$ -	$ -	$ -
Level 1 Assessment						
TCR - Total	$ 1.13	$ 0.21	$ 1.34	$ 1.08	$ 0.21	$ 1.29
AIP - Total	$ 1.63	$ 0.20	$ 1.84	$ 1.57	$ 0.20	$ 1.77
AIP - Net Change	$ 0.50	$ (0.01)	$ 0.49	$ 0.49	$ (0.01)	$ 0.48
Alternative Option - Total	$ 1.73	$ 0.23	$ 1.95	$ 1.69	$ 0.22	$ 1.91
Alternative Option - Net Change	$ 0.60	$ 0.01	$ 0.61	$ 0.60	$ 0.02	$ 0.62
Level 2 Assessment						
TCR - Total	$ 0.70	$ 0.26	$ 0.96	$ 0.68	$ 0.25	$ 0.93
AIP - Total	$ 0.90	$ 0.19	$ 1.09	$ 0.88	$ 0.18	$ 1.06
AIP - Net Change	$ 0.20	$ (0.07)	$ 0.12	$ 0.20	$ (0.07)	$ 0.13
Alternative Option - Total	$ 1.23	$ 0.28	$ 1.51	$ 1.27	$ 0.30	$ 1.57
Alternative Option - Net Change	$ 0.52	$ 0.02	$ 0.55	$ 0.60	$ 0.05	$ 0.65
Corrective Actions based on Level 1 Assessments						
TCR - Total	$ -	$ -	$ -	$ -	$ -	$ -
AIP - Total	$ 9.17	$ 0.01	$ 9.18	$ 7.77	$ 0.01	$ 7.77
AIP - Net Change	$ 9.17	$ 0.01	$ 9.18	$ 7.77	$ 0.01	$ 7.77
Alternative Option - Total	$ 9.39	$ 0.01	$ 9.40	$ 8.01	$ 0.01	$ 8.02
Alternative Option - Net Change	$ 9.39	$ 0.01	$ 9.40	$ 8.01	$ 0.01	$ 8.02
Corrective Actions based on Level 2 Assessments						
TCR - Total	$ -	$ -	$ -	$ -	$ -	$ -
AIP - Total	$ 2.72	$ 0.00	$ 2.72	$ 2.41	$ 0.00	$ 2.41
AIP - Net Change	$ 2.72	$ 0.00	$ 2.72	$ 2.41	$ 0.00	$ 2.41
Alternative Option - Total	$ 3.53	$ 0.01	$ 3.53	$ 3.36	$ 0.01	$ 3.37
Alternative Option - Net Change	$ 3.53	$ 0.01	$ 3.53	$ 3.36	$ 0.01	$ 3.37
Public Notification						
TCR - Total	$ 3.75	$ 0.44	$ 4.19	$ 3.60	$ 0.42	$ 4.03
AIP - Total	$ 0.26	$ 0.06	$ 0.33	$ 0.26	$ 0.06	$ 0.32
AIP - Net Change	$ (3.49)	$ (0.38)	$ (3.87)	$ (3.35)	$ (0.36)	$ (3.71)
Alternative Option - Total	$ 0.34	$ 0.08	$ 0.42	$ 0.35	$ 0.08	$ 0.43
Alternative Option - Net Change	$ (3.41)	$ (0.36)	$ (3.77)	$ (3.26)	$ (0.34)	$ (3.60)

Note: Assumes a certain level of assessment activity already occurs under the current TCR, as discussed in chapter 7 of the Proposed RTCR EA (USEPA 2010a).
Source: Proposed RTCR EA (USEPA 2010a).
Not all TCR components are quantified. For components not quantified for the TCR, the AIP and Alternative option totals include only an estimate of the net increase for those same rule components (*e.g.*, corrective action costs).

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2. PWS Costs

Like the current TCR, the proposed RTCR applies to all PWSs. Exhibit VI–17 presents the total and net change in annualized costs to PWSs by size and type for the three regulatory options. No net change in costs will result from a continuation of the current TCR. Among PWSs serving 4,100 or fewer people, looking at the three percent discount rate, the largest increase in aggregate net costs is incurred by the TNCWSs serving 100 or fewer people under either the AIP ($5.1M) or Alternative option ($13.4M) because of the large number of systems. On a per system basis, this translates to a net annualized present value increase of approximately $83 per system under the AIP and $217 per system under the Alternative option for the TNCWSs serving 100 or fewer people. As described in section VII.C of this preamble, none of the small TNCWSs are estimated to have costs that are greater than or equal to three percent of their revenue.

The total net change in national annualized present value costs for all PWSs serving greater than 4,100 people (approximately $6M using three percent discount rate) is the same under the AIP and Alternative option. This is expected because the provisions for PWSs serving greater than 4,100 are the same under either option. Monitoring requirements for PWSs serving greater than 4,100 people remain essentially unchanged under either the AIP or Alternative option. The observed overall net increase in costs for PWSs serving greater than 4,100 people is driven primarily by the requirements to conduct assessments and to correct any sanitary defects that are found.

Exhibit VI-17 Total and Net Change in Annualized Costs to PWSs by PWS Size and Type ($Millions, 2007$)

PWS Size (Population Served)	3% Discount Rate					7% Discount Rate				
	TCR - Total	AIP - Total	AIP - Net	Alternative Option - Total	Alternative Option - Net	TCR - Total	AIP - Total	AIP - Net	Alternative Option - Total	Alternative Option - Net
	A	B	C=B-A	D	E=D-A	F	G	H=G-F	I	J=I-F
Community Water Systems (CWSs)										
≤100	$7.4	$7.5	$0.1	$7.6	$0.2	$7.1	$7.3	$0.2	$7.4	$0.3
101-500	$9.0	$9.3	$0.3	$9.4	$0.4	$8.6	$9.1	$0.4	$9.2	$0.6
501-1,000	$3.7	$3.8	$0.0	$3.8	$0.1	$3.6	$3.7	$0.1	$3.7	$0.1
1,001-4,100	$13.2	$13.6	$0.3	$13.6	$0.3	$12.7	$13.1	$0.4	$13.1	$0.4
4,101-33,000	$42.4	$44.7	$2.3	$44.7	$2.3	$40.7	$42.7	$2.0	$42.7	$2.0
33,001-96,000	$34.9	$36.4	$1.5	$36.4	$1.5	$33.5	$34.8	$1.3	$34.8	$1.3
96,001-500,000	$34.7	$36.2	$1.5	$36.2	$1.5	$33.4	$34.6	$1.2	$34.6	$1.2
500,001-1 Million	$6.5	$6.7	$0.2	$6.7	$0.2	$6.2	$6.4	$0.1	$6.4	$0.1
> 1 Million	$5.6	$5.5	($0.0)	$5.5	($0.0)	$5.3	$5.3	($0.0)	$5.3	($0.0)
Total	**$157.4**	**$163.6**	**$6.2**	**$163.9**	**$6.5**	**$151.3**	**$157.0**	**$5.7**	**$157.3**	**$6.0**
Nontransient Noncommunity Water Systems (NTNCWSs)										
≤100	$2.6	$2.6	$0.1	$3.6	$1.0	$2.5	$2.6	$0.2	$3.8	$1.3
101-500	$1.9	$2.0	$0.1	$2.7	$0.9	$1.8	$2.0	$0.2	$2.9	$1.1
501-1,000	$0.6	$0.6	$0.0	$0.8	$0.3	$0.6	$0.6	$0.1	$0.9	$0.3
1,001-4,100	$1.2	$1.3	$0.1	$1.3	$0.1	$1.1	$1.2	$0.1	$1.2	$0.1
4,101-33,000	$0.4	$0.5	$0.1	$0.5	$0.1	$0.4	$0.5	$0.0	$0.5	$0.0
33,001-96,000	$0.1	$0.1	$0.0	$0.1	$0.0	$0.1	$0.1	$0.0	$0.1	$0.0
96,001-500,000	$0.1	$0.1	($0.0)	$0.1	($0.0)	$0.1	$0.1	($0.0)	$0.1	($0.0)
500,001-1 Million	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
> 1 Million	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total	**$6.9**	**$7.2**	**$0.4**	**$9.1**	**$2.3**	**$6.6**	**$7.2**	**$0.6**	**$9.4**	**$2.8**
Transient Noncommunity Water Systems (TNCWSs)										
≤100	$13.4	$18.5	$5.1	$26.7	$13.4	$12.8	$18.0	$5.1	$27.8	$14.9
101-500	$4.9	$6.4	$1.5	$9.1	$4.2	$4.7	$6.2	$1.5	$9.4	$4.7
501-1,000	$0.6	$0.8	$0.2	$1.1	$0.5	$0.6	$0.8	$0.2	$1.2	$0.5
1,001-4,100	$0.9	$1.0	$0.1	$1.0	$0.1	$0.9	$1.0	$0.1	$1.0	$0.1
4,101-33,000	$0.4	$0.5	$0.1	$0.5	$0.1	$0.4	$0.5	$0.0	$0.5	$0.0
33,001-96,000	$0.1	$0.1	($0.0)	$0.1	($0.0)	$0.1	$0.1	($0.0)	$0.1	($0.0)
96,001-500,000	$0.1	$0.1	($0.0)	$0.1	($0.0)	$0.1	$0.1	($0.0)	$0.1	($0.0)
500,001-1 Million	$0.2	$0.2	($0.0)	$0.2	($0.0)	$0.2	$0.2	($0.0)	$0.2	($0.0)
> 1 Million	$0.3	$0.3	$0.0	$0.3	$0.0	$0.3	$0.3	$0.0	$0.3	$0.0
Total	**$20.9**	**$27.8**	**$6.9**	**$39.1**	**$18.2**	**$20.1**	**$27.1**	**$7.0**	**$40.4**	**$20.3**
Grand Total	**$185.2**	**$198.7**	**$13.5**	**$212.1**	**$26.9**	**$177.9**	**$191.2**	**$13.2**	**$207.0**	**$29.1**

Note: Detail may not add due to independent rounding. Because only the incremental costs of some rule components are considered as part of the cost analysis, references to "total" costs in this exhibit do not refer to the complete costs for regulatory implementation but only to the specific costs considered to calculate net changes in costs.
Source: Proposed RTCR cost model.

a. *Rule implementation and annual administration.* Under the AIP and Alternative options, all PWSs subject to the proposed RTCR incur one-time costs that include time for staff to read the RTCR, become familiar with its provisions, and to train employees on rule requirements. No additional implementation burden or costs will be incurred by PWSs if the current TCR option is maintained. Under the AIP and Alternative options, all PWSs subject to the proposed RTCR perform additional or transitional implementation activities. Based on previous experience with rule implementation, EPA estimated that PWSs require a total of four hours to

read and understand the rule, and a total of eight hours to plan and assign appropriate personnel and resources to carry out rule activities.

b. *Revising sampling plans.* Under the AIP and Alternative options, all PWSs subject to the proposed RTCR incur one-time costs to revise existing sampling plans to identify sampling locations and collection schedules that are representative of water throughout the distribution system. Under the TCR, no additional burden or costs are expected to be incurred by PWSs to revise sampling plans, as these PWSs are already collecting total coliform samples in accordance with a written sampling plan. Based on previous experience, EPA estimated that PWSs require 2–8 hours to revise their sampling plan, depending on PWS size.

c. *Monitoring.* Monitoring costs for PWSs are calculated by multiplying the total numbers of routine, additional routine, and repeat samples required under the current TCR, AIP, and Alternative options by the monitoring costs per sample. Under the AIP, the increased stringency to qualify for reduced monitoring results in more routine samples being taken over time (fewer PWSs are on reduced monitoring). For the Alternative option, this effect is combined with the requirement that all PWSs start the implementation period on monthly monitoring. The Alternative option also prohibits annual monitoring, resulting in a greater increase in the number of routine samples compared to the AIP option. The resulting increases in costs due to increased monitoring are reflected in the routine monitoring costs.

The overall reductions in the numbers of additional routine samples required under the AIP and Alternative option result in reduced costs. Under the AIP and Alternative options, additional routine monitoring is no longer required for systems that monitor at least monthly, and when additional routine monitoring is required, the number of samples required is reduced from five to three. Cost reductions are greater under the Alternative option than under the AIP because under the Alternative option all PWSs start on monthly monitoring and are not required to take additional routine samples during that period.

Under the current TCR, PWSs serving 1,000 or fewer people take four repeat samples at and within five service connections upstream and downstream of the initial total coliform positive occurrence location over the course of 24 hours following the event. Under the AIP and Alternative options, they will only need to take three repeat samples, and they have greater flexibility about where to take them, consistent with the system sample siting plan that is developed in accordance with RTCR requirements and subject to review and revision by the State. The number of repeat samples required for PWSs serving more than 1,000 people is the same under the current TCR and the AIP and Alternative options, although they too have greater flexibility in sample location.

Exhibit VI–18 summarizes the cumulative number of samples taken by PWS size and category for routine, additional, and repeat monitoring under the TCR, AIP, and Alternative option over the entire 25-year period of analysis. Under the current TCR option, approximately 82.1 million samples are taken over the 25-year period of analysis compared to approximately 82.2 million samples under the AIP option and approximately 87.9 million samples under the Alternative option (less than 10 percent more than current TCR option). Appendix A of the Proposed RTCR EA (USEPA 2010a) presents additional information on the number of samples taken each individual year during the analysis period.

The annualized net present value total and net change cost estimates for PWSs and States to perform monitoring under the TCR, AIP, and Alternative options are presented in Exhibit VI–19.

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Exhibit VI-18 Cumulative Number of Samples over 25-Year Period of Analysis for Baseline (TCR) and Regulatory Alternatives (AIP and Alternative option)

PWS Size (Population Served)	TCR			AIP			Alternative Option		
	Routine Monitoring Samples	Additional Routine Monitoring Samples	Repeat Monitoring Samples	Routine Monitoring Samples	Additional Routine Monitoring Samples	Repeat Monitoring Samples	Routine Monitoring Samples	Additional Routine Monitoring Samples	Repeat Monitoring Samples
	A	B	C	D	E	F	G	H	I
Community Water Systems (CWSs) - SW									
≤100	304,098	23,747	19,160	308,849	-	12,875	308,849	-	12,875
101-500	562,214	26,578	21,338	567,486	-	15,333	567,486	-	15,333
501-1,000	306,733	14,501	11,641	309,610	-	8,366	309,610	-	8,366
1,001-4,100	1,920,789	55,202	33,730	1,950,717	-	32,222	1,950,717	-	32,222
4,101-33,000	10,636,296	-	186,781	10,636,296	-	175,689	10,636,296	-	175,689
33,001-96,000	11,058,960	-	194,204	11,058,960	-	182,671	11,058,960	-	182,671
96,001-500,000	10,190,400	-	178,951	10,190,400	-	168,324	10,190,400	-	168,324
500,001-1 Million	2,019,600	-	35,466	2,019,600	-	33,360	2,019,600	-	33,360
> 1 Million	1,686,960	-	29,624	1,686,960	-	27,865	1,686,960	-	27,865
Total	**38,686,051**	**120,028**	**710,896**	**38,728,879**	**-**	**656,704**	**38,728,879**	**-**	**656,704**
Community Water Systems (CWSs) - GW									
≤100	2,815,951	286,073	194,462	2,870,075	8,760	156,897	2,908,469	7,545	158,439
101-500	3,344,578	243,895	171,252	3,391,200	6,127	136,906	3,428,876	5,264	137,959
501-1,000	1,072,202	70,803	51,673	1,085,730	1,844	39,659	1,098,488	1,616	39,580
1,001-4,100	3,997,293	160,710	100,618	4,079,328	-	96,939	4,079,328	-	96,939
4,101-33,000	9,145,224	-	230,201	9,145,224	-	217,321	9,145,224	-	217,321
33,001-96,000	4,884,000	-	122,938	4,884,000	-	116,060	4,884,000	-	116,060
96,001-500,000	1,945,680	-	48,976	1,945,680	-	46,236	1,945,680	-	46,236
500,001-1 Million	253,440	-	6,380	253,440	-	6,023	253,440	-	6,023
> 1 Million	269,280	-	6,778	269,280	-	6,399	269,280	-	6,399
Total	**27,727,648**	**761,481**	**933,279**	**27,923,956**	**16,731**	**822,439**	**28,012,784**	**14,425**	**824,956**
Nontransient Noncommunity Water Systems (NTNCWSs) - SW									
≤100	65,009	4,918	4,005	65,986	-	2,840	65,986	-	2,840
101-500	66,038	3,734	3,008	66,766	-	2,073	66,766	-	2,073
501-1,000	22,970	1,299	1,046	23,223	-	721	23,223	-	721
1,001-4,100	41,740	2,147	1,351	42,751	-	1,183	42,751	-	1,183
4,101-33,000	50,424	-	1,632	50,424	-	1,395	50,424	-	1,395
33,001-96,000	34,320	-	1,111	34,320	-	950	34,320	-	950
96,001-500,000	31,680	-	1,025	31,680	-	877	31,680	-	877
500,001-1 Million	-	-	-	-	-	-	-	-	-
> 1 Million	-	-	-	-	-	-	-	-	-
Total	**312,182**	**12,097**	**13,179**	**315,151**	**-**	**10,038**	**315,151**	**-**	**10,038**
Nontransient Noncommunity Water Systems (NTNCWSs) - GW									
≤100	971,538	128,775	84,992	932,025	48,142	68,123	1,281,321	34,581	89,002
101-500	725,785	66,525	43,597	678,688	25,630	35,860	952,008	18,114	46,996
501-1,000	190,649	16,037	10,680	180,145	6,166	8,601	247,132	4,674	11,689
1,001-4,100	460,470	28,214	17,790	473,352	-	15,887	473,352	-	15,887
4,101-33,000	153,648	-	5,936	153,648	-	5,157	153,648	-	5,157
33,001-96,000	23,760	-	918	23,760	-	797	23,760	-	797
96,001-500,000	-	-	-	-	-	-	-	-	-
500,001-1 Million	-	-	-	-	-	-	-	-	-
> 1 Million	-	-	-	-	-	-	-	-	-
Total	**2,525,850**	**239,551**	**163,913**	**2,441,617**	**79,938**	**134,426**	**3,131,221**	**57,369**	**169,528**
Transient Noncommunity Water Systems (TNCWSs) - SW									
≤100	345,443	39,654	32,349	353,461	-	20,787	353,461	-	20,787
101-500	128,109	15,365	12,541	131,149	-	7,816	131,149	-	7,816
501-1,000	22,683	2,720	2,220	23,222	-	1,384	23,222	-	1,384
1,001-4,100	39,816	3,990	2,590	42,209	-	2,118	42,209	-	2,118
4,101-33,000	40,656	-	-	40,656	-	2,040	40,656	-	2,040
33,001-96,000	-	-	-	-	-	-	-	-	-
96,001-500,000	-	-	-	-	-	-	-	-	-
500,001-1 Million	-	-	-	-	-	-	-	-	-
> 1 Million	102,960	-	-	102,960	-	5,167	102,960	-	5,167
Total	**679,667**	**61,730**	**49,700**	**693,657**	**-**	**39,312**	**693,657**	**-**	**39,312**
Transient Noncommunity Water Systems (TNCWSs) - GW									
≤100	4,493,808	905,554	600,315	6,076,163	446,166	631,105	9,100,613	289,563	867,968
101-500	1,614,924	316,238	210,714	1,940,946	135,822	194,697	2,886,164	91,085	268,893
501-1,000	177,264	32,730	22,064	206,130	14,078	20,078	295,928	9,578	27,084
1,001-4,100	335,283	29,957	19,113	348,480	-	16,027	348,480	-	16,027
4,101-33,000	156,288	-	8,909	156,288	-	7,188	156,288	-	7,188
33,001-96,000	34,320	-	1,956	34,320	-	1,578	34,320	-	1,578
96,001-500,000	26,400	-	1,505	26,400	-	1,214	26,400	-	1,214
500,001-1 Million	63,360	-	3,612	63,360	-	2,914	63,360	-	2,914
> 1 Million	-	-	-	-	-	-	-	-	-
Total	**6,901,647**	**1,284,479**	**868,188**	**8,852,088**	**596,065**	**874,801**	**12,911,552**	**390,226**	**1,192,865**
Grand Total	**76,833,044**	**2,479,366**	**2,739,154**	**78,955,347**	**692,734**	**2,537,720**	**83,793,244**	**462,020**	**2,893,404**

Note: (B), (E), (H) For modeling purposes, additional routine sample counts include regular routine samples taken in the same month.

Source: Appendix A - Total PWS Counts (A.1z, A.2z, A.3z)

Exhibit VI-19 Annualized National PWS and State Monitoring Cost Estimates ($Millions, 2007$)

	3% discount rate	7% discount rate
TCR - Total	$ 179.57	$ 172.57
AIP - Total	$ 180.65	$ 173.46
AIP - Net Change	$ 1.08	$ 0.90
AIP - Percent Change	0.60%	0.52%
Alternative option – Total	$ 192.53	$ 187.53
Alternative option - Net Change	$ 12.96	$ 14.96
Alternative option - Percent Change	7.22%	8.67%

Note: Detail may not add due to independent rounding.
Source: Proposed RTCR EA (USEPA 2010a)

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The overall estimated increase in monitoring costs seen under the AIP is driven by increases in routine monitoring due to stricter requirements to qualify for reduced monitoring. However, this is mostly offset by reductions in additional routine and repeat monitoring required under the revised regulations. For the Alternative option, the requirement for all PWSs to sample on a monthly basis at the beginning of rule implementation results in a much larger cost differential that is only partially offset by reduced costs due to reductions in additional routine monitoring requirements.

d. *Annual site visits.* Under the AIP, any PWS on an annual monitoring schedule is required to also have an annual site visit conducted by the State or State-designated third party. A voluntary Level 2 site assessment can also satisfy the annual site visit requirement. For years in which the State performs a sanitary survey (at least every five years for NCWSs and three years for CWSs), a sanitary survey performed during the same year can also be used to satisfy this requirement. EPA uses the same assumptions to estimate costs associated with site visits for both the AIP and Alternative options.

e. *Assessments.* Annualized cost estimates for Level 1 and Level 2 assessments under the TCR, AIP, and Alternative options are calculated in the Proposed RTCR EA (USEPA 2010a) by multiplying the number of assessments estimated by the predictive modeling (summarized in Exhibit 7.13 of the EA) by the unit costs (summarized in Exhibits 7–11 and 7–12 of the EA). Appendix A of the Proposed RTCR EA (USEPA 2010a) provides a detailed breakout of the number of Level 1 and Level 2 assessments estimated by the occurrence model. Annualized cost estimates are presented in Exhibit VI–20 of this preamble.

Exhibit VI-20 Annualized National PWS Costs Estimates for Assessment Activity (current TCR) and Level 1 and Level 2 Assessments (AIP and Alternative Options) ($Millions, 2007$)

	3% discount rate	7% discount rate
	Level 1 Assessments	
TCR - Total	$ 1.13	$ 1.08
AIP - Total	$ 1.63	$ 1.57
AIP - Net Change	$ 0.50	$ 0.49
Alternative Option - Total	$ 1.73	$ 1.69
Alternative Option - Net Change	$ 0.60	$ 0.60
	Level 2 Assessments	
TCR - Total	$ 0.70	$ 0.68
AIP - Total	$ 0.90	$ 0.88
AIP - Net Change	$ 0.20	$ 0.20
Alternative Option - Total	$ 1.23	$ 1.27
Alternative Option - Net Change	$ 0.52	$ 0.60

Note: EPA estimated the level of assessment activity conducted by PWSs thought to occur under the current TCR, as discussed in chapter 7 of Proposed RTCR EA (USEPA 2010a)
Detail may not add due to independent rounding.
Source: Proposed RTCR cost model, described in chapter 7 of the Proposed RTCR EA (USEPA 2010a)

Under the proposed RTCR, all PWSs are required to conduct assessments of their systems when they exceed Level 1 or Level 2 treatment technique triggers. While PWSs are not required to conduct assessments under the current TCR, some PWSs do currently engage in assessment activity (which may or may not meet the proposed RTCR criteria) following non-acute and acute MCL violations. EPA estimates both the costs to PWSs to conduct assessments under the proposed RTCR as well as the level of effort that PWSs already put towards assessment activities under the current TCR. These estimates are based on the work of the stakeholders in the Technical Work Group (TWG) during the proceedings of the TCRDSAC. These estimates allowed EPA to determine the average net costs to conduct assessments under the proposed RTCR. EPA assumes that the numbers of non-acute and acute MCL violations would remain steady under a continuation of the current TCR (based on review of SDWIS/FED violation data). Under the proposed RTCR, EPA assumes that the numbers of assessments decreases from the steady state level seen under the current TCR over time to a new steady state level as a function of reduced fecal indicator occurrence associated with the effects of requiring assessments and corrective action.

The overall number of assessments is larger under the Alternative option compared to the AIP option. This is a result of the initial monthly monitoring requirements for all PWSs under this analysis. The modeling results indicate that a greater number of samples early in the implementation period results in more positive samples and associated assessments despite the predicted long term reductions in occurrence as informed by the assumptions. This increase in total assessments performed, combined with the higher unit cost of performing assessments compared to existing practices under the TCR, results in a higher net cost increase for the Alternative option than under the AIP. The total net change in cost for the Alternative option is estimated to be positive, and nearly twice as high as under the AIP option. *See* Exhibit 7.15 of the Proposed RTCR EA (USEPA 2010a).

f. *Corrective actions.* Under the AIP and Alternative options, all PWSs are required to correct sanitary defects found through the performance of Level 1 or Level 2 assessments. For modeling purposes, EPA estimated the net change in the number of corrective actions performed under the AIP and Alternative options. EPA assumed that any corrective actions based on a positive source water sample are accounted for under the GWR and not under the proposed RTCR. Based on discussions with State representatives, EPA assumed that additional corrective actions are performed for only 10 percent of the assessments undertaken as a result of the proposed RTCR representing the net increase over the current TCR.

To estimate the costs incurred for the correction of sanitary defects, EPA assumed the percent distribution of PWSs that perform different types of corrective actions as presented in the compliance forecast shown in Exhibit VI–21 based on best professional judgment. The compliance forecast presented in this section was informed by discussions of the TCRDSAC Technical Work Group and focuses on broad categories of types of corrective actions anticipated. EPA used best professional judgment to make simplifying assumptions on the distribution of these categories that are implemented by different systems based on size and type of system. For each of the categories listed, a PWS is assumed to take a specific action that falls under that general category. Detailed compliance forecasts showing the specific corrective actions used in the cost analysis are provided in Appendix D of the Proposed RTCR EA (USEPA 2010a), along with summary tables of the unit costs used in the analysis. Each corrective action in the detailed compliance forecast is also assigned a representative unit cost. Detailed descriptions of the derivation of unit costs are provided in Exhibits 5–1

through 5–47 of the *Technology and Cost Document for the Proposed Revised Total Coliform Rule* (USEPA 2010b).

Exhibit VI-21 Compliance Forecast for Corrective Actions based on Level 1 and Level 2 Assessments

PWS Size (Population Served)	PWS Flushing	Sampler Training	Replace/Repair of Distribution System Components	Maintenance of Adequate Pressure	Maintenance of appropriate Hydraulic Residence Time	Storage Facility Maintenance	Booster Disinfection	Cross-connection Control and Backflow Prevention	Addition or Upgrade of On-line Monitoring and Control	Addition of Security Measures	Development and Implementation of an Operations Plan
	A	B	C	D	E	F	G	H	I	J	K
Level 1 Compliance Forecast											
≤100	39%	15%	12%	9%	8%	6%	4%	1%	3%	1%	2%
101-500	39%	15%	12%	9%	8%	6%	4%	1%	3%	1%	2%
501-1,000	39%	15%	12%	9%	8%	6%	4%	1%	3%	1%	2%
1,001-4,100	39%	15%	12%	9%	8%	6%	4%	1%	3%	1%	2%
4,101-33,000	39%	15%	12%	9%	8%	6%	4%	1%	3%	1%	2%
33,001-96,000	39%	15%	12%	9%	8%	6%	4%	1%	3%	1%	2%
96,001-500,000	39%	15%	12%	9%	8%	6%	4%	1%	3%	1%	2%
500,001-1 Million	39%	15%	12%	9%	8%	6%	4%	1%	3%	1%	2%
> 1 Million	39%	15%	12%	9%	8%	6%	4%	1%	3%	1%	2%
Level 2 Compliance Forecast											
≤100	15%	4%	18%	15%	15%	11%	8%	2%	6%	2%	4%
101-500	15%	4%	18%	15%	15%	11%	8%	2%	6%	2%	4%
501-1,000	15%	4%	18%	15%	15%	11%	8%	2%	6%	2%	4%
1,001-4,100	15%	4%	18%	15%	15%	11%	8%	2%	6%	2%	4%
4,101-33,000	15%	4%	18%	15%	15%	11%	8%	2%	6%	2%	4%
33,001-96,000	15%	4%	18%	15%	15%	11%	8%	2%	6%	2%	4%
96,001-500,000	15%	4%	18%	15%	15%	11%	8%	2%	6%	2%	4%
500,001-1 Million	15%	4%	18%	15%	15%	11%	8%	2%	6%	2%	4%
> 1 Million	15%	4%	18%	15%	15%	11%	8%	2%	6%	2%	4%

Source: (A) - (K) Percent of PWSs performing corrective actions based on Level 1 and Level 2 assessments reflect EPA estimate.

As shown in the compliance forecast in Exhibit VI–21, EPA estimated that corrective actions found through Level 1 assessments result in corrective actions that focus more on transient solutions or training (columns A and B) than on permanent fixes to the PWS. However, in the case of flushing, EPA assumed that in a majority of instances, PWSs implement a regular flushing program as opposed to a single flushing, based on EPA and stakeholder best professional judgment. Level 1 assessments generally are less involved than Level 2 assessments and may result in finding less complex problems.

Corrective actions taken as a result of Level 2 assessments are expected to find a higher proportion of structural/technical issues (columns C–K) resulting in material fixes to the PWSs and distribution system. Consistent with the discussions of the TCRDSAC regarding major structural fixes or replacements, EPA did not include these major costs in the analysis. Distribution system appurtenances such as storage tanks generally have a useful life that is accounted for in water system capital planning and the assessments conducted in response to RTCR triggers could identify when that useful life has ended but are not solely responsible for the need to correct the defect. In addition, EPA ran two sensitivity analyses to assess the potential impacts of different distributions within the compliance forecast. Results of the sensitivity analyses are presented in Exhibit 7–24 of the Proposed RTCR EA (USEPA 2010a), which indicates that the low bound estimates of annualized net change in costs at three percent discount rate are approximately $3M for the AIP option and $15M for the Alternative option, and the high bound estimates are approximately $25M for the AIP option and $40M for the Alternative option. Varying the assumptions about the percentage of corrective actions identified and the effectiveness of those actions had less than a linear effect on outcomes, and the AIP option continues to be less costly than the Alternative option under all scenarios modeled.

As indicated in the more detailed analysis presented in chapter 7 of the Proposed RTCR EA (USEPA 2010a), PWSs also incur reporting and recordkeeping burden to notify the State upon completion of each corrective action. PWSs may also consult with the State or with outside parties to determine the appropriate corrective action to be implemented.

Annualized cost estimates for PWSs to perform corrective actions are estimated by multiplying the number of Level 1 and Level 2 corrective actions estimated by the predictive model, (*i.e.,* 10 percent of Level 1 and Level 2 assessments) by the percentages in the compliance forecast and unit costs of corrective actions and associated reporting and recordkeeping. Exhibit 7.13 of the proposed RTCR EA (USEPA 2010a) presents the estimated totals of non-acute and acute MCL violations (current TCR) and Level 1 and Level 2 assessments (AIP and Alternative options). The model predicts a total of approximately 109,000 single non-acute MCL violations, 58,000 cases of a second non-acute MCL violation, and 16,000 acute MCL violations for the current TCR, under which some PWSs currently engage in assessment activity which may or may not meet the proposed RTCR criteria (*see* section 7.4.5 of the proposed RTCR EA (USEPA 2010a) for details). For the AIP option, the model predicts approximately 104,000 Level 1 assessments and 52,000 Level 2 assessments. For the Alternative option, the model predicts approximately 115,000 Level 1 assessments and 78,000 Level 2 assessments. The total and net change costs of corrective actions are shown in Exhibit VI–22.

EXHIBIT VI–22—ANNUALIZED PWS COST ESTIMATES FOR CORRECTIVE ACTIONS BASED ON LEVEL 1 AND LEVEL 2 ASSESSMENTS

[$Millions, 2007$]

	3% Discount rate	7% Discount rate
	Corrective Actions based on Level 1 Assessments	
TCR—Total	.....	.....
AIP—Total	$9.17	$7.77
AIP—Net Change	9.17	7.77
Alternative option—Total	9.39	8.01
Alternative option—Net Change	9.39	8.01
	Corrective Actions based on Level 2 Assessments	
TCR—Total	.....	.....
AIP—Total	$2.72	$2.41
AIP—Net Change	2.72	2.41
Alternative option—Total	3.53	3.36
Alternative option—Net Change	3.53	3.36

Note: Detail may not add due to independent rounding.
Source: Proposed RTCR cost model, described in chapter 7 of the Proposed RTCR EA (USEPA 2010a).

The differences in the net change in corrective action costs between the AIP and Alternative option are a function of the different number of assessments estimated to be performed in the predictive model.

g. *Public notification.* Estimates of PWS unit costs for PN are derived by multiplying PWS labor rates from section 7.2.1 of the Proposed RTCR EA (USEPA 2010a) and burden hour estimates derived from the *Draft Information Collection Request for the Public Water System Supervision Program* (USEPA 2008c). PWS PN unit cost estimates are presented in Exhibit 7.19 of that document.

Total and net change in annualized net present value costs for PN are estimated by multiplying the model estimates of PWSs with acute (Tier 1 public notification) and non-acute (Tier 2 public notification) violations by the PWS unit costs for performing PN activities. The proposed RTCR cost model assumed that all violations are addressed following initial PN, and no burden is incurred by PWSs for repeat notification. Annualized total and net cost estimates for PWSs and States to perform public notification under the TCR, AIP, and Alternative options are presented in Exhibit VI–23.

EXHIBIT VI–23—ANNUALIZED NATIONAL PWS COST ESTIMATES FOR PUBLIC NOTIFICATION

[$Millions, 2007$]

	3% Discount rate	7% Discount rate
TCR—Total	$3.75	$3.60
AIP—Total	$0.26	$0.26
AIP—Net Change	$(3.49)	$(3.35)
AIP—Percent Change	−93%	−93%
Alternative Option—Total	$0.34	$0.35
Alternative Option—Net Change	$(3.41)	$(3.26)
Alternative Option—Percent Change	−91%	−90%

Note: Detail may not add due to independent rounding.
Source: Proposed RTCR cost model, described in chapter 7 of the Proposed RTCR EA (USEPA 2010a).

A significant reduction in costs is estimated due to the elimination of Tier 2 public notification for non-acute/monthly MCL violations under both the AIP and Alternative options.

3. State Costs

EPA estimated that all States nationally together incur a net increase in national annualized present value costs under the AIP option of $0.1M (at three percent discount rate) and $0.4M (at seven percent discount rate) and under the Alternative option of $0.3M (at three percent discount rate) and $0.6M (at seven percent discount rate). State costs include implementing and administering the rule, revising sampling plans, reviewing sampling results, conducting annual site visits, reviewing completed assessment forms, tracking corrective actions, and public notifications. The following sections summarize the key assumptions that EPA made to estimate the costs of the proposed RTCR. Chapter 7 of the Proposed RTCR EA (USEPA 2010a) provides a description of the analysis.

a. *Rule implementation and annual administration.* States incur administrative costs to implement the proposed RTCR. These implementation costs are not directly required by specific provisions of the proposed RTCR alternatives, but are necessary for States to ensure the provisions of the proposed RTCR are properly carried out. States need to allocate time for their staff to establish and maintain the programs necessary to comply with the proposed RTCR, including developing and adopting State regulations and

modifying data management systems to track new required PWS reports to the States. Time requirements for a variety of State agency activities and responses are estimated in this EA. Exhibit 7.4 of the Proposed RTCR EA (USEPA 2010a) lists the activities required to revise the program following promulgation of the proposed RTCR along with their respective costs and burden including, for example, the net change in State burden associated with tracking the monitoring frequencies of PWSs (captured under "modify data management systems"). EPA estimated a net increase in national annualized cost estimates incurred by States for rule implementation of $0.18M (three percent discount rate) and $0.26M (seven percent discount rate) under either the AIP or the Alternative option. Because time requirements for implementation and annual administration activities vary among State agencies, EPA recognizes that the unit costs used to develop national estimates may be an over- or under-estimate for some States.

b. *Revising sampling plans.* Under the AIP and Alternative options, States are expected to incur one-time costs to review sampling plans and recommend any revisions to PWSs. Under the TCR option, no additional burden or costs are incurred by States to review sampling plans, as these PWSs' sampling plans have already been reviewed and approved. State costs are based on the number of PWSs submitting revised sampling plans to PWSs each year. Based on previous experience, EPA estimated that States require one to four hours to review revised sampling plans and provide any necessary revisions to PWSs, depending on PWS size. EPA estimated a net increase in national annualized cost estimates incurred by States for revising sampling plans of $0.42M (three percent discount rate) and $0.59M (seven percent discount rate) under either the AIP or the Alternative option.

c. *Monitoring.* EPA assumed that States incur a monthly 15-minute burden to review each PWS's sample results under the current TCR. This estimate reflects the method used to calculate reporting and recordkeeping burden under the current TCR in the *Draft Information Collection Request for the Microbial Rules* (USEPA 2008a). Because the existing method calculates cost on a per PWS basis and the total number of PWSs is the same for cost modeling under the TCR and both proposed RTCR options, the net change in costs for reviewing monitoring results is assumed to be zero for the AIP and Alternative options. Specific actions by States related to positive samples are accounted for under the actions required in response to those samples.

d. *Annual site visits.* Under the AIP option, any PWS on an annual monitoring schedule is required to also have an annual site visit conducted by the State or State-designated third party. A voluntary Level 2 site assessment can also satisfy the annual site visit requirement. In many cases a sanitary survey performed during the same year can also be used to satisfy this requirement. Although similar site visits are not currently required under the current TCR, discussions with States during the TCRDSAC proceedings revealed that some do, in fact, conduct such site visits for PWSs on annual monitoring schedules. Because of the high cost for an annual site visit by a State, for this analysis EPA assumed that no States choose to conduct annual site visits unless they already do so under the current TCR. Therefore, for overall costing purposes, no net change in State or PWS costs are assumed for annual monitoring site visits under the AIP option or Alternative option.

e. *Assessments.* States incur burden to review completed assessment forms required to be filed by PWSs under the AIP and Alternative options. Although specific forms are not required under the current TCR, EPA assumes that PWSs engage in some form of consultation with the State. For costing purposes, EPA assumes that the level of effort required for such consultations under the current TCR is the same as that which would be required to review assessment forms under the AIP and Alternative options. State costs are based on the number of PWSs submitting assessment reports. EPA estimated that State burden to review PWS assessment forms ranges from one to eight hours depending on PWS size and type, as well as the level of the assessment. This burden includes any time required to consult with the PWS about the assessment report.

Although some States may choose to conduct assessments for their PWSs, EPA does not quantify these costs. The costs are attributed to PWSs that are responsible for insuring that assessments are done.

The reduction in the number of assessments under the AIP option compared to the current TCR (as explained in chapter 7 of the Proposed RTCR EA (USEPA 2010a), based on discussions with the technical workgroup supporting the advisory committee, EPA assumes a certain level of assessment activity already occurs under the current TCR) is estimated to translate directly to a small national cost savings ($0.08M at either three or seven percent discount rate) while the increase in the number of assessments under the Alternative option is estimated to translate directly to a national cost increase ($0.03M at three percent discount rate and $0.07M at seven percent discount rate). Under the AIP, the overall number of assessments decreases as a function of reduced occurrence over time. The overall number of assessments is higher under the Alternative option as a result of the initial monthly monitoring requirements for all PWSs.

f. *Corrective actions.* For each corrective action performed under AIP and Alternative option, States incur recordkeeping and reporting burden to review and coordinate with PWSs. This includes burden incurred from any optional consultations States may conduct with PWSs or outside parties to determine the appropriate corrective action to be implemented. The number of corrective actions under either the AIP or Alternative option is estimated to translate to a national net annualized cost increase to States of $0.01M at either three or seven percent discount rate

g. *Public notification.* Under the TCR, AIP, and Alternative options, States incur recordkeeping and reporting burden to provide consultation, review the public notification certification, and file the report of the violation. A significant reduction in costs is estimated due to the elimination of Tier 2 public notification for non-acute MCL violations under the AIP and Alternative options. Because State costs are calculated on a per-violation basis, State costs decline. Under the Alternative option, some of the decrease in cost is offset by additional Tier 1 public notification from the increase in the number of *E. coli* MCL violations detected. Burden hour estimate for State unit PN costs are derived from the *Draft Information Collection Request for the Public Water System Supervision Program* (USEPA 2008b). Exhibit VI–24 summarizes annualized State cost estimates for public notification.

EXHIBIT VI–24—ANNUALIZED STATE COST ESTIMATES FOR PUBLIC NOTIFICATION

[$Millions, 2007$]

	3% Discount rate	7% Discount rate
TCR—Total	$0.44	$0.42
AIP—Total	$0.06	$0.06
AIP—Net Change	$(0.38)	$(0.36)
AIP—Percent Change	−86%	−86%
Alternative Option—Total	$0.08	$0.08
Alternative Option—Net Change	$(0.36)	$(0.34)
Alternative Option—Percent Change	−82%	−80%

Note: Detail may not add due to independent rounding.
Source: Proposed RTCR cost model, described in chapter 7 of the Proposed RTCR EA (USEPA 2010a).

4. Nonquantifiable Costs

EPA believes that all of the rule elements that are the major drivers of the net change in costs from the current TCR have been quantified to the greatest degree possible. However, cost reductions related to fewer monitoring and reporting violations are not specifically accounted for in the cost analysis, and their exclusion from consideration may result in an overestimate of net change in cost between the TCR option and the AIP option or Alternative option.

In addition under the TCR, AIP, and Alternative options, Tier 3 public notification for monitoring and reporting violations are assumed to be reported once per year as part of the Consumer Confidence Reports (CCRs). Because of the use of the CCR to communicate Tier 3 public notification on a yearly basis, no cost differential between the current TCR and the AIP and Alternative options is estimated in the cost model. However, the advisory committee concluded that significant reductions in monitoring and reporting violations may be realized through the revised regulatory framework of the proposed RTCR, which includes new consequences for failing to comply with monitoring provisions such as the requirement to conduct an assessment or ineligibility for reduced monitoring. These possible reductions have not been quantified. System resources used to process monitoring violation notices for the CCR and respond to customer inquiries about the notices, as well as State resources to remind systems to take samples, may be reduced if significant reductions are realized. Exclusion of this potential cost savings may lead to an underestimate of the PN cost savings under both the AIP and Alternative option. Such cost savings to States may be significant given the high occurrence of monitoring and reporting violations under the current TCR.

Additionally, as an underlying assumption to the costing methodology, EPA assumed that all PWSs subject to the proposed RTCR requirements are already complying with the current TCR. There may be some PWSs that are not in full compliance with the current TCR, and if so, additional costs and benefits are incurred.

G. Potential Impact of the Proposed RTCR on Households

The household cost analysis considers the potential increase in a household's annual water bill if a CWS passed the entire cost increase resulting from the proposed rule on to their customers. This analysis is a tool to gauge potential impacts and should not be construed as a precise estimate of potential changes to household water bills. State costs and costs to TNCWSs and NTNCWSs are not included in this analysis since their costs are not typically passed through directly to households. Exhibit VI–25 presents the mean expected increases in annual household costs for all CWSs, including those systems that do not have to take corrective action. Exhibit VI–25 also presents the same information for CWSs that must take corrective action. Household costs tend to decrease as system size increases, due mainly to the economies of scale for the corrective actions.

The first category in Exhibit VI–25 presents net costs per household under the AIP and Alternative options for all rule components spread across all CWSs. In this scenario, comparison to the current TCR shows a cost savings for some households. For those households that are expected to see a cost increase, the average annual water bill is expected to increase by less than five cents on average.

While the average increase in annual household water bills to implement the AIP option is less than a dollar, customers served by a small CWS that have to take corrective actions as a result of the proposed rule incur slightly larger increases in their water bills. The subsequent categories of the exhibit present net costs per household for three different subsets of CWSs: (1) CWSs that perform assessments but no corrective actions, (2) CWSs that perform corrective actions, and (3) CWSs that do not perform assessments or corrective actions. Approximately 77 percent of households are served by CWSs that perform assessments but do not perform corrective actions over the 25-year period of analysis (because no sanitary defects are found). These households experience a slight cost savings on an annual basis. The nine percent of households belonging to CWSs that perform corrective actions over the 25-year period of analysis experience an increase in annual net household costs of less than $0.70 on average for CWSs serving greater than 4,100 people to approximately $4 on average for CWSs serving 4,100 or fewer people on an annual basis. EPA estimated that 14 percent of households are served by CWSs that do not perform assessments or corrective actions over the 25-year period of analysis. This group of households served by small systems (4,100 or fewer people) experiences a slight cost change on an annual basis, comparable to those performing assessments but no corrective actions. Overall, the main driver of additional household costs under the proposed RTCR is corrective actions.

EXHIBIT VI–25—SUMMARY OF NET ANNUAL PER-HOUSEHOLD COSTS FOR THE PROPOSED RTCR (2007$)

Population served by PWS	3% Discount rate		7% Discount rate	
	AIP option net cost per household	Alternative option net cost per household	AIP option net cost per household	Alternative option net cost per household
All Community Water Systems (CWSs)				
≤ 4,100	$0.07	$0.09	$0.10	$0.12
> 4,100	0.05	0.05	0.04	0.04
Total	0.05	0.06	0.05	0.05
Community Water Systems (CWSs) performing Level 1/Level 2 Assessments (and no Corrective Actions)				
≤ 4,100	(0.22)	(0.19)	(0.16)	(0.13)
> 4,100	(0.02)	(0.01)	(0.01)	(0.01)
Total	(0.02)	(0.01)	(0.01)	(0.01)
Community Water Systems (CWSs) performing Corrective Actions				
≤ 4,100	4.11	4.14	3.63	3.68
> 4,100	0.65	0.65	0.54	0.54
Total	0.78	0.78	0.66	0.66
Community Water Systems (CWSs) not performing Level 1/Level 2 Assessments, or Corrective Actions				
≤ 4,100	0.00	0.02	0.04	0.06
> 4,100	0.00	0.00	0.00	0.00
Total	0.00	0.01	0.01	0.02

Source: Proposed RTCR EA (USEPA 2010a).

H. Incremental Costs and Benefits

The proposed RTCR regulatory options achieve increasing levels of benefits at increasing levels of costs. The regulatory options for this proposed rule, in order of increasing costs and benefits (Option 1 lowest, and option 3 highest) are as follows:

- *Option 1:* Current TCR option
- *Option 2:* AIP option
- *Option 3:* Alternative option

More information about the options is provided in the Proposed RTCR EA (USEPA 2010a).

Incremental costs and benefits are those that are incurred or realized to reduce potential illnesses and deaths from one alternative to the next more stringent alternative. Estimates of incremental costs and benefits are useful when considering the economic efficiency of different regulatory alternatives considered by EPA. One goal of an incremental analysis is to identify the regulatory alternatives where net social benefits are maximized. However, incremental net benefits analysis is not possible when benefits are not monetized as in the case with the proposed RTCR.

However, incremental analysis can still provide information on relative cost-effectiveness of different regulatory options. For the proposed RTCR, only costs were monetized. While benefits were not quantified, an indirect proxy for benefits was. To compare the additional net cost increases and associated incremental benefits of the AIP and the Alternative options, benefits are presented in terms of corrective actions performed since performance of corrective actions is expected to have an impact that is most directly translatable into potential health benefits.

Exhibit VI–26 shows the incremental cost of the AIP over the current TCR and the Alternative option over the AIP option for costs annualized using three percent and seven percent discount rates. The incremental benefits of the Alternative option in terms of incremental corrective actions performed (114 at three percent and 135 and seven percent discount rates) are fewer than for the AIP (202 at three percent and 189 at seven percent discount rates), despite the increased costs. The non-monetized corrective action endpoints are discounted in order to make them comparable to monetized endpoints. The relationship between the incremental costs and benefits is examined further with respect to cost effectiveness in section VI.M of this preamble.

EXHIBIT VI–26—INCREMENTAL NET CHANGE IN ANNUALIZED PRESENT VALUE COSTS ($MILLIONS, 2007$) AND BENEFITS (NUMBER OF CORRECTIVE ACTIONS)

Regulatory option	Costs		Benefits (L2 corrective actions)	
	3%	7%	3%	7%
Current TCR	$186.1	$178.4	[3] No change	[3] No change
AIP	199.8	192.5	202	189
Incremental AIP [1]	13.7	13.7	202	189

EXHIBIT VI–26—INCREMENTAL NET CHANGE IN ANNUALIZED PRESENT VALUE COSTS ($MILLIONS, 2007$) AND BENEFITS (NUMBER OF CORRECTIVE ACTIONS)—Continued

Regulatory option	Costs		Benefits (L2 corrective actions)	
	3%	7%	3%	7%
Alternative	213.3	208.5	317	323
Incremental Alternative [2]	13.5	16.0	114	135

[1] Represents the incremental net change of the AIP option over the current TCR option.

[2] Represents the incremental net change of the Alternative option over the AIP option. Add incremental net change for Alternative option to incremental net change for AIP option to calculate the total net change of the Alternative option over the current TCR option.

Note: The RTCR occurrence model yields the number of corrective actions that are expected to be implemented in addition to (net of) those already implemented under the current TCR. The model does not incorporate an estimate of the number of corrective actions implemented per year under the current TCR and does not yield a total for the AIP and Alternative option that includes the current TCR corrective actions. Benefits shown include corrective actions based on L2 assessments. Detailed benefits and cost information is provided in Appendices A and C, respectively, of the Proposed RTCR EA (USEPA 2010a).

[3] As explained in section VI.F.2.f of this preamble, for modeling purposes, EPA estimates the net change only in the number of corrective actions performed under the AIP and Alternative options compared to the current TCR and thus did not quantify the (non-zero) baseline number of corrective actions performed under the Current TCR.

I. Benefits From Simultaneous Reduction of Co-Occurring Contaminants

As discussed in section VI.E, the potential benefits from the proposed RTCR include avoidance of a full range of health effects from the consumption of fecally contaminated drinking water, including the following: acute and chronic illness, endemic and epidemic disease, waterborne disease outbreaks, and death.

Systems may choose corrective actions that also address other drinking water contaminants. For example, correcting for a pathway of potential contamination into the distribution system can mitigate a variety of potential contaminants. For example, eliminating a cross connection reduces the potential for chemical contamination as well as microbial. Due to a lack of contamination co-occurrence data that could relate to the effect that treatment corrective action may have on contamination entering through distribution system pathways, EPA has not quantified such potential benefits.

J. Change in Risk From Other Contaminants

All surface water systems are already required to disinfect under the SWTR (USEPA 1989b, 54 FR 27486, June 29, 1989) but this rule could impact currently non-disinfecting ground water systems. When disinfection is first introduced into a previously undisinfected GW system, the disinfectant can react with pipe scale causing increased risk from some contaminants that may be entrained in the pipe scales and other water quality problems. Examples of contaminants that could be released include lead, copper, and arsenic. Disinfection could also possibly lead to a temporary discoloration of the water as the scale is loosened from the pipe. These risks can be addressed by gradually phasing in disinfection to the system, by targeted flushing of distribution system mains, and by maintaining a proper corrosion control program.

Introducing a disinfectant could also result in an increased risk from disinfection byproducts (DBPs). Risk from DBPs has already been addressed in the Stage 1 Disinfection Byproducts Rule (DBPR) (USEPA 1998c) and additional consideration of DBP risk has been addressed in the final Stage 2 DBPR (USEPA 2006e). In general, ground water systems are less likely to experience high levels of DBPs than surface water systems because they have lower levels of naturally occurring organic materials (generally represented by total organic carbon (TOC)) that contribute to DBP formation.

EPA does not expect many previously undisinfected systems to add disinfection as a result of either the AIP or Alternative rule options. Ground water systems that are not currently disinfecting may eventually install disinfection if RTCR distribution system monitoring and assessments, and/or subsequent source water monitoring required under the GWR, result in the determination that source water treatment is required. However, these impacts were already accounted for and costed under the GWR and EPA does not project additional systems switching to disinfection as a result of the RTCR. *See* section 7.4.6 of the Proposed RTCR EA (USEPA 2010a) for a discussion on corrective action.

K. Effects of Fecal Contamination and/or Waterborne Pathogens on the General Population and Sensitive Subpopulations

As discussed previously in this preamble, fecal contamination may contain waterborne pathogens including bacteria, viruses, and parasitic protozoa. Fecal contamination and waterborne pathogens can cause a variety of illnesses, including acute gastrointestinal illness (AGI) with diarrhea, abdominal discomfort, nausea, vomiting, and other symptoms. Most AGI cases are of short duration and result in mild illness. Other more severe illnesses caused by waterborne pathogens include hemolytic uremic syndrome (HUS) (kidney failure), hepatitis, and bloody diarrhea (WHO 2004). Chronic disease such as irritable bowel syndrome, reduced kidney function, hypertension and reactive arthritis can result from infection by a waterborne agent (Clark *et al.* 2008).

When humans are exposed to and infected by an enteric pathogen, the pathogen becomes capable of reproducing in the gastrointestinal tract. As a result, healthy humans shed pathogens in their feces for a period ranging from days to weeks. This shedding of pathogens often occurs in the absence of any signs of clinical illness. Regardless of whether a pathogen causes clinical illness in the person who sheds it in his or her feces, the pathogen being shed may infect other people directly by person-to-person spread, contact with contaminated surfaces, and other means which are referred to as secondary spread. As a result, waterborne pathogens that are initially waterborne may subsequently infect other people through a variety of routes (WHO 2004).

The general population typically experiences acute gastrointestinal illness (some illnesses may be severe such as kidney failure) when exposed to fecal contamination and/or waterborne pathogens. When sensitive subpopulations experience the same exposure as the general population,

more severe illness (and sometimes death) can occur.

Examples of sensitive subpopulations are provided in chapter 2 of the Proposed RTCR EA (USEPA 2010a). This section discusses the potential health effects associated with sensitive population groups, especially children, pregnant women, and the elderly.

It is anticipated that the requirements of the proposed RTCR will help reduce pathways of entry for fecal contamination and/or waterborne pathogens into the distribution system, thereby reducing risk to both the general population as well as to sensitive subpopulations.

1. Risk to Children, Pregnant Women, and the Elderly

Children and the elderly are particularly vulnerable to kidney failure (hemolytic uremic syndrome) caused by the pathogenic bacterium *E. coli* O157:H7. Waterborne outbreaks due to *E. coli* O157:H7 have caused kidney failure in children and the elderly as the result of disease outbreaks from consuming ground water in Cabool, Missouri (Swerdlow *et al.* 1992); Alpine, Wyoming (Olsen *et al.* 2002); Washington County, New York (NY State DOH 2000); and Walkerton, Ontario, Canada (Health Canada 2000).

The risk of acute illness and death due to viral contamination of drinking water depends on several factors, including the age of the exposed individual. Infants and young children have higher rates of infection and disease from enteroviruses than other age groups (USEPA 1999). Several enteroviruses that can be transmitted through water can have serious health consequences in children. Enteroviruses (which include poliovirus, coxsackievirus, and echovirus) have been implicated in cases of flaccid paralysis, myocarditis, encephalitis, hemorrhagic conjunctivitis, and diabetes mellitus (Dalldorf and Melnick 1965; Smith 1970; Berlin *et al.* 1993; Cherry 1995; Melnick 1996; CDC 1997; Modlin 1997). Women may be at increased risk from enteric viruses during pregnancy (Gerba *et al.* 1996). Enterovirus infections in pregnant women can also be transmitted to the unborn child late in pregnancy, sometimes resulting in severe illness in the newborn (USEPA 2000d).

Waterborne viruses can also be particularly harmful to children. Rotavirus disproportionately affects children less than five years of age (Parashar *et al.* 1998). However, the pentavalent rotavirus vaccine licensed for use in the United States has been shown to be 74 percent effective against rotavirus gastroenteritis of any severity (Dennehy 2008). For echovirus, children are disproportionately at risk of becoming ill once infected (Modlin 1986). According to CDC, echovirus is not a vaccine-preventable disease (CDC 2009).

The elderly are particularly at risk from diarrheal diseases (Glass *et al.* 2000) such as those associated with waterborne pathogens in the US. Approximately 53 percent of diarrheal deaths occur among those older than 74 years of age, and 77 percent of diarrheal deaths occur among those older than 64 years of age. In Cabool, Missouri (Swerdlow *et al.* 1992), a waterborne *E. coli* O157:H7 outbreak in a ground water system resulted in four deaths, all among the elderly. One death occurred from hemolytic uremic syndrome (kidney failure), the others from gastrointestinal illness.

Hospitalizations due to diarrheal disease are higher in the elderly than younger adults (Glass *et al.* 2000). Average hospital stays for individuals older than 74 years of age due to diarrheal illness are 7.4 days compared to 4.1 days for individuals aged 20 to 49 (Glass *et al.* 2000).

It is anticipated that the requirements of the proposed RTCR will help reduce pathways of entry for fecal contamination and/or waterborne pathogens into the distribution system, thereby reducing risk to both the general population as well as to sensitive subpopulations such as children, pregnant women, and the elderly.

2. Risk to Immunocompromised Persons

AGI symptoms may be more severe in immunocompromised persons (Frisby *et al.* 1997; Carey *et al.* 2004). Such persons include those with acquired immune deficiency syndrome (AIDS), cancer patients undergoing chemotherapy, organ transplant recipients treated with drugs that suppress the immune system, and patients with autoimmune disorders such as lupus. In AIDS patients, *Cryptosporidium,* a waterborne protozoa, has been found in the lungs, ear, stomach, bile duct, and pancreas in addition to the small intestine (Farthing 2000). Immunocompromised patients with severe persistent cryptosporidiosis may die (Carey *et al.* 2004).

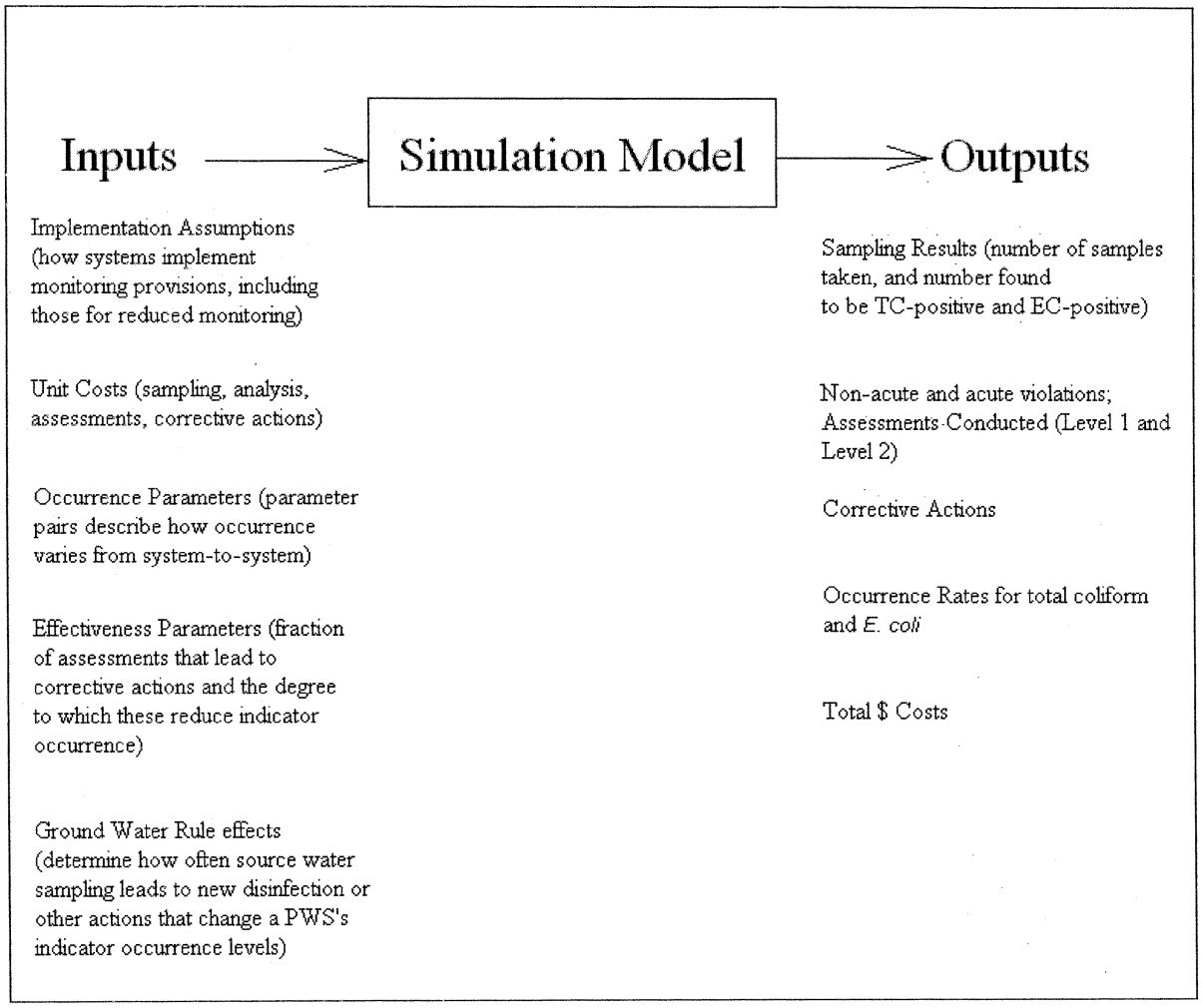
For the immunocompromised, Gerba *et al.* (1996) reviewed the literature and reported that enteric adenovirus and rotavirus are the two waterborne viruses most commonly isolated in the stools of AIDS patients. For patients undergoing bone-marrow transplants, several studies cited by Gerba *et al.* (1996) reported mortality rates greater than 50 percent among patients infected with enteric viruses.

It is anticipated that the requirements of the proposed RTCR will help reduce pathways of entry for fecal contamination and/or waterborne pathogens into the distribution system, thereby reducing risk to both the general population as well as to sensitive subpopulations such as the immunocompromised.

L. Uncertainties in the Benefit and Cost Estimates for the Proposed RTCR

A computer simulation model was used to estimate costs and indicators of benefits of the proposed RTCR. Exhibit VI–27 shows that these outputs depend on a number of key model inputs. This section describes analyses that were conducted to understand how uncertainties in these inputs contributed to uncertainty in model outputs.

Exhibit VI-27 Simulation Model, Inputs, and Outputs



1. Inputs and Their Uncertainties

It is anticipated that the requirements of the proposed RTCR will help reduce pathways of entry for fecal contamination and/or waterborne pathogens into the distribution system, thereby reducing exposure and illness from these contaminants in drinking water.

These exposure and illness reductions could not be modeled and estimated quantitatively, due to a lack of a quantitative relationship between indicators and pathogens. Section VI.E.3 of this preamble and chapter 6 of the Proposed RTCR EA (USEPA 2010a) discuss this issue qualitatively.

Model outputs include two important indicators of microbial exposure: *E. coli* occurrence in routine total coliform samples and the occurrence of Level 1 and 2 assessments. These outputs were monitored as endpoints in the sensitivity analyses described in this section.

Quantified national cost estimates include costs of required monitoring, assessments, corrective actions, and public notifications. Total costs were monitored as end-points in the sensitivity analyses described in this section.

None of the inputs shown in Exhibit VI–27 is perfectly known, so each has some degree of uncertainty. Some of these inputs are informed directly by data, so their uncertainties are due to limitations of the data. For example, uncertainty about the statistical model used to characterize occurrence is due to the limited numbers of systems and measurements per system in the Six-Year Review 2 dataset (USEPA 2010e). Other inputs are informed by professional judgment, so their uncertainties are expressed in terms of reasonable upper and lower bounds that are, themselves, based on expert judgment. For example, 10 percent of assessments (representing the incremental increase over the current TCR) are expected to result in effective corrective actions, based on professional judgment, with reasonable upper and lower bounds of 20 percent and 5 percent, respectively.

Sensitivity analyses were conducted to assess the degree to which uncertainties about selected inputs contribute to uncertainty in the resulting cost estimates. The analyses focused on the inputs that are listed in Exhibit VI–27. Varying the assumptions about the percentages of corrective actions identified and the effectiveness of those actions has a less than linear effect on outcomes, and the AIP option continues to be less costly than the Alternative option under all scenarios modeled. Exhibits 5.22a and 5.22b of the Proposed RTCR EA (USEPA 2010a) provide summaries of the driving model parameters and indicate where in the proposed RTCR EA the full discussion of uncertainty on each parameter is contained.

Not shown in Exhibit VI–27 are some inputs that are very well known. These are inventory data, which include the list of all PWSs affected by the proposed RTCR and, for each system, information on its source water type, disinfection practice, and population served. Although this information is not perfect, any uncertainty is believed to have negligible impact on model outputs. EPA did not conduct sensitivity analyses to evaluate the importance of these small uncertainties.

2. Sensitivity Analysis

Default values of the model inputs are considered reasonable best-estimates. Model outputs that are obtained when the inputs are set to these default values are also considered to be reasonable best-estimates. EPA conducted sensitivity analyses to learn how much the outputs might change when individual inputs are changed from their default values. The approach taken was to change each input to some reasonable upper and lower bounds, based on professional judgment.

Many of the uncertainties are expected to impact the model output in a similar fashion for the current TCR, AIP, and the Alternative options. For example, an increase in a total coliform occurrence tends to increase the total cost and benefit estimates for all of the rule alternatives. Because the benefit and cost analyses focus on net changes among the current TCR, AIP, and Alternative options, these common sources of uncertainty may tend to cancel out in the net change analyses. Other uncertainties were expected to have stronger influence on net changes among the current TCR, AIP, and Alternative options because they influence some options, but not others. For example, assumptions about the effectiveness of corrective actions influences total costs of the proposed RTCR options, but not the current TCR option itself.

Results of the sensitivity analyses (reported in the Proposed RTCR EA (USEPA 2010a)) showed that the fundamental conclusions of the economic analysis do not change over a wide range of assumptions. Both the AIP and Alternative options provide benefits as compared to the current TCR. Varying key assumptions has a less than linear effect on outcomes, and the AIP option continues to be less costly than the Alternative option under all scenarios modeled. *See* section 5.3.3.1 of the Proposed RTCR EA (USEPA 2010a) for details.

M. Benefit Cost Determination for the Proposed RTCR

Pursuant to SDWA section 1412(b)(6)(A), EPA has determined that the benefits of the proposed RTCR justify the costs. In making this determination, EPA considered quantified and nonquantified benefits and costs as well as the other components of the HRRCA outlined in section 1412(b)(3)(C) of the SDWA.

Additionally, EPA used several other techniques to compare benefits and costs including a break-even analysis and a cost effectiveness analysis. The break-even analysis (*see* chapter 9 of the Proposed RTCR EA (USEPA 2010a)) was conducted using two example pathogens responsible for some (unknown) proportion of waterborne illnesses in the United States: shiga toxin-producing EC O157:H7 [1] (STEC O157:H7) and *Salmonella.* Based on either example pathogen considered in the breakeven analysis, a small number of fatal cases annually would need to be avoided, relative to the CDC's estimate of cases caused by waterborne pathogens, in order to break even with rule costs. For example, under the AIP option, just two deaths would need to be avoided annually using a 3 percent discount rate based on consideration of the bacterial pathogen STEC O157:H7. Alternatively, approximately 3,000 or 8,000 non-fatal cases, using the enhanced or traditional benefits valuations approaches,[2] respectively, would need to be avoided to break even with rule costs. As expected based on its costs, the lower cost of the AIP option relative to the Alternative option means that fewer cases need to be avoided in order to break even. *See* Exhibit VI–28.

As Exhibit VI–28 shows, approximately 2 deaths would need to be avoided from a *Salmonella* infection for the rule to break even. The estimated number of non-fatal *Salmonella* cases that would need to be avoided to break even is approximately 10,000 or 65,000 cases under the enhanced and traditional benefits valuations approaches, respectively. Given the large number of potential waterborne pathogens shown to occur in PWSs and the relatively low net costs of the proposed RTCR, EPA believes, as discussed in this section and in the Proposed RTCR EA (USEPA 2010a), that the AIP option is likely to at least break even. Chapter 9 of the Proposed RTCR EA (USEPA 2010a) has a complete discussion of the break-even analysis and how costs per case were calculated.

EXHIBIT VI–28—ESTIMATED BREAKEVEN THRESHOLD FOR AVOIDED CASES OF E. COLI O157:H7 AND SALMONELLA

Cost of illness (COI) methodology	Discount rate (percent)	AIP option		Alternative option	
		Non-fatal cases only	Fatal cases only [1]	Non-fatal cases only	Fatal cases only [1]
E. coli O157:H7:					
Traditional COI	3	8,000	1.6	16,000	3.1
	7	8,000	1.5	17,000	3.4
Enhanced COI	3	3,000	1.6	5,000	3.1
	7	3,000	1.5	6,000	3.4
Salmonella:					
Traditional COI	3	65,000	1.6	130,000	3.1
	7	65,000	1.6	141,000	3.4
Enhanced COI	3	10,000	1.6	20,000	3.1

[1] According to the Web site of the American Academy of Family Physicians (*http://www.aafp.org/afp/20000401/tips/11.html*), "Shiga toxin-producing *Escherichia coli* is a group of bacteria strains capable of causing significant human disease. The pathogen is transmitted primarily by food and has become an important pathogen in industrialized North America. The subgroup enterohemorrhagic *E. coli* includes the relatively important serotype O157:H7, and more than 100 other non-O157 strains."

[2] Both traditional and enhanced COI approaches count the value of the direct medical costs and of time lost that would been spent working for a wage, but differ in their assessment of the value of time lost that would be spent in nonmarket work (*e.g.*, housework, yardwork, and raising children) and leisure (*e.g.*, recreation, family time, and sleep). They also differ in their valuation of (other) disutility, which encompasses a range of factors of well being, including both inconvenience and any pain and suffering. A complete discussion of the traditional and enhanced COI approaches can be found in Appendix E of the RTCR EA (USEPA 2010a).

EXHIBIT VI–28—ESTIMATED BREAKEVEN THRESHOLD FOR AVOIDED CASES OF E. COLI O157:H7 AND SALMONELLA—Continued

Cost of illness (COI) methodology	Discount rate (percent)	AIP option		Alternative option	
		Non-fatal cases only	Fatal cases only [1]	Non-fatal cases only	Fatal cases only [1]
	7	10,000	1.6	21,000	3.4

[1] Calculations for fatal cases include the non-fatal cost of illness (COI) component for the underlying illness prior to death.

Note: The number of cases needed to reach break-even threshold is calculated by dividing the net change in costs for the proposed RTCR by the average estimated value of avoided cases.

E. coli O157:H7 and *Salmonella* are only two of multiple pathogenic endpoints that could have been used for this analysis. Use of additional pathogenic contaminants in addition to these single endpoints would result in lower threshold values.

Detail may not add due to independent rounding.

Differences in the three percent and seven percent estimates among the AIP and Alternative Analysis can be explained by how costs accrue over the period of analysis. Cost for the AIP are relatively consistent across the period of analysis while greater costs for the Alternative occur early in the rule implementation period due to increases in monitoring and corrective actions.

Cost-effectiveness is another way of examining the benefits and costs of the proposed rule. Exhibit VI–29 shows the cost of the rule per corrective action avoided. The cost-effectiveness analysis, as with the net benefits, is limited because EPA was able to only partially quantify and monetize the benefits of the proposed RTCR. As discussed previously and demonstrated in the Proposed RTCR EA (USEPA 2010a), the proposed rule, *i.e.,* the AIP option, achieves the lowest cost per corrective action avoided among the options considered. The incremental cost-effectiveness analysis shows that the AIP has a lower cost per corrective action than the Alternative option.

EXHIBIT VI–29—TOTAL NET ANNUAL COST PER CORRECTIVE ACTION (CA) IMPLEMENTED UNDER AIP AND ALTERNATIVE OPTIONS, ANNUALIZED (USING THREE PERCENT AND SEVEN PERCENT DISCOUNT RATES)

[$2007]

Regulatory scenario	3% Discount rate	7% Discount rate
AIP Net Cost ($ Millions)	$13.7	$13.7
AIP Net Corrective Actions (L1 & L2)	598	555
AIP Cost Effectiveness Analysis (CEA) (net rule cost/CA)	$22,899	$24,610
Alternative Option Net Cost	$27.2	$29.7
Alternative Option Net Corrective Actions (L1 & L2)	785	765
Alternative Option CEA (net rule cost/CA)	$34,718	$39,812

Note: Corrective actions include those conducted as a result either Level 1 or Level 2 assessments. Total rule costs are shown in Exhibit 9.14 of the Proposed RTCR EA (USEPA 2010a). Detailed benefits and cost information is provided in Appendices A and C, respectively, of the Proposed RTCR EA (USEPA 2010a).

EPA also considered the incremental cost-effectiveness of the AIP option as compared to the Alternative option to determine the additional benefit associated with the portion of cost for the Alternative option that exceeds the cost of the AIP option. Exhibit VI–30 shows that in incremental terms for all PWSs, the AIP option has a far lower unit cost per corrective action than the Alternative option. EPA further considered the group of 60,200 TNCWSs serving 100 or fewer people and using GW, which are the largest subset of systems by size and type. This group is expected to bear the highest aggregate burden under the proposed RTCR because of the number of systems in the group, but the per system cost of this group is relatively low, ($83 annualized at 3% discount in 2007$). The two incremental analyses (Exhibit VI–30 and Exhibit VI–31) together indicate that, using a three percent discount rate to compare incremental benefits and costs, the AIP option is significantly more cost-effective than the Alternative option by a factor of about four for the most burdened subset of systems and by a factor of greater than three when considering all PWSs together. Additional information about this analysis and other methods used to compare benefits and costs can be found in chapter 9 of the Proposed RTCR EA (USEPA 2010a).

EXHIBIT VI–30—INCREMENTAL RULE COST PER CORRECTIVE ACTION (CA) IMPLEMENTED UNDER AIP AND ALTERNATIVE OPTIONS, ANNUALIZED (USING THREE PERCENT AND SEVEN PERCENT DISCOUNT RATES)

[$2007]

Regulatory scenario	3% Discount rate	7% Discount rate
A. AIP Incremental Net Costs ($ millions) [1]	$13.7	$13.7
B. AIP Incremental Net Corrective Actions (L1 & L2) [1]	598	555
C. AIP Incremental Cost per CA ($) (C = A/B)	$22,899	$24,610
D. Alternative Option Incremental Net Costs ($ millions) [2]	$13.5	$16.0
E. Alternative Option Incremental Net Corrective Actions (L1 & L2) [2]	187	210
F. Alternative Option Incremental Cost per CA ($) (F = D/E)	$72,582	$76,299

Notes: Detail may not add due to independent rounding.

Exhibit includes only the number of corrective actions predicted by the RTCR occurrence model to be implemented in addition to those implemented under the current TCR. Includes corrective actions (CAs) in response to both Level 1 and Level 2 assessments. Total net costs for each option and total CAs (not incremental) are shown in Exhibit 9.15 of the Proposed RTCR EA (USEPA 2010a). Detailed benefits and cost information is provided in Appendices A and C, respectively, of the Proposed RTCR EA (USEPA 2010a).

[1] Represents the incremental increase of the AIP option over the current TCR.

[2] Represents the incremental increase of the Alternative option over AIP option. Add incremental net values for Alternative option to incremental net values for AIP option to calculate total net values of Alternative option over current TCR.

EXHIBIT VI–31—INCREMENTAL RULE COST PER CORRECTIVE ACTION (CA) FOR TNCWSS USING GW IMPLEMENTED UNDER AIP AND ALTERNATIVE OPTIONS, ANNUALIZED (USING THREE PERCENT AND SEVEN PERCENT DISCOUNT RATES)

[2007]

Regulatory scenario	3% Discount rate	7% Discount rate
1. AIP Incremental Net Costs ($ millions) [1]	$5.1	$5.1
2. AIP Incremental Corrective Actions (L1 & L2) (TNCWS < 101 only) [1]	279	257
3. AIP Incremental Cost per CA ($)	$18,219	$19,965
4. Alternative Option Incremental Net Costs ($ millions) [2]	$8.3	$9.8
5. Alternative Option Incremental Corrective Actions (L1 & L2) (TNCWS < 101 only) [2]	128	145
6. Alternative Option Incremental Cost per CA ($)	$64,731	$67,762

[1] Represents the incremental increase of the AIP option over the current TCR.

[2] Represents the incremental increase of the Alternative option over AIP option. Add incremental net values for Alternative option to incremental net values for AIP option to calculate total net values of Alternative option over current TCR.

Note: Detail may not add due to independent rounding.

Incremental Net Costs are based on TNCWSs serving < 101 people. Detailed benefits and cost information is provided in Appendices A and C, respectively, of the Proposed RTCR EA (USEPA 2010a).

The preferred option for the proposed RTCR is the AIP option. The analyses performed as part of the Proposed RTCR EA (USEPA 2010a) support the collective judgment and consensus of the advisory committee that the AIP requirements provide for effective and efficient revisions to the current TCR regulatory requirements. The estimated net cost of the AIP option is small ($14M annually) as compared to the current TCR and small compared to the net cost of the Alternative option ($27M–$30M) as compared with the current TCR. In addition, the net benefits are expected to be positive under the AIP option and no backsliding in overall risk is predicted. While the number of corrective actions under the Alternative option is greater than under the AIP option, the achievement of these benefits is not as cost effective as under the AIP option.

EPA's Proposed RTCR EA (USEPA 2010a) shows that additional monitoring is likely to lead to more corrective actions under the Alternative option than under either the current TCR option or the AIP option. The EPA Science Advisory Board (SAB) noted in its analysis of the EA (described in section VII.K of this preamble) that they are not generally supportive of decreased monitoring, and that overall, the Alternative option appears to address and protect public health sooner in time than the AIP proposed implementation. However, EPA concluded that the increased costs associated with the Alternative option are not justified by the increased benefits because under the AIP option, States could conduct site visits in place of increased monitoring and such site visits are more protective of public health. In particular, the cost-effectiveness analysis shows that the Alternative option is not as cost-effective as the proposed AIP option.

N. Request for Comment on the Economic Analysis

EPA requests comment on the following aspects of the Proposed RTCR EA (USEPA 2010a):

- The EPA Science Advisory Board (SAB) noted in its review of the Proposed RTCR EA that overall, the Alternative option appears to address and protect public health sooner in time than the AIP proposed implementation. The SAB is concerned about decreased monitoring in the AIP option, compared to the Alternative option. Although the AIP option contains less overall monitoring than the Alternative option, EPA believes that having States conducting site visits in place of increased monitoring under the AIP option is more protective of public health. As discussed in this section, EPA evaluates the costs and benefits of all options and prefers the AIP option because the increased costs associated with the Alternative option are not justified by the increased short term benefits. EPA requests comment on whether this determination is reasonable and how the RTCR may best address the SAB's concern that the Alternative option appears to protect public health sooner in time than the proposed AIP option.

In addition, the SAB noted in its review that measures other than total coliform may provide valuable supplemental information on the health risks of distributed water. The SAB provided example measures such as water age, biofilm assessment, implementation of Best Management Practices, indicators that would inform the structural and hydraulic integrity of distribution system, etc. The TCRDSAC also suggested that EPA develop measures to evaluate the long-term effectiveness of the rule. EPA requests comment on the measures that may be monitored and tracked to indicate the long-term effectiveness of the RTCR and how these measures may be implemented effectively.

- Major distribution system appurtenances such as storage tanks generally have a useful life that is accounted for in water system capital planning. While the assessments conducted under RTCR could identify when that useful life has ended, EPA assumes the replacement or maintenance of appurtenances is part of a water system's operations and maintenance activities and the associated cost is accounted for in its capital planning. During the TCRDSAC's deliberation, EPA worked closely with stakeholders to derive this assumption and, consistent with the discussions of the TCRDSAC regarding major structural fixes or replacements, EPA's analysis did not account for these costs as part of the cost of the RTCR, although such fixes may be undertaken to address sanitary defects identified in a Level 1 or Level 2 assessment. EPA

requests comment on whether the assumption is reasonable. Are there alternative approaches that could be used to address this issue? If so, what would be the basis?

• In calculating the State cost of the rule, EPA assumed that, based on stakeholder input and the cost of annual site visits, only those States that currently allow annual monitoring and conduct annual site visits under TCR would continue under the RTCR. EPA requests comment on whether this assumption is reasonable. Are there alternative approaches that could be used to derive a more reasonable assumption? If so, what would be the basis?

• In analyzing the potential benefits of the proposed RTCR, EPA assumed that 10 percent of Level 1 and Level 2 assessments under the RTCR would lead to corrective action above what is already occurring under the current TCR. This assumption was based on conversations with States. However, EPA recognizes that information about corrective actions conducted under the current TCR is limited and requests comment on this assumption and any information that relates to it.

• In assessing the benefits of the rule, EPA assumed that because Level 2 assessments would be more comprehensive investigations than Level 1 assessments, they would generally result in finding more substantial problems than Level 1 assessments and would be more effective at reducing future occurrences of total coliforms and *E. coli.* Specifically, for modeling purposes, EPA assumed that, on average, systems performing corrective action as a result of a Level 1 assessment will experience no positive samples for the remainder of the year and one additional year, and will experience a 50 percent reduction in occurrence for three additional years, while systems performing corrective action as a result of a Level 2 assessment will experience no positive sample for the remainder of the year and two additional years, and a 75 percent reduction in occurrence for five additional years. EPA requests comment on whether these assumptions are reasonable, as well as any data or experience that commenters may provide that bears on the effectiveness of corrective action at reducing occurrence. Specifically, what differences between a Level 2 and Level 1 assessment would lead the former to identify more substantial problems and result in greater, longer-lasting occurrence reductions?

VII. Statutory and Executive Order Review

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is a significant regulatory action. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Order 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action.

EPA estimates that the proposed RTCR will have an overall impact on public water systems of $14 M and that the impact on small entities (PWSs serving 10,000 people or fewer) will be $9.4 M–$9.8 M annualized at 3 and 7 percent discount rates, respectively. These impacts are described in sections VI and VII.C of this preamble, respectively, and in the analysis that EPA prepared of the potential costs and benefits of this action, contained in the Proposed RTCR EA (USEPA 2010a).

B. Paperwork Reduction Act

The information collection requirements for the proposed RTCR have been submitted for approval to the OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document prepared by EPA has been assigned EPA ICR number 1895.06.

The Paperwork Reduction Act requires EPA to estimate the burden on public water systems (PWSs) and State/primacy Agencies of complying with the rule. The information collected as a result of EPA's efforts toward proposing the proposed RTCR should allow States/primacy agencies and EPA to determine appropriate requirements for specific systems and evaluate compliance with the proposed RTCR. Burden is defined at 5 CFR 1320.3(b) and means the total time, effort, and financial resources required to generate, maintain, retain, disclose, or provide information to or for a Federal agency. The burden includes the time needed to conduct the following State and public water system (PWS) activities:

State activities:

• Read and understand the rule;
• Mobilize (including primacy application), plan, and implement;
• Train PWS and consultant staff;
• Track compliance;
• Analyze and review PWS data;
• Review sampling plans and recommend any revisions to PWSs;
• Make determinations concerning PWS monitoring requirements;
• Respond to PWSs with positive samples;
• Recordkeeping;
• Review completed assessment forms and consult with the PWS about the assessment report;
• Review and coordinate with PWSs to determine optimal corrective actions to be implemented; and
• Provide consultation, review public notification certifications, and file reports of violations.

PWS activities:

• Read and understand the rule;
• Planning and mobilization activities;
• Revise existing sampling plans to identify sampling locations and collection schedules that are representative of water throughout the distribution system;
• Conduct routine, additional routine, and repeat monitoring;
• Complete a Level 1 Assessment if the PWS experiences a Level 1 trigger, and submit a timetable to the State to identify sanitary defects detected, corrective actions completed, and a timetable for any corrective actions not already completed;
• Complete a Level 2 Assessment if the PWS experiences a Level 2 trigger, and submit a timetable for any corrective actions not already completed;
• Correct sanitary defects found through the performance of Level 1 or Level 2 assessments;
• Develop and distribute Tier 1 public notices when *E. coli* MCL violations occur;
• Develop and distribute Tier 2 public notices when the PWSs failed to take corrective action; and
• Develop and distribute Tier 3 public notices when the PWSs failed to comply with the monitoring requirements or with mandatory reporting of required information within the specified timeframe.

For the first three years after publication of the final rule in the **Federal Register**, the major information requirements apply to 154,894 respondents. The total incremental burden associated with the change in moving from the information requirements of the current TCR to those in the proposed RTCR over the three years covered by the ICR is 2,518,878 hours, for an average of 839,526 hours per year. The total incremental cost over the three year clearance period is $71.3 million, for an average of $23.8 million per year (simple average over three years). (Note that this is higher than the annualized costs for the proposed rule because in the EA, the up-front costs that occur in the first three years, as well as future costs, are annualized over a 25-year time

horizon). The average burden per response (*i.e.,* the amount of time needed for each activity that requires a collection of information) is 5.4 hours; the average cost per response is $153.4. The collection requirements are mandatory under SDWA (42 U.S.C. 300h *et seq.*). Detail on the calculation of the proposed rule information collection burden and costs can be found in the Information Collection Request for the Proposed Revised Total Coliform Rule (USEPA 2010d) and chapter 7 of the EA (USEPA 2010a). A summary of the burdens and costs of the proposed collection is presented in Exhibit VII–1.

EXHIBIT VII–1—AVERAGE ANNUAL NET CHANGE BURDEN AND COSTS FOR THE PROPOSED RTCR ICR

Respondent type	Annual burden hours	Cost				Annual responses
		Annual labor cost	Annual operation & maintenance (O&M) cost	Annual capital cost	Total annual cost	
PWSs	747,848	$20,171,639	$0	$0	$20,171,639	103,225
States and Territories	91,678	3,595,421	0	0	3,595,421	51,669
Total	839,526	23,767,060	0	0	23,767,060	154,894

Notes: Detail may not add exactly to total due to independent rounding.
"Annual Burden Hours" reflects an annual average for all system sizes over the 3-year ICR period.
Source: Information Collection Request for the Proposed Revised Total Coliform Rule (USEPA 2010d).

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. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9. To comment on EPA's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, EPA has established a public docket for this proposed rule, which includes this ICR, under Docket ID number EPA–HQ–OW–2008–0878. Submit any comments related to the ICR to EPA and OMB. *See* **ADDRESSES** section at the beginning of this notice for where to submit comments to EPA. Send comments to OMB at the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Officer for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after July 14, 2010, a comment to OMB is best assured of having its full effect if OMB receives it by August 13, 2010. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

C. Regulatory Flexibility Act (RFA)

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

The RFA provides default definitions for each type of small entity. Small entities are defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any "not-for-profit enterprise which is independently owned and operated and is not dominant in its field." However, the RFA also authorizes an agency to use alternative definitions for each category of small entity, "which are appropriate to the activities of the agency" after proposing the alternative definition(s) in the **Federal Register** and taking comment. 5 USC 601(3)–(5). In addition, to establish an alternative small business definition, agencies must consult with SBA's Chief Counsel for Advocacy.

For purposes of assessing the impacts of the proposed RTCR on small entities, EPA considered small entities to be PWSs serving fewer than 10,000 people. This is the cut-off level specified by Congress in the 1996 Amendments to the Safe Drinking Water Act for small system flexibility provisions. As required by the RFA, EPA proposed using this alternative definition in the **Federal Register** (63 FR 7620, February 13, 1998), requested public comment, consulted with the SBA, and finalized the alternative definition in the Consumer Confidence Reports regulation (63 FR 44524, August 19, 1998). As stated in that Final Rule, the alternative definition would be applied for all future drinking water regulations.

After considering the economic impacts of today's proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. The small entities directly regulated by this proposed rule are small PWSs serving fewer than 10,000 people. These include small CWSs, NTNCWSs, and TNCWSs, entities such as municipal water systems (publicly and privately owned), and privately-owned PWSs and for profit businesses where provision of water may be ancillary, such as mobile home parks, day care centers, churches, schools and homeowner associations. We have determined that only 61 of 150,672 small systems (0.04%) will experience an impact of more than 1% of revenues, and that none of the small systems will experience an impact of 3% or greater of revenue. This information is described further in chapter 8 of the Proposed RTCR EA (USEPA 2010a).

Although this proposed rule will not have a significant economic impact on a substantial number of small entities, EPA nonetheless has tried to reduce the impact of this rule on small PWSs. Provisions in the proposed RTCR that result in reduced costs for many small entities include:

- Reduced routine monitoring for qualifying PWS serving 1,000 or fewer people.
- Reduced number of repeat samples required.
- Reduced additional routine monitoring for PWS serving 4,100 or fewer people.
- Reduced public notification requirements for all systems, including small systems.

EPA also conducted outreach to small entities and convened a Small Business Advocacy Review Panel to obtain advice

and recommendations of representatives of the small entities that potentially would be subject to the proposed rule's requirements. EPA consulted with small entity representatives before and during the review by the Panel. These small entity representatives included representatives from small water systems of various types and sizes, representatives from associations that assist and/or advocate for small systems, and Federal agencies that operate small systems. Panel members included representatives from OMB, the Small Business Administration, and the EPA Office of Ground Water and Drinking Water. The consultation led to the development of a report providing recommendations to EPA on how to revise the TCR to address small system concerns, which EPA considered in drafting this proposed RTCR (SBAR Panel 2008). EPA also made presentations to the advisory committee on the recommendations of the Panel so the advisory committee could consider their recommendations in developing the AIP.

Consistent with the RFA/Small Business Regulatory Enforcement Fairness Act (SBREFA) requirements, the Panel evaluated the assembled materials and small-entity comments on issues and prepared a final report to the EPA Administrator. A copy of the Panel report is included in the docket for this proposed rule. The proposed rule is consistent with the Panel recommendations to use total coliforms as a trigger for investigation and/or corrective action, to balance monitoring requirements and costs with risk, to further differentiate requirements based on differences in water systems, to coordinate requirements with other related rules, and to consider reporting and recordkeeping costs in estimating burden. Consistent with the Panel recommendation to evaluate which parameters are most appropriate for routine monitoring and as potential triggers for investigative and corrective actions, EPA is conducting a review of existing methods for total coliform and *E. coli* analysis and is evaluating its Alternative Test Procedure protocol for approving new methods as described in section III.A.9 of this preamble. EPA is also one of the founding members of a Research and Information Collection Partnership, described in section V of this preamble, which is considering research and information needs to evaluate the magnitude of risks and potential risk mitigation options related to potential distribution system contamination.

We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act (UMRA)

This proposed rule does not contain a Federal mandate that may result in expenditures to State, local, and Tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Expenditures associated with compliance, defined as the incremental costs beyond the current TCR, will not surpass $100 million in the aggregate in any year. Thus, this proposed rule is not subject to the requirements of sections 202 and 205 of UMRA.

This proposed rule is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. Costs to small entities are generally not significant, as described previously in section VII.C and are detailed in the Proposed RTCR EA (2010a). The regulatory requirements of the proposed RTCR are not unique to small governments, as they apply to all PWSs regardless of size.

E. Executive Order 13132: Federalism

This action does not have Federalism implications. It will not have 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 specified in Executive Order 13132. The net change in cost for State, local, and Tribal governments in the aggregate is estimated to be approximately $0.1M and $0.4M at three percent and seven percent discount rates, respectively. Thus, Executive Order 13132 does not apply to this proposed rule.

Although section 6 of Executive Order 13132 does not apply to the proposed RTCR, EPA conducted a Federalism Consultation, consistent with Executive Order 13132, in July 2008. The consultation included a stakeholder meeting where EPA requested comments on the impacts of the potential revisions to the TCR with respect to State, county and local governments. EPA did not receive any comments in response to this consultation. In addition, the advisory committee included representatives of State, local and Tribal governments, and through this process EPA consulted with State, local, and Tribal government representatives to ensure that their views were considered when the AIP recommendations for the RTCR were developed.

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed action from State and local officials.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). Thus, Executive Order 13175 does not apply to this action.

Although Executive Order 13175 does not apply to this action, EPA consulted with Tribal officials in developing this action. EPA has consulted with Tribal governments through the EPA American Indian Environmental Office, included a representative of the Native American Water Association on the advisory committee which developed recommendations regarding the proposed rule and signed the AIP, and has addressed Tribal concerns throughout the regulatory development process, as appropriate. The consultation included participation in three Tribal conference calls (EPA regional Tribal call (February 2008), National Indian Workgroup call (March 2008), and National Tribal Water Conference (March 2008)). EPA requested comments on the current TCR, requested suggestions for current TCR revisions (March 2008), and presented possible revisions to the current TCR to the National Tribal Council (April 2008). In addition, the advisory committee included entities representing Tribal governments, and through this process EPA ensured that their views were considered when the AIP recommendations for the RTCR were developed. None of these consultations identified issues that were particular to Tribal entities. As a result of the Tribal consultations and other Tribal outreach, EPA has determined that the proposed RTCR is not anticipated to have a negative impact on Tribal systems. Thus, Executive Order 13175 does not apply to this action.

EPA specifically solicits additional comment on this proposed action from Tribal officials.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The proposed RTCR is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not economically significant as defined in

Executive Order 12866. This action's health and risk assessments regarding children are contained in section VI.K.1 of this preamble and in the Proposed RTCR EA (USEPA 2010a). EPA expects that the proposed RTCR would provide additional protection to both children and adults who consume drinking water supplied from PWSs. EPA also believes that the benefits of the proposed rule, including reduced health risk, accrue more to children because young children are more susceptible than adults to some waterborne illnesses. For example, the risk of mortality resulting from diarrhea is often greatest in the very young and elderly (Rose 1997; Gerba *et al.* 1996), and viral and bacterial illnesses often disproportionately affect children. Any overall benefits of the rule would reduce this mortality risk for children.

The public is invited to submit comments or identify peer-reviewed studies and data that assess effects of early life exposure to drinking water that contains fecal contaminants.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

The proposed RTCR is not a "significant energy action" as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Additionally, none of the proposed RTCR requirements involve the installation of treatment or other components that use a measurable amount of energy.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when EPA decides not to use available and applicable voluntary consensus standards.

The proposed RTCR involves technical voluntary consensus standards. EPA proposes to use several analytical methods to monitor for total coliforms and/or *E. coli* as they are described in *Standard Methods for the Examination of Water and Wastewater,* 20th and 21st editions (Clesceri *et al.* 1998; Eaton *et al.* 2005). Methods included in *Standard Methods* are voluntary consensus standards. The proposed rule includes 11 methods that can be used to test for total coliforms. Four of the 11 are described in *Standard Methods.*

EPA welcomes comments on this aspect of the proposed rulemaking and, specifically, invites the public to identify potentially-applicable voluntary consensus standards and to explain why such standards should be used in this regulation.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission. Agencies must do this by identifying and addressing as appropriate any disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. The proposed RTCR applies uniformly to all PWSs. Consequently, the proposed RTCR provides health protection equally to all income and minority groups served by PWSs. The proposed RTCR and other drinking water regulations are expected to have a positive effect on human health regardless of the social or economic status of a specific population. To the extent that contaminants in drinking water might be disproportionately high among minority or low-income populations (which is unknown), the proposed RTCR contributes toward removing those differences by assuring that all public water systems meet drinking water standards and take appropriate corrective action whenever appropriate. Thus, the proposed RTCR meets the intent of the Federal policy requiring incorporation of environmental justice into Federal agency missions.

The Agency requests comment on whether there are any specific environmental justice considerations that EPA should analyze and consider.

K. Consultations With the Science Advisory Board, National Drinking Water Advisory Council, and the Secretary of Health and Human Services

In accordance with section 1412(d) and (e) of the SDWA, EPA consulted with the Science Advisory Board (SAB), the National Drinking Water Advisory Council (NDWAC), and the Secretary of the U.S. Department of Health and Human Services on the proposed RTCR.

EPA met with the Drinking Water Committee of the SAB to discuss the proposed RTCR on May 20, 2009 (teleconference) and June 9 and 10, 2009 (Washington, DC). The SAB Drinking Water Committee (DWC) review focused on (1) the data sources used to estimate baseline total coliform and *E. coli* occurrence, public water system profile, and sensitive subpopulations in the United States; (2) the occurrence analysis used to inform the benefits analysis; (3) the qualitative analysis used to assess the reduction in risk due to implementation of the rule requirements; and (4) analysis of the engineering costs and costs to States resulting from implementation of the revisions.

Overall, the SAB DWC supported EPA's analysis. SAB members commended EPA for making use of the best available data to assess the impacts of the proposed rule. The SAB DWC supported the decision by EPA not to quantify public health benefits, acknowledging that EPA had insufficient data to do so. However, they noted in their analysis of the EA that they are not generally supportive of decreased monitoring, and that overall, the Alternative option appears to address and protect public health sooner in time than the AIP proposed implementation. The SAB DWC recommended that EPA clarify rationales for assumptions; expand explanations of sensitivity analyses that were included; provide further justification in those areas in which sensitivity analyses were not conducted; and collect data after promulgation of the rule to allow EPA to better understand the public health impacts of the RTCR.

In response to the SAB DWC recommendations, EPA conducted sensitivity analyses to explore a wider range of assumptions regarding the

percentage of assessments leading to corrective actions and to demonstrate that using an annual average for occurrence provided results comparable to varying the occurrence based on the season. EPA also added an exhibit in the EA that summarizes all significant model parameters and assumptions, their influence on variability and uncertainty, and their most likely effect on benefits or costs. In addition, EPA added a request for comment to this preamble to obtain suggestions about what data should be collected and used to better understand the impacts of the RTCR. The added exhibits and expanded and clarified text can be found in the Proposed RTCR EA (USEPA 2010a). A copy of the SAB report (SAB 2010) is available in the docket for the proposed RTCR.

EPA consulted with NDWAC on May 28, 2009, in Seattle, Washington, to discuss the proposed RTCR. NDWAC members expressed concern that a rule based on the AIP sounds complicated. Education was a common theme in the responses from NDWAC members. Some members recommended that EPA provide the utilities and States with tools to help them understand the revised rule provisions and to assist with providing public education. A few members stated that they would like to provide EPA with additional advice on public notification. In response to NDWAC's concern, EPA is requesting comment on whether the proposed RTCR would result in requirements that would be easier to implement compared to the current TCR.

NDWAC members also suggested that EPA request comment on the costs and benefits of reduced monitoring. Specifically, NDWAC expressed concern that a reduction in the number of certain samples taken (such as the reduction in the number of repeat and additional routine samples for some small systems) could lessen the opportunity for systems to identify violations. Thus, EPA is requesting comment on the cost and benefit of reduced monitoring.

A few NDWAC members stated that they would like to provide EPA with additional advice on public notification. To follow up on this request, EPA met with several NDWAC members on July 1, 2009, to review and discuss the current TCR public notification requirements, the advisory committee's recommendations on revisions to the public notification requirements, and to obtain feedback from NDWAC members. At this meeting, NDWAC members discussed potential changes to health effects language. They noted that while some portions of the health effects language would still be appropriate under the proposed RTCR, some changes or additions may be appropriate. Potential inclusions include the use of two different types of Tier 2 public notice to account for the difference between failure to conduct assessments and failure to complete corrective actions, as well as language concerning customer actions in response to violations (such as boiling water before use), and a change in the description of health effects of coliform exposure by sensitive subpopulations. They also recommended that EPA look at the public notification requirements for the GWR as they may also be appropriate for the proposed RTCR. EPA considered the recommendations from NDWAC in developing the public notification requirements for the proposed rule and is requesting comment on these issues (*see* section III.A.7.c of this preamble).

EPA completed its consultation with the US Department of Health and Human Services on October 5, 2009, as required by SDWA section 1412(d). EPA also provided an informational briefing to the Food and Safety Group of the Food and Drug Administration.

L. Impacts on Sensitive Subpopulations as Required by Section 1412(b)(3)(C)(i) of the 1996 Amendments of the Safe Drinking Water Act (SDWA)

EPA is required to seek public comment regarding the effects of contamination associated with the proposed RTCR on the general population and sensitive subpopulations. Sensitive subpopulations include "infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population" (SDWA section 1412(b)(3)(C)(i)(V), 42 U.S.C 300g–1(b)(3)(C)(i)(V)).

Pregnant and lactating women may be at an increased risk from pathogens as well as act as a source of infection for newborns. Infection during pregnancy may also result in the transmission of infection from the mother to the child *in utero,* during birth, or shortly thereafter. Since very young children do not have fully developed immune systems, they are at increased risk and are particularly difficult to treat.

Infectious diseases are also a major problem for the elderly because immune function declines with age. As a result, outbreaks of waterborne diseases can be devastating on the elderly community (*e.g.,* nursing homes) and may increase the possibility of significantly higher mortality rates in the elderly than in the general population.

Immunocompromised individuals are a growing proportion of the population with the continued increase in HIV/AIDS, the aging population, and the escalation in organ and tissue transplantations. Immunocompromised individuals are more susceptible to severe and invasive infection. These infections are particularly difficult to treat and can result in a significantly higher mortality than in immunocompetent persons.

It is anticipated that the requirements of the proposed RTCR will help reduce pathways of entry for fecal contamination and/or waterborne pathogens into the distribution system, thereby reducing exposure and risk from these contaminants in drinking water to the entire general population. The proposed RTCR seeks to provide a similar level of drinking water protection to all groups including sensitive subpopulations, thus meeting the intent of this Federal policy.

M. Plain Language

Executive Order 12866 requires each agency to write its rules in plain language. Readable regulations help the public find requirements quickly and understand them easily. Readable regulations may also increase compliance, strengthen enforcement, and decrease mistakes, frustration, phone calls, appeals, and distrust of government. EPA has made every effort to write this preamble to the proposed rule in as clear, concise, and unambiguous manner as possible. EPA requests comments on how to improve rule language to enhance readability and make it easier to understand.

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List of Subjects

40 CFR Part 141

Environmental protection, Chemicals, Indian-lands, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Water supply.

40 CFR Part 142

Environmental protection, Administrative practice and procedure, Chemicals, Indian-lands, Radiation protection, Reporting and recordkeeping requirements, Water supply.

Dated: June 16, 2010.

Lisa P. Jackson,

Administrator.

For the reasons set forth in the preamble, Title 40 chapter 1 of the Code of Federal Regulations is proposed to be amended as follows:

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

1. The authority citation for part 141 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4, 300j–9, and 300j–11.

2. Section 141.4 is revised to read as follows:

§ 141.4 Variances and exemptions.

(a) Variances or exemptions from certain provisions of these regulations may be granted pursuant to sections 1415 and 1416 of the Act and subpart K of part 142 of this chapter (for small system variances) by the entity with primary enforcement responsibility, except that variances or exemptions from the MCLs for total coliforms and *E. coli* and variances from any of the treatment technique requirements of subpart H of this part may not be granted.

(b) EPA has stayed the effective date of this section relating to the total coliform MCL of § 141.63(a) for systems that demonstrate to the State that the violation of the total coliform MCL is due to a persistent growth of total coliforms in the distribution system rather than fecal or pathogenic contamination, a treatment lapse or deficiency, or a problem in the operation or maintenance of the distribution system. This is stayed until [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], at which time the total coliform MCL is no longer effective.

§ 141.13 [Removed and reserved]

3. Section 141.13 is removed and reserved.

4. Section 141.21 is amended by adding paragraph (h) to read as follows:

§ 141.21 Coliform sampling.

* * * * *

(h) The provisions of paragraphs (a) and (d) are applicable until [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE]. The provisions of paragraphs (b), (c), (e), (f), and (g) are applicable until all required repeat monitoring under paragraph (b) and fecal coliform or *E. coli* testing under paragraph (e) that was initiated by a total coliform-positive sample taken before [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE] is completed, as well as analytical method, reporting, recordkeeping, public notification, and consumer confidence report requirements associated with that monitoring and testing. After [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], the provisions of subpart Y of this part are applicable, with systems required to begin regular monitoring at the same frequency as the frequency required on [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE].

§ 141.22 [Removed and reserved]

5. Section 141.22 is removed and reserved.

6. Section 141.52 is revised to read as follows:

§ 141.52 Maximum contaminant level goals for microbiological contaminants.

(a) MCLGs for the following contaminants are as indicated:

Contaminant	MCLG
(1) *Giardia lamblia*	zero.
(2) Viruses	zero.
(3) *Legionella*	zero.
(4) Total coliforms (including fecal coliforms and *Escherichia coli*).	zero.
(5) *Cryptosporidium*	zero.
(6) *Escherichia coli (E. coli)*	zero.

(b) The MCLG identified in paragraph (a)(4) of this section is applicable until [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE]. The MCLG identified in paragraph (a)(6) of this section is applicable beginning [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE].

7. Section 141.63 is revised to read as follows:

§ 141.63 Maximum contaminant levels (MCLs) for microbiological contaminants.

(a) Until [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], the total coliform MCL is based on the presence or absence of total coliforms in a sample, rather than coliform density.

(1) For a system that collects at least 40 samples per month, if no more than 5.0 percent of the samples collected during a month are total coliform-positive, the system is in compliance with the MCL for total coliforms.

(2) For a system that collects fewer than 40 samples per month, if no more than one sample collected during a month is total coliform-positive, the system is in compliance with the MCL for total coliforms.

(b) Until [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], any fecal coliform-positive repeat sample or *E. coli*-positive repeat sample, or any total coliform-positive repeat sample following a fecal coliform-positive or *E. coli*-positive routine sample, constitutes a violation of the MCL for total coliforms. For purposes of the public notification requirements in subpart Q of this part, this is a violation that may pose an acute risk to health.

(c) Beginning [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], a system is in compliance with the MCL for *E. coli* for samples taken under the provisions of subpart Y of this part unless any of the conditions identified in paragraphs (c)(1) through (c)(4) of this section occur. For purposes of the public notification requirements in subpart Q of this part, violation of the MCL may pose an acute risk to health.

(1) The system has an *E. coli*-positive repeat sample following a total coliform-positive routine sample.

(2) The system has a total coliform-positive repeat sample following an *E. coli*-positive routine sample.

(3) The system fails to take all required repeat samples following an *E. coli*-positive routine sample.

(4) The system fails to test for *E. coli* when any repeat sample tests positive for total coliform.

(d) Until [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], a public water system must determine compliance with the MCL for total coliforms in paragraphs (a) and (b) of this section for each month in which it is required to monitor for total coliforms. Beginning [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], a public water system must determine compliance with the MCL for *E. coli* in paragraph (c) of this section for each month in which it is required to monitor for total coliforms.

(e) The Administrator, pursuant to section 1412 of the Act, hereby identifies the following as the best technology, treatment techniques, or other means available for achieving compliance with the maximum contaminant level for total coliforms in paragraphs (a) and (b) of this section and for achieving compliance with the maximum contaminant level for *E. coli* in paragraph (c) of this section:

(1) Protection of wells from fecal contamination by appropriate placement and construction;

(2) Maintenance of a disinfectant residual throughout the distribution system;

(3) Proper maintenance of the distribution system including appropriate pipe replacement and repair procedures, main flushing programs, proper operation and maintenance of storage tanks and reservoirs, cross connection control, and continual maintenance of positive water pressure in all parts of the distribution system;

(4) Filtration and/or disinfection of surface water, as described in subparts H, P, T, and W of this part, or disinfection of ground water, as described in subpart S of this part, using strong oxidants such as chlorine, chlorine dioxide, or ozone; and

(5) For systems using ground water, compliance with the requirements of an EPA-approved State Wellhead Protection Program developed and implemented under section 1428 of the SDWA.

8. Section 141.74 is amended by revising paragraphs (b)(6)(i) and (c)(3)(i) to read as follows:

§ 141.74 Analytical and monitoring requirements.

* * * * *

(b) * * *

(6)(i) Until [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], the residual disinfectant concentration must be measured at least at the same points in the distribution system and at the same time as total coliforms are sampled, as specified in § 141.21. Beginning [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], the residual disinfectant concentration must be measured at least at the same points in the distribution system and at the same time as total coliforms are sampled, as specified in §§ 141.854 through 141.857. The State may allow a public water system which uses both a surface water source or a ground water source under direct influence of surface water, and a ground water source, to take disinfectant residual samples at points other than the total coliform sampling points if the State determines that such points are more representative of treated (disinfected) water quality within the distribution system. Heterotrophic bacteria, measured as heterotrophic plate count (HPC) as specified in paragraph (a)(1) of this section, may be measured in lieu of residual disinfectant concentration.

* * * * *

(c) * * *

(3)(i) The residual disinfectant concentration must be measured at least at the same points in the distribution system and at the same time as total coliforms are sampled, as specified in § 141.21, and as specified in §§ 141.854 through 141.857 beginning [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], except that the State may allow a public water system which uses both a surface water source or a ground water source under direct influence of surface water, and a ground water source, to take disinfectant residual samples at points other than the total coliform sampling points if the State determines that such points are more representative of treated (disinfected) water quality within the distribution system. Heterotrophic bacteria, measured as heterotrophic plate count (HPC) as specified in paragraph (a)(1) of this section, may be measured in lieu of residual disinfectant concentration.

* * * * *

9. Section 141.132 is amended by revising paragraph (c)(1)(i) to read as follows:

§ 141.132 Monitoring requirements.

* * * * *

(c) * * *

(1) * * *

(i) Routine *monitoring.* Until [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], community and non-transient non-community water systems that use chlorine or chloramines must measure the residual disinfectant level in the distribution system at the same point in the distribution system and at the same time as total coliforms are sampled, as specified in § 141.21. Beginning [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], community and non-transient non-community water systems that use chlorine or chloramines must measure the residual disinfectant level in the distribution system at the same point in the distribution system and at the same time as total coliforms are sampled, as specified in §§ 141.854 through 141.857. Subpart H systems of this part may use the results of residual disinfectant concentration sampling conducted under § 141.74(b)(6)(i) for unfiltered systems or § 141.74(c)(3)(i) for systems which filter, in lieu of taking separate samples.

* * * * *

10. Section 141.153 is amended as follows:

(a) By revising paragraph (d)(4)(vii) introductory text.

(b) By revising paragraph (d)(4)(viii).

(c) By adding paragraphs (d)(4)(x) and (d)(4)(xi).

§ 141.153 Content of the reports.

* * * * *

(d) * * *

(4) * * *

(vii) For total coliform analytical results until [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE]:

* * * * *

(viii) For fecal coliform until [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE]: The total number of positive samples;

* * * * *

(x) For total coliform taken under subpart Y:

(A) The number of Level 1 and Level 2 assessments required and completed; and

(B) The corrective actions required and completed; and

(xi) For *E. coli:* The total number of positive samples.

* * * * *

11. In Appendix A to Subpart O of Part 141, the table is amended by revising the entries for "Total Coliform Bacteria" and "Fecal Coliform and *E. coli,*" adding a second entry for "Total

Coliform Bacteria," adding as a fourth entry "*E. coli,*" and adding two endnotes, to read as follows:

APPENDIX A TO SUBPART O OF PART 141—REGULATED CONTAMINANTS

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
Microbiological contaminants:						
Total Coliform Bacteria.†	MCL (systems that collect ≥40 samples/month) 5% of monthly samples are positive; (systems that collect <40 samples/month) 1 positive monthly sample.	.....	MCL (systems that collect ≥40 samples/month) 5% of monthly samples are positive; (systems that collect <40 samples/month) 1 positive monthly sample.	0	Naturally present in the environment.	Coliforms are bacteria that are naturally present in the environment and are used as an indicator that other, potentially-harmful, bacteria may be present. Coliforms were found in more samples than allowed and this was a warning of potential problems.
Total Coliform Bacteria‡.	TT	.....	TT	N/A	Naturally present in the environment.	Coliforms are bacteria that are naturally present in the environment and are used as an indicator that other, potentially harmful, bacteria may be present. The water system found coliforms indicating the need to look for potential problems in water treatment or distribution. When this occurs, public water systems are required to conduct assessments to identify problems and to correct any problems that are found. [THE SYSTEM MUST USE THE FOLLOWING APPLICABLE SENTENCES.] The water system failed to conduct the required assessment(s). The water system failed to correct all identified sanitary defects.
Fecal coliform and *E. coli*†.	0	.....	0	0	Human and animal fecal waste.	Fecal coliforms and *E. coli* are bacteria whose presence indicates that the water may be contaminated with human or animal wastes. Microbes in these wastes can cause short-term effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a special health risk for infants, young children, some of the elderly, and people with severely compromised immune systems.
E. coli‡	Routine and repeat samples are total coliform-positive and either is *E. coli*-positive or system fails to take repeat samples following *E. coli*-positive routine sample or system fails to analyze total coliform-positive repeat sample for *E. coli.*	.....	In compliance unless one of the following conditions occurs: (1) The system has an *E. coli*-positive repeat sample following a total coliform-positive routine sample (2) The system has a total coliform-positive repeat sample following an *E. coli*-positive routine sample (3) The system fails to take all required repeat samples following an *E. coli*-positive routine sample (4) The system fails to test for *E. coli* when any repeat sample tests positive for total coliform	0	Human and animal fecal waste.	*E. coli* are bacteria whose presence indicates that the water may be contaminated with human or animal wastes. Microbes in these wastes can cause short-term effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a greater health risk for infants, young children, some of the elderly, and people with severely-compromised immune systems.

APPENDIX A TO SUBPART O OF PART 141—REGULATED CONTAMINANTS—Continued

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
*	*	*	*	*	*	*

* * * * *
† Until [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE].
‡ Beginning [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE].
* * * * *

12. Section 141.202(a), Table 1, is amended by adding a new sentence at the end of entry (1) to read as follows:

§ 141.202 Tier 1 Public Notice—Form, manner, and frequency of notice.

* * * * *

TABLE 1 TO § 141.202—VIOLATION CATEGORIES AND OTHER SITUATIONS REQUIRING A TIER 1 PUBLIC NOTICE

(1) * * * Violation of the MCL for *E. coli* (as specified in § 141.63(c));						
*	*	*	*	*	*	*

13. Section 141.203(b)(2) is revised to read as follows:

§ 141.203 Tier 2 Public Notice—Form, manner, and frequency of notice.

* * * * *

(b) * * *

(2) The public water system must repeat the notice every three months as long as the violation or situation persists, unless the primacy agency determines that appropriate circumstances warrant a different repeat notice frequency. In no circumstance may the repeat notice be given less frequently than once per year. It is not appropriate for the primacy agency to allow less frequent repeat notice for an MCL or treatment technique violation under the Total Coliform Rule or subpart Y of this part or a treatment technique violation under the Surface Water Treatment Rule or Interim Enhanced Surface Water Treatment Rule. It is also not appropriate for the primacy agency to allow through its rules or policies across-the-board reductions in the repeat notice frequency for other ongoing violations requiring a Tier 2 repeat notice. Primacy agency determinations allowing repeat notices to be given less frequently than once every three months must be in writing.

* * * * *

14. Section 141.204(a), Table 1, is amended by revising entries (4) and (5) and adding entry (6) to read as follows:

§ 141.204 Tier 3 Public Notice—Form, manner, frequency of notice.

(a) * * *

TABLE 1 TO § 141.204—VIOLATION CATEGORIES AND OTHER SITUATIONS REQUIRING A TIER 3 PUBLIC NOTICE

*	*	*	*	*	*	*
(4) Availability of unregulated contaminant monitoring results, as required under § 141.207;						
(5) Exceedance of the fluoride secondary maximum contaminant level (SMCL), as required under § 141.208; and						
(6) Reporting violations under subpart Y of 40 CFR part 141.						

* * * * *

15. Appendix A to subpart Q of Part 141 is amended by revising entries I.A.1 and I.A.2 and adding two endnotes to read as follows:

APPENDIX A TO SUBPART Q OF PART 141—NPDWR VIOLATIONS AND OTHER SITUATIONS REQUIRING PUBLIC NOTICE [1]

Contaminant	MCL/MRDL/TT violations [2]		Monitoring, testing and reporting procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
I. Violations of National Primary Drinking Water Regulations (NPDWR): [3]				
A. Microbiological Contaminants				
1.a Total coliform bacteria †	2	141.63(a)	3	141.21(a)–(e)
1.b Total coliform (TT violations resulting from failure to perform assessments or corrective actions) ‡	2	141.860(b)	3	141.860(c)
2.a Fecal coliform/*E. coli* †	1	141.63(b)	1,3	141.21(e)
2.b *E. coli* ‡	1	141.63(c)	3	141.860(d)(2)
*	*	*	*	*

Appendix A—Endnotes
† Until [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE].

‡ Beginning [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE].

* * * * *

16. Appendix B to subpart Q of Part 141 is amended as follows:

(a) By revising entries 1a and 1b.
(b) By adding entries 1e and 1f.
(c) By adding two endnotes.

APPENDIX B TO SUBPART Q OF PART 141—STANDARDS HEALTH EFFECTS LANGUAGE FOR PUBLIC NOTIFICATION

Contaminant	MCLG;[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
National Primary Drinking Water Regulations (NPDWR)			
A. Microbiological Contaminants			
1a. Total coliform †	Zero	See footnote [3]	Coliforms are bacteria that are naturally present in the environment and are used as an indicator that other, potentially-harmful, bacteria may be present. Coliforms were found in more samples than allowed and this was a warning of potential problems.
1b. Fecal coliform/*E. coli*.†	Zero	Zero	Fecal coliforms and *E. coli* are bacteria whose presence indicates that the water may be contaminated with human or animal wastes. Microbes in these wastes can cause short-term effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a special health risk for infants, young children, some of the elderly, and people with severely compromised immune systems.
*	*	*	* * * *
1e. Subpart Y Coliform Assessment and/or Corrective Action Violations.‡.	N/A	TT [3]	Coliforms are bacteria that are naturally present in the environment and are used as an indicator that other, potentially harmful, bacteria may be present. The water system found coliforms indicating the need to look for potential problems in water treatment or distribution. When this occurs, public water systems are required to conduct assessments to identify problems and to correct any problems that are found. [THE SYSTEM MUST USE THE FOLLOWING APPLICABLE SENTENCES.] The water system failed to conduct the required assessment. The water system failed to correct all identified sanitary defects.
1f. *E. coli*‡	Zero	In compliance unless one of the following conditions occurs: (1) The system has an *E. coli*-positive repeat sample following a total coliform-positive routine sample. (2) The system has a total coliform-positive repeat sample following an *E. coli*-positive routine sample. (3) The system fails to take all required repeat samples following an *E. coli*-positive routine sample. (4) The system fails to test for *E. coli* when any repeat sample tests positive for total coliform.	*E. coli* are bacteria whose presence indicates that the water may be contaminated with human or animal wastes. Microbes in these wastes can cause short-term effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a greater health risk for infants, young children, some of the elderly, and people with severely compromised immune systems.
*	*	*	* * * *

Appendix B—Endnotes
† Until [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE].
‡ Beginning [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE].

* * * * *

17. Section 141.402 is amended by revising paragraph (a) to read as follows:

§ 141.402 Ground water source microbial monitoring and analytical methods.

(a) *Triggered source water monitoring*—

(1) *General requirements.* A ground water system must conduct triggered source water monitoring if the conditions identified in paragraphs (a)(1)(i) and either (a)(1)(ii) or (a)(1)(iii) of this section exist.

(i) The system does not provide at least 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log virus

inactivation and removal) before or at the first customer for each ground water source; and either

(ii) The system is notified that a sample collected under § 141.21(a) is total coliform-positive and the sample is not invalidated under § 141.21(c) until [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], or

(iii) The system is notified that a sample collected under §§ 141.854 through 141.857 is total coliform-positive and the sample is not invalidated under § 141.853 beginning [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE].

(2) *Sampling requirements.* A ground water system must collect, within 24 hours of notification of the total coliform-positive sample, at least one ground water source sample from each ground water source in use at the time the total coliform-positive sample was collected under § 141.21(a) until [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], or collected under §§ 141.854 through 141.857 beginning [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], except as provided in paragraph (a)(2)(ii) of this section.

(i) The State may extend the 24-hour time limit on a case-by-case basis if the system cannot collect the ground water source water sample within 24 hours due to circumstances beyond its control. In the case of an extension, the State must specify how much time the system has to collect the sample.

(ii) If approved by the State, systems with more than one ground water source may meet the requirements of this paragraph (a)(2) by sampling a representative ground water source or sources. If directed by the State, systems must submit for State approval a triggered source water monitoring plan that identifies one or more ground water sources that are representative of each monitoring site in the system's sample siting plan under § 141.21(a) until [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], or under § 141.853 beginning [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], and that the system intends to use for representative sampling under this paragraph.

(iii) Until [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], a ground water system serving 1,000 or fewer people may use a repeat sample collected from a ground water source to meet both the requirements of § 141.21(b) and to satisfy the monitoring requirements of paragraph (a)(2) of this section for that ground water source only if the State approves the use of *E. coli* as a fecal indicator for source water monitoring under this paragraph (a). If the repeat sample collected from the ground water source is *E. coli*-positive, the system must comply with paragraph (a)(3) of this section.

(iv) Beginning [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], a ground water system serving 1,000 or fewer people may use a repeat sample collected from a ground water source to meet both the requirements of subpart Y and to satisfy the monitoring requirements of paragraph (a)(2) of this section for that ground water source only if the State approves the use of *E. coli* as a fecal indicator for source water monitoring under this paragraph (a) and approves the use of a single sample for meeting both the triggered source water monitoring requirements in this paragraph (a) and the repeat monitoring requirements in § 141.858. If the repeat sample collected from the ground water source is *E. coli*-positive, the system must comply with paragraph (a)(3) of this section.

(3) *Additional requirements.* If the State does not require corrective action under § 141.403(a)(2) for a fecal indicator-positive source water sample collected under paragraph (a)(2) of this section that is not invalidated under paragraph (d) of this section, the system must collect five additional source water samples from the same source within 24 hours of being notified of the fecal indicator-positive sample.

(4) *Consecutive and wholesale systems*—

(i) In addition to the other requirements of this paragraph (a), a consecutive ground water system that has a total coliform-positive sample collected under § 141.21(a) until [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], or under §§ 141.854 through 141.857 beginning [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], must notify the wholesale system(s) within 24 hours of being notified of the total coliform-positive sample.

(ii) In addition to the other requirements of this paragraph (a), a wholesale ground water system must comply with paragraphs (a)(4)(ii)(A) and (a)(4)(ii)(B) of this section.

(A) A wholesale ground water system that receives notice from a consecutive system it serves that a sample collected under § 141.21(a) until [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], or collected under §§ 141.854 through 141.857 beginning [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], is total coliform-positive must, within 24 hours of being notified, collect a sample from its ground water source(s) under paragraph(a)(2) of this section and analyze it for a fecal indicator under paragraph (c) of this section.

(B) If the sample collected under paragraph (a)(4)(ii)(A) of this section is fecal indicator-positive, the wholesale ground water system must notify all consecutive systems served by that ground water source of the fecal indicator source water positive within 24 hours of being notified of the ground water source sample monitoring result and must meet the requirements of paragraph (a)(3) of this section.

(5) *Exceptions to the triggered source water monitoring requirements.* A ground water system is not required to comply with the source water monitoring requirements of paragraph (a) of this section if either of the following conditions exists:

(i) The State determines, and documents in writing, that the total coliform-positive sample collected under § 141.21(a) until [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], or under §§ 141.854 through 141.857 beginning [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], is caused by a distribution system deficiency; or

(ii) The total coliform-positive sample collected under § 141.21(a) until [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], or under §§ 141.854 through 141.857 beginning [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], is collected at a location that meets State criteria for distribution system conditions that will cause total coliform-positive samples.

* * * * *

18. Section 141.405 is amended by revising paragraph (b)(4) to read as follows:

§ 141.405 Reporting and recordkeeping for ground water systems.

* * * * *

(b) * * *

(4) For consecutive systems, documentation of notification to the wholesale system(s) of total coliform-positive samples that are not invalidated under § 141.21(c) until [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], or under § 141.853 beginning [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE]. Documentation

shall be kept for a period of not less than five years.

* * * * *

19. Section 141.803 is amended by revising paragraphs (a)(3) and (a)(5) to read as follows:

§ 141.803 Coliform sampling.

(a) * * *

(3) Air carriers must conduct analyses for total coliform and *E. coli* in accordance with the analytical methods approved in §§ 141.21(f)(3) and 141.21(f)(6) until [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], and under § 141.852 beginning [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE].

* * * * *

(5) The invalidation of a total coliform sample result can be made only by the Administrator in accordance with §§ 141.21(c)(1)(i), (ii), or (iii) or by the certified laboratory in accordance with § 141.21(c)(2) until [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], or in accordance with § 141.853(c) beginning [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], with the Administrator acting as the State.

* * * * *

20. Part 141 is amended by adding a new subpart Y to read as follows:

Subpart Y—Revised Total Coliform Rule

Sec.

Subpart Y—Revised Total Coliform Rule

§ 141.850 General.

(a) *General.* The provisions of this subpart include both maximum contaminant level and treatment technique requirements.

(b) *Applicability.* The provisions of this subpart apply to all public water systems.

(c) *Compliance date.* Systems must comply with the provisions of this subpart beginning [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], unless otherwise specified in this subpart.

§ 141.851 Definitions.

Clean compliance history is, for the purposes of subpart Y, a record of no MCL violations under § 141.63; no monitoring violations under § 141.21 or subpart Y; and no treatment technique trigger exceedances or treatment technique violations under subpart Y.

Sanitary defect is a defect that could provide a pathway of entry for microbial contamination into the distribution system or that is indicative of a failure or imminent failure in a barrier that is already in place.

Seasonal system is a non-community water system that is operated in three or fewer calendar quarters per calendar year.

§ 141.852 Analytical methods and laboratory certification.

(a) *Analytical methodology.* (1) The standard sample volume required for analysis, regardless of analytical method used, is 100 ml.

(2) Systems need only determine the presence or absence of total coliforms and *E. coli;* a determination of density of either is not required.

(3) The time from sample collection to initiation of test medium incubation may not exceed 30 hours. Systems are encouraged but not required to hold samples below 10 deg. C during transit.

(4) If chlorinated water is to be analyzed, sufficient sodium thiosulfate ($Na_2S_2O_3$) must be added to the sample bottle before sterilization to neutralize any residual chlorine in the water sample. Dechlorination procedures are addressed in Section 9060A.2 of *Standard Methods for the Examination of Water and Wastewater* (20th and 21st editions).

(5) Systems must conduct total coliform analyses in accordance with one of the analytical methods in the following table or one of the alternative methods listed in Appendix A to subpart C of part 141.

Organism	Methodology category	Method [1]	Citation
Total Coliforms	Lactose Fermentation Methods	Total Coliform Multiple Tube Fermentation Technique.	9221 B.1, B.2 [1 2]
		Presence-Absence (P–A) Coliform Test	9221 D.1, D.2 [1 12]
	Membrane Filtration Methods	Total Coliform Membrane Filter Technique	9222 B, C [1 3]
		Membrane Filtration using MI medium	EPA Method 1604 [3 4]
		m-ColiBlue24® Test.[3 5]	
		Chromocult.[3 6]	
	Enzyme Substrate Methods	Colilert®	9223 B [1 7]
		Colisure®	9223 B [1, 7, 8]
		E*Colite® Test.[9]	
		Readycult® Test.[10]	
		modified Colitag® Test.[11]	
Escherichia coli	*Escherichia coli* Procedure (following Lactose Fermentation Methods).	EC–MUG medium	9221 F.1 [1]
	Escherichia coli Partition Method	EC broth with MUG (EC–MUG)	9222 G.1*a*(2) [1 13]
		NA–MUG medium	9222 G.1*a*(1) [1]
	Membrane Filtration Methods	Membrane Filtration using MI medium	EPA Method 1604 [3 4]
		m-ColiBlue24® Test.[3 5]	
		Chromocult.[3 6]	
	Enzyme Substrate Methods	Colilert®	9223 B [1 7]
		Colisure®	9223 B [1 7 8]
		E*Colite® Test.[9]	
		Readycult® Test.[10]	

Organism	Methodology category	Method [1]	Citation
		modified Colitag® Test.[11]	

The procedures must be done in accordance with the documents listed below. For vendor methods, the date of the method listed here is the date/version of the approved method. The methods listed are the only versions that may be used for compliance with this rule. Laboratories should be careful to use only the approved versions of the methods, as product package inserts may not be the same as the approved versions of the methods.

The Director of the Federal Register approved the incorporation by reference of the documents listed in footnotes 1, 4, 5, 6, 9, 10, and 11 in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51.

Copies of the documents may be obtained from the sources listed below. Information regarding these documents can be obtained from the Safe Drinking Water Hotline, telephone (800) 426–4791. Documents may be reviewed at EPA's Drinking Water Docket, EPA West, 1301 Constitution Avenue, NW., EPA West, Room B102, Washington, DC 20460 (Telephone: 202–566–2426); 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/cfr/ibr-locations.html.*

[1] Methods are described in *Standard Methods for the Examination of Water and Wastewater,* 20th edition (1998), or 21st edition (2005). American Public Health Association, 800 I Street, NW., Washington, DC 20001. The cited methods published in either of these two editions may be used. In addition, the following online versions may also be used: 9221 B.1, B.2–99, D.1, D.2–99, 9222 B–97, 9222 C–97, and 9223 B–97. Standard Methods Online is available at *http://www.standardmethods.org.* The year in which each method was approved by the Standard Methods Committee is designated by the last two digits following the hyphen in the method number. The methods listed are the only online versions that may be used.

[2] Lactose broth, as commercially available, may be used in lieu of lauryl tryptose broth, if the system conducts at least 25 parallel tests between lactose broth and lauryl tryptose broth using the water normally tested, and if the findings from this comparison demonstrate that the false-positive rate and false-negative rate for total coliforms, using lactose broth, is less than 10 percent.

[3] All filtration series must begin with membrane filtration equipment that has been sterilized by autoclaving. Exposure of filtration equipment to UV light is not adequate to ensure sterilization. Subsequent to the initial autoclaving, exposure of the filtration equipment to UV light may be used to sanitize the funnels between filtrations within a filtration series.

[4] EPA Method 1604: Total Coliforms and *Escherichia coli* in Water by Membrane Filtration Using a Simultaneous Detection Technique (MI Medium); September 2002, EPA 821–R–02–024. The method is available at *http://www.epa.gov/nerlcwww/1604sp02.pdf* or from EPA's Water Resource Center (RC–4100T), 1200 Pennsylvania Avenue, NW., Washington, DC 20460.

[5] The m-ColiBlue24® test is described in the document "Membrane Filtration Method m-ColiBlue24® Broth, Revision 2, August 17, 1999", available from the Hach Company, P.O. Box 389, Loveland, CO 80539.

[6] The Chromocult test is described in the document "Chromocult® Coliform Agar Presence/Absence Membrane Filter Test Method for Detection and Identification of Coliform Bacteria and *Escherichia coli* in Finished Waters," November 2000, Version 1.0, available from EMD Chemicals (an affiliate of Merck KGaA, Darmstadt Germany), 480 S. Democrat Road, Gibbstown, NJ 08027–1297. (Telephone (800) 222–0342).

[7] Multiple-tube and multi-well enumerative formats for this method are approved for use in presence-absence determination under this regulation.

[8] Colisure® results may be read after an incubation time of 24 hours.

[9] The E*Colite® test is described in the document "Charm E*Colite™ Presence/Absence Test for Detection and Identification of Coliform Bacteria and *Escherichia coli* in Drinking Water", January 9, 1998, available from Charm Sciences, Inc., 659 Andover Street, Lawrence, MA 01843–1032.

[10] The Readycult® test is described in the document "Readycult® Coliforms 100 Presence/Absence Test for Detection and Identification of Coliform Bacteria and *Escherichia coli* in Finished Waters, January 2007, Version 1.1," available from EMD Chemicals (an affiliate of Merck KGaA, Darmstadt Germany), 480 S. Democrat Road, Gibbstown, NJ 08027–1297. (Telephone (800) 222–0342). Internet address *http://www.readycult.com.*

[11] The Colitag® test is described in the document "Modified Colitag™ Test Method for the Simultaneous Detection of *E. coli* and other Total Coliforms in Water," August 28, 2009, available from CPI International, Inc., 5580 Skylane Blvd., Santa Rosa, CA 95403. (Telephone (800) 878–7654, Fax (707) 545–7901). Internet address *http://www.cpiinternational.com.*

[12] A multiple tube enumerative format, as described in *Standard Methods for the Examination of Water and Wastewater* 9221, is approved for this method for use in presence-absence determination under this regulation.

[13] The following changes must be made to the EC broth with MUG (EC–MUG) formulation: Potassium dihydrogen phosphate, KH_2PO_4, must be 1.5g, and 4-methylumbelliferyl-Beta-D-glucuronide must be 0.05 g.

(b) *Laboratory certification.* Systems must have all compliance samples required under this subpart analyzed by a laboratory certified by the EPA or a primacy State to analyze drinking water samples. The laboratory used by the system must be certified for each method and contaminant used for compliance monitoring under this rule.

§ 141.853 General monitoring requirements for all public water systems.

(a) *Sample siting plans.* (1) Systems must develop a written sample siting plan that identifies sampling sites and a sample collection schedule that are representative of water throughout the distribution system not later than [DATE THREE YEARS AFTER PUBLICATION OF FINAL RULE]. Systems must collect total coliform samples according to the written sample siting plan. These plans are subject to State review and revision. Monitoring required by §§ 141.854 through 141.858 may take place at a customer's premise, dedicated sampling station, or other designated compliance sampling location. Routine and repeat sample sites and any sampling points necessary to meet the requirements of subpart S must be reflected in the sampling plan.

(2) Systems must collect samples at regular time intervals throughout the month, except that systems that use only ground water and serve 4,900 or fewer people may collect all required samples on a single day if they are taken from different sites.

(3) A system may conduct more monitoring than is required by this subpart to investigate potential problems in the distribution system and use monitoring as a tool to assist in uncovering problems. A system may take more than the minimum number of required routine samples and include the results in calculating whether the coliform treatment technique trigger has been exceeded only if the samples are taken in accordance with the existing sample siting plan and are representative of water throughout the distribution system.

(4) Systems must identify repeat monitoring locations in the sample siting plan. Unless the provisions of paragraphs (a)(4)(i) or (a)(4)(ii) of this section are met, the system must collect at least one repeat sample from the sampling tap where the original total coliform-positive sample was taken, and at least one repeat sample at a tap within five service connections upstream and at least one repeat sample at a tap within five service connections downstream of the original sampling site. If a total coliform-positive sample is at the end of the distribution system, or one service connection away from the end of the distribution system, the State may waive the requirement to collect at least one repeat sample upstream or

downstream of the original sampling site. Except as provided for in paragraph (a)(4)(ii) of this section, systems required to conduct triggered source water monitoring under § 141.402(a) must take ground water source sample(s) in addition to repeat samples required under this subpart.

(i) Systems may propose repeat monitoring locations to the State that the system believes to be representative of a pathway for contamination of the distribution system. A system may elect to specify either alternative fixed locations or criteria for selecting repeat sampling sites on a situational basis in a standard operating procedure (SOP) in its sample siting plan. The system must design its SOP to focus the repeat samples at locations that best verify and determine the extent of potential contamination of the distribution system area based on specific situations. The State may modify the SOP as needed.

(ii) Ground water systems serving 1,000 or fewer people may propose repeat sampling locations to the State that differentiate potential source water and distribution system contamination (*e.g.* by sampling at entry points to the distribution system). A ground water system required to conduct triggered source water monitoring may, with written State approval, take one of its repeat samples at the monitoring location required for triggered source water monitoring under § 141.402(a) if the system demonstrates to the State's satisfaction that the sample siting plan remains representative of water quality in the distribution system. If approved by the State, the system may use that sample result to meet the monitoring requirements in both § 141.402(a) and this section.

(A) If a repeat sample taken at the monitoring location required for triggered source water monitoring is *E. coli*-positive, the system has violated the *E. coli* MCL and must also comply with § 141.402(a)(3). If a system with a limited number of monitoring locations takes more than one repeat sample at the monitoring location required for triggered source water monitoring, the system may reduce the number of additional source water samples required under § 141.402(a)(3) by the number of repeat samples taken at that location that were not *E. coli*-positive.

(B) If a system with a limited number of monitoring locations takes more than one repeat sample at the monitoring location required for triggered source water monitoring under § 141.402(a), and more than one repeat sample is *E. coli*-positive, the system has violated the *E. coli* MCL and must also comply with § 141.403(a)(1).

(5) States may review, revise, and approve, as necessary, repeat sampling proposed by systems under paragraphs (a)(4)(i) and (ii) of this section. The system must demonstrate to the State's satisfaction that the sample siting plan remains representative of the water quality in the distribution system. The State may determine that monitoring at the entry point to the distribution system (especially for undisinfected ground water systems) is effective to differentiate between potential source water and distribution system problems.

(b) *Special purpose samples.* Special purpose samples, such as those taken to determine whether disinfection practices are sufficient following pipe placement, replacement, or repair, must not be used to determine whether the coliform treatment technique trigger has been exceeded. Repeat samples taken pursuant to § 141.858 are not considered special purpose samples, and must be used to determine whether the coliform treatment technique trigger has been exceeded.

(c) *Invalidation of total coliform samples.* A total coliform-positive sample invalidated under this paragraph (c) of this section does not count toward meeting the minimum monitoring requirements of this subpart.

(1) The State may invalidate a total coliform-positive sample only if the conditions of paragraph (c)(1)(i), (ii), or (iii) of this section are met.

(i) The laboratory establishes that improper sample analysis caused the total coliform-positive result.

(ii) The State, on the basis of the results of repeat samples collected as required under § 141.858(a), determines that the total coliform-positive sample resulted from a domestic or other non-distribution system plumbing problem. The State cannot invalidate a sample on the basis of repeat sample results unless all repeat sample(s) collected at the same tap as the original total coliform-positive sample are also total coliform-positive, and all repeat samples collected within five service connections of the original tap are total coliform-negative (*e.g.,* a State cannot invalidate a total coliform-positive sample on the basis of repeat samples if all the repeat samples are total coliform-negative, or if the system has only one service connection).

(iii) The State has substantial grounds to believe that a total coliform-positive result is due to a circumstance or condition that does not reflect water quality in the distribution system. In this case, the system must still collect all repeat samples required under § 141.858(a), and use them to determine whether a coliform treatment technique trigger in § 141.859 has been exceeded. To invalidate a total coliform-positive sample under this paragraph, the decision and supporting rationale must be documented in writing, and approved and signed by the supervisor of the State official who recommended the decision. The State must make this document available to EPA and the public. The written documentation must state the specific cause of the total coliform-positive sample, and what action the system has taken, or will take, to correct this problem. The State may not invalidate a total coliform-positive sample solely on the grounds that all repeat samples are total coliform-negative.

(2) A laboratory must invalidate a total coliform sample (unless total coliforms are detected) if the sample produces a turbid culture in the absence of gas production using an analytical method where gas formation is examined (*e.g.,* the Multiple-Tube Fermentation Technique), produces a turbid culture in the absence of an acid reaction in the Presence-Absence (P–A) Coliform Test, or exhibits confluent growth or produces colonies too numerous to count with an analytical method using a membrane filter (*e.g.,* Membrane Filter Technique). If a laboratory invalidates a sample because of such interference, the system must collect another sample from the same location as the original sample within 24 hours of being notified of the interference problem, and have it analyzed for the presence of total coliforms. The system must continue to re-sample within 24 hours and have the samples analyzed until it obtains a valid result. The State may waive the 24-hour time limit on a case-by-case basis.

§ 141.854 Routine monitoring requirements for non-community water systems serving 1,000 or fewer people using only ground water.

(a) *General.* (1) The provisions of this section apply to non-community water systems using only ground water (except ground water under the direct influence of surface water, as defined in § 141.2) and serving 1,000 or fewer people.

(2) Following any total coliform-positive sample taken under the provisions of this section, systems must comply with the repeat monitoring requirements and *E. coli* analytical requirements in § 141.858.

(3) Once all monitoring required by this section and § 141.858 for a calendar month has been completed, systems must determine whether any coliform

treatment technique triggers specified in § 141.859 have been exceeded. If any trigger has been exceeded, systems must complete assessments as required by § 141.859.

(b) *Monitoring frequency for total coliforms.* Systems must monitor each calendar quarter that the system provides water to the public, except for seasonal systems or as provided under paragraphs (c) though (h) and (j) of this section. Seasonal systems must meet the monitoring requirements of paragraph (i) of this section.

(c) *Transition to subpart Y.* (1) Systems, including seasonal systems, must continue to monitor according to the total coliform monitoring schedules under § 141.21 that were in effect on [DATE THREE YEARS AFTER PUBLICATION OF THE FINAL RULE] unless any of the conditions for increased monitoring in paragraph (f) of this section are triggered on or after [DATE THREE YEARS AFTER PUBLICATION OF THE FINAL RULE] or unless otherwise directed by the State.

(2) After [DATE THREE YEARS AFTER PUBLICATION OF THE FINAL RULE], the State must perform a special monitoring evaluation during each sanitary survey to review the status of the system, including the distribution system, to determine whether the system is on an appropriate monitoring schedule. After the State has performed the special monitoring evaluation during each sanitary survey, the State may modify the system's monitoring schedule as necessary. For seasonal systems on quarterly or annual monitoring, this evaluation must include review of the approved sample siting plan, which must designate the time period(s) for monitoring based on site-specific considerations (*e.g.* during periods of highest demand or highest vulnerability to contamination). The seasonal system must collect compliance samples during these time periods.

(d) *Annual site visits.* Beginning no later than [DATE FOUR YEARS AFTER PUBLICATION OF THE FINAL RULE], systems on annual monitoring, including seasonal systems, must have an initial and recurring annual site visit by the State or an annual voluntary Level 2 assessment by a party approved by the State to remain on annual monitoring.

(e) *Reduced monitoring provisions.* Beginning [DATE THREE YEARS AFTER PUBLICATION OF THE FINAL RULE], the State may reduce the monitoring frequency for a well-operated ground water system from quarterly routine monitoring to no less than annual monitoring, if the system demonstrates that it meets the criteria for reduced monitoring in paragraphs (e)(1) through (e)(3) of this section, except for a system that has been on increased monitoring under the provisions of paragraph (f) of this section. A system on increased monitoring under paragraph (f) of this section must meet the provisions of paragraph (g) of this section to go to quarterly monitoring and must meet the provisions of paragraph (h) of this section to go to annual monitoring.

(1) The most recent sanitary survey shows that the system is free of sanitary defects, has a protected water source, and meets approved construction standards;

(2) The system has a clean compliance history for a minimum of 12 months; and

(3) The State has conducted an annual site visit (recurring) within the last 12 months and the system has corrected all identified sanitary defects. The system may substitute a Level 2 assessment by a party approved by the State for the State annual site visit.

(f) *Increased Monitoring Requirements.* A system on quarterly or annual monitoring that experiences any of the events identified in paragraphs (f)(1) through (f)(4) of this section must begin monthly monitoring the month following the event. The system must continue monthly monitoring until the requirements in paragraph (g) of this section for quarterly monitoring or paragraph (h) of this section for annual monitoring are met. A system on monthly monitoring for reasons other than those identified in paragraphs (f)(1) through (f)(4) of this section is not considered to be on increased monitoring for the purposes of paragraphs (g) and (h) of this section.

(1) The system triggers a Level 2 assessment or two Level 1 assessments in a rolling 12 month period.

(2) The system has an *E. coli* MCL violation.

(3) The system has a coliform treatment technique violation.

(4) The system has two subpart Y monitoring violations in a rolling 12-month period for a system on quarterly monitoring or one subpart Y monitoring violation for a system on annual monitoring.

(g) *Requirements for returning to quarterly monitoring.* To be eligible to return to quarterly monitoring from monthly monitoring triggered under paragraph (f) of this section, a system on increased monitoring under paragraph (f) of this section must meet the criteria in paragraphs (g)(1) and (g)(2) of this section.

(1) Within the last 12 months, the system must have a completed sanitary survey or a site visit by the State or a voluntary Level 2 assessment by a party approved by the State, be free of sanitary defects, and have a protected water source; and

(2) The system must have a clean compliance history for a minimum of 12 months.

(h) *Requirements for annual monitoring.* To be eligible for annual monitoring, a system on increased monitoring under paragraph (f) of this section must meet the criteria in paragraph (g) of this section plus the criteria in paragraphs (h)(1) and (h)(2) of this section.

(1) An annual site visit (recurring) by the State and correction of all identified sanitary defects. The system may substitute a voluntary Level 2 assessment by a party approved by the State for the State annual site visit in any given year.

(2) The system must have in place or adopt one or more additional enhancements to the water system barriers to contamination in paragraphs (h)(2)(i) through (h)(2)(v) of this section.

(i) Cross connection control, as approved by the State.

(ii) An operator certified by an appropriate State certification program, which may include regular visits by a circuit rider.

(iii) Continuous disinfection entering the distribution system and a residual in the distribution system in accordance with criteria specified by the State.

(iv) Demonstration of maintenance of at least a 4-log removal or inactivation of viruses as provided for under § 141.403(b)(3).

(v) Other equivalent enhancements to water system barriers as approved by the State.

(i) *Seasonal systems.* (1) Beginning [DATE THREE YEARS AFTER PUBLICATION OF THE FINAL RULE], all seasonal systems must demonstrate completion of a State-approved start-up procedure, which may include a requirement for a startup sample prior to serving water to the public.

(2) Seasonal systems have a routine monitoring frequency of monthly.

(3) A seasonal system must meet the criteria in paragraphs (i)(3)(i) through (iii) of this section to be eligible for monitoring less frequently than monthly after [DATE THREE YEARS AFTER PUBLICATION OF FINAL RULE], except as provided under paragraph (c) of this section.

(i) The seasonal system must have an approved sample siting plan that designates the time period for monitoring based on site-specific

considerations (*e.g.* during periods of highest demand or highest vulnerability to contamination). The system must collect compliance samples during this time period.

(ii) To be eligible for reduced quarterly monitoring, the system must meet the criteria in paragraph (g) of this section.

(iii) To be eligible for reduced annual monitoring, the system must meet the criteria under paragraph (h) of this section.

(j) *Additional routine monitoring.* Systems collecting samples on a quarterly or annual frequency must conduct additional routine monitoring the month following one or more total coliform-positive samples (with or without a Level 1 treatment technique trigger). Systems must collect at least three routine samples during the next month, except that the State may waive this requirement if the conditions of paragraph (j)(1), (2), or (3) of this section are met. Systems may either collect samples at regular time intervals throughout the month or may collect all required routine samples on a single day if samples are taken from different sites. Systems must use the results of additional routine samples in coliform treatment technique trigger calculations.

(1) The State may waive the requirement to collect three routine samples the next month in which the system provides water to the public if the State, or an agent approved by the State, performs a site visit before the end of the next month in which the system provides water to the public. Although a sanitary survey need not be performed, the site visit must be sufficiently detailed to allow the State to determine whether additional monitoring and/or any corrective action is needed. The State cannot approve an employee of the system to perform this site visit, even if the employee is an agent approved by the State to perform sanitary surveys.

(2) The State may waive the requirement to collect three routine samples the next month in which the system provides water to the public if the State has determined why the sample was total coliform-positive and has established that the system has corrected the problem or will correct the problem before the end of the next month in which the system serves water to the public. In this case, the State must document this decision to waive the following month's additional monitoring requirement in writing, have it approved and signed by the supervisor of the State official who recommends such a decision, and make this document available to the EPA and public. The written documentation must describe the specific cause of the total coliform-positive sample and what action the system has taken and/or will take to correct this problem.

(3) The State may not waive the requirement to collect three additional routine samples the next month in which the system provides water to the public solely on the grounds that all repeat samples are total coliform-negative. If the State determines that the system has corrected the contamination problem before the system takes the set of repeat samples required in § 141.858, and all repeat samples were total coliform-negative, the State may waive the requirement for additional routine monitoring the next month.

§ 141.855 Routine monitoring requirements for community water systems serving 1,000 or fewer people using only ground water.

(a) *General.* (1) The provisions of this section apply to community water systems using only ground water (except ground water under the direct influence of surface water, as defined in § 141.2) and serving 1,000 or fewer people.

(2) Following any total coliform-positive sample taken under the provisions of this section, systems must comply with the repeat monitoring requirements and *E. coli* analytical requirements in § 141.858.

(3) Once all monitoring required by this section and § 141.858 for a calendar month has been completed, systems must determine whether any coliform treatment technique triggers specified in § 141.859 have been exceeded. If any trigger has been exceeded, systems must complete assessments as required by § 141.859.

(b) *Monitoring frequency for total coliforms.* The monitoring frequency for total coliforms is one sample/month, except as provided for under paragraphs (c) through (f) of this section.

(c) *Transition to subpart Y.* (1) All systems must continue to monitor according to the total coliform monitoring schedules under § 141.21 that were in effect on [DATE THREE YEARS AFTER PUBLICATION OF THE FINAL RULE] unless any of the conditions in paragraph (e) of this section are triggered on or after [DATE THREE YEARS AFTER PUBLICATION OF THE FINAL RULE] or unless otherwise directed by the State.

(2) After [DATE THREE YEARS AFTER PUBLICATION OF THE FINAL RULE], the State must perform a special monitoring evaluation during each sanitary survey to review the status of the system, including the distribution system, to determine whether the system is on an appropriate monitoring schedule. After the State has performed the special monitoring evaluation during each sanitary survey, the State may modify the system's monitoring schedule as necessary.

(d) *Reduced monitoring requirements.* (1) The State may reduce the monitoring frequency from monthly monitoring to no less than quarterly monitoring if the system is in compliance with State certified operator provisions and demonstrates that it meets the criteria in paragraphs (d)(1)(i) through (d)(1)(iii) of this section. A system that loses its certified operator must return to monthly monitoring the month following that loss.

(i) The most recent sanitary survey shows the system is free of sanitary defects (or has an approved plan and schedule to correct them), has a protected water source and meets approved construction standards.

(ii) The system has a clean compliance history for a minimum of 12 months.

(iii) The system meets at least one of the following criteria:

(A) An annual site visit by the State or a Level 2 assessment by a party approved by the State and correction of all identified sanitary defects (or an approved plan and schedule to correct them).

(B) Cross connection control, as approved by the State.

(C) Continuous disinfection entering the distribution system and a residual in the distribution system in accordance with criteria specified by the State.

(D) Demonstration of maintenance of at least a 4-log removal or inactivation of viruses as provided for under § 141.403(b)(3).

(E) Other equivalent enhancements to water systems as approved by the State.

(e) *Return to routine monitoring requirements.* Systems on quarterly monitoring that experience any of the events in paragraphs (e)(1) through (e)(4) of this section must begin monthly monitoring the month following the event. The system must continue monthly monitoring until it meets the reduced monitoring requirements in paragraph (d) of this section.

(1) The system triggers a Level 2 assessment or two Level 1 assessments in a rolling 12-month period.

(2) The system has an *E. coli* MCL violation.

(3) The system has a coliform treatment technique violation.

(4) The system has two subpart Y monitoring violations in a rolling 12-month period.

(f) *Additional routine monitoring.* Systems collecting samples on a quarterly frequency must conduct additional routine monitoring the month following one or more total coliform-positive samples (with or without a Level 1 treatment technique trigger). Systems must collect at least three routine samples during the next month, except that the State may waive this requirement if the conditions of paragraph (f)(1), (2), or (3) of this section are met. Systems may either collect samples at regular time intervals throughout the month or may collect all required routine samples on a single day if samples are taken from different sites. Systems must use the results of additional routine samples in coliform treatment technique trigger calculations.

(1) The State may waive the requirement to collect three routine samples the next month in which the system provides water to the public if the State, or an agent approved by the State, performs a site visit before the end of the next month in which the system provides water to the public. Although a sanitary survey need not be performed, the site visit must be sufficiently detailed to allow the State to determine whether additional monitoring and/or any corrective action is needed. The State cannot approve an employee of the system to perform this site visit, even if the employee is an agent approved by the State to perform sanitary surveys.

(2) The State may waive the requirement to collect three routine samples the next month in which the system provides water to the public if the State has determined why the sample was total coliform-positive and has established that the system has corrected the problem or will correct the problem before the end of the next month in which the system serves water to the public. In this case, the State must document this decision to waive the following month's additional monitoring requirement in writing, have it approved and signed by the supervisor of the State official who recommends such a decision, and make this document available to the EPA and the public. The written documentation must describe the specific cause of the total coliform-positive sample and what action the system has taken and/or will take to correct this problem.

(3) The State may not waive the requirement to collect three additional routine samples the next month in which the system provides water to the public solely on the grounds that all repeat samples are total coliform-negative. If the State determines that the system has corrected the contamination problem before the system takes the set of repeat samples required in § 141.858, and all repeat samples were total coliform-negative, the State may waive the requirement for additional routine monitoring the next month.

§ 141.856 Routine monitoring requirements for subpart H public water systems serving 1,000 or fewer people.

(a) *General.* (1) The provisions of this section apply to subpart H public water systems of this part serving 1,000 or fewer people.

(2) Following any total coliform-positive sample taken under the provisions of this section, systems must comply with the repeat monitoring requirements and *E. coli* analytical requirements in § 141.858.

(3) Once all monitoring required by this section and § 141.858 for a calendar month has been completed, systems must determine whether any coliform treatment technique triggers specified in § 141.859 have been exceeded. If any trigger has been exceeded, systems must complete assessments as required by § 141.859.

(4) Beginning [DATE THREE YEARS AFTER PUBLICATION OF THE FINAL RULE], all seasonal systems must demonstrate completion of a State-approved start-up procedure, which may include a requirement for a startup sample prior to serving water to the public.

(b) *Routine monitoring frequency for total coliforms.* Subpart H systems of this part (including consecutive systems) must monitor monthly. Systems may not reduce monitoring.

(c) *Unfiltered subpart H systems.* A subpart H system of this part that does not practice filtration in compliance with subparts H, P, T, and W must collect at least one total coliform sample near the first service connection each day the turbidity level of the source water, measured as specified in § 141.74(b)(2), exceeds 1 NTU. When one or more turbidity measurements in any day exceed 1 NTU, the system must collect this coliform sample within 24 hours of the first exceedance, unless the State determines that the system, for logistical reasons outside the system's control, cannot have the sample analyzed within 30 hours of collection *and identifies an alternative sample collection schedule.* Sample results from this coliform monitoring must be included in determining whether the coliform treatment technique trigger in § 141.859 has been exceeded.

§ 141.857 Routine monitoring requirements for public water systems serving more than 1,000 people.

(a) *General.* (1) The provisions of this section apply to public water systems serving more than 1,000 persons.

(2) Following any total coliform-positive sample taken under the provisions of this section, systems must comply with the repeat monitoring requirements and *E. coli* analytical requirements in § 141.858.

(3) Once all monitoring required by this section and § 141.858 for a calendar month has been completed, systems must determine whether any coliform treatment technique triggers specified in § 141.859 have been exceeded. If any trigger has been exceeded, systems must complete assessments as required by § 141.859.

(4) Beginning [DATE THREE YEARS AFTER PUBLICATION OF THE FINAL RULE], all seasonal systems must demonstrate completion of a State-approved start-up procedure, which may include a requirement for a startup sample prior to serving water to the public.

(b) *Monitoring frequency for total coliforms.* The monitoring frequency for total coliforms is based on the population served by the system, as follows:

TOTAL COLIFORM MONITORING FREQUENCY FOR PUBLIC WATER SYSTEMS SERVING MORE THAN 1,000 PEOPLE

Population served	Minimum number of samples per month
1,001 to 2,500	2
2,501 to 3,300	3
3,301 to 4,100	4
4,101 to 4,900	5
4,901 to 5,800	6
5,801 to 6,700	7
6,701 to 7,600	8
7,601 to 8,500	9
8,501 to 12,900	10
12,901 to 17,200	15
17,201 to 21,500	20
21,501 to 25,000	25
25,001 to 33,000	30
33,001 to 41,000	40
41,001 to 50,000	50
50,001 to 59,000	60
59,001 to 70,000	70
70,001 to 83,000	80
83,001 to 96,000	90
96,001 to 130,000	100
130,001 to 220,000	120
220,001 to 320,000	150
320,001 to 450,000	180
450,001 to 600,000	210
600,001 to 780,000	240
780,001 to 970,000	270
970,001 to 1,230,000	300

TOTAL COLIFORM MONITORING FREQUENCY FOR PUBLIC WATER SYSTEMS SERVING MORE THAN 1,000 PEOPLE—Continued

Population served	Minimum number of samples per month
1,230,001 to 1,520,000	330
1,520,001 to 1,850,000	360
1,850,001 to 2,270,000	390
2,270,001 to 3,020,000	420
3,020,001 to 3,960,000	450
3,960,001 or more	480

(c) *Unfiltered subpart H systems.* A subpart H system of this part that does not practice filtration in compliance with subparts H, P, T, and W must collect at least one total coliform sample near the first service connection each day the turbidity level of the source water, measured as specified in § 141.74(b)(2), exceeds 1 NTU. When one or more turbidity measurements in any day exceed 1 NTU, the system must collect this coliform sample within 24 hours of the first exceedance, unless the State determines that the system, for logistical reasons outside the system's control, cannot have the sample analyzed within 30 hours of collection and identifies an alternative sample collection schedule. Sample results from this coliform monitoring must be included in determining whether the coliform treatment technique trigger in § 141.859 has been exceeded.

(d) *Reduced monitoring.* Systems may not reduce monitoring, except for non-community water systems using only ground water (and not ground water under the direct influence of surface water) serving 1,000 or fewer people in some months and more than 1,000 persons in other months. In months when more than 1,000 persons are served, the systems must monitor at the frequency specified in paragraph (a) of this section. In months when 1,000 or fewer people are served, the State may reduce the monitoring frequency, in writing, to a frequency allowed under § 141.854 for a similarly situated system that always serves 1,000 or fewer people, taking into account the provisions in § 141.854(e) through (g).

§ 141.858 Repeat monitoring and E. coli requirements.

(a) *Repeat monitoring.* (1) If a sample taken under §§ 141.854 though 141.857 is total coliform-positive, the system must collect a set of repeat samples within 24 hours of being notified of the positive result. The system must collect no fewer than three repeat samples for each total coliform-positive sample found. The State may extend the 24-hour limit on a case-by-case basis if the system has a logistical problem in collecting the repeat samples within 24 hours that is beyond its control. In the case of an extension, the State must specify how much time the system has to collect the repeat samples. The State cannot waive the requirement for a system to collect repeat samples in paragraphs (a)(1) through (a)(3) of this section.

(2) The system must collect all repeat samples on the same day, except that the State may allow a system with a single service connection to collect the required set of repeat samples over a three-day period or to collect a larger volume repeat sample(s) in one or more ample containers of any size, as long as the total volume collected is at least 300 ml.

(3) The system must collect an additional set of repeat samples in the manner specified in paragraphs (a)(1) through (a)(3) of this section if one or more repeat samples in the current set of repeat samples is total coliform-positive. The system must collect the additional set of repeat samples within 24 hours of being notified of the positive result, unless the State extends the limit as provided in paragraph (a)(1) of this section. The system must continue to collect additional sets of repeat samples until either total coliforms are not detected in one complete set of repeat samples or the system determines that a coliform treatment technique trigger has been exceeded as a result of a repeat sample being total coliform-positive and notifies the State. If a trigger identified in § 141.859 is exceeded as a result of a routine sample being total coliform-positive, systems are required to conduct only one round of repeat monitoring for each total coliform-positive routine sample.

(4) After a system collects a routine sample and before it learns the results of the analysis of that sample, if it collects another routine sample(s) from within five adjacent service connections of the initial sample, and the initial sample, after analysis, is found to contain total coliforms, then the system may count the subsequent sample(s) as a repeat sample instead of as a routine sample.

(5) Results of all routine and repeat samples taken under §§ 141.854 through 141.858 not invalidated by the State must be used to determine whether a coliform treatment technique trigger § 141.859 has been exceeded.

(b) *Escherichia coli (E. coli) testing.* (1) If any routine or repeat sample is total coliform-positive, the system must analyze that total coliform-positive culture medium to determine if *E. coli* are present. If *E. coli* are present, the system must notify the State by the end of the day when the system is notified of the test result, unless the system is notified of the result after the State office is closed, in which case the system must notify the State before the end of the next business day.

(2) The State has the discretion to allow a system, on a case-by-case basis, to forgo *E. coli* testing on a total coliform-positive sample if that system assumes that the total coliform-positive sample is *E. coli*-positive. Accordingly, the system must notify the State as specified in paragraph (b)(1) of this section and the provisions of § 141.63(c) apply.

§ 141.859 Coliform treatment technique requirements for protection against potential fecal contamination.

(a) *Treatment technique triggers.* Systems must conduct assessments in accordance with paragraph (b) of this section after exceeding treatment technique triggers in paragraphs (a)(1) and (a)(2) of this section.

(1) Level 1 treatment technique triggers.

(i) For systems taking 40 or more samples per month, the system exceeds 5.0% total coliform-positive samples for the month.

(ii) For systems taking fewer than 40 samples per month, the system has two or more total coliform-positive samples in the same month.

(iii) The system fails to take every required repeat sample after any single total coliform-positive sample.

(2) Level 2 treatment technique triggers.

(i) An *E. coli* MCL violation, including failure to collect repeat samples within the required time following an *E. coli*-positive routine sample.

(ii) A second Level 1 trigger as defined in paragraph (a)(1) of this section, within a rolling 12-month period, unless the State has determined a likely reason that the initial samples that caused the Level 1 treatment technique trigger were total coliform-positive and has established that the system has corrected the problem.

(iii) For systems with approved annual monitoring, a Level 1 trigger in two consecutive years.

(b) *Requirements for assessments.* (1) Systems must ensure that Level 1 and 2 assessments are conducted in order to identify the possible presence of sanitary defects and defects in distribution system coliform monitoring practices. Level 2 assessments must be conducted by parties approved by the State.

(2) When conducting assessments, systems must ensure that the assessor evaluates minimum elements that include review and identification of inadequacies in sample sites; sampling protocol; sample processing; atypical events that could affect distributed water quality or indicate that distributed water quality was impaired; changes in distribution system maintenance and operation that could affect distributed water quality (including water storage); source and treatment considerations that bear on distributed water quality, where appropriate (*e.g.,* small ground water systems); and existing water quality monitoring data. The State may tailor specific assessment elements to the size and type of the system. Systems may tailor their assessment activities based on the characteristics of the distribution system (consistent with any State directives).

(3) Level 1 Assessments. A system must conduct a Level 1 assessment consistent with State requirements if the system exceeds one of the treatment technique triggers in paragraph (a)(1) of this section.

(i) The system must complete a Level 1 assessment as soon as practical after failure to take a repeat sample or after notification of monitoring results. In the completed assessment form, the system must identify sanitary defects detected, corrective actions completed, and a timetable for any corrective actions not already completed. The assessment form may also note that no sanitary defects were identified. The system must submit the completed Level 1 assessment form to the State within 30 days after determination of exceeding the trigger.

(ii) If the State reviews the completed Level 1 assessment and determines that the assessment is not sufficient, the State must consult with the system. If necessary after consultation, the system must submit a revised assessment form to the State on an agreed-upon schedule not to exceed 30 days from the date of the consultation. Upon completion and submission of the assessment form by the system, the State must determine if the system has identified a likely cause for the Level 1 trigger and, if so, establish that the system has corrected the problem, or has included a schedule acceptable to the State for correcting the problem.

(4) Level 2 Assessments. A system must ensure that a Level 2 assessment consistent with State requirements is conducted if the system exceeds one of the treatment technique triggers in paragraph (a)(2) of this section. The State may direct expedited actions or additional actions in the case of an *E. coli* MCL violation.

(i) The system must ensure that a Level 2 assessment is completed by the State or by a party approved by the State as soon as practical after failure to take a repeat sample or after notification of monitoring results. The system must submit a completed Level 2 assessment form to the State within 30 days after the determination of exceeding the trigger. The assessment form must describe sanitary defects detected, corrective actions completed, and a timetable for any corrective actions not already completed. The assessment form may also note that no sanitary defects were identified.

(ii) The system may conduct Level 2 assessments if the system has staff or management with the certification or qualifications specified by the State unless otherwise directed by the State.

(iii) If the State reviews the completed Level 2 assessment and determines that the assessment is insufficient, the State must consult with the system. If necessary after consultation, the system must submit a revised assessment form to the State on an agreed-upon schedule not to exceed 30 days. Upon completion and submission of the assessment form by the system, the State must determine if the system has identified a likely cause for the Level 2 trigger and determine whether the system has corrected the problem, or has included a schedule acceptable to the State for correcting the problem.

(c) *Corrective Action.* Systems must correct sanitary defects found through either Level 1 or 2 assessments conducted under paragraph (b) of this section. For corrections not completed by the time of submission of the assessment form, the system must complete the corrective action(s) in compliance with a schedule determined by the State in consultation with the system. The system must notify the State when each scheduled corrective action is completed.

(d) *Consultation.* At any time during the assessment or corrective action phase, either the water system or the State may request a consultation with the other party to determine the appropriate actions to be taken. The system may consult with the State on all relevant information that may impact on its ability to comply with a requirement of this subpart, including the method of accomplishment, an appropriate timeframe, and other relevant information.

§ 141.860 Violations.

(a) *E. coli MCL Violation.* A system is in violation of the MCL for *E. coli* when any of the conditions identified in paragraphs (a)(1) through (a)(4) of this section occur.

(1) The system has an *E. coli*-positive repeat sample following a total coliform-positive routine sample.

(2) The system has a total coliform-positive repeat sample following an *E. coli*-positive routine sample.

(3) The system fails to take all required repeat samples following an *E. coli*-positive routine sample.

(4) The system fails to test for *E. coli* when any repeat sample tests positive for total coliform.

(b) *Treatment technique violation.* A treatment technique violation occurs when a system exceeds a treatment technique trigger specified in § 141.859(a) and then fails to conduct the required assessment or corrective actions within the timeframe specified in § 141.859(b) and (c).

(c) *Monitoring violations.* Failure to take every required routine or additional routine sample in a compliance period is a routine monitoring violation. Failure to analyze for *E. coli* following a total coliform routine sample is a monitoring violation.

(d) *Reporting violations.* (1) Failure to submit a monitoring report or completed assessment form after a system properly conducts monitoring or assessment is a reporting violation.

(2) Failure to notify the State following an *E. coli*-positive sample as required by § 141.858(b)(1) is a reporting violation.

§ 141.861 Reporting and recordkeeping.

(a) *Reporting.* (1) A system that has violated the *E. coli* MCL must report the violation to the State no later than the end of the next business day after it learns of the violation, and notify the public in accordance with subpart Q of this part. A system must notify the State no later than the end of the next business day after it learns of an *E. coli*-positive sample.

(2) A system that has violated the treatment technique for total coliforms in § 141.859 must report the violation to the State no later than the end of the next business day after it learns of the violation, and notify the public in accordance with subpart Q of this part. The system must notify the State in accordance with § 141.859(c) when each scheduled corrective action is completed for corrections not completed by the time of submission of the assessment form.

(3) A system that has failed to comply with a coliform monitoring requirement must report the monitoring violation to the State within 10 days after the system discovers the violation, and notify the

public in accordance with subpart Q of this part.

(b) *Recordkeeping.* The system must maintain any assessment form, regardless of who conducts the assessment, and documentation of corrective actions completed as a result of those assessments, or other available summary documentation of the sanitary defects and corrective actions taken under § 141.858 for State review. This record must be maintained by the system for a period not less than five years after completion of the assessment or corrective action.

PART 142—NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION

21. The authority citation for part 142 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4, 300j–9, and 300j–11.

22. Section 142.14 is amended by revising paragraph (a)(1)(iii) and adding a new paragraph (a)(10) to read as follows:

§ 142.14 Records kept by States.

(a) * * *

(1) * * *

(iii) The analytical results, set forth in a form that makes possible comparison with the limits specified in §§ 141.63, 141.71, and 141.72 of this chapter and with the limits specified in subpart Y of this chapter.

* * * * *

(10) Records of each of the following decisions made pursuant to the provisions of subpart Y of part 141 must be made in writing and retained by the State.

(i) Records of the following decisions or activities must be retained for five years.

(A) Sections 141.858(a), 141.853(b)(2), 141.856(c), and 141.857(c) of this chapter—Any decision to waive the 24-hour time limit for collecting repeat samples after a total coliform-positive routine sample, or to extend the 24-hour limit for collection of samples following invalidation, or for an unfiltered subpart H system of this part to collect a total coliform sample following a turbidity measurement exceeding 1 NTU.

(B) Sections 141.854(j) and 141.855(f) of this chapter—Any decision to allow a system to waive the requirement for three routine samples the month following a total coliform-positive sample. The record of the waiver decision must contain all the items listed in those sections.

(C) Section 141.853(c) of this chapter—Any decision to invalidate a total coliform-positive sample. If the decision to invalidate a total coliform-positive sample as provided in § 141.853(c)(1) of this chapter is made, the record of the decision must contain all the items listed in that section.

(D) Section 141.859 of this chapter—Completed and approved subpart Y assessments, including reports from the system that corrective action has been completed as required by § 141.861(a)(2) of this chapter.

(ii) Records of each of the following decisions must be retained in such a manner so that each system's current status may be determined:

(A) Section 141.855(d) of this chapter—Any decision to reduce the total coliform monitoring frequency for a community water system serving 1,000 or fewer people to less than once per month, as provided in § 141.855(d) of this chapter, including what the reduced monitoring frequency is. A copy of the reduced monitoring frequency must be provided to the system.

(B) Section 141.854(e) of this chapter—Any decision to reduce the total coliform monitoring frequency for a non-community water system using only ground water and serving 1,000 or fewer people to less than once per quarter, as provided in § 141.854(e) of this chapter, including what the reduced monitoring frequency is. A copy of the reduced monitoring frequency must be provided to the system.

(C) Section 141.857(d) of this chapter—Any decision to reduce the total coliform monitoring frequency for a non-community water system using only ground water and serving more than 1,000 persons during any month the system serves 1,000 or fewer people, as provided in § 141.857(d) of this chapter. A copy of the reduced monitoring frequency must be provided to the system.

(D) Section 141.858(b)(2) of this chapter—Any decision to allow a system to forgo *E. coli* testing of a total coliform-positive sample if that system assumes that the total coliform-positive sample is *E. coli*-positive.

* * * * *

23. Section 142.15 is amended by adding paragraph (c)(3) to read as follows:

§ 142.15 Reports by States.

* * * * *

(c) * * *

(3) *Total coliforms under subpart Y.* A list of systems that the State is allowing to monitor less frequently than once per month for community water systems or less frequently than once per quarter for non-community water systems as provided in §§ 141.855 and 141.854 of this chapter, including the applicable date of the reduced monitoring requirement for each system.

* * * * *

24. Section 142.16 is amended by adding a new paragraph (q) to read as follows:

§ 142.16 Special primacy requirements.

* * * * *

(q) *Requirements for States to adopt 40 CFR part 141 subpart Y—Revised Total Coliform Rule.* In addition to the general primacy requirements elsewhere in this part, including the requirements that State regulations be at least as stringent as federal requirements, an application for approval of a State program revision that adopts 40 CFR part 141, subpart Y, must contain the information specified in this paragraph (q).

(1) In their application to EPA for approval to implement the federal requirements, the primacy application must indicate what baseline and reduced monitoring provisions of 40 CFR part 141, subpart Y the State will adopt and must describe how they will implement 40 CFR part 141, subpart Y in these areas so that EPA can be assured that implementation plans meet the minimum requirements of the rule.

(2) The State's application for primacy for subpart Y must include a written description for each provision included in paragraphs (q)(2)(i) through (viii) of this section.

(i) Sample Siting Plans—The frequency and process used to review and revise sample siting plans in accordance with 40 CFR part 141, subpart Y to determine adequacy.

(ii) Reduced Monitoring Criteria—An indication of whether the State will adopt the reduced monitoring provisions of 40 CFR part 141, subpart Y. If the State adopts the reduced monitoring provisions, it must describe the specific types or categories of water systems that will be covered by reduced monitoring and whether the State will use all or a reduced set of the optional criteria. For each of the reduced monitoring criteria, both mandatory and optional, the State must describe how the criteria will be evaluated to determine when systems qualify.

(iii) Assessments and Corrective Actions—The process for implementing the new assessment and corrective action phase of the rule, including the elements in paragraphs (q)(2)(iii)(A) through (D) of this section.

(A) Elements of Level 1 and Level 2 assessments. This must include an explanation of how the State will ensure

that Level 2 assessments provide a more detailed examination of the system (including the system's monitoring and operational practices) than do Level 1 assessments through the use of more comprehensive investigation and review of available information, additional internal and external resources, and other relevant practices.

(B) Examples of sanitary defects.

(C) Examples of assessment forms or formats.

(D) Methods that systems may use to consult with the State on appropriate corrective actions.

(iv) Invalidation of routine and repeat samples collected under 40 CFR part 141, subpart Y—The criteria and process for invalidating total coliform and *E. coli*-positive samples under 40 CFR part 141, subpart Y. This description must include criteria to determine if a sample was improperly processed by the laboratory, reflects a domestic or other non-distribution system plumbing problem or reflects circumstances or conditions that do not reflect water quality in the distribution system.

(v) Approval of individuals allowed to conduct Level 2 assessments under 40 CFR part 141, subpart Y—The criteria and process for approval of individuals allowed to conduct Level 2 assessments under 40 CFR part 141, subpart Y.

(vi) Special monitoring evaluation—The procedure for performing special monitoring evaluations during sanitary surveys for ground water systems serving 1,000 or fewer people to determine whether systems are on an appropriate monitoring schedule.

(vii) Seasonal systems—How the State will identify seasonal systems, how the State will determine when systems on less than monthly monitoring must monitor, and what start-up provisions seasonal system must meet under 40 CFR part 141, subpart Y.

(viii) Additional criteria for reduced monitoring—How the State will require systems on reduced monitoring to demonstrate:

(A) Continuous disinfection entering the distribution system and a residual in the distribution system.

(B) Cross connection control.

(C) Other enhancements to water system barriers.

25. Section 142.63 is amended by revising paragraph (b) to read as follows:

§ 142.63 Variances and exemptions from the maximum contaminant level for total coliforms.

* * * * *

(b) EPA has stayed this section as it relates to the total coliform MCL of § 141.63(a) of this chapter for systems that demonstrate to the State that the violation of the total coliform MCL is due to a persistent growth of total coliforms in the distribution system rather than fecal or pathogenic contamination, a treatment lapse or deficiency, or a problem in the operation or maintenance of the distribution system. This stay is applicable until [DATE THREE YEARS FOLLOWING PUBLICATION OF THE FINAL RULE], at which time the total coliform MCL is no longer applicable.

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Wednesday,
July 14, 2010

Part IV

Securities and Exchange Commission

17 CFR Part 275
Political Contributions by Certain Investment Advisers; Final Rule

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 275

[Release No. IA–3043; File No. S7–18–09]

RIN 3235–AK39

Political Contributions by Certain Investment Advisers

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Securities and Exchange Commission is adopting a new rule under the Investment Advisers Act of 1940 that prohibits an investment adviser from providing advisory services for compensation to a government client for two years after the adviser or certain of its executives or employees make a contribution to certain elected officials or candidates. The new rule also prohibits an adviser from providing or agreeing to provide, directly or indirectly, payment to any third party for a solicitation of advisory business from any government entity on behalf of such adviser, unless such third parties are registered broker-dealers or registered investment advisers, in each case themselves subject to pay to play restrictions. Additionally, the new rule prevents an adviser from soliciting from others, or coordinating, contributions to certain elected officials or candidates or payments to political parties where the adviser is providing or seeking government business. The Commission also is adopting rule amendments that require a registered adviser to maintain certain records of the political contributions made by the adviser or certain of its executives or employees. The new rule and rule amendments address "pay to play" practices by investment advisers.

DATES: *Effective Date:* September 13, 2010.

Compliance Dates: Investment advisers subject to rule 206(4)–5 must be in compliance with the rule on March 14, 2011. Investment advisers may no longer use third parties to solicit government business except in compliance with the rule on September 13, 2011. Advisers to registered investment companies that are covered investment pools must comply with the rule by September 13, 2011. Advisers subject to rule 204–2 must comply with amended rule 204–2 on March 14, 2011. However, if they advise registered investment companies that are covered investment pools, they have until September 13, 2011 to comply with the amended recordkeeping rule with respect to those registered investment companies. *See* section III of this Release for further discussion of compliance dates.

FOR FURTHER INFORMATION CONTACT: Melissa A. Roverts, Senior Counsel, Matthew N. Goldin, Branch Chief, Daniel S. Kahl, Branch Chief, or Sarah A. Bessin, Assistant Director, at (202) 551–6787 or *IArules@sec.gov,* Office of Investment Adviser Regulation, Division of Investment Management, U.S. Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–8549.

SUPPLEMENTARY INFORMATION: The Commission is adopting rule 206(4)–5 [17 CFR 275.206(4)–5] and amendments to rules 204–2 [17 CFR 275.204–2] and 206(4)–3 [17 CFR 275.206(4)–3] under the Investment Advisers Act of 1940 [15 U.S.C. 80b] ("Advisers Act" or "Act").[1]

Table of Contents

I. Background

Investment advisers provide a wide variety of advisory services to State and local governments,[2] including managing their public pension plans.[3] These pension plans have over $2.6 trillion of assets and represent one-third of all U.S. pension assets.[4] They are among the largest and most active institutional investors in the United States;[5] the management of these funds affects

[1] 15 U.S.C. 80b. Unless otherwise noted, when we refer to the Advisers Act, or any paragraph of the Advisers Act, we are referring to 15 U.S.C. 80b of the United States Code, at which the Advisers Act is codified, and when we refer to rule 206(4)–5, rule 204–2, rule 204A–1, rule 206(4)–3, or any paragraph of these rules, we are referring to 17 CFR 275.206(4)–5, 17 CFR 275.204–2, 17 CFR 275.204A–1 and 17 CFR 275.206(4)–3, respectively, of the Code of Federal Regulations, in which these rules are published.

[2] *See* Sofia Anastopoulos, An Introduction to Investment Advisers for State and Local Governments (2d ed. 2007); Werner Paul Zorn, *Public Employee Retirement Systems and Benefits,* Local Government Finance, Concepts and Practices 376 (John E. Peterson & Dennis R. Strachota eds., 1st ed. 1991) (discussing the services investment advisers provide for public funds).

[3] To simplify the discussion, we use the term "public pension plan" interchangeably with "government client" and "government entity" in this Release. However, our rule applies broadly to investment advisory activities for government clients, such as those mentioned here in this Section of the Release, regardless of whether they are retirement funds. For a discussion of how the proposed rule would apply with respect to investment programs or plans sponsored or established by government entities, such as "qualified tuition plans" authorized by section 529 of the Internal Revenue Code [26 U.S.C. 529] and retirement plans authorized by section 403(b) or 457 of the Internal Revenue Code [26 U.S.C. 403(b) or 457], *see* section II.B.2(e) of this Release.

[4] Board of Governors of the Federal Reserve System, Flow of Funds Accounts of the United States, Flows and Outstandings, Fourth Quarter 2009 78 tbl.L.119 (Mar. 11, 2010). Since 2002, total financial assets of public pension funds have grown by 28%. *Id.*

[5] According to a recent survey, seven of the ten largest pension funds were sponsored by State and municipal governments. *The Top 200 Pension Funds/Sponsors,* Pens. & Inv. (Sept. 30, 2008), available at *http://www.pionline.com/article/20090126/CHART/901209995.*

publicly held companies [6] and the securities markets.[7] But most significantly, their management affects taxpayers and the beneficiaries of these funds, including the millions of present and future State and municipal retirees [8] who rely on the funds for their pensions and other benefits.[9] Public pension plan assets are held, administered and managed by government officials who often are responsible for selecting investment advisers to manage the funds they oversee.

Elected officials who allow political contributions to play a role in the management of these assets and who use these assets to reward contributors violate the public trust. Moreover, they undermine the fairness of the process by which public contracts are awarded. Similarly, investment advisers that seek to influence government officials' awards of advisory contracts by making or soliciting political contributions to those officials compromise their fiduciary duties to the pension plans they advise and defraud prospective clients. These practices, known as "pay to play," distort the process by which advisers are selected.[10] They can harm pension plans that may subsequently receive inferior advisory services and pay higher fees. Ultimately, these violations of trust can harm the millions of retirees that rely on the plan or the taxpayers of the State and municipal governments that must honor those obligations.[11]

Pay to play practices are rarely explicit: participants do not typically let it be publicly known that contributions or payments are made or accepted for the purpose of influencing the selection of an adviser. As one court noted, "[w]hile the risk of corruption is obvious and substantial, actors in this field are presumably shrewd enough to structure their relations rather indirectly." [12] Pay to play practices may take a variety of forms, including an adviser's direct contributions to government officials, an adviser's solicitation of third parties to make contributions or payments to government officials or political parties in the State or locality where the adviser seeks to provide services, or an adviser's payments to third parties to solicit (or as a condition of obtaining) government business. As a result, the full extent of pay to play practice remains hidden and is often hard to prove.

Public pension plans are particularly vulnerable to pay to play practices. Management decisions over these investment pools, some of which are quite large, are typically made by one or more trustees who are (or are appointed by) elected officials. And the elected officials or appointed trustees that govern the funds are also often involved, directly or indirectly, in selecting advisers to manage the public pension funds' assets. These officials may have the sole authority to select advisers,[13] may be members of a governing board that selects advisers,[14] or may appoint some or all of the board members who make the selection.[15]

Numerous developments in recent years have led us to conclude that the selection of advisers, whom we regulate under the Investment Advisers Act, has been influenced by political contributions and that, as a result, the quality of management service provided to public funds may be negatively affected. We have been particularly concerned that these contributions have been funneled through "solicitors" and "placement agents" that advisers engage (or believe they must engage) in order to secure a client relationship with a public pension plan or an investment from one.[16] As we will discuss in more detail below, in such an arrangement the contribution may be made in the form of a substantial fee for what may constitute no more than an introduction service by a "well connected" individual who may use the proceeds of the fee to make (or reimburse himself for having made) political contributions or provide some form of a "kickback" to an official or his or her family or friends.[17]

The details of pay to play arrangements have been widely reported as a consequence of the growing number of actions that we and State authorities have brought involving investment advisers seeking to manage the considerable assets of the New York State Common Retirement Fund.[18] In

[6] *See* Stephen J. Choi & Jill E. Fisch, *On Beyond CalPERS: Survey Evidence on the Developing Role of Public Pension Funds in Corporate Governance,* 61 Vand. L. Rev. 315 (2008) ("Collectively, public pension funds have the potential to be a powerful shareholder force, and the example of CalPERS and its activities have spurred many to advocate greater institutional activism.").

[7] Federal Reserve reports indicate that, of the $2.6 trillion in non-Federal government plans, $1.5 trillion is invested in corporate equities. Board of Governors of the Federal Reserve System, *supra* note 4, at 78 tbl.L.119.

[8] *See* Paul Zorn, 1997 Survey of State and Local Government Employee Retirement Systems 61 (1997) (hereinafter "1997 Survey") ("[t]he investment of plan assets is an issue of immense consequence to plan participants, taxpayers, and to the economy as a whole" as a low rate of return will require additional funding from the sponsoring government, which "can place an additional strain on the sponsoring government and may require tax increases").

[9] The most current census data reports that public pension funds have 18.6 million beneficiaries. 2007 Census of Governments, U.S. Bureau of Census, Number and Membership of State and Local Government Employee-Retirement Systems by State: 2006–2007 (2007) (at Table 5), available at *http://www.census.gov/govs/retire/2007ret05.html.*

[10] Among other things, pay to play practices may manipulate the market for advisory services by creating an uneven playing field among investment advisers. These practices also may hurt smaller advisers that cannot afford the required contributions.

[11] *See* 1997 Survey, *supra* note 8.

[12] *Blount v. SEC,* 61 F.3d 938, 945 (D.C. Cir. 1995), *cert. denied,* 517 U.S. 1119 (1996).

[13] *See, e.g.,* 2 N.Y. Comp. Codes R. & Regs. tit. 2 § 320.2 (2009) (placement of State and local government retirement systems assets (valued at $109 billion as of March 2009) is under the sole custodianship of the New York State Comptroller).

[14] *See, e.g.,* S.C. Code Ann. §§ 9–1–20, 1–11–10 (2008) (board consists of all elected officials); Cal. Gov't Code § 20090 (Deering 2008) (board consists of some elected officials, some appointed members, and some representatives of interest groups chosen by the members of those groups); Md. Code Ann., State Pers. & Pens. § 21–104 (2008) (pension board consists of some elected officials, some appointed members, and some representatives of interest groups chosen by the members of those groups).

[15] *See, e.g.,* Ariz. Rev. Stat. Ann. § 38–713 (2008) (governor appoints all nine members); Hawaii Rev. Stat. § 88–24 (2008) (governor appoints three of eight members); Idaho Code Ann. § 59–1304 (2008) (governor appoints all five members).

[16] For example, in one recent action we alleged that, in connection with a pay to play scheme in New York State, investment advisers paid sham "placement agent" fees, portions of which were funneled to public officials, as a means of obtaining public pension fund investments in the funds those advisers managed and that participants, in some instances, concealed the third-party solicitor's role in transactions from the investment management firms that paid fees to the solicitor by making misrepresentations about the solicitor's involvement and covertly using one of the solicitor's legal entities as an intermediary to funnel payments to the solicitor. *SEC* v. *Henry Morris, et al.,* Litigation Release No. 20963 (Mar. 19, 2009).

[17] *See id.* (along with the Commission's complaint in the action, available by way of a hyperlink from the litigation release). *See also, e.g., In the Matter of Quadrangle Group LLC,* AGNY Investigation No. 2010–044 (Apr. 15, 2010) (finding that "private equity firms and hedge funds frequently use placement agents, finders, lobbyists, and other intermediaries * * * to obtain investments from public pension funds * * *, that these placement agents are frequently politically connected individuals selling access to public money* * *"); Complaint, *Cal.* v. *Villalobos, et al.,* No. SC107850 (Cal. Super. Ct., W. Dist. of L.A. County, May 5, 2010), available at *http://ag.ca.gov/cms_attachments/press/pdfs/n1915_filed_complaint_for_civil_penalties.pdf* (alleging, *inter alia,* that a top executive and a board member at CalPERS accepted various gifts from a former CalPERS board member, "known among private equity firms as a person who attempts to exert pressure on CalPERS' representatives," who was acting as a placement agent trying to secure investments from the California public pension fund).

[18] *See SEC* v. *Henry Morris, et al.,* Litigation Release No. 21036 (May 12, 2009); *In the Matter of Quadrangle Group LLC,* AGNY Investigation No. 2010–044 (Apr. 15, 2010); *In the Matter of GKM Newport Generation Capital Servs., LLC,* AGNY Investigation No. 2010–017 (Apr. 14, 2010); *In the Matter of Kevin McCabe,* AGNY Investigation No. 2009–152 (Apr. 14, 2010); *In the Matter of Darius Anderson Platinum Advisors LLC,* AGNY Investigation No. 2009–153 (Apr. 14, 2010); *In the Matter of Global Strategy Group,* AGNY Investigation No. 2009–161 (Apr. 14, 2010); *In the Matter of Freeman Spogli & Co.,* AGNY Investigation No. 2009–174 (Feb. 1, 2010); *In the*

Continued

addition, we have brought enforcement actions against the former treasurer of the State of Connecticut and other parties in which we alleged that the former treasurer awarded State pension fund investments to private equity fund managers in exchange for payments, including political contributions, funneled through the former treasurer's friends and political associates.[19] Criminal authorities have in recent years brought cases in New York,[20] New Mexico,[21] Illinois,[22] Ohio,[23] Connecticut,[24] and Florida,[25] charging defendants with the same or similar conduct.

Allegations of pay to play activity involving State and municipal pension plans in other jurisdictions continue to be reported.[26] In the course of this rulemaking we received a letter from one public official detailing the role of pay to play arrangements in the selection of public pension fund managers and the harms it can inflict on the affected plans.[27] In addition, other public officials wrote to express support for a Commission rule to prohibit investment advisers from participating in pay to play arrangements.[28]

On August 3, 2009, we proposed a new antifraud rule under the Advisers Act designed to prevent investment advisers from obtaining business from government entities in return for political contributions or fund raising—*i.e.,* from participating in pay to play practices.[29] We modeled our proposed rule on those adopted by the Municipal Securities Rulemaking Board, or MSRB, which since 1994 has prohibited municipal securities dealers from participating in pay to play practices.[30] We believe these rules have significantly curbed pay to play practices in the municipal securities market.[31]

Matter of Falconhead Capital, LLC, AGNY Investigation No. 2009–125 (Sept. 17, 2009); *In the Matter of HM Capital Partners I, LP,* AGNY Investigation No. 2009–117 (Sept. 17, 2009); *In the Matter of Ares Management LLC,* AGNY Investigation No. 2009–173 (Feb. 17, 2010); *In the Matter of Levine Leichtman Capital Partners,* AGNY Investigation No. 2009–124 (Sept. 17, 2009); *In the Matter of Access Capital Partners,* AGNY Investigation No. 09–135 (Sept. 17, 2009); *In the Matter of The Markstone Group,* AGNY Investigation No. 10–012 (Feb. 28, 2010); *In the Matter of Wetherly Capital Group, LLC and DAV/Wetherly Financial, L.P.,* AGNY Investigation No. 2009–172 (Feb. 8, 2010) (in each case, banning the use of third-party placement agents pursuant to a "Pension Reform Code of Conduct").

[19] *See SEC* v. *Paul J. Silvester, et al.,* Litigation Release No. 16759 (Oct. 10, 2000); Litigation Release No. 20027 (Mar. 2, 2007); Litigation Release No. 19583 (Mar. 1, 2006); Litigation Release No. 18461 (Nov. 17, 2003); Litigation Release No. 16834 (Dec. 19, 2000); *SEC* v. *William A. DiBella et al.,* Litigation Release No. 20498 (Mar. 14, 2008) (2007 U.S. Dist. LEXIS 73850 (D. Conn., May 8, 2007), *aff'd* 587 F.3d 553 (2nd Cir. 2009)). *See also U.S.* v. *Ben F. Andrews,* Litigation Release No. 19566 (Feb. 15, 2006); *In the Matter of Thayer Capital Partners, TC Equity Partners IV, L.L.C., TC Management Partners IV, L.L.C., and Frederick V. Malek,* Investment Advisers Act Release No. 2276 (Aug. 12, 2004); *In the Matter of Frederick W. McCarthy,* Investment Advisers Act Release No. 2218 (Mar. 5, 2004); *In the Matter of Lisa A. Thiesfield,* Investment Advisers Act Release No. 2186 (Oct. 29, 2003).

[20] *See New York* v. *Henry* "*Hank*" *Morris and David Loglisci,* Indictment No. 25/2009 (NY Mar. 19, 2009) (alleging that the deputy comptroller and a "placement agent" engaged in enterprise corruption and State securities fraud for selling access to management of public funds in return for kickbacks and other payments for personal and political gain).

[21] *See U.S.* v. *Montoya,* Criminal No. 05–2050 JP (D.N.M. Nov. 8, 2005) (the former treasurer of New Mexico pleaded guilty); *U.S.* v. *Kent Nelson,* Criminal Information No. 05–2021 JP, (D.N.M. 2007) (defendant pleaded guilty to one count of mail fraud); *U.S.* v. *Vigil,* 523 F.3d 1258 (10th Cir. 2008) (affirming the conviction for attempted extortion of the former treasurer of New Mexico for requiring that a friend be hired by an investment manager at a high salary in return for the former treasurer's willingness to accept a proposal from the manager for government business).

[22] *See* Jeff Coen, *et al., State's Ultimate Insider Indicted,* Chi. Trib., Oct. 31, 2008, available at *http://www.chicagotribune.com/news/local/chi-cellini-31-oct31,0,6465036.story* (describing the thirteenth indictment in an Illinois pay to play probe); Ellen Almer, Oct. 27, 2000, available at *http://www.chicagobusiness.com/cgi-bin/news.pl?id=775* (discussing the guilty plea of Miriam Santos, the former treasurer of the City of Chicago, who told representatives of financial services firms seeking city business that they were required to raise specified campaign contributions for her and personally make up any shortfall in the amounts they raised). *See also SEC* v. *Miriam Santos, et al.,* Litigation Release No. 17839 (Nov. 14, 2002); Litigation Release No. 19269 (June 14, 2005) (355 F. Supp. 2d 917 (N.D. Ill. 2003)).

[23] *See* Reginald Fields, *Four More Convicted in Pension Case: Ex-Board Members Took Gifts from Firm,* Cleveland Plain Dealer, Sept. 20, 2006 (addressing pay to play activities of members of the Ohio Teachers Retirement System).

[24] *See U.S.* v. *Joseph P. Ganim,* 2007 U.S. App. LEXIS 29367 (2d Cir. 2007) (affirming the district court's decision to uphold an indictment of the former mayor of Bridgeport, Connecticut, in connection with his conviction for, among other things, requiring payment from an investment adviser in return for city business); *U.S.* v. *Triumph Capital Group, et al.,* No. 300CR217 JBA (D. Conn. 2000) (the former treasurer, along with certain others, pleaded guilty—while others were ultimately convicted). One of the defendants, who had been convicted at trial, recently won a new trial. *U.S.* v. *Triumph Capital Group, et al.,* 544 F.3d 149 (2d Cir. 2008).

[25] *United States* v. *Poirier,* 321 F.3d 1024 (11th Cir.), *cert. denied sub nom. deVegter* v. *United States,* 540 U.S. 874 (2003) (partner at Lazard Freres & Co., a municipal services firm, was convicted for conspiracy and wire fraud for fraudulently paying $40,000 through an intermediary to Fulton County's independent financial adviser to secure an assurance that Lazard would be selected for the Fulton County underwriting contract).

[26] *See, e.g.,* Aaron Lester, *et al., Cahill Taps Firms Tied to State Pension Investor,* Boston.com, Mar. 21, 2010 (suggesting that an investment adviser may have bundled out-of-State donations to the Massachusetts State Treasurer's campaign in return for a State pension fund investment management contract); Kevin McCoy, *Do Campaign Contributions Help Win Pension Fund Deals,* USA Today, Aug. 28, 2009; Ted Sherman, *Pay to Play Alive and Well in New Jersey,* NJ.com, Nov. 28, 2009 (noting more generally that pay to play continues to occur with government contracts of all kinds in New Jersey); Imogen Rose-Smith and Ed Leefeldt, *Pension Pay to Play Casts Shadow Nationwide,* Institutional Investor, Oct. 1, 2009 (suggesting connections between a private equity fund principal's fundraising activities and pension investments in the fund). *See also* sources cited *supra* note 17.

[27] Comment Letter of Suzanne R. Weber, Erie County Controller (Oct. 6, 2009) ("Weber Letter") ("I have seen money managers awarded contracts with our fund which involved payments to individuals who served as middlemen, creating needless expense for the fund. These middlemen were political contributors to the campaigns of board members who voted to contract for money management services with the companies who paid them as middlemen."). *See also* Comment Letter of David R. Pohndorf (Aug. 4, 2009) ("Pohndorf Letter") (noting that when the sole trustee of a major pension fund changed several years ago, a firm managing some of the fund's assets "began to receive invitations to fundraising events for the new trustee with suggested donation amounts.").

[28] *See, e.g.,* Comment Letter of New York State Comptroller Thomas P. DiNapoli (Oct. 2, 2009) ("DiNapoli Letter"); Comment Letter of New York City Mayor Michael R. Bloomberg (Sept. 9, 2009) ("Bloomberg Letter"). *See also* Comment Letter of Kentucky Retirement Systems Trustee Chris Tobe (Sept. 18, 2009) ("Tobe Letter") (suggesting the negative effects of pay to play activities on the Kentucky Retirement System's investment performance).

[29] *Political Contributions by Certain Investment Advisers,* Investment Advisers Act Release No. 2910 (Aug. 3, 2009) [74 FR 39840 (Aug. 7, 2009)] (the "Proposing Release").

[30] MSRB rule G–37 was approved by the Commission and adopted in 1994. *See In the Matter of Self-Regulatory Organizations; Order Approving Proposed Rule Change by the Municipal Securities Rulemaking Board Relating to Political Contributions and Prohibitions on Municipal Securities Business and Notice of Filing and Order Approving on an Accelerated Basis Amendment No. 1 Relating to the Effective Date and Contribution Date of the Proposed Rule,* Exchange Act Release No. 33868 (Apr. 7, 1994) [59 FR 17621 (Apr. 13, 1994)]. The MSRB's pay to play rules include MSRB rules G–37 and G–38. They are available on the MSRB's Web site at *http://www.msrb.org/msrb1/rules/ruleg37.htm* and *http://www.msrb.org/msrb1/rules/ruleg38.htm,* respectively.

[31] *See* Proposing Release, at n.23. *See also infra* note 101; Comment Letter of the Municipal

Along the lines of MSRB rule G–37,[32] our proposed rule would have prohibited an investment adviser from providing advisory services for compensation to a government client for two years after the adviser or certain of its executives or employees make a contribution to certain elected officials or candidates.[33] It also would have prohibited an adviser and certain of its executives and employees from soliciting from others, or coordinating, contributions to certain elected officials or candidates or payments to political parties where the adviser is providing or seeking government business.[34] In addition, similar to MSRB rule G–38,[35] our proposed rule would have prohibited the use of third parties to solicit government business.[36] We also proposed amendments to rule 204–2 under the Advisers Act that would have required registered advisers to maintain certain records regarding political contributions and government clients. As discussed in more detail below, our proposed rule departed in some respects from the MSRB rules to reflect differences between advisers and broker-dealers and the scope of the statutory authority we have sought to exercise.

We received some 250 comment letters on our proposal, many of which were from advisers, third-party solicitors, placement agents, and their representatives.[37] Public pension plans and their officials were divided—some embraced the rule, including one that stated that the rule is an important means to "increase transparency and public confidence in the investment activities of all public pension funds," [38] while others were critical, arguing, for example, that our proposal "may result in unintended hardships being placed upon public pension funds." [39] We received no letters from plan beneficiaries whom we sought to protect with the proposed rule,[40] although two public interest groups supported it strongly.[41] Advisers, third-party solicitors and placement agents, fund sponsors, and others whose business arrangements could be affected by the rule generally supported our goal of eliminating advisers' participation in pay to play practices involving public plans.[42] Nonetheless, most of them objected to our adoption under the Advisers Act of a rule similar to MSRB rules G–37 and G–38.[43] Most particularly opposed the proposed prohibition on payments to third parties for soliciting or marketing to government entities modeled on MSRB rule G–38.[44] Several urged that, if we were to adopt a rule based on the approach taken in our proposal, we should broaden exceptions and exemptions under the rule to accommodate certain business arrangements.[45] We respond to these comments below.[46]

II. Discussion

As discussed in more detail below, we have decided to adopt rule 206(4)–5, which we have revised to reflect comments we received. For the reasons we discuss above and in the Proposing Release, we believe rule 206(4)–5 is a proper exercise of our rulemaking authority under the Advisers Act to prevent fraudulent and manipulative conduct.

The Commission regulates investment advisers under the Investment Advisers Act of 1940. Section 206(1) of the Advisers Act prohibits an investment adviser from employ[ing] any device, scheme or artifice to defraud any client

Securities Rulemaking Board (Oct. 23, 2009) ("MSRB Letter"); Comment Letter of Common Cause (Oct. 6, 2009) ("Common Cause Letter").

[32] *See* MSRB rule G–37(b). Our proposal, like MSRB rule G–37, was designed to address our concern that pay to play activities were "undermining the integrity" of the relevant market, in particular the market for the provision of investment advisory services to government entity clients. *See Blount,* 61 F.3d at 939 (referring to the MSRB's concerns that pay to play practices were "undermining the integrity of the $250 billion municipal securities market" as its motivation for proposing MSRB rule G–37).

[33] Proposed rule 206(4)–5(a)(1). *See also* MSRB rule G–37(b).

[34] Proposed rule 206(4)–5(a)(2)(ii). *See also* MSRB rule G–37(c).

[35] *See* MSRB rule G–38(a).

[36] Proposed rule 206(4)–5(a)(2)(i).

[37] Other commenters included pension plans and their officials, trade associations, law firms, and public interest groups. Comments letters submitted in File No. S7–25–06 are available on the Commission's Web site at: *http://www.sec.gov/comments/s7-18-09/s71809.shtml.*

[38] Comment Letter of New York City Comptroller William C. Thompson, Jr. (Oct. 6, 2009) ("Thompson Letter").

[39] Comment Letter of Executive Director and Secretary to the Board of Trustees of the State Retirement and Pension System of Maryland R. Dean Kenderdine (Oct. 5, 2009).

[40] We note, however, that subsequent to our proposal, AFSCME, which represents 1.6 million State and local employees and retirees, issued a report that strongly endorses sanctions to prevent pay to play activities. AFSCME, Enhancing Public Retiree Pension Plan Security: Best Practice Policies for Trustees and Pension Systems (2010), available at *http://www.afscme.org/docs/AFSCME-report-pension-best-practices.pdf.*

[41] *See, e.g.,* Common Cause Letter; Comment Letter of Fund Democracy/Consumer Federation of America (Oct. 6, 2009) ("Fund Democracy/Consumer Federation Letter").

[42] *See, e.g.,* Comment Letter of the Investment Adviser Association (Oct. 5, 2009) ("IAA Letter") (noting "support [for] measures to combat pay to play activities, *i.e.,* the practice of investment advisers or their employees making political contributions intended to influence the selection or retention of advisers by government entities. Pay to play practices undermine the principle that advisers are selected on the basis of competence, qualifications, expertise, and experience. The practice is unethical and undermines the integrity of the public pension plan system and the process of selecting investment advisers."); Comment Letter of John R. Dempsey (Aug. 8, 2009) ("Dempsey Letter") (noting applause for efforts "to stop the 'pay-to-play' practice which only serves to undermine public trust in investment advisors and regulators."); Comment Letter of Barry M. Gleicher (Sept. 7, 2009) (noting strong support for the proposal "with no modifications. * * * The Rule is necessary to curb elaborated practices that would deprive taxpayers and beneficiaries of cost effective and honest administration of pension funds"); Tobe Letter.

[43] *See, e.g.,* IAA Letter ("We respectfully submit, however, that the structure of the MSRB rules is not appropriately tailored to the investment advisory business. * * * We believe the Commission should make significant changes to the Proposal, which would permit it to accomplish its important goals."); Comment Letter of Wesley Ogburn (Aug. 4, 2009) ("Ogburn Letter"); Comment Letter of the Third Party Marketers Association (Aug. 27, 2009) ("3PM Letter"); Comment Letter of Preqin (Aug. 28, 2009) ("Preqin Letter I") (suggesting that institutional private equity investors polled favored a private equity specific proposal rather than relying on the framework from the municipal securities industry); Comment Letter of Dechert LLP (Oct. 22, 2009) ("Dechert Letter"); Comment Letter of the Committee on Federal Regulation of Securities of the Section of Business Law of the American Bar Association (Oct. 13, 2009) ("ABA Letter"); Comment Letter of Fidelity Investments (Oct. 7, 2009) ("Fidelity Letter"); Comment Letter of Sutherland Asbill & Brennan LLP (Oct. 6, 2009) ("Sutherland Letter"); Comment Letter of the Investment Company Institute (Oct. 6, 2009) ("ICI Letter"); Comment Letter of the Massachusetts Mutual Life Insurance Company (Oct. 6, 2009) ("MassMutual Letter"); Comment Letter of Skadden, Arps, Slate, Meagher & Flom LLP (Oct. 6, 2009) ("Skadden Letter"); Comment Letter of the Managed Funds Association (Oct. 6, 2009) ("MFA Letter").

[44] *See, e.g.,* Comment Letter of Ounavarra Capital, LLC (Aug. 28, 2009) ("Ounavarra Letter") (noting that banning third-party marketers in the municipal securities industry did not adversely affect most bankers' ability to conduct basic marketing whereas banning third-party marketers for small advisers could have a stronger impact on advisers that have either no or very limited marketing capability of their own); Comment Letter of MVision Private Equity Advisers USA LLC (Sept. 2, 2009) ("MVision Letter") (arguing that, whereas placement agents for municipal bond offerings are usually regulated entities, the restrictions in the municipal securities arena were targeted at consultants who offer only their contacts and influence with government officials and provided no valuable services to the financial services industry or investors); Comment Letter of Kalorama Capital (Sept. 8, 2009) (arguing that a better analogy, at least with respect to the operation of third-party marketers, is to the licensed professional presenting an IPO to a pension fund). For further discussion of these comments, *see* section II.B.2(b) of this Release.

[45] *See, e.g.,* Comment Letter of the Committee on Investment Management Regulation and the Committee on Private Investment Funds of the Association of the Bar of the City of New York (Oct. 26, 2009) ("NY City Bar Letter") (arguing that broker-dealer rules have sufficient safeguards and that adopting the proposed pay to play rule will interfere with traditional distribution arrangements); Dechert Letter; Sutherland Letter; MFA Letter.

[46] Particular comments on the various aspects of our proposal are summarized in the corresponding sub-sections of section II of this Release.

or prospective client."[47] Section 206(2) prohibits an investment adviser from engaging in "any transaction, practice, or course of business which operates as a fraud or deceit upon any client or prospective client."[48] The Supreme Court has construed section 206 as establishing a Federal fiduciary standard governing the conduct of advisers.[49]

We believe that pay to play is inconsistent with the high standards of ethical conduct required of fiduciaries under the Advisers Act. We have authority under section 206(4) of the Act to adopt rules "reasonably designed to prevent, such acts, practices, and courses of business as are fraudulent, deceptive or manipulative."[50] Congress gave us this authority to prohibit "specific evils" that the broad antifraud provisions may be incapable of covering.[51] The provision thus permits the Commission to adopt prophylactic rules that may prohibit acts that are not themselves fraudulent.[52]

Investment advisers that seek to influence the award of advisory contracts by public pension plans, by making political contributions to, or soliciting them for, those officials who are in a position to influence the awards, compromise their fiduciary obligations to the public pension plans they advise and defraud prospective clients.[53] In making such contributions, the adviser hopes to benefit from officials who "award the contracts on the basis of benefit to their campaign chests rather than to the governmental entity"[54] or by retaining a contract that might otherwise not be renewed. If pay to play is a factor in the selection or retention process, the public pension plan can be harmed in several ways. The most qualified adviser may not be selected or retained, potentially leading to inferior management or performance. The pension plan may pay higher fees because advisers must recoup the contributions, or because contract negotiations may not occur on an arm's-length basis. The absence of arm's-length negotiations may enable advisers to obtain greater ancillary benefits, such as "soft dollars," from the advisory relationship, which might be used for the benefit of the adviser, potentially at the expense of the pension plan, thereby using the pension plan's assets for the adviser's own purposes.[55]

As we discuss above, pay to play practices are rarely explicit and often hard to prove.[56] In particular, when pay to play involves granting of government advisory business in exchange for political contributions, it may be difficult to prove that an adviser (or one of its executives or employees) made political contributions for the purpose of obtaining the government business, or that it engaged a solicitor for his or her political influence rather than substantive expertise.[57] Pay to play practices by advisers to public pension plans, which may generate significant contributions for elected officials and yield lucrative management contracts for advisers, will not stop through voluntary efforts. This is, in part, because these activities create a "collective action" problem in two respects.[58] First, government officials who participate may have an incentive to continue to accept contributions to support their campaigns for fear of being disadvantaged relative to their opponents. Second, advisers may have an incentive to participate out of concern that they may be overlooked if they fail to make contributions.[59] Both the stealth in which these practices occur and the inability of markets to properly address them argue strongly for the need for us to adopt the type of

[47] 15 U.S.C. 80b–6(1).

[48] 15 U.S.C. 80b–6(2).

[49] *Transamerica Mortgage Advisors, Inc. v. Lewis,* 444 U.S. 11, 17 (1979); *SEC v. Capital Gains Research Bureau, Inc.,* 375 U.S. 180, 191–192 (1963).

[50] 15 U.S.C. 80b–6(4).

[51] S. Rep. No. 1760, 86th Cong., 2d Sess. 4, 8 (1960). The Commission has used this authority to adopt seven rules addressing abusive advertising practices, custodial arrangements, the use of solicitors, required disclosures regarding advisers' financial conditions and disciplinary histories, proxy voting, compliance procedures and practices, and deterring fraud with respect to pooled investment vehicles. 17 CFR 275.206(4)–1; 275.206(4)–2; 275.206(4)–3; 275.206(4)–4; 275.206(4)–6; 275.206(4)–7; and 275.206(4)–8.

[52] Section 206(4) was added to the Advisers Act in Public Law 86–750, 74 Stat. 885, at sec. 9 (1960). *See* H.R. Rep. No. 2197, 86th Cong., 2d Sess., at 7–8 (1960) ("Because of the general language of section 206 and the absence of express rulemaking power in that section, there has always been a question as to the scope of the fraudulent and deceptive activities which are prohibited and the extent to which the Commission is limited in this area by common law concepts of fraud and deceit . . . [Section 206(4)] would empower the Commission, by rules and regulations to define, and prescribe means reasonably designed to prevent, acts, practices, and courses of business which are fraudulent, deceptive, or manipulative. This is comparable to Section 15(c)(2) of the Securities Exchange Act [15 U.S.C. 78o(c)(2)] which applies to brokers and dealers."). *See also* S. Rep. No. 1760, 86th Cong., 2d Sess., at 8 (1960) ("This [section 206(4) language] is almost the identical wording of section 15(c)(2) of the Securities Exchange Act of 1934 in regard to brokers and dealers."). The Supreme Court, in *United States v. O'Hagan,* interpreted nearly identical language in section 14(e) of the Securities Exchange Act [15 U.S.C. 78n(e)] as providing the Commission with authority to adopt rules that are "definitional and prophylactic" and that may prohibit acts that are "not themselves fraudulent * * * if the prohibition is 'reasonably designed to prevent * * * acts and practices [that] are fraudulent.'" *United States v. O'Hagan,* 521 U.S. 642, 667, 673 (1997). The wording of the rulemaking authority in section 206(4) remains substantially similar to that of section 14(e) and section 15(c)(2) of the Securities Exchange Act. *See also Prohibition of Fraud by Advisers to Certain Pooled Investment Vehicles,* Investment Advisers Act Release No. 2628 (Aug. 3, 2007) [72 FR 44756 (Aug. 9, 2007)] (stating, in connection with the suggestion by commenters that section 206(4) provides us authority only to adopt prophylactic rules that explicitly identify conduct that would be fraudulent under a particular rule, "We believe our authority is broader. We do not believe that the commenters' suggested approach would be consistent with the purposes of the Advisers Act or the protection of investors.").

[53] *See* Proposing Release, at section I; *Political Contributions by Certain Investment Advisers,* Investment Advisers Act Release No. 1812 (Aug. 4, 1999) [64 FR 43556 (Aug. 10, 1999)] ("1999 Proposing Release"). As a fiduciary, an adviser has a duty to deal fairly with clients and prospective clients, and must make full disclosure of any material conflict or potential conflict. *See, e.g., Capital Gains Research Bureau,* 375 U.S. at 189, 191–92; *Applicability of the Investment Advisers Act of 1940 to Financial Planners, Pension Consultants, and Other Persons Who Provide Others with Investment Advice as a Component of Other Financial Services,* Investment Advisers Act Release No. 1092 (Oct. 8, 1987) [52 FR 38400 (Oct. 16, 1987)]. Most public pension plans establish procedures for hiring investment advisers, the purpose of which is to obtain the best possible management services. When an adviser makes political contributions for the purpose of influencing the selection of the adviser to advise a public pension plan, the adviser seeks to interfere with the merit-based selection process established by its prospective clients—the public pension plan. The contribution creates a conflict of interest between the adviser (whose interest is in being selected) and its prospective client (whose interest is in obtaining the best possible management services).

[54] *See Blount,* 61 F.3d at 944–45.

[55] *Cf. In re Performance Analytics, et al.,* Investment Advisers Act Release No. 2036 (June 17, 2002) (settled enforcement action in which an investment consultant for a union pension fund entered into a $100,000 brokerage arrangement with a soft dollar component in which the investment consultant would continue to recommend the investment adviser to the pension fund as long as the investment adviser sent its trades to one particular broker-dealer).

[56] *Cf. Blount,* 61 F.3d at 945 ("no smoking gun is needed where, as here, the conflict of interest is apparent, the likelihood of stealth great, and the legislative purpose prophylactic").

[57] *See id.* at 944 ("actors in this field are presumably shrewd enough to structure their relations rather indirectly").

[58] Collective action problems exist, for example, where participants may prefer to abstain from an unsavory practice (such as pay to play), but nonetheless participate out of concern that, even if they abstain, their competitors will continue to engage in the practice profitably and without adverse consequences. As a result, collective action problems, such as those raised by pay to play practices, call for a regulatory response. For further discussion, *see infra* note 459 and accompanying text.

[59] In our view, the collective action problem we are trying to address is analogous to the one noted in the case upholding MSRB rule G–37. *See Blount,* 61 F.3d at 945 ("Moreover, there appears to be a collective action problem tending to make the misallocation of resources persist"). For a discussion of concerns raised regarding our proposed rule that are similar to those raised regarding MSRB rule G–37, see section II.A of this Release.

prophylactic rule that section 206(4) of the Advisers Act authorizes.

A. First Amendment Considerations

The Commission believes that rule 206(4)–5 is a necessary and appropriate measure to prevent fraudulent acts and practices in the market for the provision of investment advisory services to government entities by prohibiting investment advisers from engaging in pay to play practices. We have examined a range of alternatives to our proposal, carefully considered some 250 comments we received on the proposal and made revisions to the proposed rule where we concluded it was appropriate. We believe the rule represents a balanced response to the developments we discuss above regarding pay to play activities occurring in the market for government investment advisory services. The rule provides specific prohibitions to help ensure that adviser selection is based on the merits, not on the amount of money given to a particular candidate for office, while respecting the rights of industry participants to participate in the political process. The rule is not unique; Congress, for instance, has barred Federal contractors from making contributions to public officials.[60]

Before we address particular aspects of the rule, we would like to respond to commenters' assertions that the fact that the rule's limitations on compensation are triggered by political contributions represents an infringement on the First Amendment guarantees of freedom of speech and association.[61] These commenters acknowledge that selection of an investment adviser by a government entity should not be a "pay back" for political contributions, but argue that the rule impermissibly restricts the ability of advisers and certain of their employees to demonstrate support for State and local officials.

The Commission is sensitive to, and has carefully considered, these constitutional concerns in adopting the rule. Though it is not a ban on political contributions or an attempt to regulate State and local elections, we acknowledge that the two-year time out provision may affect the propensity of investment advisers to make political contributions. Although political contributions involve both speech and associational rights protected by the First Amendment, a "limitation upon the amount that any one person or group may contribute to a candidate or political committee entails only a marginal restriction upon the contributor's ability to engage in free communication."[62] Limitations on contributions are permissible if justified by a sufficiently important government interest that is closely drawn to avoid unnecessary abridgment of protected rights.[63]

Prevention of fraud is a sufficiently important government interest.[64] We believe that payments to State officials as a *quid pro quo* for obtaining advisory business as well as other forms of "pay to play" violate the antifraud provisions of section 206 of the Advisers Act. As discussed in our Proposing Release, "pay to play" arrangements are inconsistent with an adviser's fiduciary obligations, distort the process by which investment advisers are selected, can harm advisers' public pension plan clients and the beneficiaries of those plans, and can have detrimental effects on the market for investment advisory services.[65] The restrictions inherent in rule 206(4)–5 are in the nature of conflict of interest limitations which are particularly appropriate in cases of government contracting and highly regulated industries.[66] Pursuant to our authority under section 206(4) of the Advisers Act, which we discuss above, we may adopt rules that are reasonably designed to prevent such acts, practices and courses of business.

As detailed in the following pages, we have closely drawn rule 206(4)–5 to accomplish its goal of preventing *quid pro quo* arrangements while avoiding unnecessary burdens on the protected speech and associational rights of investment advisers and their covered employees. The rule is therefore closely drawn in terms of the conduct it prohibits, the persons who are subject to its restrictions, and the circumstances in which it is triggered. The United States Court of Appeals for the District of Columbia Circuit upheld the similarly designed MSRB rule G–37 in *Blount* v. *SEC*.[67] Indeed, the *Blount* opinion has served as an important guidepost in helping us shape our rule.[68]

[60] 2 U.S.C. 441c.

[61] *See, e.g.,* Comment Letter of W. Hardy Callcott (Aug. 3, 2009) ("Callcott Letter I"); Comment Letter of W. Hardy Callcott (Jan. 21, 2010) ("Callcott Letter II"); Comment Letter of the National Association of Securities Professionals, Inc. (Oct. 6, 2009) ("NASP Letter"); Comment Letter of Caplin & Drysdale, Chartered (Oct. 6, 2009) ("Caplin & Drysdale Letter"); Comment Letter of the Securities Industry and Financial Markets Association (Oct. 5, 2009) ("SIFMA Letter"); ABA Letter; Sutherland Letter; Comment Letter of IM Compliance LLC (Oct. 6, 2009) ("IM Compliance Letter"); Comment Letter of the American Bankers Association (Oct. 6, 2009) ("American Bankers Letter").

[62] *Buckley v. Valeo,* 424 U.S. 1, 20 (1976). *See also SpeechNow.org, et al. v. FEC,* 599 F.3d 686 (D.C. Cir. 2010); *McConnell v. FEC,* 540 U.S. 93, 135–36 (2003).

[63] *Buckley,* 424 U.S. at 25. *See also FEC v. Wisconsin Right to Life, Inc.,* 551 U.S. 449 (2007); *Republican Nat'l Comm. v. FEC,* No. 08–1953, 2010 U.S. Dist. LEXIS 29163 (D.D.C. Mar. 26, 2010) (three judge panel). This standard is lower than the strict scrutiny standard employed in reviewing such forms of expression as independent expenditures. Under the higher level of scrutiny, a restriction must be narrowly tailored to serve a compelling governmental interest. *Blount,* 61 F.3d at 943. *See also Citizens United v. FEC,* 130 S. Ct. 876 (2010) (distinguishing restrictions on "independent expenditures" from restrictions on "direct contributions" and leaving restrictions on direct contributions untouched while striking down a restriction on independent expenditures as unconstitutional). We note that in *Blount,* 61 F.3d at 949, the court upheld MSRB rule G–37 even assuming that strict scrutiny applied. For the reasons stated by the court in that decision, we believe that Rule 206(4)–5 would be upheld under a strict scrutiny standard as well as under the standard the Supreme Court has applied to contribution restrictions.

[64] *Blount,* 61 F.3d at 944.

[65] *See* Proposing Release, at section I. The prohibitions on solicitation and coordination of campaign contributions are justified by the same overriding purposes which support the two-year time out provisions. The provisions are intended to prevent circumvention of the time out provisions in cases where an investment adviser has or is seeking to establish a business relationship with a government entity. Absent these restrictions, solicitation and coordination of contributions could be used as effectively as political contributions to distort the adviser selection process. The solicitation and coordination restrictions relate only to fundraising activities and would not prevent advisers and their covered employees from expressing support for candidates in other ways, such as volunteering their time.

[66] *See In the Matter of Self-Regulatory Organizations; Order Approving Proposed Rule Change by the Municipal Securities Rulemaking Board Relating to Political Contributions and Prohibitions on Municipal Securities Business and Notice of Filing and Order Approving on an Accelerated Basis Amendment No. 1 Relating to the Effective Date and Contribution Date of the Proposed Rule,* Exchange Act Release No. 33868 (Apr. 7, 1994) [59 FR 17621 (Apr. 13, 1994)] (noting, in connection with the Commission's approval of MSRB rule G–37, that the restrictions inherent in that pay to play rule "are in the nature of conflict of interest limitations which are particularly appropriate in cases of government contracting and highly regulated industries.").

[67] 61 F.3d at 947–48.

[68] Notwithstanding the *Blount* decision, some commenters asserted that subsequent Supreme Court jurisprudence, including *Randall v. Sorrell,* 548 U.S. 230 (2006), and *Citizens United,* 130 S. Ct. 876 (decided following the closing of the comment period for rule 206(4)–5), would result in the proposed rule being found unconstitutional because it is not narrowly tailored to advance the Commission's interests in addressing pay to play by investment advisers. *See, e.g.,* Callcott Letter I; Callcott Letter II; NASP Letter; American Bankers Letter. We disagree. The cases cited by commenters are distinguishable. *Citizens United* deals with certain independent expenditures (rather than contributions to candidates), which are not implicated by our rule. *Randall* involved a generally applicable State campaign finance law limiting overall contributions (and expenditures), which the Court feared would disrupt the electoral process by limiting a candidate's ability to amass sufficient resources and mount a successful campaign. *Randall,* 548 U.S. at 248–49. By contrast, our rule is not a general prohibition or limitation, but rather is a focused effort to combat *quid pro quo* payments by investment advisers seeking

Continued

First, the rule is limited to contributions to officials of government entities who can influence the hiring of an investment adviser in connection with money management mandates.[69] These restrictions are triggered only in situations where a business relationship exists or will be established in the near future between the investment adviser and a government entity.[70]

Second, the rule does not in any way impinge on a wide range of expressive conduct in connection with elections. For example, the rule imposes no restrictions on activities such as making independent expenditures to express support for candidates, volunteering, making speeches, and other conduct.[71]

Third, it does not prevent anyone from making a contribution to any candidate, as covered employees may contribute $350 to candidates for whom they may vote, and $150 to other candidates. A limitation on the amount of a contribution involves little direct restraint on political communication, because a person may still engage in the symbolic expression of support evidenced by a contribution.[72] Furthermore, the rule takes the form of a restriction on providing compensated advisory business following the making of contributions rather than a prohibition on making contributions in excess of the relevant ceilings.[73]

Fourth, the rule only applies to investment advisers that are registered with us,[74] or unregistered in reliance on section 203(b)(3) of the Advisers Act, that have (or that are seeking) government clients.[75] It applies only to the subset of the significantly broader set of advisers over which we have antifraud authority that we believe are most likely to be engaged by government clients to manage public assets either directly or though investment pools.[76]

Finally, the rule is not a restriction on contributions that is applicable to the public and is not intended to eliminate corruption in the electoral process. Rather, it is focused exclusively on conduct by professionals subject to fiduciary duties, seeking profitable business from governmental entities. The rule is targeted at those employees of an adviser whose contributions raise the greatest danger of *quid pro quo* exchanges,[77] and it covers only contributions to those governmental officials who would be the most likely targets of pay to play arrangements because of their authority to influence the award of advisory business.[78]

B. Rule 206(4)–5

We are today adopting new rule 206(4)–5 under the Advisers Act that is designed to protect public pension plans and other government investors from the consequences of pay to play practices by deterring advisers' participation in such practices.[79] As we noted in the Proposing Release, advisers and government officials might, in order to circumvent our rule, attempt to structure their transactions in a manner intended to hide the true purpose of a contribution or payment.[80] Therefore, our pay to play restrictions are intended to capture not only direct political contributions by advisers, but also other ways that advisers may engage in pay to play arrangements. Rule 206(4)–5 prohibits several principal avenues for pay to play activities.

First, the rule makes it unlawful for an adviser to receive compensation for providing advisory services to a government entity for a two-year period after the adviser or any of its covered associates makes a political contribution to a public official of a government entity or candidate for such office who is or will be in a position to influence the award of advisory business.[81]

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governmental business. Comparable restrictions targeted at a particular industry have been upheld under *Randall* because the loss of contributions from such a small segment of the electorate "would not significantly diminish the universe of funds available to a candidate to a non-viable level." *Green Party of Conn. v. Garfield,* 590 F. Supp. 2d 288, 316 (D. Conn. 2008). *See also Preston v. Leake,* 629 F. Supp. 2d 517, 524 (E.D.N.C. 2009) (differentiating the "broad sweep of the Vermont statute" that "restricted essentially any potential campaign contribution" from a statute that "only applies to lobbyists"); *In re Earle Asphalt Co.,* 950 A.2d 918, 927 (N.J. Super. Ct. App. Div. 2008), *aff'd* 957 A.2d 1173 (N.J. 2008) (holding that a limitation on campaign contributions by government contractors and their principals did not have the same capacity to prevent candidates from amassing the resources necessary for effective campaigning as the statute in *Randall*). One commenter expressly dismissed arguments that *Randall* would have implications for the Commission's proposed rule. Fund Democracy/Consumer Federation Letter.

[69] *See* section II.B.2(a)(2) of this Release (discussing the definition of "official" of a government entity for purposes of rule 206(4)–5).

[70] *See* section II.B.2(a)(1) of this Release (discussing the prohibition on compensation for providing advisory services to the client during rule 206(4)–5's two-year time out).

[71] *See Citizens United,* 130 S. Ct. at 908–09 (noting that a government interest cannot be sufficiently compelling to limit independent expenditures by corporate entities). *See also SpeechNow.org,* 599 F.3d at 692 (spelling out the different standards of constitutional review established by the Supreme Court for restrictions on independent expenditures and direct contributions). Some commenters expressed concern, for example, that rule 206(4)–5 may quell volunteer activities, deter employees of investment advisers from running for office, or chill charitable contributions. *See, e.g.,* Caplin & Drysdale Letter; NASP Letter. We have expressly clarified that volunteer activities and charitable contributions generally would not trigger the rule's time out provision and that employees running for office would not be subject to the contribution limitation. *See infra* notes 157 and 139, respectively.

[72] *Buckley,* 424 U.S. at 21. *See also* section II.B.2(a)(6) of this Release (discussing the *de minimis* exceptions to covered associates' contributions triggering the two-year time out). Some commenters raised constitutional concerns regarding the levels of the *de minimis* exception in our proposal. *See, e.g.,* Callcott Letter I; Callcott Letter II; Caplin & Drysdale Letter; IM Compliance Letter; Sutherland Letter. As discussed below, we have both raised the amount of the *de minimis* exception in line with inflation and added an additional exception.

[73] *See* section II.B.2(a)(1) of this Release (discussing the two-year time out on receiving compensation for advisory services).

[74] Unless indicated expressly otherwise, each time we refer to a "registered" investment adviser in this Release, we mean an adviser registered with the Commission.

[75] *See* section II.B.1 of this Release (discussing advisers covered by the rule). One commenter raised constitutional concerns by arguing that the rule would apply beyond the advisory business of an adviser that solicits government clients, no matter how separate the other product or service offerings of the adviser are from the governmental business. ABA Letter. But we believe we have made clear that the rule's time out provisions, which are designed to eliminate *quid pro quo* arrangements and ameliorate market distortions, apply only with respect to the provision of advisory services to government clients, which is consistent with our authority under the Advisers Act. *See* section II.B.2(a)(1) of this Release.

[76] *See* section II.B.1 of this Release.

[77] *See* section II.B.2(a)(4) of this Release (discussing the definition of "covered associates," whose contributions could trigger the two-year time out).

[78] *See* section II.B.2(a)(2) of this Release (discussing the definition of "official" of a government entity for purposes of the rule 206(4)–(5)). Some commenters argued that the definition of "official" we included in our proposal was ambiguous. *See, e.g.,* Caplin & Drysdale Letter. In response, we have provided additional guidance. *See* section II.B.2(a)(2) of this Release.

[79] Rule 206(4)–5 is targeted to a concrete business relationship between contributors and candidates' governmental entities. It is not intended to restrict the voices of persons and interest groups, reduce the overall scope of election campaigns, or equalize the relative ability of all votes to affect electoral outcomes. Indeed, if investment advisers do not seek government business from those to whom they and their covered associates make contributions or for whom they solicit contributions, the rule's limitations will not be triggered. Rather, the rule is intended to prevent direct *quid pro quo* arrangements, fraudulent and manipulative acts and practices, and improve the mechanism of a free and open market for investment advisory services for government entity clients. With pay to play activities, the conflict of interest is apparent, the likelihood of stealth in the arrangements is great, and our regulatory purpose is prophylactic. *See Blount,* 61 F.3d at 945 (describing the court's similar characterization of MSRB rule G–37).

[80] Proposing Release, at section II.A.

[81] Rule 206(4)–5(a)(1) makes it unlawful for any investment adviser covered by the rule to provide investment advisory services for compensation to a government entity within two years after a contribution to an official of the government entity is made by the investment adviser or any covered associate, as defined in the rule, of the investment adviser (including a person who becomes a covered associate within two years after the contribution is made). As noted below, an "official" includes an incumbent, candidate or successful candidate for elective office of a government entity if the office

Importantly, as we noted in the Proposing Release, rule 206(4)–5 would not ban or limit the amount of political contributions an adviser or its covered associates could make; rather, it would impose a two-year time out on conducting compensated advisory business with a government client after a contribution is made.[82] This first prohibition is substantially similar to our proposal. However, as discussed below, we have made certain modifications to some of the definitions of terms in this prohibition.[83]

Second, the rule generally prohibits advisers from paying third parties to solicit government entities for advisory business unless such third parties are registered broker-dealers or registered investment advisers, in each case themselves subject to pay to play restrictions.[84] That is, an adviser is prohibited from providing or agreeing to provide, directly or indirectly, payment to any person for solicitation of government advisory business on behalf of such adviser unless that person is registered with us and subject to pay to play restrictions either under our rule or the rules of a registered national securities association.[85] This represents a modification from our proposal, which included a flat ban without an exception for any brokers or investment advisers.[86] As discussed below, commenters persuaded us that the objective of the rule in eliminating pay to play activities of advisers could be preserved if the third parties they hire are themselves registered investment advisers subject to Commission oversight or are broker-dealers subject to pay to play restrictions imposed by a registered national securities association that the Commission must approve.

Third, the rule makes it unlawful for an adviser itself or any of its covered associates to solicit or to coordinate: (i) Contributions to an official of a government entity to which the investment adviser is seeking to provide investment advisory services; or (ii) payments to a political party of a State or locality where the investment adviser is providing or seeking to provide investment advisory services to a government entity.[87] We are adopting this aspect of the rule as proposed.

Fourth, as it is not possible for us to anticipate all of the ways advisers and government officials may structure pay to play arrangements to attempt to evade the prohibitions of our rule, the rule includes a provision that makes it unlawful for an adviser or any of its covered associates to do anything indirectly which, if done directly, would result in a violation of the rule.[88] This provision in the rule we are adopting today is identical to our proposal.[89]

Finally, for purposes of our rule, an investment adviser to certain pooled investment vehicles in which a government entity invests or is solicited to invest will be treated as though the adviser were providing or seeking to provide investment advisory services directly to the government entity.[90] This provision is substantially similar to our proposal, although we have made certain modifications described below.[91]

1. Advisers Subject to the Rule

Rule 206(4)–5 applies to registered investment advisers and certain advisers exempt from registration. In particular, it applies to any investment adviser registered (or required to be registered) with the Commission, or unregistered in reliance on the exemption available under section 203(b)(3) of the Advisers Act (15 U.S.C. 80b–3(b)(3)).[92] The rule would not, however, apply to most small advisers that are registered with State securities authorities instead of the Commission,[93] or advisers that are unregistered in reliance on exemptions other than section 203(b)(3) of the Advisers Act.[94]

We received limited comment on this aspect of the rule. One commenter explicitly agreed with the scope of our proposed rule, noting that it would capture most, if not all, advisers that provide discretionary management with respect to public pension fund assets, regardless of whether they are registered.[95] Other commenters recommended that the rule apply more

is directly or indirectly responsible for, or can influence the outcome of, the hiring of an investment adviser or has the authority to appoint any person who is directly or indirectly responsible for or can influence the outcome of the hiring of an investment adviser. *See* section II.B.2(a)(2) of this Release.

[82] Proposing Release, at section II.A.

[83] *See generally* section II.B.2(a) of this Release.

[84] Rule 206(4)–5(a)(2)(i) makes it unlawful for any investment adviser covered by the rule and its covered associates (as defined in the rule) to provide or agree to provide, directly or indirectly, payment to any person to solicit a government entity for investment advisory services on behalf of such investment adviser unless such person is a regulated person or is an executive officer, general partner, managing member (or, in each case, a person with a similar status or function), or employee of the investment adviser. "Regulated person" is defined in rule 206(4)–5(f)(9). *See* section II.B.2(b) of this Release for a discussion of this definition.

[85] *See* section II.B.2(b) of this Release. While our rule would apply to any registered national securities association, the Financial Industry Regulatory Authority, or FINRA, is currently the only registered national securities association under section 19(a) of the Exchange Act [15 U.S.C. 78s(b)]. As such, for convenience, we will refer directly to FINRA in this Release when describing the exception for certain broker-dealers from the rule's ban on advisers paying third parties to solicit government business on their behalf. The Commission's authority to consider rules proposed by a registered national securities association is governed by section 19(b) of the Exchange Act [15 U.S.C. 78s(b)] ("No proposed rule change shall take effect unless approved by the Commission or otherwise permitted in accordance with the provisions of this subsection.").

[86] *See* Proposing Release, at section II.A.3(b).

[87] Rule 206(4)–5(a)(2)(ii) makes it unlawful for any investment adviser covered by the rule and its covered associates to coordinate, or to solicit any person [including a political action committee] to make, any: (A) contribution to an official of a government entity to which the investment adviser is providing or seeking to provide investment advisory services; or (B) payment to a political party of a State or locality where the investment adviser is providing or seeking to provide investment advisory services to a government entity. *See* section II.A.2.(c) of this Release.

[88] Rule 206(4)–5(d) makes it unlawful for any investment adviser covered by the rule and its covered associates to do anything indirectly which, if done directly, would result in a violation of this section. *See* section II.B.2(d) of this Release.

[89] *See* Proposing Release, at section II.A.3(d).

[90] Rule 206(4)–5(c) states that, for purposes of rule 206(4)–5, an investment adviser to a covered investment pool in which a government entity invests or is solicited to invest, shall be treated as though that investment adviser were providing or seeking to provide investment advisory services directly to the government entity. See section II.B.2(e) of this Release.

[91] *See* section II.B.2(e) of this Release.

[92] Rule 206(4)–5(a)(1) and (2). Section 203(b)(3) [15 U.S.C. 80b–3(b)(3)] exempts from registration any investment adviser that is not holding itself out to the public as an investment adviser and had fewer than 15 clients during the last 12 months. We are including this category of exempt advisers within the scope of the rule in order to make the rule applicable to the many advisers to private investment companies that are not registered under the Advisers Act.

[93] Advisers with less than $25 million of assets under management are prohibited from registering with the Commission by section 203A of the Advisers Act [15 U.S.C. 80b–3A].

[94] The rule would also not apply to certain other advisers that are exempt from registration with the Commission. *See, e.g.,* section 203(b)(1) of the Advisers Act [15 U.S.C. 8b–3(b)(1)] (exempting from registration intrastate investment advisers). As explained in the Proposing Release, we believe these advisers are unlikely to advise public pension plans. *See* Proposing Release, at n.64 and accompanying text. The rule would also not apply to persons who are excepted from the definition of investment adviser under section 202(a)(11) of the Advisers Act [15 U.S.C. 80b–2(a)(11)]. For a discussion, in particular, of the exclusion of banks and bank holding companies which are not investment companies from the Advisers Act's definition of "investment adviser," see *infra* note 274.

[95] Comment Letter of the California Public Employees' Retirement System (Oct. 6, 2009) ("CalPERS Letter") ("CalPERS agrees that the scope of the proposed rule would capture most if not all external managers who have discretion over the investment of public pension fund assets, including hedge fund managers, real estate managers, private equity managers, traditional long-only managers, money managers, and others, regardless of whether the managers are registered investment advisors. CalPERS supports application of the rule to investment advisers, as defined in the proposed rule.").

broadly to all advisers that may manage assets of government entities.[96] The primary effect of such an expansion of the rule would be to apply it to smaller firms, the regulatory responsibility for which Congress has previously allocated to the State securities authorities.[97] It is our understanding that few of these firms manage public pension plans or other public funds.[98] Accordingly, we have decided to adopt this provision as proposed.

2. Pay to Play Restrictions

(a) Two-Year "Time Out" for Contributions

Rule 206(4)–5(a)(1) prohibits investment advisers from receiving compensation for providing advice to a "government entity" within two years after a "contribution" to an "official" of the government entity has been made by the investment adviser or by any of its "covered associates."[99] The rule does not ban political contributions and does not limit the amount of any political contribution. Instead, the rule imposes a ban—a "time out"—on receiving compensation for conducting advisory business with a government client for two years after certain contributions are made. The two-year time out is intended to discourage advisers from participating in pay to play practices by requiring a "cooling-off period" during which the effects of a political contribution on the selection process can be expected to dissipate.

Rule 206(4)–5(a)(1) is based largely on MSRB rule G–37 under which a broker-dealer is prohibited from engaging in the municipal securities business for two years after making a political contribution.[100] As noted above and as explained in the Proposing Release, we modeled the rule on the MSRB rules because we believe that they have significantly curbed pay to play practices in the municipal securities market.[101] We also pointed out that our approach would minimize the compliance burdens on firms that would be subject to both rule regimes. But we requested comment on our proposed approach and whether alternative models might be appropriate.

Several commenters supporting the rule explicitly addressed the appropriateness of the MSRB approach. One, for example, asserted that the proposed rule "appropriately expands upon MSRB G–37 and G–38."[102] Another agreed that the MSRB rules "provide an appropriate regulatory analogy for addressing [pay to play] issues."[103] Many other commenters, however, sought to distinguish advisers and municipal securities dealers, and asserted that, because of the differences between the two, MSRB rule G–37 is an inappropriate model on which to base an investment adviser pay to play rule.[104] Some argued that the long-term nature of advisory relationships is fundamentally different from discrete municipal underwriting transactions, and consequently, the two-year time out is more disruptive and severe for advisers and the governments that retain them than for municipal securities dealers who are simply banned from obtaining "new" business as opposed to terminating a long-term relationship.[105] Some commenters asserted that the relationships are different because advisers provide ongoing and continuous advice as a fiduciary, rather than a one-time transaction such as an underwriting, and that advisory services are typically subject to an open competitive bid process instead of through negotiated transactions that are typical of municipal underwritings.[106]

We disagree that the differences between municipal securities underwriting and money management are sufficient to warrant an alternative approach. Commenters are correct that municipal securities underwriters provide episodic services rather than ongoing services often provided by money managers. But underwriters seek to provide repeated, if not ongoing, services, and the imposition of a two-year time out can have considerable

[96] These suggestions included applying the rule to all registered (including SEC-registered and State-registered) and unregistered advisers (*see, e.g.,* 3PM Letter (arguing that selective application of the rule could lead to convoluted organizational structures designed to bypass its reach and that the proposal represents the kind of patchwork regulation that will lead to the kind of inconsistency the Commission is seeking to correct), and extending the rule to State-registered advisers (*see, e.g.,* Comment Letter of the Cornell Securities Law Clinic (Oct. 6, 2009) ("Cornell Law Letter")).

[97] Amendments to the Advisers Act in 1996 placed the regulatory responsibility for these advisers in the hands of State regulators. *See* section 203A of the Advisers Act [15 U.S.C. 80b–3a] enacted as part of Title III of the National Securities Markets Improvement Act of 1996, Public Law 104–290, 110 Stat. 3416 (1996) (codified in scattered sections of the United States Code).

[98] *See* Proposing Release, at n.64. We did not receive any comment challenging our understanding.

[99] Rule 206(4)–5(a)(1).

[100] Proposing Release, at section II.A.2.

[101] *See id.* at n.23 (citing others, including the MSRB, who agree that the MSRB rules have been effective: MSRB, *MSRB Notice 2009–62, Amendments Filed to Rule G–37 Regarding Contributions to Bond Ballot Campaigns* (Dec. 4, 2009), available at *http://msrb.org/msrb1/archive/2009/2009-62.asp* ("Rule G–37, in effect since 1994, has provided substantial benefits to the industry and the investing public by greatly reducing the direct connection between political contributions given to issuer officials and the awarding of municipal securities business to brokers, dealers and municipal securities dealers ("dealers"), thereby effectively assisting with eliminating pay-to-play practices in the new issue municipal securities market."); MSRB, *MSRB Notice 2009–35, Request for Comment: Rule G–37 on Political Contributions and Prohibitions on Municipal Securities Business—Bond Ballot Campaign Committee Contributions* (June 22, 2009) ("The MSRB believes the rule has provided substantial benefits to the industry and the investing public by greatly reducing the direct connection between political contributions given to issuer officials and the awarding of municipal securities business to dealers, thereby effectively eliminating pay-to-play practices in the new issue municipal securities market." [footnote omitted]); MSRB, *MSRB Notice 2003–32, Notice Concerning Indirect Rule Violations: Rules G–37 and G–38* (Aug. 6, 2003) ("The impact of Rules G–37 and G–38 has been very positive. The rules have altered the political contribution practices of municipal securities dealers and opened discussion about the political contribution practices of the entire municipal industry."); Letter from Darrick L. Hills and Linda L. Rittenhouse of the CFA Institute to Jill C. Finder, Asst. Gen. Counsel of the MSRB (Oct. 19, 2001), available at *http://www.cfainstitute.org/Comment%20Letters/20011019.pdf* (stating, "We generally believe that the existing [MSRB] pay-to-play prohibitions have been effective in stemming practices that compromise the integrity of the [municipal securities] market by using political contributions to curry favor with politicians in positions of influence."); Comm. on Capital Mkts. Regulation, Interim Report of the Committee on Capital Markets Regulation (Nov. 30, 2006), available at *http://www.capmktsreg.org/pdfs/11.30Committee_Interim_ReportREV2.pdf* (stating, upon describing MSRB Rule G–37 and the 2005 amendments to MSRB Rule G–38, "Taken together, the MSRB's rules have largely put an end to the old "pay to play" practices in municipal underwriting."). *See also* Comment letter of Professors Alexander W. Butler, Larry Fauver and Sandra Mortal (Sept. 30, 2009) ("Butler Letter") (citing Alexander W. Butler, Larry Fauver & Sandra Mortal, *Corruption, Political Integrity, and Municipal Finance,* 22 R. of Fin. Stud. 2673–705 (2009)).

[102] Common Cause Letter.

[103] Comment Letter of Credit Suisse Securities (USA) LLC (Sept. 14, 2009) ("Credit Suisse Letter").

[104] *See, e.g.,* IAA Letter; ICI Letter; SIFMA Letter; ABA Letter; Dechert Letter; Skadden Letter; Comment Letter of Jones Day (Oct. 5, 2009) ("Jones Day Letter"); Comment Letter of Simpson Thacher & Bartlett LLP on behalf of Park Hill Group LLC and its affiliates (Sept. 21, 2009) ("Park Hill Letter"); Comment Letter of Monument Group, Inc. (Sept. 18, 2009) ("Monument Group Letter"). One commenter suggested, in particular, that the rule's two-year time out provision is outside of our authority because it imposes an "automatic penalty, subject only to discretionary post facto review." Comment Letter of Edwin C. Laurenson (Dec. 31, 2009). We disagree. The two-year time out is not a penalty. Rather, it is a "cooling-off period" to dissipate any effects of a *quid pro quo.* A violation of the provision would result from receiving, or continuing to receive, payment after making the contribution, not from the making of the contribution itself.

[105] *See, e.g.,* IAA Letter; ABA Letter; Dechert Letter; Skadden Letter; Jones Day Letter; Park Hill Letter; Monument Group Letter. *But see* Credit Suisse Letter ("G–37 and G–38 provide an appropriate regulatory analogy"); Butler Letter ("This practice [municipal underwriting pay to play] was analogous to the type of pay to play currently under consideration by the Commission").

[106] *See, e.g.,* IAA Letter; ICI Letter; SIFMA Letter; ABA Letter; Dechert Letter; Skadden Letter; Jones Day Letter; Park Hill Letter; Monument Group Letter.

competitive consequences to a broker-dealer whose government client must employ the services of a competitor whose services it may continue to employ after MSRB rule G–37's two-year time out has run its course. That advisers are in a fiduciary relationship with their public pension plan clients argues for at least as significant consequences for participation in pay to play practices that can harm these clients.

Our decision to adopt a rule based on the MSRB model is influenced primarily by our judgment that the MSRB rules have significantly curbed pay to play practices in the municipal securities market[107] and that alternative approaches, including those suggested by commenters, would fail to provide an adequate deterrent to pay to play activities. We considered each of the principal suggestions offered by commenters.

Some commenters suggested requiring advisers to disclose their contributions to State and local officials.[108] Statutes requiring disclosure of political contributions are, in part, designed to inform voters about a candidate's financial supporters; an informed electorate can then use the information to vote for or against a candidate.[109] But voters' possible reactions, if any, to such disclosure would not necessarily resolve the concerns we are trying to address in this rulemaking. Our concern is protecting advisory clients and investors whom we have the responsibility to protect under the Advisers Act—namely, the public pension plans and their beneficiaries who are affected by pay to play practices.[110] Disclosure to a plan's trustees might be insufficient where the trustee (particularly a sole trustee) has received the contributions and is presumably well aware of the conflicts involved. Moreover, and as we pointed out in the Proposing Release, requiring advisers to disclose political contributions to beneficiaries would be unlikely to protect them since most cannot act on the information by moving their pension assets to a different plan or by reversing the plan trustees' adviser hiring decisions.[111] Not all beneficiaries may be entitled to vote (or withhold their vote) for the official to whom a contribution was made, and those that are may need to wait a substantial period of time until a future election to exercise their vote. Further, as beneficiaries may constitute only a small proportion of the electorate, they may not be able to influence an election; therefore, reliance on the electoral process may be insufficient to protect government plans and their beneficiaries from pay to play. In addition, even if the fact of a contribution is disclosed (which is required in many states), the contribution's true purpose is unlikely to be disclosed.

Several commenters suggested that the Commission adopt a requirement that an adviser include in its code of ethics[112] a policy that prohibits contributions made for the purpose of influencing the selection of the adviser.[113] Several commenters recommended, similarly, that we require advisers to adopt policies and procedures[114]reasonably designed to prevent and detect contributions designed to influence the selection of an adviser.[115] Many of these commenters suggested that preclearance of employee contributions could be required under an adviser's code of ethics or compliance policies and procedures.[116] One commenter asserted that an advantage of this approach is that it would allow an adviser to customize sanctions based on the severity of the violation.[117]

We do not, however, believe that codes of ethics or compliance procedures alone would be adequate to stop pay to play practices, particularly when the adviser or senior officers of the adviser are involved either directly or indirectly. First, it is those senior officers who, as noted below, have the greatest incentives to engage in pay to play and therefore are most likely to make contributions, who would themselves ultimately be responsible for enforcing their own compliance with the firm's ethics code or compliance procedures. Second, violations of codes of ethics or compliance procedures do not themselves establish violations of the Federal securities laws. Moreover, the comments suggesting these alternatives would have us require the codes or procedures be designed to prevent or detect contributions intended to influence the selection of the adviser by a government entity. As discussed extensively above and in our Proposing Release, pay to play is an area in which intent is often very difficult to prove, and is often hidden in the guise of legitimate conduct.[118] Political contributions are made ostensibly to support a candidate; the burden on a regulator or prosecutor of proving a different intent presents substantial challenges absent unusual evidence. Commenters would thus have us give the adviser, which stands to benefit from the contribution, the discretion to determine whether contributions were intended to influence its selection by the government entity. We do not believe codes of ethics or policies and procedures alone, without a rule providing for specific, prophylactic prohibitions, are adequate to address this type of conduct.[119]

On balance, we believe that adopting a two-year time out for investment advisers similar to the two-year time out applicable to broker-dealers underwriting municipal securities is appropriate. Our years of experience with MSRB rule G–37 suggests that the "strong medicine" provided by that rule has both significantly curbed participation in pay to play and provides a reasonable cooling-off period to mitigate the effect of a political contribution. We are sensitive about

[107] *See supra* notes 31 and 101 and accompanying text.

[108] *See, e.g.,* SIFMA Letter; Preqin Letter I; Comment Letter of Triton Pacific Capital, LLC (Sept. 1, 2009) ("Triton Pacific Letter"); Comment Letter of the State Association of County Retirement Systems (Sept. 8, 2009); Comment Letter of CapLink Partners (Sept. 9, 2009) ("CapLink Letter"); Comment Letter of Parenteau Associates, LLC (Aug. 7, 2009) ("Parenteau Letter").

[109] *See Buckley,* 424 U.S. at 67 (1976) (noting that campaign financing disclosure requirements "deter actual corruption and avoid the appearance of corruption by exposing large contributions and expenditures to the light of publicity").

[110] As discussed above, our purposes in this rulemaking are preventing fraud, protecting investors and maintaining the integrity of the adviser selection process, not campaign finance reform. *See* section I of this Release.

[111] *See* Proposing Release, at section II.A.2. Some commenters made the same points. *See, e.g.,* NY City Bar Letter; Cornell Law Letter; 3PM Letter. *See also Blount,* 61 F.3d at 947 (explaining, in the context of the municipal securities industry, the potential inadequacy of disclosure to address pay to play concerns, that "disclosure would not likely cause market forces to erode 'pay to play * * *'" because the "* * * purpose of protecting the integrity of the market [would] * * * 'be achieved less effectively.'").

[112] Registered investment advisers are required to have codes of ethics under the Advisers Act. *See* Advisers Act rule 204A–1.

[113] *See, e.g.,* IAA Letter; ABA Letter; Comment letter of the National Society of Compliance Professionals, Inc. (Oct. 6, 2009) ("NSCP Letter"); NY City Bar Letter; Fidelity Letter.

[114] Registered investment advisers are required to adopt and implement policies and procedures reasonably designed to prevent violation by the adviser or its supervised persons of the Advisers Act and the rules the Commission has adopted thereunder. *See* Advisers Act rule 206(4)–7.

[115] *See, e.g.,* ABA Letter; NY City Bar Letter; IAA Letter; ICI Letter; NSCP Letter.

[116] *See, e.g.,* IAA Letter; NY City Bar Letter; ABA Letter.

[117] ABA Letter.

[118] *See, e.g.,* Proposing Release, at n.16 and accompanying text.

[119] We note that, under our rules, an adviser's code of ethics must require compliance with the rule we are today adopting (rule 204A–1(a)(2)) and the adviser must adopt policies and procedures designed to prevent violation of the rule (rule 206(4)–7(a)).

potential implications of the operation of the rule on public pension funds, which could lose the services of an investment adviser subject to a time out. While we have designed the rule to reduce its impact,[120] investment advisers are best positioned to protect these clients by developing and enforcing robust compliance programs designed to prevent contributions from triggering the two-year time out.

(1) Prohibition on Compensation

As noted above, investment advisers subject to new rule 206(4)–5 are not prohibited from providing advisory services to a government client, even after triggering the two-year time out. Instead, an adviser is prohibited from receiving compensation for providing advisory services to the government client during the time out.[121] We have taken this approach to enable an adviser to act consistently with its fiduciary obligations so it will not have to abandon a government client after making a triggering contribution, but rather may provide uncompensated advisory services for a reasonable period of time to allow the government client to replace the adviser.[122] We are adopting this element of the rule as proposed.

One commenter supported the prohibition on compensation as the least disruptive option to government clients,[123] while others argued that the prohibition on compensation was unreasonable and, in some cases, difficult or near impossible to implement.[124] A coalition of commenters representing State and local governments asserted that, due to restrictions on accepting uncompensated services under State and local law, it was unlikely that government entities would accept uncompensated services even if an adviser were willing or required to provide them.[125] Commenters representing advisers took the opposite view, expressing concern that they would be locked into providing uncompensated services for extended periods of time as a result, and wanted the Commission to provide guidelines as to what a reasonable amount of time is for a government client to claim or move its assets.[126] One asserted that it would be unreasonable to require advisers to provide uncompensated services altogether.[127]

Few of the commenters who opposed this provision appeared to favor its elimination, which would require the adviser to immediately cease providing advisory services upon making a triggering contribution.[128] Rather, they appeared to oppose the two-year time out more generally.[129]

We are not persuaded by their arguments. We believe the prohibition on compensation is both appropriate and administrable. The incentives to engage in pay to play may be significant, precisely because of the long-term nature of many advisory relationships from which the adviser could benefit for several years. As a result, the consequences of engaging in pay to play need to be commensurate with these incentives for the prophylactic rule to have a meaningful deterrent effect.[130] We acknowledge that the rule will involve compliance costs and could adversely affect an adviser's business.[131] On the other hand, a political contribution would not affect the ability of an adviser to provide compensated services to other clients, including other government clients. Moreover, the fiduciary obligations of an adviser would not require it to provide uncompensated advice indefinitely—rather, the adviser may need to continue to provide advice for only a reasonable period of time during which its client can seek to obtain advisory services from others.[132]

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[120] *See, e.g.,* section II.B.2(a)(6) of this Release (discussing the *de minimis* exceptions to the two-year time out); section II.B.2(f) of this Release (discussing the rule's exemptive provision).

[121] Rule 206(4)–5(a)(1) makes it unlawful for investment advisers covered by the rule to provide investment advisory services for compensation to a government entity within two years after a triggering contribution. Under the rule, the two-year time out begins to run once the contribution is made and not when the contribution is discovered either by our examination staff or by the adviser. The adviser, therefore, should return all such compensation promptly upon discovering the triggering contribution. For the application of the rule to investments by government entities in pooled investment vehicles, see section II.B.2(e) of this Release.

[122] Proposing Release, at section II.A.3(a)(1). An investment adviser's fiduciary duties may require it to continue providing advisory services for a reasonable period of time under these circumstances. For another instance in which an adviser's fiduciary duties may require its continued provision of services, *see Temporary Exemption for Certain Investment Advisers,* Investment Advisers Act Release No. 1736 (July 22, 1998) [63 FR 40231, 40232 (July 28, 1998)] (describing an investment adviser's fiduciary duties to an investment company in the case of an assignment of the advisory contract).

[123] Cornell Law Letter.

[124] *See, e.g.,* ICI Letter; Jones Day Letter. Some commenters argued for more flexibility in sanctions (Skadden Letter; ABA Letter; Fidelity Letter; ICI Letter; MassMutual Letter; Comment Letter of Wells Fargo Advisors (Oct. 6, 2009) ("Wells Fargo Letter"); IAA Letter).

[125] Comment Letter of the National Conference of State Legislatures, National Association of Counties, National League of Cities, International City/County Management Association, National Association of State Auditors, Comptrollers and Treasurers, Government Finance Officers Association, National Association of State Retirement Administrators, National Conference on Public Employee Retirement Systems, and National Council on Teacher Retirement (Oct. 6, 2009) ("National Organizations Letter"). With respect to direct advisory relationships, because restrictions on governments receiving services without payment would be a function of particular State or local laws, we believe government entities and their advisers are in the best position to work out arrangements that are consistent with both State and local law and the compensation prohibition of our rule. With respect to investments by government entities in pooled investment vehicles, in particular, such restrictions could be avoided. *See* section II.B.2(e)(2) of this Release (describing possible arrangements for continued payment to investment pools even after a time out is triggered).

[126] *See, e.g.,* Comment Letter of Davis Polk & Wardwell LLP (Oct. 6, 2009) ("Davis Polk Letter") (recommending that three months would be reasonable); ICI Letter (suggesting 30 days). Other commenters raised concern regarding the potential harm of a time out to government investors for whom identifying new managers may be a lengthy process. *See, e.g.,* NASP Letter. We believe, however, that, on balance, pension funds and their beneficiaries are best served by the rule's deterrent effect against engaging in pay to play activities. An adviser's fiduciary obligations to continue to provide services for a reasonable amount of time, combined with the extended compliance dates described in section III of this Release which should afford the ability of market participants to organize themselves in a way to adapt to the rule's requirements, should be sufficient to minimize the impact on pension plans to the extent they need to prepare to transition to a new money manager after a two-year time out is triggered.

[127] Jones Day Letter. Other commenters argued that the specter of a two-year time out might cause some firms to ban or require pre-clearance of all employees' contributions. *See, e.g.,* Caplin & Drysdale Letter. Although the rule does not require this approach, as a result of commenters' assertions, we address this possibility in our cost-benefit analysis. *See* section IV of this Release.

[128] *See, e.g.,* Davis Polk Letter; ICI Letter.

[129] *See, e.g.,* National Organizations Letter; ICI Letter; Jones Day Letter; Dechert Letter.

[130] This deterrent effect is the basis for our view that the two-year time out should not apply only to "new business" and that advisers should not be able to "negotiate" for lesser consequences. *See supra* note 124 (pointing to commenters who called for more flexibility regarding the two-year time out). As we point out above, our concerns extend to contributions designed to enable advisers to retain contracts that might not otherwise be renewed.

[131] For a discussion of costs and other burdens that may be imposed by our rule, see generally sections IV–V of this Release.

[132] *See supra* note 122 and accompanying text. The amount of time a client might need in good faith to find and engage a successor to the adviser would, in our view, be the primary consideration of the length of a reasonable period, which may depend in part on such matters as applicable law, the client's customary process of finding and engaging advisers and the types of assets managed by the adviser that is subject to the time out. In some cases, a client may be able to quickly engage a "transition adviser" to manage its assets until a permanent successor is found. *See, e.g., Illinois State Board Sets Transition Manager RFP,* Pensions & Investments, Feb. 8, 2010 available at *http://www.pionline.com/article/20100208/PRINTSUB/302089976*. In other cases, the client may be required by the law under which it operates to undertake a specified process to obtain a new manager, such as a solicitation for proposals from potential managers.

Some commenters urged us to permit advisers to continue to receive compensation during the two-year time out for services provided pursuant to an existing management contract,[133] without distinguishing whether the contract was acquired as a result of political contributions. One commenter further suggested specifically that we permit advisory services to continue to be provided by the adviser at cost during the time out to remove the profit motive of pay to play.[134] We are also not persuaded by their suggestions. Allowing contracts acquired as a result of political contributions to continue uninterrupted would eviscerate the rule. Were a "free pass" available for contracts merely because they were entered into prior to discovery of a contribution, advisers would be strongly incentivized against "discovering" contributions.[135] Because no new business from a government client may even be available to the adviser until the two-year period has run its course, advisers whose contributions succeeded in acquiring a management contract for two years or more could escape any consequences under such an exception.[136] Further, in our judgment, the potential loss of profits will not operate as an adequate deterrent. It is our understanding that being selected to manage public pension plan assets has a reputational value that itself contributes to advisory profits by attracting additional assets under management regardless of the profits derived directly from the management of government client assets.[137]

(2) Officials of a Government Entity

The rule's two-year time out is triggered by a contribution to an "official" of a "government entity."[138] An official includes an incumbent, candidate or successful candidate for elective office of a government entity if the office is directly or indirectly responsible for, or can influence the outcome of, the hiring of an investment adviser or has authority to appoint any person who is directly or indirectly responsible for, or can influence the outcome of, the hiring of an investment adviser.[139] Government entities include all State and local governments, their agencies and instrumentalities, and all public pension plans and other collective government funds, including participant-directed plans such as 403(b), 457, and 529 plans.[140]

The two-year time out is thus triggered by contributions, not only to elected officials who have legal authority to hire the adviser, but also to elected officials (such as persons with appointment authority) who can influence the hiring of the adviser. We have not modified this approach from our proposal.[141] As we noted in the Proposing Release, a person appointed by an elected official is likely to be subject to that official's influences and recommendations.[142] It is the scope of authority of the particular *office* of an official, not the influence actually exercised by the individual, that would determine whether the individual has influence over the awarding of an investment advisory contract under the definition.[143] We are adopting these provisions as proposed.[144]

Some commenters asserted that the rule should be more specific as to which public officials to whom a contribution is made would trigger application of the rule in order to reduce uncertainty and compliance burdens.[145] But State and municipal statutes vary substantially with respect to whom they entrust with the management of public funds, and any effort we make in a rule of general application to identify specific officials who are in a position to influence the selection of an adviser would certainly be over-inclusive in some circumstances and under-inclusive in others.[146] Others

[133] *See, e.g.,* Dechert Letter; Fidelity Letter; ICI Letter; Jones Day Letter (in some instances, pointing to the MSRB's approach of not necessarily applying MSRB rule G–37's two-year time out when a contribution is made after a business contract is signed). *See* MSRB, *Interpretation on the Effect of a Ban on Municipal Securities Business under Rule G–37 Arising During a Pre-Existing Engagement Related to Municipal Fund Securities,* MSRB Rule G–37 Interpretive Notice (April 2, 2002), available at *http://msrb.org/msrb1/archive/ContributionsNotice.htm*). As we explain above, due to the long-term nature of typical advisory contracts and our belief that the consequences of giving a contribution need to be commensurate with the potential benefits obtained, we are not taking this approach.

[134] Dechert Letter.

[135] An approach that applied the two-year time out only to new business would preclude the adviser from receiving compensation only from additional contracts that might be awarded by the government entity during the two-year period. In our judgment, the risk of the potential loss of additional advisory contracts for a two-year period would provide an inadequate deterrent to contributions designed to influence the award of such additional advisory contracts.

[136] We are concerned that limiting application of the rule to new business could invite abuse. For example, pension officials seeking contributions after a contract has been awarded could attempt to offer an adviser additional assets to manage under the existing contract with the condition that the adviser subsequently make political contributions.

[137] *See, e.g.,* Kevin McCoy, *Do Campaign Contributions Help Win Pension Fund Deals,* USA Today, Aug. 28, 2009, available at *http://www.usatoday.com/money/perfi/funds/2009-08-26-pension-fund-political-donations_N.htm* (referring to advisory firms winning management mandates from pension funds, stating: "The awards generate lucrative fees and lend prestige that could help lure new clients."); Louise Story, *Quadrangle Facing Questions Over Pension Funds, N.Y. Times,* Apr. 21, 2009, available at *http://www.nytimes.com/2009/04/22/business/22quadrangle.html* (highlighting an indirect benefit of a pension fund investment, stating: "the prestige associated with it helped the firm lure other big investors.").

[138] Rule 206(4)–5(a)(1) makes it unlawful for covered investment advisers to provide investment advisory services for compensation to a government entity within two years after a contribution to an *official* of the *government entity* is made by the investment adviser or any of its covered associates.

[139] Rule 206(4)–5(f)(6). For purposes of the rule, we would not interpret the definition of "official" as covering an individual who is also a "covered associate" of the adviser. Accordingly, under the rule, a covered associate who is an incumbent or candidate for office is not limited to contributing the *de minimis* amount to his or her own campaign. The MSRB takes a similar view with respect to its rule G–37. MSRB, *Questions and Answers Concerning Political Contributions and Prohibitions on Municipal Securities Business: Rule G–37,* MSRB rule G–37 Interpretive Notice, available at *http://www.msrb.org/Rules-and-Interpretations/MSRB-Rules/General/Rule-G37-Frequently-Asked-Questions.aspx* ("MSRB Rule G–37 Q&A"), Question II.10 (May 24, 1994).

[140] Rule 206(4)–5(f)(5).

[141] *See* Proposing Release, at section II.A.3(a)(2).

[142] *Id.*

[143] As such, executive officers or legislators whose official position gives them the authority to influence the hiring of an investment adviser generally would be "government officials" under the rule. For example, a State may have a pension fund whose board of directors, which has authority to hire an investment adviser, is constituted, at least in part, by appointees of the governor and members of the State legislature. *See, e.g.,* The Commonwealth of Pennsylvania Public School Employees' Retirement Board, *Statement of Organization, By-Laws and Other Procedures* (rev. Jun. 11, 2009), art. II, sec. 2.1, available at *http://www.psers.state.pa.us/org/board/policies/201001_bylaws.pdf* (noting that the board shall be composed of, *inter alia,* two persons appointed by the Pennsylvania State Governor, two Pennsylvania State senators and two members of the Pennsylvania State house of representatives). In such circumstances, the governor and the members of the State legislature serving on the board would be officials of the government entity. Conversely, a public official who is tasked with performing an audit of the selection process but has no influence over hiring outcomes would not be an official of a government entity for purposes of the rule.

[144] These definitions and their application are substantively the same as those in MSRB rule G–37. *See* MSRB rule G–37(g)(ii) and (g)(vi).

[145] *See, e.g.,* IAA Letter; NSCP Letter; Comment Letter of T. Rowe Price Associates, Inc. (Oct. 6, 2009) ("T. Rowe Letter"); MFA Letter; Davis Polk Letter. For a discussion of the potential costs involved in identifying officials to whom contributions could trigger the rule's prohibitions, see section IV of this Release (presenting our cost-benefit analysis). Another commenter suggested that advisers should be able to rely on certifications from candidates and officials regarding whether their office would render them an "official" for purposes of the rule—*i.e.,* identifying the range, if any, of public investment vehicles over which the relevant office directly or indirectly influences the selection of investment advisers or appoints individuals who do). Caplin & Drysdale Letter. We are concerned that such a safe harbor would undercut the purposes of the rule, not least because officials will be incentivized to offer such certifications liberally (and will presumably sometimes do so inappropriately) to encourage contributions.

[146] Like us, the MSRB does not specify which officials have the authority to influence the granting

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urged that triggering contributions should be limited to contributions to officials directly responsible for the selection of advisers.[147] Excluding from the application of the rule contributions to those who are in a position to indirectly influence the selection of an investment adviser could simply lead officials to re-structure their relationships to avoid application of the rule to advisers that may contribute to those officials.

Two commenters argued that the rule should not cover contributions to candidates for Federal office,[148] while another contended that it should.[149] Under our rule, as proposed, a candidate for Federal office could be an "official" under the rule not because of the office he or she is running for, but as a result of an office he or she currently holds.[150] So long as an official has influence over the hiring of investment advisers as a function of his or her current office, contributions by an adviser could have the same effect, regardless to which of the official's campaigns the adviser contributes. For that reason, we are not persuaded that an incumbent State or local official should be excluded from the definition solely because he or she is running for Federal office.[151]

(3) Contributions

The rule's time out provisions are triggered by contributions made by an adviser or any of its covered associates.[152] A contribution is defined to include a gift, subscription, loan, advance, deposit of money, or anything of value made for the purpose of influencing an election for a Federal, State or local office, including any payments for debts incurred in such an election.[153] It also includes transition or inaugural expenses incurred by a successful candidate for State or local office.[154] The definition is the same as we proposed and as the one used in MSRB rule G–37.[155]

We received requests that we clarify the application of the rule to some common circumstances that may arise in the course of an adviser's relationship with a government client.[156] We would not consider a donation of time by an individual to be a contribution, provided the adviser has not solicited the individual's efforts and the adviser's resources, such as office space and telephones, are not used.[157] Similarly, we would not consider a charitable donation made by an investment adviser to an organization that qualifies for an exemption from Federal taxation under the Internal Revenue Code,[158] or its equivalent in a foreign jurisdiction, at the request of an official of a government entity to be a contribution for purposes of rule 206(4)–5.[159]

The few commenters that addressed the definition of "contribution" generally urged us to adopt a narrower version. Some, for example, recommended that contributions be expressly limited to political contributions and more explicitly exclude expenditures not clearly made for the purpose of influencing an election.[160] We are not narrowing our definition. We are instead adopting our definition as proposed due to our concern that "contributions" may also take the form of payment of election-related debts and transition or inaugural expenses. Further, our definition of "contribution" already requires that the payment be made for the purpose of influencing an election for a Federal, State or local office.[161] We believe that the scope of our proposed definition is appropriate in light of the conduct we are seeking to address.

Commenters were divided as to whether contributions to PACs or local political parties should trigger the two-year time out.[162] Such contributions were not explicitly covered by the proposed rule and do not necessarily

of government business for purposes of its rule G–37. *See* MSRB, *Campaign for Federal Office,* MSRB Rule G–37 Interpretive Notice (May 31, 1995), available at *http://msrb.org/msrb1/rules/interpg37.htm* ("The Board does not make determinations concerning whether a particular individual meets the definition of "official of an issuer.").

[147] *See, e.g.,* IAA Letter; NASP Letter; NY City Bar Letter; Davis Polk Letter.

[148] *See, e.g.,* NSCP Letter; Dechert Letter.

[149] Fund Democracy/Consumer Federation Letter.

[150] As a result, if a State or municipal official were, for example, a candidate for the U.S. Senate, House of Representatives, or presidency, an adviser's contributions to that official would be covered by the rule. MSRB rule G–37's time out provision is also triggered by contributions to State and local officials running for Federal office. *See* MSRB Rule G–37 Q&A, Questions IV.2–3.

[151] Under certain circumstances, a State or municipal official running for Federal office could remove herself from being an "official" for purposes of rule 206(4)–5 by eliminating her ability to influence the outcome of the hiring of an investment adviser. This might occur, for example, if she were to: (i) Formally withdraw from participation in or influencing adviser hiring decisions; (ii) be leaving office, so that he or she could not participate in subsequent decision-making; and (iii) have held direct influence over the adviser hiring process (as opposed to, for example, having designated an appointee with such influence who would remain in a position to influence such hiring).

[152] Rule 206(4)–5(a)(1) makes it unlawful for covered investment advisers to provide investment advisory services for compensation to a government entity within two years after a contribution to an official of the government entity is made by the investment adviser or any of its covered associates. As suggested above, we are concerned that contributions may be used "as the cover for what is much like a bribe: a payment that accrues to the private advantage of the official and is intended to induce him to exercise his discretion in the donor's favor, potentially at the expense of the polity he serves." *Blount,* 61 F.3d at 942 (describing the Commission's approval of MSRB rule G–37 as based on a wish to curtail this function).

[153] Rule 206(4)–5(f)(1).

[154] MSRB rule G–37 also covers payment of transition or inaugural expenses as contributions for purposes of its time out provision. *See* MSRB Rule G–37 Q&A, Question II.6. However, under neither rule does a contribution include the transition or inaugural expenses of a successful candidate for *Federal* office. Contributions to political parties are not specifically covered by the definition and thus would not trigger the rule's two-year time out unless they are a means to do indirectly what the rule prohibits if done directly (for example, the contributions are earmarked or known to be provided for the benefit of a particular political official). We also note that "contributions" are not intended to include independent "expenditures," as that term is defined in 2 U.S.C. 431 & 441b (the Federal statutory provisions limiting contributions and expenditures by national banks, corporations, or labor organizations invalidated by *Citizens United* v. *Federal Election Commission,* 130 S. Ct. 876 (2010) (holding that corporate funding of independent political broadcasts in candidate elections cannot be limited under the First Amendment)). Indeed, it is our intent that, under the rule, advisers and their covered associates "are not in any way restricted from engaging in the vast majority of political activities, including making direct expenditures for the expression of their views, giving speeches, soliciting votes, writing books, or appearing at fundraising events." *Blount,* 61 F.3d at 948.

[155] MSRB rule G–37(g)(i).

[156] *See, e.g.,* Caplin & Drysdale Letter; Callcott Letter I (volunteer activities); NASP Letter (charitable contributions); Sutherland Letter; IAA Letter (entertainment expenses and conference expenses). We address entertainment and conference expenses in section II.B.2(c) of this Release (which discusses the prohibition on soliciting or coordinating contributions from others).

[157] *See* Proposing Release, at n.91. A covered associate's donation of his or her time generally would not be viewed as a contribution if such volunteering were to occur during non-work hours, if the covered associate were using vacation time, or if the adviser is not otherwise paying the employee's salary (*e.g.,* an unpaid leave of absence). *But see* rule 206(4)–5(d) (prohibiting an adviser from doing indirectly what the rule would prohibit if done directly). The MSRB deals similarly with this issue. *See* MSRB Rule G–37 Q&A, Question II.19.

[158] Section 501(c)(3) of the Internal Revenue Code (26 U.S.C. 501(c)(3)) contains a list of charitable organizations that are exempt from Federal income taxation.

[159] The MSRB deals similarly with this issue. *See* MSRB Rule G–37 Q&A, Question II.18. *But see* rule 206(4)–5(d) (prohibiting an adviser from doing indirectly what the rule would prohibit if done directly).

[160] *See, e.g.,* National Organizations Letter; NASP Letter.

[161] Rule 206(4)–5(f)(1).

[162] *See, e.g.,* CalPERS Letter; NSCP Letter (should not apply to contributions to PACs or State or local parties, unless a particular candidate directly solicits contributions for those entities); Comment Letter of James J. Reilly (Aug. 24, 2009) ("Reilly Letter") (contributions to political parties should be included because in State and local elections contributions to political parties may effectively amount to contributions to an individual candidate); SIFMA Letter.

trigger the two-year time out in MSRB rule G–37.[163] In some cases, such contributions may effectively operate as a funnel to the campaigns of the government officials.[164] In other cases, however, they may fund general party political activities or the campaigns of other candidates.[165] Therefore, we have decided not to explicitly include all such contributions among those that trigger the time out, although they may violate the provision of the rule, discussed below, which prohibits an adviser or any of its covered persons from indirect actions that would result in a violation of the rule if done directly.[166]

The MSRB rule G–37 definition of "contribution" has, in our view, proved to be workable. The types of contributions relevant to money managers and elected officials are unlikely to be different than those made to influence the awarding of municipal securities business by broker-dealers. On balance, we believe that the MSRB's definition of "contribution," which we mirrored in our proposal, achieves the goals of this rulemaking. Therefore, we are adopting the definition as proposed.

(4) Covered Associates

Contributions made to influence the selection process are typically made not by the firm itself, but by officers and employees of the firm who have a direct economic stake in the business relationship with the government client.[167] Accordingly, under the rule, contributions by each of these persons, which the rule defines as "covered associates," trigger the two-year time out.[168] A "covered associate" of an investment adviser is defined as: (i) Any general partner, managing member or executive officer, or other individual with a similar status or function; (ii) any employee who solicits a government entity for the investment adviser and any person who supervises, directly or indirectly, such employee; and (iii) any political action committee controlled by the investment adviser or by any of its covered associates.[169]

Owners. Contributions by sole proprietors are contributions by the adviser itself.[170] If the adviser is a partnership, the rule covers contributions by the adviser's general partners.[171] If the adviser is a limited liability company, the rule covers contributions made by managing members.[172] A contribution by an owner that is a limited partner or non-managing member (of a limited liability company) is not covered, however, unless the limited partner or non-managing member is also an executive officer or solicitor (or person who supervises a solicitor) covered by the rule, or unless the contribution is an indirect contribution by the adviser, executive officer, solicitor, or supervisor.[173] Similarly, if the adviser is a corporation, shareholder contributions are not covered unless the shareholder is also an executive officer or solicitor covered by the rule, or unless the contribution is an indirect contribution by the adviser, executive officer, solicitor, or supervisor.[174]

Executive Officers. Contributions by an executive officer of an investment adviser trigger the two-year time out.[175] Executive officers include: (i) The president; (ii) any vice president in charge of a principal business unit, division or function (such as sales, administration or finance); (iii) any other officer of the investment adviser who performs a policy-making function; or (iv) any other person who performs similar policy-making functions for the investment adviser.[176] Whether a person is an executive officer depends on his or her function, not title; for example, an officer who is the chief executive of an advisory firm but whose title does not include "president" is nonetheless an executive officer for purposes of the rule.

The definition reflects changes we have made from our proposal that are designed to clarify the rule and to tailor it to apply to those officers of an investment adviser whose position in the organization is more likely to incentivize them to obtain or retain clients for the investment adviser (and, therefore, to engage in pay to play practices) while still achieving our objectives. We have clarified that "other executive officers" under the rule—*i.e.,* those other than the president and vice presidents in charge of principal business units or functions—include only those officers or other persons who perform a policy-making function for the investment adviser.[177] This limitation, which was recommended by commenters,[178] excludes persons who enjoy certain titles as a formal matter but do not engage in the kinds of activities that we believe should trigger the prohibitions in the rule.[179] We have

[163] *See, e.g.,* MSRB, *Payments to Non-Political Accounts of Political Organizations,* MSRB rule G–37 Interpretive Letter (Sept. 25, 2007), available at *http://msrb.org/msrb1/rules/interpg37.htm* (explaining that not all payments to political organizations that, in turn, make contributions to officials trigger Rule G–37's time out). With regard to solicitations from a PAC or a political party with no indication of how the collected funds will be disbursed, advisers should inquire how any funds received from the adviser or its covered associates would be used. For example, if the PAC or political party is soliciting funds for the purpose of supporting a limited number of government officials, then, depending upon the facts and circumstances, contributions to the PAC or payments to the political party might well result in the same prohibition on compensation for providing investment advisory services to a government entity as would a contribution made directly to the official. Our approach is consistent with the MSRB's. *See* MSRB Rule G–37 Q&A, Question III.5.

[164] *See, e.g.,* Reilly Letter.

[165] *See, e.g.,* Caplin & Drysdale Letter (explaining that "leadership PACs," for example, are commonly established by officeholders to donate to other candidates and issues).

[166] *See* section II.B.2(d) of this Release. For the MSRB's approach to this issue, see MSRB Rule G–37 Q&A, Question III.4. *But see* rule 206(4)–5(d) (noting that the rule's definition of "official" of a government entity includes any election committee for that person).

[167] Proposing Release, at section II.A.3(a)(4). Based on enforcement actions, we believe that such persons are more likely to have an economic incentive to make contributions to influence the advisory firm's selection. *See id.*

[168] Rule 206(4)–5(a)(1).

[169] Rule 206(4)–5(f)(2).

[170] We note, however, that a sole proprietor may, in a personal capacity, avail herself or himself of the *de minimis* exceptions described in section II.B.2(a)(6) of this Release.

[171] Rule 206(4)–5(f)(2)(i).

[172] *Id.*

[173] *See* rule 206(4)–5(a)(1), (d) and (f)(2)(i)–(ii).

[174] *Id.*

[175] The definition of "covered associate" includes, among others, any executive officer or other individual with a similar status or function. Rule 206(4)–5(f)(2)(i).

[176] Rule 206(4)–5(f)(4).

[177] Rule 206(4)–2(f)(4). This modification also aligns the definition more closely with the definition of "executive officer" in our other rules. *See, e.g.,* rule 205–3(d)(4) under the Advisers Act [17 CFR 275.205–3(d)(4)] (defining executive officer for purposes of determinations of who is a qualified client exempting an adviser from the prohibition on entering into, performing, renewing or extending an investment advisory contract that provides for compensation on the basis of a share of the capital gains upon, or the capital appreciation of, the funds, or any portion of the funds, under the Advisers Act) and rule 3c–5(a)(3) [17 CFR 270.3c–5(a)(3)] under the Investment Company Act of 1940 [15 U.S.C. 80a] ("Investment Company Act") (defining executive officer for purposes of determinations of the number of beneficial owners of a company excluded from the definition of "investment company" by section 3(c)(1) of the Investment Company Act, and whether the outstanding securities of a company excluded from the definition of "investment company" by section 3(c)(7) of the Investment Company Act are owned exclusively by qualified purchasers, as defined in that Act). It also more closely aligns the definition to the MSRB approach. *See* MSRB rule G–37(g)(v).

[178] *See, e.g.,* Sutherland Letter.

[179] Several commenters urged us expressly to exclude from the definition the CEO, officers and employees of a parent company. *See, e.g.,* SIFMA Letter; ICI Letter; MFA Letter; Skadden Letter. Depending on facts and circumstances, there may be instances in which a supervisor of an adviser's covered associate (who, for example, engages in solicitation of government entity clients for the adviser) formally resides at a parent company, but whose contributions should trigger the two-year time out because they raise the same conflict of interest issues that we are concerned about, irrespective of that person's location or title. In other words, whether a person is a covered

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also modified the definition to remove the limitation that the officer, as part of his or her regular duties, performs or supervises any person who performs advisory services for the adviser, or solicits or supervises any person who solicits for the adviser. We agree with the commenter who asserted that "* * * all of the adviser's executive officers should be included because the nature of their status alone creates a strong incentive to engage in pay to play practices." [180] Even if these senior officers are not directly involved in advisory or solicitation activities, as part of senior management, their success within the advisory firm is likely to be tied to the firm's success in obtaining clients.[181]

Employees who Solicit Government Clients. Contributions by any employee who solicits a government entity for the adviser would trigger the two-year time out.[182] An employee need not be primarily engaged in solicitation activities to be a "covered associate" under the rule.[183] We are also including persons who supervise employees who solicit government entities because we believe these persons are strongly incentivized to engage in pay to play activities to obtain government entity clients.[184] We have revised this aspect of the definition to include all supervisors of those solicitors that solicit government entities because we believe the incentives to engage in pay to play exist for all such supervisors, not just those that have a certain level of seniority.

Rule 206(4)–5 defines "solicit" to mean, with respect to investment advisory services, to communicate, directly or indirectly, for the purpose of obtaining or retaining a client for, or referring a client to, an investment adviser.[185] Commenters asked us to provide further guidance on what we mean by "solicit." [186] The determination of whether a particular communication is a solicitation is dependent upon the specific facts and circumstances relating to such communication. As a general proposition any communication made under circumstances reasonably calculated to obtain or retain an advisory client would be considered a solicitation unless the circumstances otherwise indicate that the communication does not have the purpose of obtaining or retaining an advisory client. For example, if a government official asks an employee of an advisory firm whether the adviser has pension fund advisory capabilities, such employee generally would not be viewed as having solicited advisory business if he or she provides a limited affirmative response, together with either providing the government official with contact information for a covered associate of the adviser or informing the government official that advisory personnel who handle government advisory business will contact him or her.[187]

Political Action Committees. A covered associate includes a political action committee controlled by the investment adviser or by any of its covered associates.[188] Under the rule, we would regard an adviser or its covered associate to have "control" over a political action committee if the adviser or its covered associate has the ability to direct or cause the direction of the governance or operations of the PAC.[189]

Two commenters asserted that we should narrow the definition of "covered associate" with respect to political action committees.[190] Specifically, they asserted that the definition should only include PACs controlled by the adviser and not those controlled by other covered associates, which could be a separate legal entity over which the adviser may have little influence.[191] We are not adopting this suggestion. As we discussed in the Proposing Release, PACs are often used to make political contributions.[192] The

associate ultimately depends on the activities of the individual and not his or her title. We recently considered a similar issue in a report addressing whether MSRB rule G–37 could include contributions by employees of parent companies as triggering that rule's time out provision, see *Report of Investigation Pursuant to Section 21(a) of the Securities Exchange Act of 1934: JP Morgan Securities, Inc.,* Exchange Act Release No. 61734 (Mar. 18, 2010), available at *http://www.sec.gov/litigation/investreport/34-61734.htm* ("This Report serves to remind the financial community that placing an executive who supervises the activities of a broker, dealer or municipal securities dealer outside of the corporate governance structure of such broker, dealer or municipal securities dealer does not prevent the application of MSRB Rule G–37 to that individual's conduct."). The MSRB also takes the view that it is an individual's activities and not his or her title that may render his or her contributions a trigger for that rule's time out provision. *See* MSRB Rule G–37 Q&A, Question IV.18.

[180] *See* Fund Democracy Letter.

[181] Commenters also suggested that our definition exclude vice presidents in charge of business units, divisions or functions whose function is unrelated to investment advisory or solicitation activities. *See, e.g.,* IAA Letter. For the reasons described above, we do not believe such an exclusion is appropriate.

[182] We are not adopting the suggestion of several commenters that we treat third-party solicitors the same way as employees. *See, e.g.,* 3PM Letter; Triton Pacific Letter; Comment Letter of Arrow Partners, Inc. Partner Ken Rogers (Sept. 2, 2009) ("Arrow Letter"). We explained in the Proposing Release that we determined not to propose this approach out of concern for the difficulties that advisers may have when monitoring the activities of their third-party solicitors. *See* Proposing Release, at nn.135 and accompanying text. Commenters did not persuade us that these concerns can reasonably be expected to be overcome. Therefore, whereas contributions by covered associates of the adviser trigger the two-year compensation time out, an adviser is prohibited from hiring third parties to solicit government business on its behalf unless the third party is a "regulated person." *See* section II.B.2(b) of this Release. Our approach is similar to MSRB's rule G–38, which restricts third-party solicitation activities differently from the two-year time out. *See* MSRB rule G–38.

[183] The MSRB also takes the approach that an associated person need not be "primarily engaged" in activities that would make his or her contributions trigger rule G–37's time out provision, particularly where he or she engages in soliciting business. *See* MSRB Rule G–37 Q&A, Question IV.8.

[184] Rule 206(4)–5(f)(2)(ii). The proposed rule would only have applied to *senior officers* who supervise employee solicitors. *See* proposed rule 206(4)–5(f)(4)(ii). MSRB rule G–37 also applies to supervisors of persons who solicit relevant business from government entities. *See* MSRB Rule G–37 Q&A, Question IV.14.

[185] Rule 206(4)–5(f)(10)(i). We are adopting this definition as proposed.

[186] *See, e.g.,* Skadden Letter.

[187] Similarly, if a government official is discussing governmental asset management issues with an employee of an adviser, the employee generally would not be viewed as having solicited business if he or she provides a limited communication to the government official that such alternative may be appropriate, together with either providing the government official with contact information for a covered associate or informing the government official that advisory personnel who handle asset management for government clients will contact him or her. In these examples, however, if the adviser's employee receives compensation such as a finder's or referral fee for such business or if the employee engages in other activities that could be deemed a solicitation with respect to such business, the employee generally would be viewed as having solicited the advisory business. Our interpretation of what it means to "solicit" government business is consistent with the MSRB's. *See* MSRB, *Interpretive Notice on the Definition of Solicitation under Rules G–37 and G–38* (June 8, 2006), available at *http://msrb.org/msrb1/rules/notg38.htm.*

[188] Rule 206(4)–5(f)(2)(iii) (which we are adopting as proposed). One commenter suggested that we define a "political action committee," or PAC, as any organization required to register as a political committee under Federal, State or local law. Caplin & Drysdale Letter. But we have not included this definition of PAC because we do not believe a definition linked to the registration status of a political committee would serve our purpose of deterring evasion of the rule as registration requirements vary among election laws. We note, however, that we would construe the term PAC to include (but not necessarily be limited to) those political committees generally referred to as PACs, such as separate segregated funds or non-connected committees within the meaning of the Federal Election Campaign Act, or any State or local law equivalent. *See* Federal Election Commission, Quick Answers to PAC Questions, available at *http://www.fec.gov/ans/answers_pac.shtml#pac.* Determination of whether an entity is a PAC covered by our rule would not, in our view, turn on whether the PAC was, or was required to be, registered under relevant law.

[189] One commenter suggested a similar interpretation of "control." Caplin & Drysdale Letter. For the MSRB's approach to this definition, see MSRB Rule G–37 Q&A, Question IV.24.

[190] SIFMA Letter; Sutherland Letter.

[191] *Id.*

[192] Proposing Release, at n.101.

recommended changes would permit an executive of the adviser or another covered person of the adviser to use a PAC he or she controls to evade the rule. Even where the adviser itself does not control such PACs directly, we are concerned about their use to evade our rule where they are controlled by covered associates (whose positions in the organization, as we note above, are more likely to incentivize them to obtain or retain clients for the investment adviser).[193]

Other Persons. Several commenters urged that our definitions be broadened to encompass other persons whose contributions should trigger the two-year time out.[194] One urged that in some cases all employees should be covered associates because of the likelihood they could directly benefit from engaging in pay to play.[195] Another urged that the definition of covered associate include affiliates of the adviser that solicit government business on the adviser's behalf, any director of the adviser, and any significant owner of the adviser.[196] These suggestions would expand the rule to a range of persons that could engage in pay to play activities.[197] In our judgment, however, contributions from these types of persons are less likely to involve pay to play unless the contributions were made by these persons for the purpose of avoiding application of the rule, which could result in the adviser's violation of a separate provision of the rule.[198] We do not believe that the incremental benefits of capturing conduct of other individuals less likely to engage in pay to play based on the record before us today outweigh the additional burden such an expansion would impose.[199] Thus, we are not expanding the definition as these commenters have suggested.

Other commenters urged us to narrow our definition of "covered associate" to include fewer persons.[200] For example, one commenter recommended that the definition of "covered associate" expressly exclude all "support personnel."[201] Another suggested that we limit the definition to those who solicit government clients with a "major purpose" of obtaining that government client.[202] Expressly excluding all "support personnel" is unnecessary because, in almost all cases, such persons would not be "covered associates," as that term is defined in the rule. We have not limited the definition to those who solicit government clients with a "major purpose" of obtaining that government client because we believe that our rule's definition of "solicit," as discussed above, adequately takes into account the purpose of the communication and adding an additional element of intent may exclude employees who have an incentive to engage in pay to play practices.

(5) "Look Back"

The rule attributes to an adviser contributions made by a person within two years (or, in some cases, six months) of becoming a covered associate of that adviser.[203] In other words, when an employee becomes a covered associate, the adviser must "look back" in time to that employee's contributions to determine whether the time out applies to the adviser.[204] If, for example, the contributions were made more than two years (or, pursuant to the exception described below for non-solicitors, six months) prior to the employee becoming a covered associate, the time out has run; if the contribution was made less than two years (or six months) from the time the person becomes a covered associate, the rule prohibits the adviser that hires or promotes the contributing covered associate from receiving compensation for providing advisory services from the hiring or promotion date until the two-year period has run.[205] The look-back provision, which is similar to that in MSRB rule G–37, is designed to prevent advisers from circumventing the rule by influencing the selection process by hiring persons who have made political contributions.[206]

We received many comments on our proposed look-back provision,[207] which would have applied the two-year look back with respect to all contributions of new covered associates.[208] One commenter asserted that such a provision is necessary to prevent advisers from circumventing the

[193] Advisers are responsible for supervising their supervised persons, including their covered associates. We have the authority to seek sanctions where an investment adviser, or an associated person, has failed reasonably to supervise, with a view to preventing violations of the Federal securities laws or rules, a person who is subject to the adviser's (or its associated person's) supervision and who commits such violations. Sections 203(e)(6) and 203(f) of the Advisers Act [15 U.S.C. 80b–3(e)(6) and (f)].

[194] *See, e.g.,* Fund Democracy/Consumer Federation Letter; DiNapoli Letter (suggesting the rule also cover contributions from family members); Ounavarra Letter.

[195] Ounavarra Letter.

[196] Fund Democracy/Consumer Federation Letter.

[197] *See, e.g., supra* note 179 (discussing why we have chosen not to limit the definition of "executive officer" in other ways as suggested by some commenters).

[198] *See* Rule 206(4)–5(d). We also note that the MSRB takes a similar approach. *See, e.g.,* MSRB Rule G–37 Q&A, Question IV.9 (noting that the universe of those whose contributions above the *de minimis* level *per se* trigger the two-year time out is limited and does not include their consultants, lawyers or spouses). The MSRB also leaves contributions by affiliates and personnel beyond those identified as triggering the two-year time out to be addressed by a provision prohibiting municipal securities dealers from doing indirectly what they are prohibited from doing directly under rule G–37. *See* MSRB Rule G–37(d).

[199] In this instance, as in others, we are sensitive to First Amendment concerns that further expansion of the scope of covered associates could broaden the rule's scope beyond what is necessary to accomplish its purposes.

[200] *See, e.g.,* T. Rowe Price Letter; NSCP Letter; Skadden Letter.

[201] T. Rowe Price Letter.

[202] Skadden Letter.

[203] Rule 206(4)–5(a)(1). The "look back" applies to any person who becomes a covered associate, including a current employee who has been transferred or promoted to a position covered by the rule. A person becomes a covered associate for purposes of the rule's look-back provision at the time he or she is hired or promoted to a position that meets the definition of "covered associate" in rule 206(4)–5(f)(2). For a discussion of the definition of "covered associate," see section II.B.2(a)(4) of this Release.

[204] Rule 206(4)–5(a)(1) (including among those covered associates whose contributions can trigger the two-year time out a person who becomes a covered associate within two years after the contribution is made); Rule 206(4)–5(b)(2) (excepting from the two-year look back those contributions made by a natural person more than six months prior to becoming a covered associate of the investment adviser unless such person, after becoming a covered associate, solicits clients on behalf of the investment adviser).

[205] In no case would the prohibition imposed by the rule be longer than two years from the date the covered associate makes a covered contribution. If, for example, a covered associate becomes employed by an investment adviser (and engages in solicitation activity for it) one year and six months after making a contribution, the new employer would be subject to the proposed rule's prohibition for the remaining six months of the two-year period. We also note that the rule's exemptive process may be available in instances where an adviser believes application of the look-back provision would yield an unintended result. Rule 206(4)–5(e). For a discussion of the rule's exemptive provision, see section II.B.2(f) of this Release.

[206] Similarly, to prevent advisers from channeling contributions through departing employees, advisers must "look forward" with respect to covered associates who cease to qualify as covered associates or leave the firm. The covered associate's employer at the time of the contribution would be subject to the proposed rule's prohibition for the entire two-year period, regardless of whether the covered associate remains a covered associate or remains employed by the adviser. Thus, dismissing a covered associate would not relieve the adviser from the two-year time out. MSRB rule G–37 also includes a "look-forward provision." *See* MSRB Rule G–37 Q&A, Question IV.17 ("* * * any contributions by [an] associated person [who leaves the dealer's employ] (other than those that qualify for the *de minimis* exception under Rule G–37(b)) will subject the dealer to the rule's ban on municipal securities business for two years from the date of the contribution").

[207] *See, e.g.,* Fund Democracy/Consumer Federation Letter; ICI Letter; Davis Polk Letter; NY City Bar Letter; Fidelity Letter; Wells Fargo Letter; MFA Letter; IAA Letter; NASP Letter; American Bankers Letter; Comment Letter of Seward & Kissel LLP (Oct. 6. 2009) ("Seward & Kissel Letter"); Park Hill Letter; Dechert Letter; Skadden Letter.

[208] *See* Proposing Release, at section II.A.3(a)(5).

prohibitions on pay to play.[209] Most commenters, however, argued that the rule should not contain a look-back provision or should contain a shorter one because it could prevent advisers from hiring qualified individuals who have made unrelated political contributions,[210] or it could be disruptive to public pension plans seeking to hire qualified managers.[211] While some urged that we eliminate the look-back provision altogether,[212] most asked us to shorten the period to three to six months.[213] Others suggested alternative approaches to the look back, including adopting a higher contribution threshold to trigger the look-back provision [214] or permitting advisers to hire and promote persons to be covered associates who have made prohibited contributions, but not permitting them to solicit government clients or otherwise create firewalls between them and government clients.[215]

Upon consideration of the comments, we believe that applying the full two-year look back to all new covered associates may be unnecessary to achieve the goals of the rulemaking. We are adopting a suggestion offered by several commenters to shorten the look-back period with respect to certain new covered associates whose contributions are less likely to be involved in pay to play.[216] Under an exception to the rule, the two-year time out is not triggered by a contribution made by a natural person more than six months prior to becoming a covered associate, unless he or she, after becoming a covered associate, solicits clients.[217] As a result, the two-year look back applies only to covered associates who solicit for the investment adviser.[218]

The potential link between obtaining advisory business and contributions made by an individual prior to his or her becoming a covered associate that is uninvolved in solicitation activities is likely more attenuated and therefore, in our judgment, should be subject to a shorter look back. We have modeled this shortened look-back period [219] on the MSRB's six-month look back for certain personnel, which it implemented as a result of feedback it received from dealers that indicated the two-year look back was negatively affecting in-firm transfers and promotions and "preclud[ing] them from hiring individuals who had made contributions, even though the contributions (which may have been relatively small) were made at a time when the individuals had no reason to be familiar with Rule G–37." [220] This approach balances commenters' concerns about the implications for their hiring decisions with the need to protect against individuals marketing to prospective investment adviser employers their connections to, or influence over, government entities those advisers might be seeking as clients.[221]

(6) Exceptions for De Minimis Contributions

Rule 206(4)–5 permits individuals to make aggregate contributions without triggering the two-year time out of up to $350, per election, to an elected official or candidate for whom the individual is entitled to vote,[222] and up to $150, per election, to an elected official or candidate for whom the individual is not entitled to vote.[223] These *de minimis* exceptions are available only for contributions by individual covered associates, not the investment adviser itself.[224] Under both exceptions,

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[209] Fund Democracy/Consumer Federation Letter.

[210] *See, e.g.,* ICI Letter; Davis Polk Letter; NY City Bar Letter; Fidelity Letter; Wells Fargo Letter; MFA Letter.

[211] *See, e.g.,* Comment Letter of Connecticut Treasurer Denise L. Nappier (Sept. 10, 2009) ("CT Treasurer Letter"); CalPERS Letter.

[212] *See, e.g.,* IAA Letter; ICI Letter; Wells Fargo Letter; NASP Letter; American Bankers Letter; MFA Letter; Seward & Kissel Letter.

[213] *See, e.g.,* ICI Letter (three-month look back); IAA Letter (six-month look back); Park Hill Letter (six-month look back); Wells Fargo Letter (six-month look back); Davis Polk Letter (six-month look back); Dechert Letter (six-month look back); MFA Letter (six-month look back).

[214] *See, e.g.,* Wells Fargo Letter; NSCP Letter.

[215] *See, e.g.,* Comment Letter of Strategic Capital Partners (Oct. 1, 2009) ("Strategic Capital Letter"); Comment Letter of B. Jack Miller (Oct. 3, 2009); Comment Letter of RP Realty Partners, LLC Chief Financial Officer Jerry Gold (Oct. 2, 2009); SIFMA Letter.

[216] *See, e.g.,* MFA Letter; Fidelity Letter; Dechert Letter; Wells Fargo Letter; Skadden Letter. The MSRB shortened the look-back period under MSRB rule G–37 to six months for certain municipal finance professionals in response to similar industry concerns about the impact on hiring. *See* MSRB, *Amendments Filed to Rule G–37 Concerning the Exemption Process and the Definition of Municipal Finance Professional* (Sept. 26, 2002), *available at http://www.msrb.org/msrb1/archive/g%2D37902notice.htm.*

[217] Rule 206(4)–5(b)(2). An adviser is subject to the two-year time out regardless of whether it is "aware" of the political contributions. Thus, statements by prospective employees regarding whether they have made relevant contributions are insufficient to inoculate the adviser, as some commenters urged (*see, e.g.,* IAA Letter; ICI Letter; NSCP Letter; Caplin & Drysdale Letter), to ensure that investment advisers are not encouraged to relax their efforts to promote compliance with the rule's prohibitions. Nonetheless, advisers who advise or are considering advising any government entity should consider requiring full disclosure of any relevant political contributions from covered associates or potential covered associates to ensure compliance with rule 206(4)–5. Advisers are required to request similar reports about securities holdings by Advisers Act rule 204A–1(b)(1)(ii) [17 CFR 275.204A–1(b)(1)(ii)], which requires each of a firm's "access persons" to submit an initial "holdings report" of securities he or she beneficially owns at the time he or she becomes an access person, even though the securities would likely have been acquired in transactions prior to becoming an access person. For a discussion of an adviser's recordkeeping obligations with regard to records of contributions by a new covered associate during that new covered associate's look-back period, see *infra* note 428.

[218] *See* rule 206(4)–5(f)(2) (defining covered associate of an investment adviser as: (i) Any general partner, managing member or executive officer, or other individual with a similar status or function; (ii) any employee who solicits a government entity for the investment adviser and any person who supervises, directly or indirectly, such employee).

[219] *See* rule 206(4)–5(b)(2).

[220] MSRB, *Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Municipal Securities Rulemaking Board Relating to Amendments to Rules G–37, on Political Contributions and Prohibitions on Municipal Securities Business, G–8, on Books and Records, Revisions to Form G–37/G–38 and the Withdrawal of Certain Rule G–37 Questions and Answers,* Exchange Act Release No. 47609 (April 1, 2003) [67 FR 17122 (Apr. 8, 2003)]. *See also* MSRB, *Self-Regulatory Organizations; Order Granting Approval of a Proposed Rule Change and Amendment No. 1 Thereto by the Municipal Securities Rulemaking Board Relating to Amendments to Rules G–37, on Political Contributions and Prohibitions on Municipal Securities Business, G–8, on Books and Records, Revisions to Form G–37/G–38 and the Withdrawal of Certain Rule G–37 Questions and Answers,* Exchange Act Release No. 47814 (May 8, 2003) [68 FR 25917 (May 14, 2003)] (Commission order approving amendments to MSRB rule G–37); MSRB rule G–37(b)(iii).

[221] We are not adopting the suggestion of commenters to exclude from the look-back provision contributions made before a merger or acquisition by an adviser by not attributing the contributions of the acquired adviser to the acquiring adviser. *See, e.g.,* Dechert Letter; ICI Letter. We believe that an acquisition of another adviser could raise identical concerns where the acquired adviser has made political contributions designed to benefit the acquiring adviser. Rule 206(4)–5 is not intended to prevent mergers in the investment advisory industry or, once a merger is consummated, to hinder the surviving adviser's government advisory business unless the merger was an attempt to circumvent rule 206(4)–5. Thus, the adviser may wish to seek an exemption from the ban on receiving compensation pursuant to rule 206(4)–5(a) from the Commission. The MSRB takes the same approach to this issue. *See* MSRB Rule G–37 Q&A, Question II.16.

[222] For purposes of rule 206(4)–5, a person would be "entitled to vote" for an official if the person's principal residence is in the locality in which the official seeks election. For example, if a government official is a State governor running for re-election, any covered associate of an adviser who resides in that State may make a *de minimis* contribution to the official without causing a ban on that adviser being compensated for providing advisory services for that government entity. In the example of a government official running for President, any covered associate in the country can contribute the *de minimis* amount to the official's Presidential campaign. The MSRB has issued a similar interpretation of what it means to be "entitled to vote" for purposes of MSRB rule G–37. *See MSRB Reports,* Vol. 16. No. 1 (January 1996) at 31–34.

[223] *See* Rule 206(4)–5(b)(1) (excepting "*de minimis*" contributions to "officials" (*see supra* note 139 and accompanying text) from the rule's two-year time out provision).

[224] *Id.* Under the rule, each covered associate, taken separately, would be subject to the *de*

primary and general elections would be considered separate elections.[225]

We proposed a $250 *de minimis* exception for contributions to candidates for whom a covered associate is entitled to vote,[226] which reflects the current *de minimis* exception in MSRB rule G–37.[227] Many commenters urged us to increase the *de minimis* amount (either to a larger number or by indexing it to inflation), arguing that a contribution as large as $1,000 would be unlikely to influence the award of an advisory contract by a public pension plan.[228]

The $1,000 amount suggested by some commenters strikes us as a rather large contribution that could influence the hiring decisions, depending upon the size of the jurisdiction, the amount of campaign contributions to opposing candidates, and the competitiveness of the primary or prospective election. Instead, we are taking the suggestion of several commenters [229] that we should increase the *de minimis* amount to reflect the effects of inflation since the MSRB first established its $250 *de minimis* amount in 1994.[230] We may consider increasing the $350 amount in the future if, for example, the value of it decreases materially as a result of further inflation.

Commenters also urged us to eliminate the condition that a covered associate must be able to vote for the candidate.[231] They asserted that persons can have a legitimate interest in contributing to campaigns of people for whom they are unable to vote.[232] We acknowledge that persons can have such an interest, such as in large metropolitan areas where a covered associate may work and live in different jurisdictions. But commenters did not confine their recommendations to such circumstances and we remain concerned that contributions by executives of advisers living in distant jurisdictions may be less likely to be made for purely civic purposes. Accordingly, we have added a *de minimis* exception for contributions of up to $150 to officials for whom a covered associate is not entitled to vote, which is lower than the *de minimis* exception of $350 for candidates for whom a covered associate is entitled to vote. We believe that $150 is a reasonable amount for the additional *de minimis* exception we are adopting because of the more remote interest a covered associate is likely to have in contributing to a person for whom he or she is not entitled to vote.

(7) Exception for Certain Returned Contributions

We are adopting, largely as proposed, an exception that will provide an adviser with a limited ability to cure the consequences of an inadvertent political contribution to an official for whom the covered associate making it is not entitled to vote.[233] The exception is available for contributions that, in the aggregate, do not exceed $350 to any one official, per election.[234] The adviser must have discovered the contribution which resulted in the prohibition within four months of the date of such contribution [235] and, within 60 days after learning of the triggering contribution, the contributor must obtain the return of the contribution.[236]

The scope of this exception is limited to the types of contributions that we believe are less likely to raise pay to play concerns. The prompt return of the contribution provides an indication that the contribution would not affect an official of a government entity's decision to award an advisory contract.[237] The relatively small amount of the contribution, in conjunction with the other conditions of the exception, suggests that it was unlikely to be made for the purpose of influencing the award of an advisory contract. Repeated triggering contributions suggest otherwise or that the adviser has not implemented effective compliance controls. Therefore, the rule limits an adviser's reliance on the exception to no more than two or three per 12-month period (based on the size of the adviser),[238] and no more than once for

minimis exceptions. In other words, the limit applies per covered associate and is not an aggregate limit for all of an adviser's covered associates. *But see supra* note 170 (pointing out that a sole proprietor may, in a personal capacity, avail herself or himself of the *de minimis* exceptions even though his or her contributions are otherwise considered contributions of the adviser itself).

[225] Accordingly, a covered person of an investment adviser could, without triggering the prohibitions of the rule, contribute up to the limit in both the primary election campaign and the general election campaign of each official for whom the person making the contribution would be entitled to vote. The MSRB takes the same approach of excepting from rule G–37's time out trigger contributions up to the rule's *de minimis* amount for *each* election (including a primary and general election). *See* MSRB Rule G–37 Q&A, Question II.8. *See also In the Matter of Pryor, McClendon, Counts & Co., Inc., et al.,* Exchange Act Release No. 48095 (June 26, 2003) (noting that contributions must be limited to MSRB rule G–37's *de minimis* amount *before* the primary, with the same *de minimis* amount allowed *after* the primary for the general election).

[226] *See* Proposing Release, at section II.A.3(a)(6).

[227] *See* MSRB rule G–37(b)(i).

[228] *See, e.g.,* SIFMA Letter; NASP Letter; Comment Letter of Philip K. Holl (Oct. 5, 2009) ("Holl Letter"); NSCP Letter; Caplin & Drysdale Letter; Cornell Law Letter; ICI Letter; MFA Letter; Seward & Kissel Letter; Callcott Letter II; Comment Letter of the California State Teachers' Retirement System (Oct. 6, 2009) (adopted policies that limit contributions to board members by those seeking investment relationships with the fund to $1,000). Several commenters suggested our proposed *de minimis* limit could be subject to a challenge on constitutional grounds. For a discussion of, and response to, these comments, see *supra* note 72 and accompanying text.

[229] *See, e.g.,* Caplin & Drysdale Letter (recommending that we index the *de minimis* threshold for inflation); Cornell Law Letter (recommending that we index the *de minimis* threshold for inflation). *See also* Callcott Letter I.

[230] We multiplied the $250 *de minimis* amount that we proposed (which was adopted by the MSRB in 1994) by the annual consumer price index (a measure of inflation) change since 1994, as reported by the Bureau of Labor Statistics (*available at http://www.bls.gov/data/*). The result was approximately $365 in 2009; we rounded it down to $350 for administrative convenience.

[231] *See, e.g.,* T. Rowe Price Letter; Dechert Letter; MFA Letter; NASP Letter; Callcott Letter I; Cornell Law Letter; IAA Letter.

[232] *See, e.g.,* T. Rowe Price Letter; Dechert Letter; MFA Letter; NASP Letter; Callcott Letter I; Cornell Law Letter.

[233] Rule 206(4)–5(b)(3).

[234] Rule 206(4)–5(b)(3)(i). We note that a contribution would not trigger the two-year ban at all to the extent it falls within the *de minimis* exception described in rule 206(4)–5(b)(1). *See* section II.B.2(a)(6) of this Release for a discussion of this exception.

[235] *Id.*

[236] Rule 206(4)–5(b)(3)(i).

[237] The 60-day limit is designed to give contributors sufficient time to seek its return, but still require that they do so in a timely manner. Also, this provision is consistent with MSRB rule G–37(j)(i). If the recipient will not return the contribution, the adviser would still have available the opportunity to apply for an exemption under paragraph (e) of the rule. Paragraph (e), which sets forth factors we would consider in determining whether to grant an exemption, includes as a factor whether the adviser has taken all available steps to cause the contributor involved in making the contribution which resulted in such prohibition to obtain a return of the contribution.

[238] Rule 206(4)–5(b)(3)(ii). The approach we have taken will generally create some flexibility to accommodate a limited number of contributions by covered associates that would otherwise trigger the two-year time out. In a modification from our proposal that we believe is responsive to certain commenters' concerns (*see* note 251 and accompanying text below), "larger" advisers may avail themselves of three automatic exceptions, instead of two, in any calendar year. Rule 206(4)–5(b)(3)(ii). In contrast, our proposal would have permitted each adviser, regardless of its size, to rely on the automatic exception twice each year. The rule identifies a "larger" adviser for these purposes as any adviser who has reported in response to Item 5.A on its most recently filed Form ADV, Part 1A [17 CFR 279.1] that it has more than 50 employees. *Id.* Investment Adviser Registration Depository (IARD) data as of April 1, 2010 indicate that approximately 10 percent of registered advisers have more than 50 employees (and would therefore be limited to three "automatic" exceptions per calendar year instead of two). In particular, the data indicate that there are 11,607 registered investment advisers. Of those, 1,072 advisers (9.2% of the total) have indicated in their responses to Item 5.A of Part 1A of Form ADV that they have more than 50 employees. We chose the 50 employee cut-off because the number of employees is independently reported on Form ADV (and therefore cross-verifiable)—each adviser filing Form ADV must check a box indicating an approximation of the

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each covered associate,[239] regardless of the time period.[240]

Commenters who addressed it generally supported our inclusion of an automatic exception provision,[241] although several suggested modifications.[242] Some urged us to eliminate the requirement that the contributor succeed in obtaining the return of the contribution.[243] We are not making this change, which could undermine our goals in adopting the rule if it led to contributors asking for the return of a contribution where such requests were expected to be refused by the government official. We would have to discern whether the contributor itself, who may (or whose employer may) be seeking to influence government officials, has tried "hard enough" to get the contribution back.

Other commenters recommended an alternative exception for inadvertent contributions that would not require that an otherwise-triggering contribution be returned.[244] They contended that such an exception should be available to advisers with policies and procedures in place to prevent pay to play that include sanctions for employees violating the policies.[245] Such an approach excludes any objective indication that the contribution was inadvertent. As noted above, policies and procedures are required to ensure compliance with our rule. But policies and procedures alone, without critical objective criteria, such as obtaining a return of the contribution, are insufficient in our view to justify an exception to our prophylactic rule.

Some commenters urged us to modify or eliminate the requirement that the contribution be discovered by the adviser within four months.[246] We believe, however, that four months is the appropriate timeframe. We believe advisers should have a reasonable amount of time to discover contributions made by covered associates if, for example, their covered associates disclose their contributions to the adviser on a quarterly basis.[247] The absence of such a time limitation would encourage advisers not to seek to discover such contributions if they believed they could simply rely on the exception any time a contribution happened to come to light.

A number of commenters suggested the exception be allowed for *all* contributions regardless of dollar amount, while a few recommended raising the dollar amount to $1,000.[248] As we noted above, we view the limitation on the amount of such a contribution, in conjunction with the other conditions of the exception, important to the rule because it is more likely that the contribution was, in fact, inadvertent. We have modified this "automatic" exception from our proposal by raising the limit on contributions eligible for the exception to $350, the same amount we have adopted as a *de minimis* threshold for contributions to an official for whom a covered associate is entitled to vote.[249] In addition, at the suggestion of commenters who argued that our proposed limitation on the annual use of such exception failed to take into consideration the different size of advisers,[250] we have modified our proposal to permit use of the exception three times in any year by an adviser that has reported on its Form ADV registration statement that it had more than 50 employees who perform investment advisory functions.[251]

The exception is intended to provide advisers with the ability to undo certain mistakes. Because it operates automatically,[252] we believe it should be subject to conditions that are objective and limited in order to capture only those contributions that are unlikely to raise pay to play concerns.[253]

(b) Ban on Using Third Parties To Solicit Government Business

Rule 206(4)–5 makes it unlawful for any investment adviser subject to the rule or any of the adviser's covered associates to provide or agree to provide, directly or indirectly,

number of employees it has, choosing among 1–5, 6–10, 11–50, 51–250, 251–500, 501–1,000, or more than 1,000—and because we believe that inadvertent violations of the rule are more likely at advisers with greater numbers of employees. We think that the twice per year limit is appropriate for small advisers and the three times per year limit is appropriate for larger advisers. We do not believe it is appropriate for there to be greater variation in the number of times advisers may rely on the exception than that based either on their size or on other characteristics. We are seeking to encourage robust monitoring and compliance.

[239] Rule 206(4)–5(b)(3)(iii). Once a covered associate has been made aware of an "inadvertent" violation, a justification for a second violation would be more questionable.

[240] Although we have included different allowances for larger and smaller advisers (based on the number of employees they report on Form ADV), our approach otherwise generally tracks MSRB rule G–37's "automatic exemption" provision. *See* MSRB rule G–37(j).

[241] *See, e.g.,* T. Rowe Price Letter; NSCP Letter; CT Treasurer Letter; Skadden Letter; ICI Letter; IAA Letter.

[242] *See, e.g.,* NY City Bar Letter; Dechert Letter; IAA Letter.

[243] *See, e.g.,* T. Rowe Price Letter; NSCP Letter; CT Treasurer Letter.

[244] *See, e.g.,* IAA Letter (suggesting that we require, as a condition for such an exception, that "such contribution resulted in an inadvertent violation, meaning violations that are not reasonably known or condoned by the investment adviser and where the contributor lacked intent to influence the award of the advisory contract or violate the rule in making the contribution, as evidenced by the facts and circumstances surrounding such contribution").

[245] *See, e,g.,* IAA Letter; Dechert Letter; NY City Bar Letter.

[246] *See, e.g.,* T. Rowe Price Letter (arguing that, if an adviser has in place procedures to require covered associates to report all contributions no less frequently than quarterly, and an associate fails to report a contribution in violation of the procedures, the discovery of a prohibited contribution outside this four-month window should not preclude the use of this exception.). *But see* Fund Democracy/Consumer Federation Letter (urging us to consider shortening the time in which a contribution must be discovered for the exception to be available to one month).

[247] Quarterly compliance reporting is familiar to advisory personnel. *See, e.g.,* rule 204A–1 under the Advisers Act (requiring that, under an adviser's code of ethics, personnel report personal securities trading activity at least quarterly). We do not believe the exception should be available where it takes longer for advisers to discover contributions made by covered associates because they might enjoy the benefits of a contribution's potential influence for too long a period of time. The condition that the contribution be discovered within four months is consistent with the MSRB's approach. *See* MSRB rule G–37(j)(i).

[248] *See, e.g.,* SIFMA Letter; NASP Letter; Holl Letter; NSCP Letter; ICI Letter; MFA Letter.

[249] Rule 206(4)–5(3)(i)(B). No automatic exception is available for any contributions to an official for whom the covered associate is entitled to vote that exceed the *de minimis* $350 amount. As explained above, we believe that $350 is the appropriate *de minimis* threshold for contributions to officials for whom a covered associate is entitled to vote and $150 is the appropriate *de minimis* threshold for contributions to officials for whom a covered associate it not entitled to vote. *See* section II.B(6) of this Release. Because these thresholds are different, we anticipate that covered associates could mistakenly make contributions up to the higher threshold under the mistaken belief that they are entitled to vote for an official when in fact they are not entitled to do so. So long as those contributions are returned and the other conditions of the exception are met, we believe they should be eligible for the automatic exception.

[250] *See, e.g.,* Skadden Letter; T. Rowe Price Letter; NSCP Letter; ICI Letter; IAA Letter.

[251] *See supra* note 238.

[252] The exception is "automatic" in the sense that an adviser relying on it may do so without notifying the Commission or its staff. However, we note that the recordkeeping obligations for registered advisers mandate specifically that an adviser maintain records regarding contributions with respect to which the adviser has invoked this exception. Rule 204–2(a)(18)(ii)(D). *See also* section II.D of this Release.

[253] As discussed below in section II.B.2(f) of this Release, in other circumstances, advisers can apply to the Commission for an exemption from the rule's two-year time out. *See* rule 206(4)–5(e).

payment [254] to any person to solicit [255] government clients for investment advisory services on its behalf.[256] The prohibition is limited to third-party solicitors. Thus, the prohibition does not apply to any of the adviser's employees, general partners, managing members, or executive officers.[257] Contributions by these persons, however, may trigger the two-year time out. As discussed in more detail below, the prohibition also does not apply to certain "regulated persons" that themselves are subject to prohibitions against engaging in pay to play practices.[258]

We proposed to prohibit advisers from paying third parties in order to prevent advisers from circumventing the rule.[259] We observed in the Proposing Release that solicitors or "placement agents" have played a central role in actions that we and other authorities have brought involving pay to play schemes; [260] in several instances, advisers allegedly made significant payments to placement agents and other intermediaries in order to influence the award of advisory contracts.[261] We noted that government authorities in New York and other jurisdictions have prohibited or are considering limiting or prohibiting the use of consultants, solicitors, or placement agents by investment advisers to solicit government business.[262] We considered the MSRB's experience with solicitors, which ultimately led it to ban municipal securities dealers from hiring consultants to solicit government clients after concluding that less restrictive approaches were ineffective to prevent circumvention of MSRB rule G–37.[263] We recalled comment letters we received in 1999 from advisers asserting that they should not be held accountable for the political contributions of their third-party solicitors whom, they asserted, advisers lacked the ability to control.[264]

The record before us raised deeply troubling concerns about advisers' use of third-party solicitors to engage in pay to play activities.[265] We were concerned that a rule that failed to address the use of these solicitors would be ineffective were advisers simply to begin using solicitors and placement agents that have made political contributions or payments funded in part or in whole by the fees they receive from advisers.[266] Therefore, we proposed to prohibit advisers from engaging third parties to solicit government clients on their behalf.[267] In doing so, we requested comments on alternative approaches we could take.[268] We wanted to know whether there might be a more effective means to accomplish our objectives, or means that would be less restrictive.

We received a large number of comments on this question. We received letters from the New York State Comptroller and New York City Comptroller that expressed strong support for the ban on using third

[254] The term "payment" is defined in rule 206(4)–5(5)(f) as any gift, subscription, loan, advance, or deposit of money or anything of value. Depending on the specific facts and circumstances, payment can include *quid pro quo* arrangements whereby a non-affiliated person solicits advisory business for the adviser in exchange for being hired by the adviser to provide other unrelated services. This approach is consistent with the MSRB's with regard to MSRB rule G–38's third-party solicitor ban. *See* MSRB, *Interpretive Notice on the Definition of Solicitation under Rules G–37 and G–38* (June 8, 2006), available at *http://msrb.org/msrb1/rules/notg38.htm. But see infra* note 257 (discussing the provision of professional services by third parties).

[255] For the definition of what it means to "solicit" a client or prospective client to provide investment advisory services, which we are adopting as proposed, see text accompanying note 185. This definition is consistent with the definition the MSRB employs for similar purposes in rule G–38, the MSRB's rule that restricts third-party solicitation activity. MSRB rule G–38(b)(i).

[256] Rule 206(4)–5(a)(2)(i). *See also* Proposing Release, at section II.A.3(b).

[257] Rule 206(4)–5(a)(2)(i). We note that, so long as non-affiliated persons providing legal, accounting, or other professional services in connection with specific investment advisory business are not being paid directly or indirectly by an investment adviser for communicating with a government entity (or its representatives) for the purpose of obtaining or retaining investment advisory business for the adviser—*i.e.*, they are paid solely for their provision of legal, accounting, or other professional services with respect to the business—they would not become subject to the ban on payments by advisers to third-party solicitors. This approach is similar to the MSRB's with regard to MSRB rule G–38's third-party solicitor ban. *See* MSRB, *Interpretive Notice on the Definition of Solicitation under Rules G–37 and G–38* (June 8, 2006), available at *http://msrb.org/msrb1/rules/notg38.htm.*

[258] This exception, which is responsive to commenters' concerns, is a modification of our proposal. As discussed below, we also eliminated an exception in our proposal that would have applied to "related persons" of the adviser and, if such "related person" were a company, an employee of the "related person." *See* Proposing Release, at section II.A.3(b).

[259] *See* Proposing Release, at section II.A.3(b).

[260] *Id.* at sections I and II.A.3(b).

[261] *Id.* at section II.A.3(b).

[262] *Id.* Since our proposal, a few State and local governments have undertaken actions to prohibit or regulate pay to play practices involving placement agents in response to concerns about to pay to play activities in their jurisdictions. For example, New York City Comptroller John C. Liu announced reforms relating to how the New York City pension funds make investments (including prohibitions on gifts and campaign contributions, strict rules on employees of the Office of New York City Comptroller, employees and trustees of the New York City pension systems, fund managers, and placement agents, and an expansion of the ban on private equity placement agents to include placement agents to other types of funds while providing an exclusion for legitimate placement agents who provide value-added services). *See* Office of the New York City Comptroller, *Comptroller Liu Announces Major Reforms to Pension Fund Investments,* Press Release, Feb. 18, 2010, available at *http://www.comptroller.nyc.gov/press/2010_releases/pr10-02-022.shtm.* A bill was introduced in California that would treat placement agents soliciting government entity clients as lobbyists and therefore restrict them from charging contingency fees. *See* Assem. B. 1743, 2009–10 Leg., Reg. Sess. (Cal. 2010), available at *http://info.sen.ca.gov/pub/09-10/bill/asm/ab_1701-1750/ab_1743_bill_20100208_introduced.html. See also* Cal. Gov't. Code § 86205(f) (Deering 2010). Another law was passed in California on an emergency basis imposing new disclosure obligations and prohibitions regarding placement agents. *See* Assem. B. 1854, 2009–10 Leg., Reg. Sess. (Cal. 2010) available at *http://info.sen.ca.gov/pub/09-10/statute/ch_0301-0350/ch_301_st_2009_ab_1584. See also* CalPERS, *CalPERS Releases Placement Agent Disclosures,* Press Release, Jan. 14, 2010, available at *http://www.calpers.ca.gov/index.jsp?bc=/about/press/pr-2010/jan/agent-disclosures.xml.* (discussing recent actions by CalPERS to make public more than 600 placement agent disclosures from the fund's external managers).

[263] *See* Proposing Release, at n.130 and accompanying text. *See also* MSRB Letter ("Due to concerns regarding questionable practices by some consultants and a determination by the MSRB that it would be in the public interest to make the process of soliciting municipal securities business fully subject to the MSRB rules of fair practice and professionalism, the MSRB rescinded its original rule in 2005 and adopted new Rule G–38, on solicitation of municipal securities business, to prohibit dealers from using paid third-party consultants to obtain municipal securities business on their behalf.").

[264] In 1999, the Commission proposed a similar rule, which also would have been codified as rule 206(4)–5 under the Advisers Act, had it been adopted. *See Political Contributions by Certain Investment Advisers,* Investment Advisers Act Release No. 1812 (Aug. 4, 1999) [64 FR 43556 (Aug. 10, 1999)] ("1999 Proposing Release"). Comments on that proposal received electronically (comment file S7–19–99) are available at *http://www.sec.gov/rules/proposed/s71999.shtml.* Among the commenters on the 1999 Proposing Release who argued that advisers should not be held accountable for the political contributions of their third-party solicitors are: Comment Letter of Davis Polk (Nov. 1, 1999); Comment Letter of Legg Mason (Nov. 1, 1999); Comment Letter of MSDW (Nov. 1, 1999). At least one commenter on our 2009 proposal, although opposing the proposed third-party solicitor ban, took the same view. *See* MFA Letter ("We strongly agree with the SEC's comment in the Release that "covered associates" should not include employees of entities unaffiliated with an investment adviser, such as the employees of a third-party placement agent. An investment adviser would not have the authority or capability to monitor and restrict political contributions made by individuals not employed by the adviser.").

[265] *See* Proposing Release, at section I; section I of this Release. Moreover, "no smoking gun is needed where, as here, the conflict of interest is apparent, the likelihood of stealth great, and the legislative purpose prophylactic." *Blount,* 61 F.3d at 945.

[266] *See* Proposing Release, at section II.A.3(b). Some commenters have supported this approach. *See, e.g.,* Fund Democracy/Consumer Federation Letter ("Permitting advisers to circumvent pay-to-play restrictions by hiring solicitors would eviscerate the heart of the direct prohibition against advisers' bribing politicians in return for money management contracts."). We also noted commenters' concerns regarding the difficulties advisers face in monitoring the activities of their third-party solicitors. *See* Proposing Release, at section II.A.3(b).

[267] *See* Proposing Release, at section II.A.3(b).

[268] *See id.*

parties to solicit government plans.[269] One commenter supporting the ban pointed out the key role that placement agents have played in pay to play practices.[270] It expressed concern that adopting the rule without the ban would exacerbate the problem by placing more pressure on advisers to pay "well-connected" placement agents for access since the advisers will be limited in their contributions.[271] Another commenter expressed the view that "the most egregious violations of the public trust in this area have come from placement agents and those seeking finder's fees. The outright ban on their use to deter pay-to-play schemes is entirely appropriate."[272]

Most commenters, including many representing advisers, broker-dealers, placement agents and solicitors, and some government officials, however, strongly opposed the ban. Many asserted that solicitors, consultants and placement agents provide valuable services both for advisers seeking clients and for the public pension plans that employ them and that banning their use would have several deleterious effects.[273] Several claimed that the rule would favor banks because banks are excluded from the definition of "investment adviser" under the Advisers Act and therefore are not subject to the Commission's rules, including rule 206(4)–5.[274] Others claimed the rule would favor larger investment advisers (which have internal marketing departments) over smaller firms.[275] Other commenters asserted the ban would harm smaller pension funds that do not have the resources to conduct a search for advisers on their own, and harm advisers that rely on the services that placement agents provide.[276] A number of commenters argued that the prohibition would reduce competition by reducing the number of advisers competing for government business,[277] and limit the universe of investment opportunities presented to public pension funds.[278]

Many of these commenters conceded that there is a problem with placement agents and other intermediaries, but asserted it is caused by a few bad actors, for which an entire industry should not be penalized.[279] A common theme among many commenters was that the rule failed to distinguish "illegitimate" consultants and placement agents from the "legitimate" ones who provide an important service.[280]

We believe that many of the comments overstate the likely consequences of adoption of the rule. First, the rule will not prevent public pension plans from hiring their own consultants—*i.e.*, using their own resources—to assist them in their search for an investment adviser.[281] These consultants would have access to information about smaller advisers whose services may be appropriate for the plan. Many public pension plans already make—or are required to make—specific accommodations for so-called "emerging money managers" that otherwise may have difficulty getting noticed by public pension plans.[282]

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[269] DiNapoli Letter; Thompson Letter (as indicated in note 262 above, NYC Comptroller Liu recently announced his office's approach to third-party solicitors).

[270] Fund Democracy/Consumer Federation Letter.

[271] *Id.*

[272] Common Cause Letter. *See also* Cornell Law Letter (generally supporting the prohibition on using third-party solicitors "given that third-party solicitors have played a central role in each of the enforcement actions against investment advisors that the Commission has brought in the past several years involving pay-to-play schemes.").

[273] *See, e.g.,* Comment Letter of Senator Christopher J. Dodd (Feb. 2, 2010) ("Dodd Letter"); NY City Bar Letter; Dechert Letter; ABA Letter; Comment Letter of Teacher Retirement System of Texas (Oct. 12, 2009); Comment Letter of Bryant Law (Oct. 9, 2009) ("Bryant Law Letter"); Comment Letter of Probitas Partners (Oct. 6, 2009) ("Probitas Letter"); Comment Letter of Larry Simon (Oct. 6, 2009) ("Simon Letter"); Comment Letter of MarketCounsel, LLC (Oct. 6, 2009); ICI Letter; Comment Letter of Colorado Public Employees' Retirement Association (Oct. 6, 2009); Skadden Letter.

[274] *See* Advisers Act section 202(a)(11)(A) [15 U.S.C. 80b–2(a)(11)(A)] (excepting from the definition of "investment adviser," and therefore from regulation under the Advisers Act, "a bank, or any bank holding company as defined in the Bank Holding Company Act of 1956, which is not an investment company * * *."). We discuss possible competitive effects of our rule's inapplicability to banks in section VI of this Release. We believe that the concerns the rule is designed to address, as discussed throughout this Release, warrant its adoption, notwithstanding these potential competitive effects.

[275] *See, e.g.,* SIFMA Letter; IAA Letter; MFA Letter; Comment Letter of National Conference on Public Employee Retirement Systems (Oct. 6, 2009) ("NCPERS Letter"); Comment Letter of European Private Equity & Venture Capital Association (Sept. 9, 2009) ("EVCA Letter"); Seward & Kissel Letter; Comment Letter of Sadis & Goldberg LLP (Oct. 2, 2009) ("Sadis & Goldberg Letter"); Comment Letter of State of Wisconsin Investment Board (Aug. 31, 2009) ("WI Board Letter"); Comment Letter of the Executive Director of Georgia Firefighters' Pension Fund, James R. Meynard, (Sept. 3, 2009) ("GA Firefighters Letter"); Comment Letter of Minnesota State Board of Investment (Sept. 8, 2009) ("MN Board Letter"); Comment Letter of Illinois Public Pension Fund Association (Sept. 29, 2009) ("IL Fund Association Letter"); Comment Letter of Melvyn Aaronson, Sandra March and Mona Romain, Trustees of the Teachers' Retirement System of the City of New York (Oct. 1, 2009) ("NYC Teachers Letter"); Comment Letter of the Texas Association of Public Employee Retirement Systems (Oct. 6, 2009) ("TX Public Retirement Letter"); Comment Letter of the Pennsylvania Public School Employees' Retirement Board (Oct. 6, 2009) ("PA Public School Retirement Letter"); Comment Letter of the California State Association of County Retirement Systems (Sept. 8, 2009) ("CA Assoc. of County Retirement Letter"); Caplin & Drysdale Letter; Comment Letter of Paul Ehrmann (Aug. 10, 2009) ("Ehrmann Letter"); Comment Letter of Joseph Finn (Aug. 10, 2009) ("Finn Letter"); Comment Letter of the Managing Partner of The Savanna Real Estate Fund I, LLP, Nicholas Bienstock (Aug. 11, 2009) ("Savanna Letter"); Comment Letter of Atlantic-Pacific Capital, Inc. (Aug. 12, 2009) ("Atlantic-Pacific Letter"); Comment Letter of Tricia Peterson (Aug. 14, 2009) ("Peterson Letter"); Comment Letter of Devon Self Storage Holdings (US) LLC (Aug. 21, 2009) ("Devon Letter"); Comment Letter of Thomas Capital Group, Inc. (Aug. 24, 2009) ("Thomas Letter"); Comment Letter of Stephen R. Myers (Aug. 26, 2009) ("Myers Letter"); Comment Letter of Chaldon Associates LLC (Aug. 26, 2009) ("Chaldon Letter"); Comment Letter of The Meridian Group (Aug. 26, 2009) ("Meridian Letter"); Comment Letter of Benedetto, Gartland & Company, Inc. (Sept. 30, 2009) ("Benedetto Letter"); Comment Letter of the Partners of CSP Securities, LP and Capstone Partners, LP (Sept. 17, 2009) ("Capstone Letter"); Comment Letter of Presidio Partners LLC Managing Partner Alan R. Braxton (Sept. 21, 2009) ("Braxton Letter"); Comment Letter of Littlejohn & Co., LLC (Sept. 14, 2009) ("Littlejohn Letter"); Comment Letter of Alta Communications (Sept. 18, 2009) ("Alta Letter"); Comment Letter of Charles River Realty Investors LLC (Sept. 23, 2009) ("Charles River Letter"); Comment Letter of W. Allen Reed (Sept. 19, 2009) ("Reed Letter"); Comment Letter of Glovista Investments LLC (Sept. 23, 2009) ("Glovista Letter"); Comment Letter of The Blackstone Group (Sept. 14, 2009) ("Blackstone Letter"); Park Hill Letter. Two commenters noted that the ban would result in less transparency as these services go "in-house." CalPERS Letter; Bryant Law Letter. Others commented on the effects on minority and women-owned firms. *See, e.g.,* NYC Teachers Letter, Myers Letter; GA Firefighters Letter; MN Board Letter; Blackstone Letter.

[276] *See, e.g.,* Dodd Letter; NY City Bar Letter; Dechert Letter; ABA Letter; Probitas Letter; Seward & Kissel Letter; MFA Letter.

[277] *See, e.g.,* Seward & Kissel Letter; Meridian Letter; NY City Bar Letter; Probitas Letter; Simon Letter; MFA Letter.

[278] *See, e.g.,* SIFMA Letter; IAA Letter; Strategic Capital Letter; Alta Letter; Benedetto Letter; Comment Letter of Jim Glantz (Sept. 24, 2009) ("Glantz Letter"); Comment Letter of Venera Kurmanaliyeva (Sept. 15, 2009) ("Kurmanaliyeva Letter"); Park Hill Letter.

[279] *See, e.g.,* Comment Letters of Brady Pyeatt (Aug. 4, 2009) & (Oct. 6, 2009); Comment Letter of Andrew Wang (Aug. 10, 2009); Comment Letter of Monomoy Capital Management, LLC (Aug. 25, 2009) ("Monomoy Letter"); Comment Letter of Ted Carroll (Aug. 4, 2009); Comment Letter of James C. George (Sept. 10, 2009) ("George Letter"); Comment Letter of Ariane Capital Partners LLC (Sept. 17, 2009); Blackstone Letter; Comment Letter of Nancy Fossland (Sept. 16, 2009); Comment Letter of Steven A. Friedmann (Sept. 14, 2009); Comment Letter of Keith P. Harney (Sept. 15, 2009); Comment Letter of Robert F. Muhlhauser III (Sept. 14, 2009); Comment Letter of XT Capital Partners, LLC (Sept. 30, 2009); CapLink Letter.

[280] *See, e.g.,* Bryant Law Letter; Comment Letter of Hedgeforce (Oct. 6, 2009) ("Hedgeforce Letter").

[281] *See* Fund Democracy/Consumer Federation Letter ("The proposed ban would "deny access" to nothing. There is nothing [in the proposed rule] preventing pension funds from retaining their own consultants whose sole responsibility is to the pension fund and its beneficiaries.").

[282] *See, e.g.,* Randy Diamond, *CalPERS CIO Joe Dear says Emerging Managers Don't Need Placement Agents,* Pensions & Investments, Feb. 24, 2010, available at *http://www.pionline.com/article/20100224/REG/100229965;* Michael Marois, *CalPERS, Blackstone Clash over Placement Agent "Jackpot" Fees,* Bloomberg (Apr. 7, 2010), available at *http://www.bloomberg.com/apps/news?pid=newsarchive&sid=acPNrTn1q7pw*

Second, these commenters failed to consider the potentially significant costs of hiring consultants and placement agents,[283] which already may make them unavailable to smaller advisers. Eliminating the cost of pay to play may, in fact, provide greater access to pension plans by those advisers which are unable to afford the costs of direct or indirect political contributions or placement agent fees.[284] We expect that prohibiting pay to play may reduce the costs to plans and their beneficiaries of inferior asset management services arising from adviser selection based on political contributions rather than investment considerations.[285] Finally, commenters failed to identify any meaningful way in which our rule might distinguish "legitimate" from "illegitimate" solicitors or placement agents. Even solicitors and placement agents that engage in pay to play may appear to operate "legitimately."[286]

Some commenters suggested alternatives to our proposed ban to address our concern that pay to play activities are often carried out through or with the assistance of third parties.[287] Several commenters, for example, suggested that we instead require greater disclosure by advisers of payments to solicitors.[288] Such an approach could be helpful to give plan fiduciaries information necessary for them to satisfy their legal obligations and uncover abuses,[289] but it would not be useful when plan fiduciaries themselves are participants in the pay to play activities.[290] In addition, as one commenter pointed out, the MSRB had already sought unsuccessfully to address the problem of placement agents and consultants engaging in pay to play activities on their principals' behalf through mandating greater disclosure.[291]

(quoting CalPERS CIO Joe Dear, "There's clear evidence in past practice that it's possible to develop an investment relationship with us by making a normal approach, without the assistance of a contingent-paid placement agent."); Ohio Pub. Employees Ret. Sys., *Ohio-Qualified and Minority Manager Policy* (May 2006), available at *https://www.opers.org/pdf/investments/policies/Ohio-Qualified-Minority-Manager-Policy.pdf;* Teachers' Ret. Sys. of the State of Ill., Fiscal Year 2009 Annual Report on the use of Women, Minority and Disabled-Owned (W/MBE) Investment Advisors and Broker/Dealers (Aug. 31, 2009), available at *http://trs.illinois.gov/subsections/investments/minorityrpt.pdf;* Md. State Ret. and Pension Sys., *Terra Maria: The Maryland Developing Manager Program,* available at *http://www.sra.state.md.us/Agency/Investment/Downloads/TerraMariaDevelopingManagerProgram-Description.pdf;* Thurman V. White, Jr., Progress Inv. Mgmt. Co., *Successful Emerging Manager Strategies for the 21st Century,* 3 (2008), available at *http://www.progressinvestment.com/content/files/successful_emerging_manager_strategies.pdf* (containing a "representative list of known U.S. Pension Plans that have committed assets to emerging manager strategies").

[283] One commenter made a similar point: "The proposed ban would simply replace the indirect cost of placement agents incurred by pension plan sponsors with the direct cost of hiring their own placement agents—without the conflict of interest and potential for abuse that relying on advisers' placement agents creates. It is not the cost of independent advice that the Commission has not accounted for in its proposal, but the cost of conflicts that critics have failed to acknowledge in their analysis." Fund Democracy/Consumer Federation Letter.

[284] At least one commenter agreed. *See* Butler Letter ("[W]e find some evidence that the pay to play practices by underwriters [before rule G–37 was adopted] distorted not only the fees, but which firms were allocated business. The current proposal mentions that pay to play practices may create an uneven playing field among investment advisers by hurting smaller advisers that cannot afford to make political contributions. We find evidence that is consistent with this view [in our research on pay to play by municipal underwriters]. During the pay to play era, municipal bonds were underwritten by investment banks with larger underwriting market shares compared to afterward. One interpretation of this result is that smaller underwriters were passed over in favor of larger underwriters (who presumably had deeper pockets for political contributions)."). As we indicated in the Proposing Release, pay to play practices may hurt smaller advisers that cannot afford the required contributions. Curtailing pay to play arrangements enables advisory firms, particularly smaller advisory firms, to compete on merit, rather than their ability or willingness to make contributions. *See* Proposing Release, at sections I and IV.

[285] *See* Tobe Letter (describing an underperforming money manager that was fired after the commenter, a pension official, began to inquire into how it was selected); Weber Letter ("I have seen money managers awarded contracts with our fund which involved payments to individuals who served as middlemen, creating needless expense for the fund. These middlemen were political contributors to the campaigns of board members who voted to contract for money management services with the companies who paid them as middlemen.").

[286] *See Blount,* 61 F.3d at 944 ("actors in this field are presumably shrewd enough to structure their relations rather indirectly").

[287] We note that, in addition to the alternatives discussed below, some commenters called for approaches outside the scope of our authority, such as an outright ban on all political contributions by third-party solicitors, the imposition of criminal penalties, or modification of the structure of pension boards. *See, e.g.,* Monomoy Letter (arguing that the Commission or the appropriate criminal authority should mandate jail time for public officials and intermediaries where the official gets a benefit from a public fund investment in a particular fund, that all managers of intermediaries who receive fees in such transactions should be banned from the financial services industry for life, and that all members of the general partner (manager) of the fund in which the investment is made be banned from the financial services industry for life); NCPERS Letter (arguing that the most effective method of eliminating pay to play is by having multiple trustees on public pension boards); Thomas Letter (suggesting that stronger internal control procedures, segregation of duties and dispersed or committee approval of granting pension business could help prevent pay to play activities, each of which historically has involved a complicit senior public plan fund official); Comment Letter of the Massachusetts Pension Reserves Investment Management Board (Aug. 26, 2009) ("PRIM Board Letter"); Preqin Letter I (acknowledging that it is outside the remit of the Commission, but arguing that there should be better oversight of public pension funds, and investment committees should consist of a minimum number of members in order to prevent a sole official being responsible for the investment-decision process); Triton Pacific Letter (arguing that the Commission should adopt regulation of pension officials who are often responsible for initiating pay to play arrangements).

[288] Several commenters urged us to require advisers to disclose to clients their payments to third-party solicitors and placement agents. *See, e.g.,* ABA Letter; 3PM Letter; ICI Letter; NY City Bar Letter; Comment Letter of Forum Capital Securities, LLC (Oct. 5, 2009) ("Forum Letter"); Jones Day Letter; CapLink Letter. Some asserted that existing disclosure requirements, such as those included in the Commission's investment adviser cash solicitation rule, are sufficient to address pay to play. *See, e.g.,* Comment Letter of Steven Rubenstein (Aug. 17, 2009) ("Rubenstein Letter") (noting that Advisers Act rule 206(4)–3 [17 CFR 275.206(4)–3], the "cash solicitation rule," is adequate as is, but "just needs to be followed"); Thomas Letter (supporting "enforcement of existing disclosure rules"); Chaldon Letter (arguing that, in the scandals that have recently occurred, if the fee sharing arrangements had been disclosed to pension fund boards, no law or regulation would have been violated, and that third-party marketers should adhere to current law instead of banning a legitimate business practice); Comment Letter of Ray Wirta (Sept. 4, 2009) (arguing that all that is necessary is that penalties should be heightened, enforcement stepped up and results highly publicized); Arrow Letter (arguing that enforcement of the Advisers Act and FINRA requirements have ensured lawful and ethical business practices for decades); 3PM Letter (arguing that the rule's scope could be extended to include various additional disclosures). But we do not believe, for the reasons described above, that enforcement of existing obligations alone is sufficient to deter pay to play activities.

[289] Some public pension plans have adopted policies requiring advisers they hire to disclose information about placement agents, including their political connections. *See, e.g.,* Cal. Pub. Employees Ret. Sys., *CalPERS Adopts Placement Agent Policy—Requires Disclosure of Agents, Fees,* Press Release (May 11, 2009), available at *http://www.calpers.ca.gov/index.jsp?bc=/about/press/pr-2009/may/adopts-placement-agent-policy.xml.*

[290] For examples of cases in which plan fiduciaries themselves have allegedly participated in pay to play activities involving placement agents, *see New York* v. *Henry* "*Hank*" *Morris and David Loglisci,* Indictment No. 25/2009 (NY Mar. 19, 2009) (a public official was alleged to be a beneficiary of the pay to play activities); *SEC* v. *Paul J. Silvester, et al.,* Litigation Release No. 16759, Civil Action No. 3:00–CV–19411 DJS (D. Conn. 2000) (former Connecticut State Treasurer was alleged to be a beneficiary of a pay to play scheme in which an investment adviser to a private equity fund had paid third-party solicitors to obtain public pension fund investments in the fund). *See also* Proposing Release, at n.49 (discussing additional reasons why we believe a disclosure approach would not effectively address our concerns regarding pay to play activities).

[291] Cornell Law Letter ("For example, after concluding that required disclosure was neither adequate to prevent circumvention nor consistently being made, the [MSRB] amended its own rules on pay-to-play practices in the municipal securities markets to impose a complete ban on the use of third-party consultants to solicit government clients." (citations omitted)). *See also* 3PM Letter (acknowledging that, although increased transparency by all parties involved in the investment process who might have the ability to exert influence, including advisers, third-party

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Other commenters recommended that we rely on voluntary industry codes of conduct.[292] But we believe, in light of the growing body of evidence of advisers' use of third-party solicitors to engage in pay to play activities we describe above, that voluntary actions are insufficient to deter pay to play, which may yield lucrative management contracts.[293] As we discuss above, pay to play involves a "collective action" problem that is unlikely to be resolved by voluntary actions.[294] Elected officials who accept contributions from State contractors may believe they have an advantage over their opponents who foreswear the contributions, and firms that do not "pay" may fear that they will lose government business to those that do.[295]

Other commenters recommended that we amend our rules to require that advisers amend their codes of ethics to monitor contributions by third-party solicitors.[296] But advisers using third-party solicitors to circumvent pay to play restrictions are well aware of these payments, and are unlikely to be deterred by a monitoring requirement. In addition, adviser codes of ethics are unlikely to be a sufficient means to induce third-party solicitors to be transparent about their own pay to play activities.

Instead of suggesting alternative approaches, other commenters urged us to apply the rule more narrowly by exempting from the ban solicitors that are registered broker-dealers or associated persons of broker-dealers.[297] Some were concerned that the rule would interfere with traditional distribution arrangements of mutual funds and private funds, which are usually distributed by registered broker-dealers that may be compensated by the adviser in some form.[298] Many argued that registration as a broker-dealer generally differentiates placement agents that provide "legitimate" services from those that merely offer political influence.[299] Others expressed concern that some broker-dealer firms that rely on placement agent business could be harmed.[300] We recognize that services that commenters have identified as beneficial would typically require broker-dealer registration. But registration under the Exchange Act does not preclude a broker-dealer from participating in pay to play practices—MSRB rules G–37 and G–38 do not apply, for example, to broker-dealers soliciting investments on behalf of investment companies or private funds.[301] Thus, amending our rule to limit third parties soliciting governments to broker-dealers registered under the Exchange Act would not achieve the prophylactic purpose of this rulemaking. We believe that our approach is appropriate in light of the concerns we are seeking to address.[302]

Several commenters proposed that we achieve our goals by permitting advisers to engage solicitors and placement agents that are registered broker-dealers and subject to rules similar to those adopted by the MSRB.[303] One asserted that such rules would be "a logical extension of the already-existing regulatory scheme governing broker-dealers."[304] Another agreed, arguing that such rules would be consistent with the approach the MSRB took when it adopted MSRB rule G–38, the effect of which was to sweep "all solicitors of municipal business (underwriting, sales and advisory) into the broker-dealer registration regime" where they would be subject to oversight of a registered broker-dealer and are required to conform their municipal securities activities to applicable MSRB rules,

marketers, public officials or other trustees, *etc.,* is necessary to minimize the adverse effects of pay to play, the issue will not be completely solved by disclosure).

[292] *See, e.g.,* MVision Letter (arguing that self-regulatory initiatives such as the EVCA's Code of Conduct for Placement Agents are working and that many public pension plans' own anti-pay to play policies have been successful); EVCA Letter (describing its Code of Conduct that prohibits pay to play and is supported by various stakeholders and arguing that it, along with strong punishment of wrongdoers, should restore confidence in the process). Another commenter suggested a code of conduct enforceable by regulators. Comment Letter of Charlie Eaton on behalf of a Coalition of Professional Institutional Placement Agents (Sept. 9, 2009) (proposing an industry Code of Conduct that could be enforced by FINRA and the Commission, which should ban firms that do not adhere from doing business with all potential investors, public and private). In our view, the rule we are adopting today not only essentially serves this purpose, but more appropriately reflects prohibitions we, instead of others, have determined appropriately address our concerns.

[293] *See* Proposing Release, at sections I and II.A.3(b). *See also* section I of this Release.

[294] *See supra* note 58 and accompanying text.

[295] *See Blount,* 61 F.3d at 945–46 (describing the parallel dynamics applicable in municipal underwriting, "As beneficiaries of the practice, politicians vying for State or local office may be reluctant to stop it legislatively; some, of course, may seek to exploit their rivals' cozy relation with bond dealers as a campaign issue, but if they refuse to enter into similar relations, their campaigns will be financially handicapped. Bond dealers are in a still worse position to initiate reform: Individual firms that decline to pay will have less chance to play, and may even be the object of explicit boycott if they do.").

[296] *See, e.g.,* ABA Letter; 3PM Letter; ICI Letter; NY City Bar Letter; Forum Letter; Jones Day Letter.

[297] *See, e.g.,* Davis Polk Letter; Comment Letter of UBS Securities LLC (Oct. 2, 2009) ("UBS Letter").

[298] *See, e.g.,* SIFMA Letter; NY City Bar Letter; Monomoy Letter; IAA Letter. Mutual fund distribution fees are typically paid by the fund pursuant to a 12b–1 plan, and therefore generally would not constitute payment by the fund's adviser. As a result, such payments would not be prohibited by rule 206(4)–5 by its terms. Where an adviser pays for the fund's distribution out of its "legitimate profits," however, the rule would generally be implicated. For a discussion of a mutual fund adviser's ability to use "legitimate profits" for fund distribution, see *Bearing of Distribution Expenses by Mutual Funds,* Investment Company Act Release No. 11414 (Oct. 28, 1980) [45 FR 73898 (Nov. 7, 1980)] (explaining, in the context of the prohibition on the indirect use of fund assets for distribution, unless pursuant to a 12b–1 plan, "[h]owever, under the rule there is no indirect use of fund assets if an adviser makes distribution related payments out of its own resources * * *. Profits which are legitimate or not excessive are simply those which are derived from an advisory contract which does not result in a breach of fiduciary duty under section 36 of the [Investment Company] Act."). For private funds, third parties are often compensated by the adviser or its affiliated general partner and, therefore, those payments are subject to the rule. Structuring such a payment to come from the private fund for the purpose of evading the rule would violate the rule. *See* Rule 206(4)–5(d).

[299] *See, e.g.,* Bryant Law Letter; Hedgeforce Letter; Comment Letter of Girard Miller (Aug. 8, 2009); Comment Letter of Frank Schmitz (Aug. 11, 2009) ("Schmitz Letter"); Atlantic-Pacific Letter; Rubenstein Letter; Thomas Letter; Monomoy Letter; MVision Letter; Comment Letter of Lime Rock Management (Sept. 28, 2009); Benedetto Letter; Strategic Capital Letter; Comment Letter of Portfolio Advisors, LLC (Oct. 2, 2009) ("Portfolio Advisors Letter"); UBS Letter; Comment Letter of Brian Fitzgibbon (Oct. 5, 2009); Comment Letter of GenNx360 Capital Partners, L.P. (Oct. 5, 2009).

[300] Comment Letter of the National Association of Independent Broker-Dealers (Oct. 5, 2009).

[301] At least one commenter suggested that there are "inherent" safeguards in the broker-dealer regulatory regime sufficient to protect against pay to play practices. *See, e.g.,* ABA Letter. But the broker-dealer regulatory regime does not specifically address pay to play activities, as demonstrated by the MSRB's adoption of rules G–37 and G–38.

[302] We acknowledge that there are costs associated with our rule. For further analysis of these, along with the benefits, see sections I and IV of this Release.

[303] Skadden Letter ("The Commission and FINRA could directly impose and enforce restrictions on such broker-dealers."); Davis Polk Letter ("Registered broker-dealers that provide legitimate placement agent services could be required by the Commission to comply with "pay-to-play" restrictions"); Credit Suisse Letter (preclude an investment adviser from using a placement agent that is not subject to pay to play restrictions analogous to rule G–37); Comment Letter of the President of M Advisory Group J. Daniel Vogelzang (Sept. 18, 2009) ("M Advisory Letter") (treat "[a]ll placement agents, investment advisers and consultants * * * exactly the same regarding prohibited political contributions; *i.e.,* a two-year ban on doing business with any governmental agency to which a prohibited political contribution is made."). *See also* Comment Letter of Hudson Capital Management (NY), L.P. (Oct. 5, 2009) (suggesting Commission take measures to properly license and regulate third-party solicitors); SIFMA Letter ("The pay-to-play and political activity of registered placement agents involved in soliciting government investment could * * * be directly regulated under the Exchange Act."). We believe our rule, as adopted, which allows advisers to pay certain regulated third parties to solicit government clients on their behalf, addresses these concerns. *See infra* notes 312–26 and accompanying text.

[304] Davis Polk Letter.

including MSRB rule G–37.[305] Others suggested we could similarly achieve our goals by permitting advisers to engage as solicitors registered investment advisers that are themselves subject to pay to play restrictions under an Advisers Act rule.[306]

We are persuaded by these comments and have decided to revise the proposed rule to permit advisers to make payments to certain "regulated persons" to solicit government clients on their behalf.[307] As described in more detail below, "regulated persons" include certain broker-dealers and registered investment advisers that are themselves subject to prohibitions against participating in pay to play practices and are subject to our oversight and, in the case of broker-dealers, the oversight of a registered national securities association, such as FINRA.[308] As one commenter observed, "the Commission would have the direct authority to determine these restrictions as well as the oversight, control and enforcement of penalties over any violations. The restrictions could be tailored to operate with the same underlying purpose and effect on [solicitors] as the "pay-to-play" restrictions imposed on investment advisers."[309] We believe that the application of such rules would provide an effective deterrent to these solicitors or placement agents from participating in pay to play arrangements because political contributions or payments would subject solicitors to similar consequences, as discussed below.[310] Because rule 206(4)–5 prohibits an adviser from compensating a registered adviser solicitor for solicitation activities if that adviser solicitor does not meet the definition of "regulated person," the adviser that hired the solicitor must immediately cease compensating a solicitor that no longer meets these conditions.[311]

In light of our decision to permit advisers to make payments to certain "regulated persons," described below, to solicit government clients on their behalf, we no longer believe that our proposed exception from the prohibition on advisers paying third-party solicitors for payments to related persons and employees of related person companies of the adviser is necessary.[312] We had proposed the exception to enable advisers to compensate these persons for government entity solicitation activities because we recognized there may be efficiencies in allowing advisers to rely on these particular types of persons to assist them in seeking clients. We requested comment regarding whether the exception would undermine the rule's efficacy by allowing advisers to compensate certain employees of related person companies whose contributions would not have triggered the two-year time out. Although we did not receive comment specifically addressing our concern,[313] we believe the approach we are adopting that allows advisers to pay "regulated persons" to solicit government entities on their behalf will still allow advisers to use employees of certain related companies—*i.e.,* of those related companies that qualify as "regulated persons"—as solicitors.[314]

(1) Registered Broker-Dealers

Registered national securities association rules of similar scope and consequence as the rule we are today adopting could sufficiently satisfy the concerns that led us to propose to prohibit advisers from paying brokers to solicit potential government clients. Advisers could not easily use placement agents covered by such rules to circumvent rule 206(4)–5. Under this approach, placement agents would be deterred from engaging in pay to play directly on account of the registered national securities association's rules. There would be no need for the Commission to prove in an enforcement action that a contribution by a placement agent amounted to an indirect contribution by the investment adviser because the placement agent itself could be charged with violating the registered national securities association's rules. Therefore, as adopted, rule 206(4)–5 allows an adviser to compensate "regulated persons," which includes registered brokers subject to a registered national securities

[305] SIFMA Letter ("Although Rule G–38(a) specifically prohibits a municipal dealer from paying a fee to a nonaffiliated person for solicitation of municipal securities business, the policies underlying Rule G–38 were to bring solicitors within the purview of the Federal securities laws—not to exclude the involvement of registered broker-dealers, including those registered broker-dealers not affiliated with advisers and private funds."). *See also* Monument Group Letter ("We believe that MSRB Rule G–38 is not analogous to the proposed rule. Rule G–38 permits a broker-dealer that is unaffiliated with an issuer to market that issuer's securities to a public pension plan or any other investor. Proposed Rule 206(4)–5(a)(2)(i) prevents this and seeks to entirely disintermediate the process between the issuer of a security and the ultimate investor."); Credit Suisse Letter ("[W]e strongly believe that a more complete analogy to the MSRB Pay-to-Play Rules would not preclude regulated broker-dealers from performing placement agent services in the context of municipal investors, as the Proposed Rule would do. Notably, the MSRB Pay-to-Play Rules do not preclude SEC-registered broker-dealers from acting as placement agents to municipal issuers. Instead, the MSRB Pay-to-Play Rules subject such placement agents to "pay-to-play" restrictions and requirements and preclude them from retaining unregulated third-party finders and solicitors.").

[306] *See, e.g.,* IAA Letter.

[307] *See* Rule 206(4)–5(a)(2)(i).

[308] Rule 206(4)–5(f)(9). *See supra* note 85 (noting that, in this Release, we will refer directly to FINRA, currently the only registered national securities association). As noted below, under the definition of "regulated persons" as it applies to brokers, the Commission must find, by order, that a registered national securities association's pay to play rule applicable to such brokers imposes substantially equivalent or more stringent restrictions on them than rule 206(4)–5 imposes on investment advisers and that such rule is consistent with the objectives of rule 206(4)–5. Rule 206(4)–5(f)(9)(ii)(B).

[309] Davis Polk Letter.

[310] Another group of commenters argued that third-party solicitors should be treated as covered associates—that is, their contributions should trigger the two-year ban for advisers that hire them. *See, e.g.,* ABA Letter; 3PM Letter; ICI Letter; NY City Bar Letter; Forum Letter; Jones Day Letter. In explaining our rejection of this approach in the Proposing Release, we noted that this approach—which we included in our 1999 pay to play proposal—was criticized by commenters at that time. *See* Proposing Release, at section II.A.3(b). They primarily argued that it was unfair to impute the activities of third parties to advisers, especially given what they perceived as the harsh consequences caused by a triggering contribution—*i.e.,* a two-year time out imposed on the adviser. *See id.* They further argued that an approach in which contributions by third-party solicitors triggered a two-year time out for an adviser would create over-burdensome compliance challenges because the adviser could not meaningfully control the contribution activities of such third parties. *See id.* We continue to be sympathetic to these concerns and believe that an approach in which a contribution by a third party triggered a two-year time out for the adviser that hires the third party as a solicitor could lead to unfair consequences. *See, e.g.,* Capstone Letter; Monument Group Letter; Park Hill Letter. For example, if a solicitor gives a triggering contribution in order to assist one client, we are concerned about the harsh result that such a contribution could have on all of the solicitor's other clients seeking business with the same prospective government entity client.

[311] It would be a violation of the rule for an adviser to compensate a third party for solicitation of government entity clients at any time that third party did not meet the definition of "regulated person," regardless of whether the "regulated person" failed to meet the definition at the time it was hired or subsequently.

[312] *See* Proposing Release, at section II.A.3(b).

[313] One commenter asked that we clarify the proposed exception for related parties (Sutherland Letter) and another recommended a case-by-case determination of whether independent contractors may be eligible for the exception, due to concern for life insurance agents who may not technically have qualified as "employees" for purposes of the exception (Skadden Letter). As noted, however, we have eliminated this exception in favor of allowing advisers to pay "regulated persons," affiliated or not, to solicit government clients on their behalf.

[314] We acknowledge that some advisers may have to bear certain additional costs of hiring outside parties as a result of our elimination of our proposal's "related person" exception, which would have allowed advisers to compensate related persons that are not registered broker-dealers or advisers for solicitation activities. For a discussion of costs relating to the rule, *see* section IV of this Release. But, we also note that the rule, as adopted, does not favor an adviser with affiliates (which our proposal would have allowed an adviser to use to solicit on its behalf) over another adviser without affiliates. Instead, our rule, as adopted, allows an adviser to pay a "regulated person" affiliated or not, to solicit on its behalf.

association's rules, for soliciting government clients on its behalf.[315] An adviser may engage a registered broker to solicit government clients on its behalf so long as the broker continues to meet the definition of "regulated person" throughout its engagement as a solicitor by the adviser.

For a broker-dealer to be a "regulated person" under rule 206(4)–5, the broker-dealer must be registered with the Commission and be a member of a registered national securities association that has a rule: (i) That prohibits members from engaging in distribution or solicitation activities if certain political contributions have been made; and (ii) that the Commission finds both to impose substantially equivalent or more stringent restrictions on broker-dealers than rule 206(4)–5 imposes on investment advisers and to be consistent with the objectives of rule 206(4)–5.[316] We have included the requirement that a broker-dealer, in order to qualify as a regulated person, be subject to a pay to play rule of a registered national securities association of which it is a member so that brokers seeking to act as placement agents for investment advisers are, in turn, adequately deterred from engaging in pay to play activities on behalf of those advisers by such a rule.

FINRA has informed us that it is preparing rules for consideration that would prohibit its members from soliciting advisory business from a government entity on behalf of an adviser unless they comply with requirements prohibiting pay to play activities.[317] FINRA has said its rule would impose regulatory requirements on member brokers[318] "as rigorous and as expansive" as would be imposed on investment advisers by rule 206(4)–5, and that in developing its proposal it intends to "draw closely upon all the substantive and technical elements of the SEC's proposal as well as our regulatory expertise in examining and enforcing the MSRB rules upon which the SEC's proposal is based."[319] The rules, including any recordkeeping requirements, would be enforced by FINRA, which has substantial experience enforcing MSRB rules G–37 and G–38.[320]

For the Commission to adopt a rule prohibiting advisers from using placement agents until FINRA adopts a rule could impose substantial hardships on a significant number of advisers and solicitors that wrote to us. It could also disrupt pension funds' investment opportunities. Therefore, as we discuss in more detail below, we are delaying application of the prohibition on compensating third-party solicitors for one year from the effective date of this rule, in part to give FINRA time to propose such a rule.[321]

(2) Registered Investment Advisers

We are also permitting advisers covered by the rule to pay solicitors for government clients that are registered investment advisers subject to similar limitations.[322] Under the rule, a "regulated person" includes (in addition to a registered broker subject to the conditions described above), an investment adviser that is registered with the Commission under the Advisers Act, provided that the solicitor and its covered associates have not, within two years of soliciting a government entity: (i) Made a contribution to an official of that government entity (other than a *de minimis* contribution, as permitted by the rule); or (ii) coordinated, or solicited any person (including a PAC) to make, any contribution to an official of a government entity to which the investment adviser that hired the solicitor is providing or seeking to provide investment advisory services, or payment to a political party of a State or locality where the investment adviser that hired the solicitor is providing or seeking to provide investment advisory services to a government entity.[323]

We received comments urging us to permit advisers to compensate registered investment advisers for soliciting government officials, subject to rules or rule amendments the Commission could adopt under the Advisers Act.[324] We believe such an allowance is appropriate for similar reasons to those for permitting advisers to compensate broker-dealers subject to pay to play rules we have determined meet our objectives under rule 206(4)–5. We have direct oversight authority over investment advisers registered with us. Accordingly, we believe it is appropriate to allow them to act as third-party solicitors for other advisers. Therefore, the rule, as adopted, limits the advisers that another adviser may pay to solicit government entities on its behalf to those advisers that are registered with the Commission[325] and that have neither made the types of political contributions that would trigger the two-year time out nor otherwise engaged in activities (*e.g.,* bundling of contributions) that the adviser could not engage in under the rule.[326]

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[315] Rule 206(4)–5(a)(2)(i) (which prohibits advisers and their covered associates from providing or agreeing to provide, directly or indirectly, payment to any third party other than a regulated person to solicit a government entity for investment advisory services on behalf of such investment adviser). Rule 206(4)–5 defines a "regulated person" to include a "broker," as defined in section 3(a)(4) of the Securities Exchange Act of 1934 [15 U.S.C. 78c(a)(4)] or a "dealer," as defined in section 3(a)(5) of that Act [15 U.S.C. 78c(a)(5)], that is registered with the Commission, and is a member of a registered national securities association registered under section 15A of that Act [15 U.S.C. 78o–3], *provided that* (A) the rules of the association prohibit members from engaging in distribution or solicitation activities if certain political contributions have been made; and (B) the Commission finds that such rules impose substantially equivalent or more stringent restrictions on broker-dealers than [rule 206(4)–5] imposes on investment advisers and that such rules are consistent with the objectives of [rule 206(4)–5]. The rule's definition of "regulated person" also includes certain investment advisers. *See infra* text accompanying note 323.

[316] Rule 206(4)–5(f)(9)(ii).

[317] *See* Letter from Richard G. Ketchum, Chairman & Chief Executive Officer, FINRA, to Andrew J. Donohue, Director, Division of Investment Management, U.S. Securities and Exchange Commission (Mar. 15, 2010), available at *http://www.sec.gov/comments/s7-18-09/s71809-252.pdf* ("Ketchum Letter") ("[w]e believe that a regulatory scheme targeting improper pay to play practices by broker-dealers acting on behalf of investment advisers is * * * a viable solution to a ban on certain private placement agents serving a legitimate function"). *See also* Letter from Andrew J. Donohue, Director, Division of Investment Management, U.S. Securities and Exchange Commission, to Richard G. Ketchum, Chairman & Chief Executive Officer, FINRA (Dec. 18, 2009), available at *http://www.sec.gov/comments/s7-18-09/s71809-252.pdf.*

[318] As used in this Section, "broker" means a "broker" or "dealer," as each term is defined in section 3(a) of the Securities Exchange Act of 1934 [15 U.S.C. 78c(a)].

[319] Ketchum Letter.

[320] *See* MSRB, *About the MSRB: Enforcement of Board Rules,* available at *http://msrb.org/msrb1/whatsnew/default.asp* ("Responsibility for examination and enforcement of Board rules is delegated to the Financial Industry Regulatory Authority for all securities firms, and to the Federal Deposit Insurance Corporation, the Federal Reserve Board, the Comptroller of the Currency, and the Office of Thrift Supervision for banks.").

[321] For a discussion of transition issues, *see* section III of this Release.

[322] Rule 206(4)–5(a)(2)(i) (which prohibits advisers and their covered associates from providing or agreeing to provide, directly or indirectly, payment to any third party other than a regulated person to solicit a government entity for investment advisory services on behalf of such investment adviser).

[323] Rule 206(4)–5(f)(9)(i).

[324] *See, e.g.,* IAA Letter.

[325] We are not including within the definition of "regulated person" investment advisers registered solely with State securities authorities as some commenters suggested. *See id.* We do not have regulatory authority over those advisers as we do over advisers who are registered with us (and as we do over FINRA in connection with its oversight of brokers and dealers and enforcement of its own rules). In fact, such advisers are subject neither to our oversight nor to the recordkeeping rules we are adopting today.

[326] Importantly, a person that is registered under the Exchange Act as a broker-dealer and under the Advisers Act as an investment adviser could potentially be a "regulated person" under the rule if it met the conditions for either prong of the definition. Such a regulated person should follow

Advisers compensating other advisers that qualify as "regulated persons" for soliciting government entities must adopt policies and procedures reasonably designed to prevent a violation of the rule.[327] Such policies and procedures should include, among other things, a careful vetting of candidates and ongoing review of "regulated person" investment advisers acting as solicitors currently being used. Such review would need to determine whether the adviser (and its covered persons) acting as a solicitor has made political contributions or otherwise engaged in conduct that would disqualify it from the definition of "regulated person" and thereby preclude the hiring adviser from paying it for the solicitation activity.

(c) Restrictions on Soliciting and Coordinating Contributions and Payments

Rule 206(4)–5 prohibits advisers and covered persons from coordinating or soliciting[328] any person or PAC to make (i) any contribution[329] to an official of a government entity to which the adviser is providing or seeking to provide investment advisory services,[330] or (ii) any payment[331] to a political party of a State or locality where the investment adviser is providing or seeking to provide investment advisory services to a government entity.[332] These restrictions are intended to prevent advisers from circumventing the rule's prohibition on direct contributions to certain elected officials such as by "bundling" a large number of small employee contributions to influence an election, or making contributions (or payments) indirectly through a State or local political party.[333]

We received only a few comments on this provision. One supporter of our proposal asserted that it "would close an important gap in which contributions might be made indirectly to government officials for the purpose of influencing their choice of investment advisers."[334] Most commenters that addressed the provision focused on the prohibition relating to contributions and payments to State and local political parties where the adviser is providing, or seeking to provide, advisory services. One State official suggested that this prohibition would unfairly affect states with strict limitations on individual contributions to candidates as they are now more reliant on party money for campaigns.[335] Another State official, however, explained the importance of the provision by pointing out that it is often difficult or impossible to differentiate between individuals seeking an office and the political party, which often merely passes contributions it receives on to the candidate, and may direct successful candidates to place pension business with contributors.[336]

We are adopting this provision, as proposed. These restrictions on soliciting and coordinating

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the rules that apply to the services it is performing, rather than complying with both investment adviser and broker-dealer pay to play requirements. The Exchange Act generally requires brokers and dealers to register with the Commission and become members of at least one self-regulatory organization. Exchange Act sections 15(a), 15(b)(8) [15 U.S.C. 78o(a), (b)(8)]. Section 3(a)(4)(A) of the Exchange Act generally defines a "broker" as any person engaged in the business of effecting transactions in securities for the account of others [15 U.S.C. 78c(a)(4)(A)]. *See, e.g., Definition of Terms in and Specific Exemptions for Banks, Savings Associations, and Savings Banks Under Sections 3(a)(4) and 3(a)(5) of the Securities Exchange Act of 1934,* Exchange Act Release No. 44291, at n.124 (May 11, 2001) [66 FR 27759 (May 18, 2001)] ("Solicitation is one of the most relevant factors in determining whether a person is effecting transactions."); *Strengthening the Commission's Requirements Regarding Auditor Independence,* Exchange Act Release No. 47265, at n.82 (Jan. 28, 2003) [68 FR 6006 (Feb. 5, 2003)] (noting that a person may be "engaged in the business," among other ways, by receiving compensation tied to the successful completion of a securities transaction). *See also Persons Deemed Not to Be Brokers,* Exchange Act Release No. 22172, at sec. II.A (Jun. 27, 1985) [50 FR 27940 (Jul. 9, 1985)] (noting that attorneys, accountants, insurance brokers, financial service organizations and financial consultants are engaged in the business of effecting transactions in securities for the account of others if they are retained by an issuer specifically for the purpose of selling securities to the public and receive transaction based-compensation for their services).

[327] *See* Advisers Act rule 206(4)–7 [17 CFR 275.206(4)–7] (requiring advisers to adopt and implement compliance policies and procedures).

[328] Rule 206(4)–5(f)(10)(ii) (defining "solicit," with respect to a contribution or payment, as communicating, directly or indirectly, for the purpose of obtaining or arranging a contribution or payment). Some commenters requested that we provide guidance regarding when an adviser would be deemed to be soliciting contributions for purposes of the rule. *See, e.g.,* Caplin & Drysdale Letter. An adviser that consents to the use of its name on fundraising literature for a candidate would be soliciting contributions for that candidate. Similarly, an adviser that sponsors a meeting or conference which features a government official as an attendee or guest speaker and which involves fundraising for the government official would be soliciting contributions for that government official. Whether a particular activity involves a solicitation or coordination of a contribution or payment for purposes of the rule will depend on the facts and circumstances, thus we have not attempted to draw a bright line. The MSRB takes a similar approach. *See* MSRB, *Solicitation of Contributions,* MSRB Interpretive Letter (May 21, 1999), available at *http://msrb.org/msrb1/rules/interpg37.htm* (determination of whether activity constitutes "soliciting" under rule G–37 is a facts and circumstances analysis). *See also supra* note 255.

[329] In the case of the fundraising meeting or conference described as an example in note 328, expenses incurred by the adviser for hosting the event would be a contribution by the adviser, thereby triggering the two-year ban on the adviser receiving compensation for providing advisory services to the government entity over which that official has influence. *See* section II.B.2(a) of this Release. Such expenses may include, but are not limited to, the cost of the facility, the cost of refreshments, any expenses paid for administrative staff, and the payment or reimbursement of any of the government official's expenses for the event. The *de minimis* exception under rule 206(4)–5(b)(1) would not be available with respect to these expenses because they would have been incurred by the firm, not by a natural person. *See* MSRB, *Supervision When Sponsoring Meetings and Conferences Involving Issuer Officials,* MSRB Rule G–37 Interpretive Notice (Mar. 26, 2007), available at *http://www.msrb.org/msrb1/rules/notg37.htm* (rather than addressing meetings and conferences in its rules directly, the MSRB applies a facts and circumstances test on a case-by-case basis).

[330] Rule 206(4)–5(a)(2)(ii). An investment adviser would be seeking to provide advisory services to a government entity when it responds to a request for proposal, communicates with a government entity regarding that entity's formal selection process for investment advisers, or engages in some other solicitation of investment advisory business of the government entity. A violation of paragraph (a)(2)(ii) of the rule would not trigger a two-year ban on the provision of investment advisory services for compensation, but would be a violation of the rule.

[331] A payment is defined as any gift, subscription, loan, advance, or deposit of money or anything of value. Rule 206(4)–5(f)(7). This definition is similar to the definition of "contribution," but broader, in the sense that it does not include limitations on the purposes for which such money is given (*e.g.,* it does not have to be made for the purpose of influencing an election). We are including the broader term "payments," as opposed to "contributions," here to deter an adviser from circumventing the rule's prohibitions by coordinating indirect contributions to government officials by making payments to political parties.

[332] Rule 206(4)–5(a)(2)(ii). This provision prohibits, for example, an adviser from soliciting a payment to the political party of a State if the adviser is providing or seeking to provide advisory services to the State, but would not preclude that adviser from soliciting a payment to a local political party (as long as the adviser is not also providing or seeking to provide advisory services to a government entity in that locality). In these circumstances, the rule would, however, prohibit an adviser from soliciting the payment to a local political party as a means to indirectly make payments to the State party. *See* rule 206(4)–5(d).

[333] We note that this provision is not limited to the bundling of employee contributions. Another example of conduct that would be prohibited by this section would be an adviser or its covered associates soliciting contributions from professional service providers.

[334] Cornell Law Letter.

[335] CT Treasurer Letter. In upholding restrictions targeted at a particular industry, courts have found that the loss of contributions from a small segment of the electorate "would not significantly diminish the universe of funds available to a candidate to a non-viable level." *Green Party of Conn. v. Garfield,* 590 F. Supp. 2d 288, 316 (D. Conn. 2008); *see also Preston v. Leake,* 629 F. Supp. 2d 517, 524 (E.D.N.C. 2009) (differentiating the "broad sweep of the Vermont statute" that "restricted essentially any potential campaign contribution" from a statute that "only applies to lobbyists"); *In re Earle Asphalt Co.,* 950 A.2d 918, 927 (N.J. Super. Ct. App. Div. 2008), *aff'd* 957 A.2d 1173 (N.J. 2008) (holding that a limitation on campaign contributions by government contractors and their principals did not have the same capacity to prevent candidates from amassing the resources necessary for effective campaigning as the statute in *Randall*). *See supra* note 68.

[336] Reilly Letter.

contributions and payments close what would otherwise be a potential gap in the rule as advisers could circumvent its limitations on direct contributions through soliciting and coordinating others to make contributions to influence an election or a government official's investment adviser selection process.[337] We disagree that this prohibition would unfairly affect candidates in states that limit individual contributions, because the rule is non-discriminatory and would affect contributions (and payments) to all candidates equally that were being bundled or made through a gatekeeper for the benefit of an investment adviser seeking or doing business with the State or local government.

(d) Direct and Indirect Contributions or Solicitations

Rule 206(4)–5(d) prohibits acts done indirectly, which, if done directly, would violate the rule.[338] As a result, an adviser and its covered associates could not funnel payments through third parties, including, for example, consultants, attorneys, family members, friends or companies affiliated with the adviser as a means to circumvent the rule.[339] We emphasize, however, that contributions by these other persons would not otherwise trigger the rule's two-year time out.[340] We received no comments on this aspect of the proposed rule and are adopting it as proposed.

(e) Covered Investment Pools

Rule 206(4)–5 includes a provision that applies each of the prohibitions of rule 206(4)–5 to an investment adviser that manages assets of a government entity through a hedge fund or other type of pooled investment vehicle ("covered investment pool").[341] For example, a political contribution to a government official that would, under the rule, trigger the two-year time out from providing advice for compensation to the government entity would also trigger a two-year time out from the receipt of compensation for the management of those assets through a covered investment pool. This provision extends the protection of the rule to public pension plans that increasingly access the services of investment advisers through hedge funds and other types of pooled investment vehicles they sponsor or advise.

This provision will generally affect two common types of arrangements in which a government official is in a position to influence investment of funds in pooled investment vehicles. The first is the investment of public funds in a hedge fund or other type of pooled investment vehicle. The other is the selection of a pooled investment vehicle sponsored or advised by an investment adviser as a funding vehicle or investment option in a government-sponsored plan, such as a "529 plan."[342]

An adviser that makes political contributions to steer assets to a pooled investment vehicle it manages facilitates fraud by implementing a government official's *quid pro quo* scheme.[343] Public pension plan beneficiaries are harmed when a government official violates the public trust, for example, by failing to disclose that the government official has directed the investment of the plan's assets in a pooled investment vehicle not because of the vehicle's financial merits but rather because the official has received a political contribution.[344] By engaging in such conduct, the adviser engages in a scheme to defraud the beneficiaries of the government plan or program.[345] Additionally, an investment adviser to a pooled investment vehicle that is an investment option in a government plan or program may prepare information about the pooled investment vehicle that may be used by plan officials to evaluate the vehicle and by pension plan beneficiaries to decide whether to allocate assets to the vehicle. Such an adviser engages in or facilitates an act, practice, or course of business which is fraudulent, deceptive, or manipulative when the adviser does not disclose that it made a contribution for the purpose of inducing an investment by the government officials and that the

[337] We note that a direct contribution to a political party by an adviser or its covered associates would not violate the rule, unless the contribution was a means for the adviser to do indirectly what the rule would prohibit if done directly (for example, if the contribution was earmarked or known to be provided for the benefit of a particular government official). *See* section II.B.2(d) of this Release. The MSRB amended rule G–37 in 2005 to expand its prohibition on soliciting others to make, and on coordinating, payments to State and local political parties to close what the MSRB identified as a gap in which contributions were being made indirectly to officials through payments to political parties for the purposes of influencing their choice of municipal securities dealers. The MSRB had not previously been able to deter this misconduct, despite issuing informal guidance in both 1996 and 2003. *See Rule G–37: Request for Comments on Draft Amendments to Rule G–37(c), Relating to Prohibiting Solicitation and Coordination of Payments to Political Parties, and Draft Question and Answer Guidance Concerning Indirect Rule Violations,* MSRB Notice 2005–11 (Feb. 15, 2005), available at *http://www.msrb.org/msrb1/archive/2005/2005–11.asp* ("Both the 1996 Q&A guidance and the 2003 Notice were intended to alert dealers and [municipal finance professionals] to the realities of political fundraising and guide them toward developing procedures that would lead to compliance with both the letter and the spirit of the rule. The MSRB continues to be concerned, however, that dealer, [municipal finance professional], and affiliated persons' payments to political parties, including "housekeeping", "conference" or "overhead" type accounts, and PACs give rise to at least the appearance that dealers may be circumventing the intent of Rule G–37."); *Self-Regulatory Organizations; Municipal Securities Rulemaking Board; Order Approving Proposed Rule Change Concerning Solicitation and Coordination of Payments to Political Parties and Question and Answer Guidance on Supervisory Procedures Related to Rule G–37(d) on Indirect Violations,* Exchange Act Release No. 52496 (Sept. 22, 2005) (SEC order approving change to MSRB G–37 to prohibit soliciting or coordinating payments to political parties).

[338] Paragraph (d) of the rule is substantially similar to section 208(d) of the Advisers Act [15 U.S.C. 80b–8(d)], which states, "It shall be unlawful for any person indirectly, or through or by any other person, to do any act or thing which it would be unlawful for such person to do directly under the provisions of this title or any rule or regulation thereunder." MSRB rule G–37 contains a similar provision. *See* MSRB rule G–37(d).

[339] This provision would also cover, for example, situations in which contributions by an adviser are made, directed or funded through a third party with an expectation that, as a result of the contributions, another contribution is likely to be made by a third party to an "official of the government entity," for the benefit of the adviser. Contributions made through gatekeepers thus would be considered to be made "indirectly" for purposes of the rule. In approving MSRB rule G–37, the Commission stated: "[rule G–37(d)] is intended to prevent dealers from funneling funds or payments through other persons or entities to circumvent the [rule]'s requirements. For example, a dealer would violate the [rule] if it does business with an issuer after contributions were made to an issuer official from or by associated persons, family members of associated persons, consultants, lobbyists, attorneys, other dealer affiliates, their employees or PACs, or other persons or entities as a means to circumvent the rule. A dealer also would violate the rule by doing business with an issuer after providing money to any person or entity when the dealer knows that the money will be given to an official of an issuer who could not receive the contribution directly from the dealer without triggering the rule's prohibition on business." *Self-Regulatory Organizations; Order Approving Proposed Rule Change by the Municipal Securities Rulemaking Board Relating to Political Contributions and Prohibitions on Municipal Securities Business and Notice of Filing and Order Approving on an Accelerated Basis Amendment No. 1 Relating to the Effective Date and Contribution Date of the Proposed Rule,* Exchange Act Release No. 33868 (Apr. 7, 1994) [59 FR 17621 (Apr. 13, 1994)].

[340] Like MSRB rule G–37(d), rule 206(4)–5(d) requires a showing of intent to circumvent the rule in order for such persons to trigger the time out. *See Blount,* 61 F.3d at 948 ("In short, according to the SEC, the rule restricts such gifts and contributions only when they are intended as end-runs around the direct contribution limitations.").

[341] *See* rule 206(4)–5(c). We discuss the types of pooled investment vehicles that are "covered investment pools" below at section II.B.2.(e)(1) of this release.

[342] We note that if an adviser is selected by a government entity to advise a government-sponsored plan (regardless of whether the plan selects one of the pools the adviser offers or manages as an option available under its plan), the prohibitions of the rule *directly* apply. *See* rule 206(4)–5(a)(1) and (a)(2).

[343] *SEC v. DiBella,* 587 F.3d 553, 568 (2d Cir. 2009).

[344] *Id.* at 566.

[345] *See id.* at 568–69; section 206(4) of the Advisers Act. *See also* Exchange Act rule 10b–5 [17 CFR 240.10b–5].

government officials sponsoring the plan chose the vehicle as an investment option for beneficiaries not solely on the basis of its merits, but rather as the consequence of improper *quid pro quo* payments.[346] The rule also operates to prevent an adviser from engaging in pay to play practices indirectly through an investment pool that it would not be permitted to do if it directly managed (or sought to directly manage) the assets of a government entity.[347]

Although a few commenters asserted that the rule or parts of it should not apply to pooled investment vehicles,[348] none made a persuasive argument that the problems the rule is designed to address are not present in the management of public pension plan and other public monies invested in pooled investment vehicles. As we discussed in the Proposing Release,[349] when a decision to invest public funds in a pooled investment vehicle is based on campaign contributions, the public pension plan may make inferior investment choices and may pay higher fees. And such pension plans may invest in pooled investment vehicles that pay substantially higher advisory fees and assume significantly greater risks than other investment alternatives.[350]

We find nothing in the structure of pooled investment vehicles or the variety of investment strategies they employ that suggests a reason for treating advisers to pooled investment vehicles differently from advisers to separately managed advisory accounts, except, as we discuss below, registered investment companies to which we apply a more limited version of the rule. That an investment in a pooled investment vehicle may not involve a direct advisory relationship with a government sponsored plan does not change the nature of the fraud or the harm that may be inflicted as a consequence of the adviser's pay to play activity.

Indeed, many of our recent enforcement cases alleged political contributions or kickbacks designed to induce public officials to invest public pension plan assets in pooled investment vehicles.[351] We are concerned that our failure to apply the rule to advisers who manage assets through these vehicles would ignore an area where there has been considerable growth, both in the amount of public assets invested in such pooled investment vehicles and allegations of pay to play activity involving public pension plans.[352] We believe a failure to apply the rule in this area could, in some cases, even encourage the use of covered investment pools as a means of avoiding application of the rule.

Nonetheless, as described in more detail below, we have made several changes from the proposal to more narrowly tailor the applicability of the rule to pooled investment vehicles in order to achieve our regulatory purpose while reducing compliance burdens that commenters brought to our attention. In addition, we have made certain clarifying changes to the rule, as described below.

(1) Definition of "Covered Investment Pool"

Under the rule, a "covered investment pool" [353] includes: (i) Any investment company registered under the Investment Company Act of 1940 that is an investment option of a plan or program of a government entity; or (ii) any company that would be an investment company under section 3(a) of that Act but for the exclusion provided from that definition by section 3(c)(1), section 3(c)(7) or section 3(c)(11) of that Act.[354] Accordingly, it includes such unregistered pooled investment vehicles as hedge funds, private equity funds, venture capital funds and collective investment trusts.[355] It also

[346] *See, e.g., Oran v. Stafford,* 226 F.3d 275, 285–86 (3d Cir. 2000) ("a duty to disclose may arise when there is * * * an inaccurate, incomplete or misleading prior disclosure"); *Glazer v. Formica Corp.,* 964 F.2d 149, 157 (2d Cir. 1992) ("when a corporation does make a disclosure—whether it be voluntary or required—there is a duty to make it complete and accurate") (quoting *Roeder v. Alpha Industries, Inc.,* 814 F.2d 22, 26 (1st Cir. 1987). *See also* Exchange Act Rule 10b–5(b).

[347] *See* rule 206(4)–5(d). *See also* section 208(d) of the Act.

[348] *See, e.g.,* Comment Letter of Abbott Capital Management, LLC (Oct. 6, 2009) ("Abbott Letter"); ICI Letter; NY City Bar Letter; SIFMA Letter; Skadden Letter; Sutherland Letter.

[349] *See* Proposing Release, at section II.A.3.(e)(2).

[350] *See, e.g.,* Nanette Burns, *Can Retirees Afford This Much Risk?* Business Week (Sept. 17, 2007), available at *http://www.businessweek.com/magazine/content/07_38/b4050048.htm* (asserting that public pension plan assets are increasingly being invested in higher risk alternative investments, including hedge funds); Hannah M. Terhune, *Accounts Training,* Money Science (Dec. 11, 2006), available at *http://www.moneyscience.com/Hedge_Fund_Tutorials/Hedge_Fund_Management_and_Performance_Fees.html* (noting an "enormous difference in rewards for the managers of hedge funds versus those of mutual funds" because hedge fund managers are entitled to performance fees).

[351] *See, e.g., SEC v. Paul J. Silvester, et al.,* Litigation Release No. 16759, Civil Action No. 3:00–CV–19411 DJS (D. Conn.) (Oct. 10, 2000) (action in which investment adviser allegedly paid third-party solicitors who kicked back a portion of the money to the former Connecticut State Treasurer in order to obtain public pension fund investments in a hedge fund managed by the adviser); *SEC v. William A. DiBella, et al.,* Litigation Release No. 20498, Civil Action No. 3:04 CV 1342 (EBB) (D. Conn.) (Mar. 14, 2008) (consultant was found to have aided and abetted the former Connecticut State Treasurer in a pay to play scheme involving an investment adviser to a private equity fund who had paid third-party solicitors to obtain public pension fund investments in the fund). There are examples of pay to play activity in the context of pooled investment vehicles in other jurisdictions as well. *See, e.g., supra* note 18 (listing various actions relating to the recent pay to play allegations surrounding the New York Common Retirement Fund). *See also Guilty Plea in Fraud Case Tied to New York Pension,* Associated Press (Dec. 4, 2009), available at h*http://www.nytimes.com/2009/12/04/nyregion/04pension.html* (describing the guilty plea of an adviser to a venture capital fund to charges that he helped his company land a lucrative deal with New York's public pension fund by giving nearly $1 million worth of illegal gifts to State officials).

[352] *See, e.g.,* Investment Company Institute, *529 Plan Program Statistics, Mar. 2009* (Feb. 5, 2010), available at *http://www.ici.org/research/stats/529s/529s_03-09* (indicating that 529 plan assets have increased from $8.6 billion in 2000 to $100.3 billion in the first quarter of 2009, and that 529 plan accounts have increased from 1.3 million in 2000 to 11.2 million in the first quarter of 2009); Investment Company Institute, *The U.S. Retirement Market, 2008,* 18 Research Fundamentals, No. 5 (June 2009), available at *http://www.ici.org/pdf/fm-v18n5.pdf* (indicating that 403(b) plan and 457 plan assets have increased from $627 billion in 2000 to $712 billion in the fourth quarter of 2008); SEI, *Collective Investment Trusts: The New Wave in Retirement Investing* (May 2008), available at *https://longjump.com/networking/RepositoryPublicDocDownload?id=80031025axe139509557&docname=SEI%20CIT%20White%20Paper%205.08.pdf&cid=80031025&encode=application/pdf* (citing Morningstar data indicating that collective investment trust assets nearly tripled from 2004 to 2007 and grew by more than 150 percent between 2005 and 2007 alone). *See also* Michael Marois, *CalPERS, Blackstone Clash over Placement Agent 'Jackpot' Fees,* Bloomberg (Apr. 7, 2010), available at *http://www.bloomberg.com/apps/news?pid=newsarchive&sid=acPNrTn1q7pw* (noting that placement agents working for private equity, hedge funds, venture capital and real estate firms typically earn the equivalent of 0.5 percent to 3 percent of the money they place under the management of their client, quoting California State Treasurer Bill Lockyer, a member of the CalPERS board, "[t]he contingency fees are too much of a jackpot for the placement agents * * * [they] invite corrupt practices").

[353] Rule 206(4)–5(f)(3).

[354] 15 U.S.C. 80a–3(c)(1), (7) or (11). We note that a bank maintaining a collective investment trust would not be subject to the rule if the bank falls within the exclusion from the definition of "investment adviser" in section 202(a)(11)(A) of the Advisers Act [15 U.S.C. 80b–2(a)(11)(A)]. A non-bank adviser that provides advisory services with respect to a collective investment trust in which a government entity invests, however, would be subject to the rule's prohibitions with respect to all of its government entity clients, including the collective investment trust in which a government entity invests, unless another exemption is available.

[355] One commenter questioned the Commission's authority to apply the rule in the context of covered investment pools in light of the opinion of the Court of Appeals for the District of Columbia Circuit in *Goldstein v. SEC,* 451 F.3d 873 (D.C. Cir. 2006). Sutherland Letter. That case created some uncertainty regarding the application of sections 206(1) and 206(2) of the Advisers Act in certain cases where investors in a pool are defrauded by an investment adviser to that pool. *See Prohibition of Fraud by Advisers to Certain Pooled Investment Vehicles,* Investment Advisers Act Release No. 2628 (Aug. 3, 2007) [72 FR 44756 (Aug. 9, 2007)],

Continued

includes registered pooled investment vehicles, such as mutual funds, but only if those registered pools are an investment option of a participant-directed plan or program of a government entity.[356] These plans or programs may include college savings plans like "529 plans"[357] and retirement plans like "403(b) plans"[358] and "457 plans"[359] that typically allow participants to select among pre-established investment "options," or particular investment pools (often invested in registered investment companies or funds of funds, such as target date funds), that a government official has directly or indirectly selected to include as investment choices for participants.[360]

We proposed to include in the definition of "covered investment pool" the types of pooled investment vehicles that are likely to be used as funding vehicles for, or investments of, government-sponsored savings and retirement plans. We explained that we included registered investment companies because of the significant growth in government-sponsored savings plans in recent years, which increasingly use these funds as investment options,[361] and the increased competition among advisers for selection of their fund as an investment option for these plans.[362] We were concerned that advisers to pooled investment vehicles, including registered investment companies, may make political contributions to influence the decision by government officials to include their funds as options in such plans.

We recognized in our proposal, however, that an adviser to a registered investment company might have difficulty in identifying when or if a government investor was a fund shareholder for purposes of preventing the adviser (or its covered associates) from making contributions that would trigger a two-year time out.[363] Therefore, we proposed to only include publicly offered registered investment companies in the definition of covered investment pool for purposes of the two-year time out provision to the extent they were investments or investment options of a plan or program of a government entity.[364]

Several commenters asserted that an adviser to a publicly offered investment company would have similar difficulties in identifying government investors in registered investment companies for purposes of complying with other provisions of the rule.[365] One opposed application of the rule to registered investment companies "even if the [company] is not included in a plan or program of a government entity,"[366] although several generally urged us to exclude registered investment companies from the rule altogether.[367] Another commenter urged us to apply the rule's recordkeeping requirements (discussed below) prospectively and after a period of time that would be adequate to enable funds to redesign their processes and systems to capture information about whether an investor is a "government entity," which would be necessary to comply with the rule and our proposed amendment to the Act's recordkeeping rule.[368] Some noted that identifying government investors would be particularly challenging when shares were held through an intermediary.[369]

We continue to believe for the reasons discussed above[370] and in the Proposing Release, that advisers to registered investment companies should be subject to the rule. In response to comments, we have modified our

(adopting rule 206(4)–8 [17 CFR 275.206(4)–8]). In addressing the scope of the exemption from registration in section 203(b)(3) of the Advisers Act and the meaning of "client" as used in that section, the Court of Appeals expressed the view that, for purposes of sections 206(1) and (2), the "client" of an investment adviser managing a pool is the pool itself, not an investor in the pool. In its opinion, the Court of Appeals distinguished sections 206(1) and (2) from section 206(4) of the Advisers Act, which applies to persons other than clients. *Id.* at n.6. *See also United States v. Elliott,* 62 F.3d 1304, 1311 (11th Cir. 1995). Section 206(4) permits us to adopt rules proscribing fraudulent conduct that is potentially harmful to investors in pooled investment vehicles. We are adopting rule 206(4)–5 under this authority.

[356] Rule 206(4)–5(f)(8).

[357] A 529 plan is a "qualified tuition plan" established under section 529 of the Internal Revenue Code of 1986 [26 U.S.C. 529]. States generally establish 529 plans as State trusts which are considered instrumentalities of States for Federal securities law purposes. As a result, the plans themselves are generally not regulated under the Federal securities laws and many of the protections of the Federal securities laws do not apply to investors in them. *See* section 2(b) of the Investment Company Act [15 U.S.C. 80a–2(b)] and section 202(b) of the Advisers Act [15 U.S.C. 80b–2(b)] (exempting State-owned entities from those statutes). However, the Federal securities laws do generally apply to, and the Commission does generally regulate, the brokers, dealers, and municipal securities dealers that effect transactions in interests in 529 plans. *See generally* sections 15(a)(1) and 15B of the Exchange Act [15 U.S.C. 78a–15(a)(1) and 15B]. A bank effecting transactions in 529 plan interests may be exempt from the definition of "broker" or "municipal securities dealer" under the Exchange Act if it can rely on an exception from the definition of broker in the Exchange Act. In addition, State sponsors of 529 plans may hire third-party investment advisers either to manage 529 plan assets on their behalf or to act as investment consultants to the agency responsible for managing plan assets. These investment advisers, unless they qualify for a specific exemption from registration under the Advisers Act, are generally required to be registered with the Commission as investment advisers and would therefore be subject to our rule.

[358] A 403(b) plan is a tax-deferred employee benefit retirement plan established under section 403(b) of the Internal Revenue Code of 1986 [26 U.S.C. 403(b)].

[359] A 457 plan is a tax-deferred employee benefit retirement plan established under section 457 of the Internal Revenue Code of 1986 [26 U.S.C. 457].

[360] We would consider a registered investment company to be an investment option of a plan or program of a government entity where the participant selects a model fund or portfolio (such as an age-based investment option of a 529 plan) and the government entity selects the specific underlying registered investment company or companies in which the portfolio's assets are invested.

[361] *See supra* note 352 and accompanying text.

[362] *See, e.g.,* Charles Paikert, *TIAA–CREF Stages Comeback in College Savings Plans,* Crain's New York Bus., Apr. 23, 2007 (depicting TIAA–CREF's struggle to remain a major player in managing State 529 plans because of increasing competition from the industry's heavyweights); Beth Healy, *Investment Giants Battle for Share of Exploding College-Savings Market,* Boston Globe, Oct. 29, 2000, at F1 (describing the increasing competition between investment firms for State 529 plans and increasing competition to market their plans nationally). *See also* AnnaMaria Andriotis, *529 Plan Fees are Dropping,* SmartMoney, Dec. 16, 2009, available at *http://www.smartmoney.com/personal-finance/college-planning/529-plan-fees-are-dropping-but-for-how-long/?hpadref=1* ("Costs on these plans are falling for a few reasons, and the biggest one has little to do with the State of the economy: The nature of their contracts creates competition. When a contract for a State 529 plan expires, program managers compete against each other and may lower their fees to try to secure the new contract.").

[363] *See* Proposing Release, at nn. 185–87 and accompanying text.

[364] *See* proposed rule 206(4)–5(f)(3) ("Covered investment pool means any investment company, as defined in section 3(a) of the Investment Company Act of 1940 (15 U.S.C. 80a–3(a)) * * * except that for purposes of paragraph (a)(1) of this section, an investment company registered under the Investment Company Act of 1940 (15 U.S.C. 80a), the shares of which are registered under the Securities Act of 1933 (15 U.S.C. 77a), shall be a covered investment pool only if it is an investment or an investment option of a plan or program of a government entity.").

[365] *See* Davis Polk Letter; Fidelity Letter; ICI Letter; NSCP Letter; Comment Letter of Standard & Poor's Investment Advisory Services LLC and Standard & Poor's Securities Evaluations, Inc. (Oct. 5, 2009) ("S&P Letter"); SIFMA Letter; T. Rowe Price Letter.

[366] T. Rowe Price Letter.

[367] Fidelity Letter; ICI Letter; NSCP Letter; SIFMA Letter. We disagree that registered investment companies should be excluded from our rule. Pay to play activity is fraudulent, regardless of whether it occurs in the context of a pooled investment vehicle or a separately managed account. One commenter asserted that the existence of a regulatory regime applicable to investment companies precludes the need for pay to play prohibitions with respect to these pools. *See* ICI Letter. However, existing laws and regulations applicable to investment companies do not specifically address pay to play practices.

[368] ICI Letter. *See also* section II.D of this Release.

[369] *See* T. Rowe Price Letter; ICI Letter, Fidelity Letter.

[370] *See supra* notes 361–362 and accompanying text.

proposal to include a registered investment company in the definition of covered investment pool, for purposes of all three of the rule's pay to play prohibitions, but *only* if it is an investment option of a plan or program of a government entity.[371] We believe this approach strikes the right balance between applying the rule in those contexts, discussed in the Proposing Release,[372] in which advisers to registered investment companies may be more likely to engage in pay to play conduct, while recognizing the compliance challenges relating to identifying government investors in registered investment companies [373] that may result from a broader application of the rule. When an adviser's investment company is an investment option in a participant-directed government plan or program, we believe it is reasonable to expect the adviser will know (or can reasonably be expected to acquire information about) the identity of the government plan.[374] We recognize that when shares are held through an intermediary, an adviser may have to take additional steps to identify a government entity.[375] Therefore, we have provided advisers to registered investment companies with additional time to modify current systems and processes.[376]

We have also made several minor changes from our proposal intended to clarify and simplify application of the rule. First, at the suggestion of commenters,[377] we are clarifying that an adviser to a registered investment company is only subject to the rule—*i.e.,* the investment company is only considered a covered investment pool—if the investment company is an investment option of a plan or program of a government entity that is *participant-directed.*[378] This change reflects our intent, as demonstrated by the examples we give in the definition (*i.e.,* 529 plans, 403(b) plans, and 457 plans) that the definition is intended to encompass those covered investment pools that have been pre-selected by the government sponsoring or establishing the plan or program as part of a limited menu of investment options from which participants in the plan or program may allocate their account. We have also added, as additional examples to the definition of "government entity," a defined benefit plan and a State general fund to better distinguish these pools of assets from a plan or program of a government entity.[379] We have also made minor organizational changes within the definition of government entity from our proposal to make clear that such pools are not "plans or programs of a government entity."

Finally, we have simplified the definition of "covered investment pool" as it applies to registered investment companies. The definition as adopted includes investment companies registered under the Investment Company Act that are an option of a plan or program of a government entity, regardless of whether, as proposed, their shares are registered under the Securities Act of 1933 ("1933 Act"). As discussed above, under the rule as adopted an adviser to a registered investment company is only subject to the rule if the company is an investment option of a plan or program. As a result, we believe it is unnecessary to distinguish between registered investment companies based on whether their shares are registered under the 1933 Act, although we understand that those shares will typically be registered where the fund is an option in a plan or program of a government entity.

(2) Application of the Rule

Under rule 206(4)–5 (and as proposed) an investment adviser is subject to the two-year time out if it manages a covered investment pool in which the assets of a government entity are invested.[380] The rule does not require a government entity's withdrawal of its investment or cancellation of any commitment it has made. Indeed, the rule prohibits advisers not from providing advice subsequent to a triggering political contribution, but rather from receiving compensation for providing advice. If a government entity is an investor in a covered investment pool at the time a contribution triggering a two-year "time out" is made, the adviser must forgo any compensation related to the assets invested or committed by that government entity.[381]

Application of the two-year time out may present different issues for covered investment pools than for separately managed accounts due to various structural and legal differences. Having made a contribution triggering the two-year time out, the adviser may have multiple options available to comply with the rule in light of its fiduciary obligations and the disclosure it has made to investors. For instance, in the case of a private pool, the adviser could seek to cause the pool to redeem the investment of the government entity.[382]

[371] Rule 206(4)–5(f)(3).

[372] Proposing Release, at nn.185–87 and accompanying text. *See also supra* notes 352 and 362 and accompanying text (describing the growth in government-sponsored savings plans in recent years and the increased competition for an adviser's fund to be selected as an investment option of such a plan).

[373] Identifying government investors in other types of covered investment pools does not generally present similar compliance challenges. *See, e.g.,* rule 2(a)(51) under the Investment Company Act [17 CFR 270.2(a)(51)] (defining "qualified purchaser," as that term is used in section 3(c)(7) of that Act); Rule 501(a) of Regulation D under the Securities Act of 1933 ("Securities Act") [17 CFR 230.501(a)] (defining "accredited investor" for purposes of limited offerings without registration under the Securities Act of 1933); and Advisers Act rule 205–3 (creating an exception from the prohibition against an adviser receiving performance-based compensation from clients that are not "qualified clients," and which is relied on by many advisers to funds that are exempt from Investment Company Act registration under section 3(c)(1) of that Act).

[374] With respect to a 529 plan, for example, an adviser would know that its investment company is an investment option of the plan and will know the identity of the government entity investor because a 529 plan can only be established by a State, which generally establishes a trust to serve as the direct investor in the investment company, while plan participants invest in various options offered by the 529 trust. The rule does not require an adviser to identify plan participants, only the government plan or program. *See* rule 206(4)–5(f)(5)(iii) (defining a "government entity" to include a plan or program of a government entity. The definition does not include the participants in those plans or programs).

[375] For example, while 403(b) plans and 457 plans are generally associated with retirement plans for government employees, they are not used exclusively for this purpose. For instance, certain non-profit or tax-exempt entities can establish these types of plans. We also understand that it is not uncommon for contributions of 403(b) and 457 plans to be commingled into an omnibus position that is forwarded to the fund, making it more challenging for an adviser to distinguish government entity investors from others.

[376] *See* section III.D of this Release. We received several letters addressing this concern. ICI Letter; T. Rowe Price Letter; Fidelity Letter.

[377] *See, e.g.,* ICI Letter; Davis Polk Letter; SIFMA Letter.

[378] Rule 206(4)–5(f)(8).

[379] Rule 206(4)–5(f)(5).

[380] Rule 206(4)–5(c).

[381] As we noted above and in the Proposing Release, the phrase "for compensation" includes both profits and the recouping of costs, so an adviser is not permitted to continue to manage assets at cost after a disqualifying contribution is made. Proposing Release, at n.191. *See also supra* note 137 and accompanying text. As we discussed above in section II.B.2(a)(1) of this Release, we are not persuaded by commenters who suggested permitting the adviser to be compensated at cost following payment of a triggering contribution or payment. *See, e.g.,* Dechert Letter; NY City Bar Letter. In our judgment, the potential loss of profits from the government client alone may be insufficient to deter pay to play activities. However, costs specifically attributable to the covered investment pool and not normally incurred in connection with a separately managed account, such as costs attributable to an annual audit of the pool's assets and delivery of its audited financial statements, would not be considered compensation to the adviser for these purposes.

[382] To the extent the adviser may seek to cause the private pool to redeem the investment of a government entity investor under these circumstances, it should consider disclosing this as an investment risk in a private placement

Continued

Such redemptions may be relatively simple matters in the case of, for example, a highly liquid private pool.[383] Commenters pointed out to us that, for some private pools, such as venture capital and private equity funds, a government entity's withdrawal of its capital or cancellation of its commitment may have adverse implications for other investors in the fund.[384] In such cases, the adviser could instead comply with the rule by waiving or rebating the portion of its fees or any performance allocation or carried interest attributable to assets of the government client.[385]

For registered investment companies, the options for restricting compensation involving government investors are more limited, due to both Investment Company Act provisions and potential tax consequences.[386] In our proposal, we suggested one approach that would meet the requirements of the rule—an adviser of a registered investment company could waive its advisory fee for the fund as a whole in an amount approximately equal to fees attributable to the government entity.[387] One commenter agreed with our approach,[388] while another commenter suggested we could, alternatively, permit the government entity to continue to pay its portion of the advisory fee, but require the adviser to rebate that portion of the fee to the fund as a whole.[389] We believe either approach would meet the requirements of the rule we are adopting today.

(3) Subadvisory Arrangements

A number of commenters urged that we exclude from the rule subadvisers to covered investment pools because, being in a subordinate role to the adviser, they may have no involvement in the adviser's solicitation activities including no ability to identify government entities being solicited, and therefore should not be held accountable for the adviser's actions.[390] None of these commenters, however, indicated that a subadviser could not obtain from the adviser the information necessary to comply with the rule. Additionally, no commenter provided us with a basis to distinguish advisers from subadvisers that would be adequate to avoid undermining the prophylactic nature of our rule. "Subadviser" is not defined under the Act,[391] and significant variation exists in subadvisory relationships.[392] There is no readily available way to draw meaningful distinctions between advisers and subadvisers by, for example, looking at who controls marketing and solicitation activities,[393] who has an advisory contract directly with the government client,[394] or other factors. In addition, subadvisers generally have the same economic incentives as advisers to obtain new business and increase assets under management. We are concerned that under the approaches suggested by commenters, an adviser that sought to avoid compliance with the prophylactic provisions of our rule and engage in pay to play could organize itself to operate as a subadviser in such an arrangement. We therefore believe it is not appropriate to exclude subadvisers from the rule.

We are, however, providing some guidance that may assist advisers in subadvisory and fund of funds arrangements in complying with the rule.[395] First, by the terms of the rule, if an adviser or subadviser makes a contribution that triggers the two-year time out from receiving compensation, the subadviser or adviser, as applicable, that did not make the triggering contribution could continue to receive compensation from the government entity,[396] unless the arrangement were a means to do indirectly what the adviser or subadviser could not do directly under the rule.[397] Second, advisers to underlying funds in a fund of funds arrangement are not required to look through the investing fund to determine whether a government entity is an investor in the investing fund unless the investment were made in that manner as a means for the adviser to do indirectly

memorandum, prospectus or other disclosure document to current and prospective investors in such a fund. *See, e.g.,* Rule 502 of Regulation D under the Securities Act [17 CFR 230.502] (addressing disclosure obligations for non-accredited investors who purchase securities in a limited offering pursuant to rules 505 or 506 of Regulation D under the Securities Act [17 CFR 230.505 or 17 CFR 230.506].

[383] We understand that other types of pooled investment vehicles, including private equity and venture capital funds, already have special withdrawal and transfer provisions related to the regulatory and tax considerations applicable to certain types of investors, such as those regulated by the Employee Retirement Income Security Act of 1974 ("ERISA") [29 U.S.C. 18]. *See generally* James M. Schell, Private Equity Funds—Business Structure and Operations (Law Journal Press 2000) (2010).

[384] *See* Abbott Letter; ICI Letter; NY City Bar Letter.

[385] As we noted in the Proposing Release, some commenters to our 1999 Proposal asserted that a performance fee waiver raises various calculation issues. *See* Proposing Release, at n.192. An adviser making a disqualifying contribution could comply with rule 206(4)–5 by waiving a performance fee or carried interest determined on the same basis as the fee or carried interest is normally calculated—*e.g.,* on a mark-to-market basis. For arrangements like those typically found in private equity and venture capital funds where the fee or carry is calculated based on realized gains and losses and mark-to-market calculations are not feasible, advisers could use a straight-line method of calculation which assumes that the realized gains and losses were earned over the life of the investment.

[386] *See* Proposing Release, at n.193 and accompanying text. *See, e.g.,* rule 18f–3 under the Investment Company Act [17 CFR 270.18f–3]. Moreover, other regulatory considerations, such as those under ERISA, may impact these arrangements with respect to collective investment trusts.

[387] This may also be done at the class level or series level for private funds organized as corporations.

[388] ICI Letter.

[389] NY City Bar Letter.

[390] *See, e.g.,* IAA Letter; S&P Letter; Skadden Letter; Davis Polk Letter.

[391] "Subadviser" also is not defined under the Investment Company Act, which requires that both advisory and subadvisory contracts ("which contract, whether with such registered company or with an investment adviser of such registered company * * *") be approved by a vote of a majority of the outstanding voting securities of the registered investment company. *See* section 15(a) of the Investment Company Act [15 U.S.C. 80a–15(a)].

[392] *See, e.g.,* Investment Company Institute, *Board Oversight of Subadvisers* (Jan. 2010), available at *http://www.ici.org/pdf/idc_10_subadvisers.pdf* (providing guidance to mutual fund boards of directors with respect to overseeing subadvisory arrangements and recognizing that "there is no one 'correct' approach to effective subadvisory oversight by fund boards" because there are a wide variety of potential subadvisory arrangements).

[393] *See, e.g.,* Davis Polk Letter (suggesting that we limit the application of the prohibitions to a subadviser to a covered investment pool that has the ability to control the soliciting, marketing or acceptance of government clients); S&P Letter (suggesting that we limit the application of the prohibitions to a subadviser to a covered investment pool that: (1) Has the ability to control the soliciting, marketing or acceptance of government clients; and (2) is not a related person of the investment adviser or distributor or other investment pool).

[394] *See, e.g.,* IAA Letter; Skadden Letter. *See also* sections 2(a)(20) and 15(a) of the Investment Company Act (treating a subadviser as an adviser to a registered investment company even in the absence of a direct contractual relationship with the investment company).

[395] *See, e.g.,* IAA Letter (requesting clarification as to how the rule would apply when an adviser becomes subject to the compensation ban after hiring a subadviser or vice versa). *See also* Fidelity Letter; MFA Letter; SIFMA Letter (each expressing concern about how the rule would apply in the fund of funds context).

[396] We understand that, under some advisory arrangements, the government entity has a contract only with the adviser and not the subadviser. Under those circumstances, it would be consistent with the rule for an adviser that has triggered the two-year time out to pass through to the subadviser that portion of the fee to which the subadviser is entitled, as long as the adviser retains no compensation from the government entity and the subadviser (and its own covered associates) has not triggered a time out as well.

[397] *See* Rule 206(4)–5(d). For instance, an adviser that hires an affiliated subadviser to manage a covered investment pool in which a government entity invests so that the adviser could make contributions to that government entity would be doing indirectly what it would be prohibited from doing directly under the rule. A subadviser would be providing "investment advisory services for compensation to a government entity" regardless of whether the subadviser is paid directly by the government entity or by the adviser.

what it could not do directly under the rule.[398]

(f) Exemptions

An adviser may apply to the Commission for an order exempting it from the two-year compensation ban.[399] Under this provision, which we are adopting as proposed, we can exempt advisers from the rule's time out requirement where the adviser discovers contributions that trigger the compensation ban only after they have been made, and when imposition of the prohibition is unnecessary to achieve the rule's intended purpose. This provision will provide advisers with an additional avenue by which to seek to cure the consequences of an inadvertent violation by the adviser that falls outside the limits of the rule's *de minimis* exception and exception for returned contributions,[400] such as when a disgruntled employee makes a greater than $350 contribution as he or she exits the firm. In determining whether to grant an exemption, we will take into account the varying facts and circumstances that each application presents. Among other factors, we will consider: (i) whether the exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Advisers Act; (ii) whether the investment adviser, (A) before the contribution resulting in the prohibition was made, adopted and implemented policies and procedures reasonably designed to prevent violations of rule 206(4)–5; (B) prior to or at the time the contribution which resulted in such prohibition was made, had no actual knowledge of the contribution; and (C) after learning of the contribution, (1) has taken all available steps to cause the contributor involved in making the contribution which resulted in such prohibition to obtain a return of the contribution; and (2) has taken such other remedial or preventive measures as may be appropriate under the circumstances; (iii) whether, at the time of the contribution, the contributor was a covered associate or otherwise an employee of the investment adviser, or was seeking such employment; (iv) the timing and amount of the contribution which resulted in the prohibition; (v) the nature of the election (*e.g.,* Federal, State or local); and (vi) the contributor's apparent intent or motive in making the contribution which resulted in the prohibition, as evidenced by the facts and circumstances surrounding such contribution.[401] We intend to apply these factors with sufficient flexibility to avoid consequences disproportionate to the violation, while effecting the policies underlying the rule.

We received limited comment on this provision. A few commenters suggested that the operation of the rule should toll until a decision is made about an applicant's request.[402] We are concerned that such an approach could encourage frivolous applications and encourage applicants to delay the disposition of their applications. As we explained in the Proposing Release, an adviser seeking an exemption could place into an escrow account any advisory fees earned between the date of the contribution triggering the prohibition and the date on which we determine whether to grant an exemption.[403] Some commenters recommended the rule build in a specified length of time for the Commission to respond to requests for relief.[404] We recognize that applications for an exemptive order will be time-sensitive and will consider such applications expeditiously. We note that the escrow arrangements discussed above may lessen the hardship on advisers.

D. Recordkeeping

We are adopting amendments to rule 204–2 to require registered investment advisers that have government clients, or that provide investment advisory services to a covered investment pool in which a government entity investor invests, to make and keep certain records that will allow us to examine for compliance with new rule 206(4)–5.[405] The rule amendments reflect several changes from our proposal, which are discussed below. These requirements are similar to the MSRB recordkeeping requirements for brokers, dealers and municipal securities dealers.[406]

Amended rule 204–2 requires registered advisers that provide investment advisory services to a government entity, or to a covered investment pool in which a government entity is an investor, to make and keep records of contributions made by the adviser and covered associates to government officials (including candidates), and of payments to State or local political parties and PACs.[407] The adviser's records of contributions and payments must be listed in chronological order identifying each contributor and recipient, the amounts and dates of each contribution or payment and whether a contribution was subject to rule 206(4)–5's exception for certain returned contributions.[408] The rule also requires an adviser that has government clients to make and keep a list of its covered associates,[409] and the government entities to which the adviser has provided advisory services in the past five years.[410] Similarly, advisers to covered investment pools must make and keep a list of government entities that invest, or have invested in the past five years, in a covered investment pool, including any government entity that selects a covered investment pool to be an option of a plan or program of a government entity, such as a 529, 457 or 403(b)

[398] *See* rule 206(4)–5(d).

[399] Rules 0–4, 0–5, and 0–6 under the Advisers Act [17 CFR 275.0–4, 0–5, and 0–6] provide procedures for filing applications under the Act, including applications under the rule 206(4)–5.

[400] *See* sections II.B.2(a)(6) and (7) of this Release, describing exceptions to the two-year time out prohibition of the rule.

[401] *See* Rule 206(4)–5(e). These factors are similar to those considered by FINRA and the appropriate bank regulators in determining whether to grant an exemption under MSRB rule G–37(i).

[402] ICI Letter; Skadden Letter.

[403] *See* Proposing Release, at n.199. The escrow account would be payable to the adviser if the Commission grants the exemption. If the Commission does not grant the exemption, the fees contained in the account would be returned to the government entity client. In contrast, MSRB rule G–37, on which rule 206(4)–5 is based, does not permit a municipal securities dealer to continue to engage in municipal securities business with an issuer while an application is pending. *See* MSRB Rule G–37 Q&A, Question V.1.

[404] IAA Letter; ICI Letter; NASP Letter (each suggesting all applications be granted if they are not acted upon in 30 days); Skadden Letter (suggesting a 45-day deadline).

[405] Rule 204–2(a)(18) and (h)(1). An adviser is required to make and keep these records only if it provides investment advisory services to a government entity or if a government entity is an investor in any covered investment pool to which the investment adviser provides investment advisory services. Advisers that solicit government clients on behalf of other advisers are also subject to the amended recordkeeping requirements. Advisers that are exempt from Commission registration under section 203(b)(3) of the Advisers Act, however, are not subject to the recordkeeping requirements under amended 204–2 unless they do register with us, although as discussed earlier, *supra* note 92 and accompanying text, they are subject to rule 206(4)–5. Advisers keeping substantially the same records under rules adopted by the MSRB are not required to keep duplicate records. Rule 204–2(h)(1).

[406] MSRB rule G–8(a)(xvi). The MSRB also requires certain records to be made and kept in accordance with disclosure requirements that our rule does not contain.

[407] Contributions and payments by PACs controlled by the adviser or a covered associate would also have to be recorded as these PACs are "covered associates" under the rule. Rule 206(4)–5(f)(2)(iii). *See* section II.B.2(a)(4) of this Release.

[408] Rule 204–2(a)(18)(ii).

[409] The adviser must record the name, title(s), and business and residence addresses of each covered associate. Rule 204–2(a)(18)(i)(A).

[410] Advisers do not have to maintain a record of government entities that were clients before the effective date. For additional information regarding the implementation of rule 206(4)–5, see section III of this Release.

plan.[411] An investment adviser, regardless of whether it currently has a government client, must also keep a list of the names and business addresses of each regulated person to whom the adviser provides or agrees to provide, directly or indirectly, payment to solicit a government entity on its behalf.[412] The amended rule reflects several changes from our proposal, which we describe below.

First, in response to comments,[413] we have limited the rule to provide that only records of contributions,[414] not payments,[415] to government officials and candidates are required to be kept under the rule.[416] We have made this change because, unlike contributions, which are one type of payment, all payments do not trigger the two-year time out. As a result of this change, the recordkeeping obligations better reflect the activities of an adviser or a covered associate that could result in the adviser being subject to the two-year time out. Commenters also argued that we should not require, as proposed, advisers to maintain records of payments to PACs.[417] Although those payments do not trigger application of the two-year time out, payments to PACs can be a means for an adviser or covered associate to funnel contributions to a government official without directly contributing. We are, therefore, adopting the amendment to require advisers to keep records of payments to PACs as these records will allow our staff to identify situations that might suggest an intent to circumvent the rule.[418]

Second, an investment adviser to a registered investment company must maintain records identifying government entity investors only if the investments are made as part of a plan or program of a government entity or provide participants in the plan or program with the option of investing in the fund.[419] This change would narrow the records required to those necessary to support the rule as modified from our proposal, and we believe addresses commenters' concerns regarding the ability of advisers to registered investment companies to identify government entity investors.[420] As discussed above, we believe it is reasonable to expect advisers to know the identity of the government entity when a registered fund they advise is part of a plan or program. In addition, as commenters suggested, we are providing a substantial transition period for advisers to registered investment companies that should allow these advisers to make the necessary changes to account documents and systems to allow them to identify government entities that provide one or more of the investment companies they advise as an investment option.[421]

Third, the amended rule requires an adviser to maintain a list of only those government entities to which it provides, or has provided in the past five years, investment advisory services.[422] We are not requiring, as proposed, a list of government entities the adviser solicited for advisory business.[423] Some commenters expressed concerns about the potential scope of this requirement and noted that solicitation does not trigger rule 206(4)–5's two-year time out, rather it is providing advice for compensation that does so.[424] In light of these concerns, and the record before us today, we are not requiring advisers to maintain lists of government entities solicited that do not become clients.

Fourth, as discussed above, rule 206(4)–5 permits an adviser to use certain third parties to solicit on its behalf. We are, therefore, requiring that advisers that provide or agree to provide, directly or indirectly, payment to advisers or broker-dealers registered with the Commission that act as regulated persons under rule 206(4)–5 to maintain a list of the names and business addresses of each such regulated person.[425] These records will enable the Commission's staff to review and compare the regulated person's records to those of the adviser that hired the regulated person.

Finally, the amendments require advisers to make and keep records of their covered associates, and their own and their covered associates' contributions, *only if* they provide advisory services to a government client.[426] Commenters had expressed concerns that requiring advisers with no government business to make and keep these records could be unnecessarily intrusive to employees and burdensome on advisers.[427] In light of those concerns, and the record before us today, we are not requiring advisers with no government business to make and keep these records.[428] As a consequence, an adviser with no government clients would not have to require employees to report their political contributions.

E. Amendment to Cash Solicitation Rule

We are adopting, as proposed, a technical amendment to rule 206(4)–3 under the Advisers Act, the "cash solicitation rule." That rule makes it

[411] Amended rule 204–2 does not require an adviser to a covered investment pool that is an option of a government plan or program to make and keep records of participants in the plan or program, but only the government entity. *See supra* note 374. Consistent with changes we have made to the definition of covered investment pool, we note that an adviser's recordkeeping obligations with respect to a registered investment company apply only if such an investment company is an option of a plan or program of a government entity. *See* section II.B.2(e) of this Release.

[412] Rule 204–2(a)(18)(i)(D).

[413] Fidelity Letter; IAA Letter; SIFMA Letter.

[414] *See supra* note 153 and accompanying text (defining "contribution").

[415] *See supra* note 331 (defining "payment").

[416] Rule 204–2(a)(18)(i)(C).

[417] *See, e.g.,* IAA Letter; SIFMA Letter.

[418] Accordingly, as part of a strong compliance program, an adviser or covered associate that receives a general solicitation to make a contribution to a PAC should consider inquiring about how the collected funds would be used to determine whether the PAC is closely associated with a government official to whom a direct contribution would subject the adviser to the two-year time out. *See* section II.B.2(d) of this Release and rule 206(4)–5(d). The MSRB takes a similar approach regarding whether a payment to a PAC is an indirect contribution to a government official. *See* MSRB Rule G–37 Q&A, Questions III.4 and III.5.

[419] Rule 204–2(a)(18)(i)(B). Amended rule 204–2 does not require an adviser to a covered investment pool that is an option of a government plan or program to make and keep records of participants in the plan or program, but only the government entity. For a discussion of the application of the rule to a covered investment pool that is an option of a government plan or program, see *supra* note 371 and accompanying text. Consistent with changes we have made to the definition of covered investment pool, we note that an adviser's recordkeeping obligations with respect to a registered investment company apply only if such an investment company is an option of a plan or program of a government entity. *See* section II.B.2(e) of this Release.

[420] Advisers to covered investment pools that are relying on Investment Company Act exclusions in sections 3(c)(1), 3(c)(7) and 3(c)(11) must identify government entity investors regardless of whether they are an investment option of a plan or program of a government entity. Rule 204–2(a)(18)(i)(B).

[421] *See* section III of this Release.

[422] *See* rule 204–2(a)(18)(i)(B).

[423] *See* proposed rule 204–2(a)(18)(i)(B).

[424] Dechert Letter; SIFMA Letter; Skadden Letter.

[425] Rule 204–2(a)(18)(i)(D). If an adviser does not specify which types of clients the regulated person should solicit on its behalf (*e.g.,* that it should *only* solicit government entities), the adviser could satisfy this requirement by maintaining a list of all of its regulated person solicitors. *Supra* note 412.

[426] Rule 204–2(a)(18)(iii).

[427] IAA Letter; Dechert Letter; SIFMA Letter.

[428] Although advisers that do not have government entity clients are not required to maintain records under the amendments, the look-back requirements of rule 206(4)–5 continue to apply. As a result, an adviser that has not maintained records of the firm's and its covered associates' contributions would have to determine whether any contributions by the adviser, its covered associates, and any former covered associates would subject the firm to the two-year time out prior to accepting compensation from a new government entity client. The same applies to newly-formed advisers. The records an adviser develops during this determination process, would fall under the adviser's obligation to maintain records of all direct or indirect contributions made by the investment adviser or its covered associates to an official of a government entity, or payments to a political party of a State or political subdivision thereof, or to a political action committee. Rule 204–2(a)(18)(i)(C).

unlawful, except under specified circumstances and subject to certain conditions, for an investment adviser to make a cash payment to a person who directly or indirectly solicits any client for, or refers any client to, an investment adviser.[429]

Paragraph (iii) of the cash solicitation rule contains general restrictions on third-party solicitors that cover solicitation activities directed at any client, regardless of whether it is a government entity client. New paragraph (e) to rule 206(4)–3 alerts advisers and others that special prohibitions apply to solicitation activities involving government entity clients under rule 206(4)–5.[430]

III. Effective and Compliance Dates

Rule 206(4)–5 and the amendments to rules 204–2 and 206(4)–3 are effective on September 13, 2010. Investment advisers subject to rule 206(4)–5 must be in compliance with the rule on March 14, 2011. Investment advisers may no longer use third parties to solicit government business except in compliance with the rule on September 13, 2011.[431] Advisers to registered investment companies that are covered investment pools must comply with the rule by September 13, 2011.[432] Advisers subject to rule 204–2 must comply with amended rule 204–2 on March 14, 2011. However, if they advise registered investment companies that are covered investment pools, they have until September 13, 2011 to comply with the amended recordkeeping rule with respect to those registered investment companies.

A. Two-Year Time Out and Prohibition on Soliciting or Coordinating Contributions

We are providing advisers with a six month transition period to give them time to identify their covered associates and current government entity clients and to modify their compliance programs to address new compliance obligations under the rule.[433] Accordingly, rule 206(4)–5's prohibition on providing advisory services for compensation within two years of a contribution will not apply to, and the rule's prohibition on soliciting or coordinating contributions will not be triggered by contributions made before March 14, 2011.[434] We believe that the length of the transition period should address commenters' concerns that advisers have sufficient time to implement policies and procedures regarding contributions to avoid violations of the rule and that the rule not affect the 2010 elections for which some advisory personnel may already have committed to make political contributions.[435]

B. Prohibition on Using Third Parties To Solicit Government Business and Cash Solicitation Rule Amendment

Advisers must comply with the new rule's prohibition on making payments to third parties to solicit government entities for investment advisory services on September 13, 2011.[436] Before this compliance date, advisers are not prohibited by the rule from making payments to third-party solicitors regardless of whether they are registered as broker-dealers or investment advisers.[437]

We have provided an extended transition period to provide advisers and third-party solicitors with sufficient time to conform their business practices to the new rule, and to revise their compliance policies and procedures to prevent violation of the new rule. In addition, the transition period will provide an opportunity for a registered national securities association to propose a rule that would meet the requirements of rule 206(4)–5(f)(9)(ii)(B) and for the Commission to consider such a rule. If, after one year, a registered national securities association has not adopted such rules, advisers would be prohibited from making payments to broker-dealers for distribution or solicitation activities with respect to government entities, but would be permitted to make payments to registered investment advisers that meet the definition of "regulated person" under the rule.[438] We understand from our staff, however, that FINRA plans to act within the timeframe; if they do not, we will consider whether we should take further action.

Finally, the compliance date for the technical amendment to the cash solicitation rule, rule 206(4)–3, which is intended to alert advisers that rule 206(4)–5 is applicable to solicitations of a government entity, is one year from the effective date, as the amendment to the cash solicitation rule need only be operative when rule 206(4)–5's third-party solicitor provisions are in effect.

C. Recordkeeping

As discussed above, the amendments to rule 204–2 apply only to investment advisers with clients who are government entities. Such advisers must comply with the amended rule on March 14, 2011 except as noted below. By March 14, 2011, these advisers must begin to maintain records of all persons who are covered associates under the rule and keep records of political contributions they make on and after that date. Advisers must also make and keep a record of all government entities that they provide advisory services to on and after March 14, 2011. Advisers are not, however, required to look back for the five years prior to the effective date to identify former government clients. Advisers that pay regulated persons to solicit government entities for advisory services on their behalf must make and keep a list of those persons beginning on and after September 13, 2011.[439]

D. Registered Investment Companies

Advisers to registered investment companies that are "covered investment pools" under the rule[440] must comply with rule 205(4)–5 with respect to those covered pools September 13, 2011. During the transition period, contributions by the adviser or its employees to government entity clients that have selected an adviser's registered investment company as an investment option of a plan or program will not trigger the prohibitions of rule 206(4)–5.[441]

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[429] 17 CFR 275.206(4)–3.

[430] Rule 206(4)–3(e). We received no comments on this proposed amendment.

[431] Rule 206(4)–5(a)(2).

[432] Rule 206(4)–5(f)(3).

[433] Section III.D of this Release addresses when advisers to "covered investment pools" that are registered investment companies must comply with the rule; section III.E of this Release addresses transition considerations specific to certain other pooled investment vehicles.

[434] Likewise, these prohibitions do not apply to contributions made before March 14, 2011 by new covered associates to which the look back applies. *See* section II.B.2(a)(5) of this Release for a discussion of the rule's look-back provision. For example, if an individual who becomes a covered associate of an adviser on or after March 14, 2011 made a contribution before March 14, 2011, that new covered associate's contribution would not trigger the two-year time out for the adviser. On the other hand, if an individual who later becomes a covered associate made the contribution on or after March 14, 2011, the contribution would trigger the two-year time out for the adviser if it were made less than, as applicable, six months or two years before the individual became a covered associate.

[435] Commenters recommended that we provide advisers with six months to one year as a transition for rule 206(4)–5. *See* Davis Polk Letter; MFA Letter; ICI Letter; IAA Letter; NASP Letter; Skadden Letter.

[436] Rule 206(4)–5(a)(2).

[437] We note, however, that the antifraud provisions of the Federal securities laws continue to apply during the transition period.

[438] *See* rule 206(4)–5(f)(9)(i).

[439] Rule 204–2(a)(18)(i)(D).

[440] A registered investment company is only a covered investment pool if it is an investment option of a plan or program of a government entity, such as a 529 plan, 403(b) plan or 457 plan. *See* rule 206(4)–5(f)(3).

[441] Advisers to covered investment pools other than registered investment companies—*i.e.,*

Continued

We have provided for an extended compliance date to respond to concerns expressed by commenters that an adviser to a registered investment company may require additional time to identify government entities that have selected that registered investment company as an investment option when shares of the fund are held through omnibus arrangements such that the identity of the fund investor is not readily available to the adviser.[442] The changes we have made to the proposed rule that limit the application of the two-year time out with respect to registered investment companies to those that are options in a plan or program of a government entity,[443] together with this extended compliance date should provide advisers to registered investment companies sufficient time to put into place those system enhancements or business arrangements, such as those with intermediaries, that may be necessary to identify those government plans or programs in which the funds serve as investment options.[444]

As noted above, we are providing for an extended compliance date for advisers that manage registered investment companies that are covered investment pools under the rule, which we are applying, for the same reasons, to recordkeeping obligations that arise as a result of those covered investment pools. Thus, advisers to these covered investment pools must make and keep a record of all government entity investors on and after September 13, 2011.[445]

IV. Cost-Benefit Analysis

We are sensitive to the costs and benefits imposed by our rules, and understand that there will be costs associated with compliance with rule 206(4)–5 and the amendments to rule 204–2.[446] We recognize that the rule and amendments will place burdens on advisers that provide or seek to provide advisory services to government entities, and that advisers may in turn choose to limit the ability of certain persons associated with an adviser to make contributions to candidates for certain offices and to solicit contributions for certain candidates and payments to political parties. We believe there are practical, cost-effective means to comply with the rule without an adviser imposing a blanket ban on political contributions by its covered associates. We have closely drawn the rule, and modified it based on comments received, to achieve our goal of addressing adviser participation in pay to play practices, while seeking to limit the burdens imposed by the rule.

The rule and rule amendments are designed to address pay to play practices by investment advisers that provide advisory services to government entity clients and to certain covered investment pools in which a government entity invests. The rule prohibits an investment adviser from providing advisory services for compensation to a government client for two years after the adviser or certain of its executives or employees make a contribution to certain elected officials or candidates. The rule also prohibits an adviser from providing or agreeing to provide, directly or indirectly, payment to any third party that is not a "regulated person" for a solicitation of advisory business from any government entity, or for a solicitation of a government entity to invest in certain covered investment pools, on behalf of such adviser. Additionally, the rule prevents an adviser from coordinating or soliciting from others contributions to certain elected officials or candidates or payments to certain political parties. The rule applies both to advisers registered with us (or required to be registered) and those that are unregistered in reliance on the exemption available under section 203(b)(3) of the Advisers Act (15 U.S.C. 80b–3(b)(3)). Our amendment to rule 204–2 requires a registered adviser to maintain certain records of the political contributions made by the adviser or certain of its executives or employees, as well as records of the regulated persons the adviser pays or agrees to pay to solicit government entities on the adviser's behalf.

In the Proposing Release, we requested comment on the effects of the proposed rule and rule amendments on pension plan beneficiaries, participants in government plans or programs, investors in pooled investment vehicles, investment advisers, the advisory profession as a whole, government entities, third party solicitors, and political action committees.[447] We requested that commenters provide analysis and empirical data to support their views on the costs and benefits associated with the proposal. For example, we requested comment on the costs of establishing compliance procedures to comply with the proposed rule, both on an initial and ongoing basis and on the costs of using compliance procedures of an affiliated broker-dealer that the broker-dealer established as a result of MSRB rules G–37 and G–38. In addition, we requested data regarding our assumptions about the number of unregistered advisers that would be subject to the proposed rule, and the number of covered associates of these exempt advisers. Finally, in the context of the objectives of this rulemaking, we sought comments that address whether these rules will promote efficiency, competition and capital formation, and what effect the rule would have on the market for investment advisory services and third-party solicitation services.

We received approximately 250 comment letters on the proposal. Almost all of the commenters agreed that pay to play is a serious issue that should be addressed. One commenter stated that "the benefits derived from the application of pay to play limitations to public sector advisory services will far outweigh any temporary dislocations that may occur as private and public sector professionals make the necessary adjustments to their activities to transition to the Commission's new standards."[448] Many, however, expressed concern about costs,[449] particularly those related to the proposed ban on payments to third parties. Some suggested that the

companies that would be investment companies under section 3(a) of the Investment Company Act but for the exclusion provided from that definition by either section 3(c)(1), section 3(c)(7) or section 3(c)(11)—are subject to the six-month transition period. We believe advisers to these types of funds, because the interests in them are typically held in the name of the investor, should be able to identify government entities without significant difficulty.

[442] *See* ICI Letter; T. Rowe Price Letter.

[443] *See* section II.B.2(a) of this Release.

[444] A few commenters recommended that the rule apply only to new government investors in registered investment companies after the effective date of the rule. *See* ICI Letter; T. Rowe Price Letter. We do not believe this would be appropriate because pay to play can be just as troubling in the context of an adviser renewing an advisory contract (or including a registered investment company as an investment option in a plan or program) as one that is endeavoring to obtain business for the first time.

[445] Amended rule 204–2 does not require an adviser to a covered investment pool that is an option of a government plan or program to make and keep records of participants in the plan or program, but only the government entity. *See supra* note 411.

[446] As proposed, we are also making a conforming technical amendment to rule 206(4)–3 to address potential areas of conflict with proposed rule 206(4)–5. We do not believe that this technical amendment affects the costs associated with the rulemaking. It will benefit advisers because it provides clarity about the application of our rules when they potentially overlap.

[447] Proposing Release, at section III.C.

[448] MSRB Letter. *See also* Thompson Letter; Common Cause Letter; Fund Democracy/Consumer Federation Letter (each identifying benefits of the rule).

[449] *See, e.g.,* Davis Polk Letter (generally commenting that any benefits of the proposed rule were outweighed by its likely costs). *See also* ICI Letter; Monument Group Letter.

Commission underestimated the costs of compliance with the rule and rule amendments.[450] As discussed below, many of the commenters that did comment specifically on the costs and benefits of the proposal did not provide empirical data to support their views.

A. Benefits

As we discuss extensively throughout this Release, we expect that rule 206(4)-5 will yield several important direct and indirect benefits. Overall, the rule is intended to address pay to play relationships that interfere with the legitimate process by which advisers are chosen based on the merits rather than on their contributions to political officials. The potential for fraud to invade the various, intertwined relationships created by pay to play arrangements is without question. We believe that rule 206(4)-5 will reduce the occurrence of fraudulent conduct resulting from pay to play and thus will achieve its goals of protecting public pension plans, beneficiaries, and other investors from the resulting harms. One commenter who agreed with us commended the proposed rule as a "strong start in controlling corruption, balancing the rights of the advisors and their executives with the very real detriment to the public which the numerous cases of pay-to-play involving public pension funds and other public entities have caused."[451]

Addressing pay to play practices will help protect public pension plans and investments of the public in government-sponsored savings and retirement plans and programs by addressing situations in which a more qualified adviser may not be selected, potentially leading to inferior management, diminished returns or greater losses. One commenter who agreed, observed, "[w]hen lucrative investment contracts are awarded to those who pay to play, public pension funds may end up receiving substandard services and higher fees, resulting in lower earnings."[452] One public official commenter detailed the role of pay to play arrangements in the selection of public pension fund managers and the harm it can inflict on the affected plans,[453] while other officials wrote to us explicitly expressing support for a Commission rule.[454] By addressing pay to play practices, we will help level the playing field so that the advisers selected to manage retirement funds and other investments for the public are more likely to be selected based on the quality of their advisory services. These benefits, although difficult to quantify, could result in substantial savings and better performance for the public pension plans, their beneficiaries, and participants.[455] Two commenters noted that the rule would promote the interests of plan beneficiaries.[456]

By leveling the playing field among advisers competing for State and local government business, the rule will help minimize or eliminate manipulation of the market for advisory services provided to State and local governments.[457] For example, direct political contributions or payments made to third-party solicitors as part of pay to play practices create artificial barriers to competition for firms that cannot, or will not, make those contributions or payments.[458] They also increase costs for firms that may feel they have no alternative but to pay to play. The rule addresses a collective action problem created by this dynamic analogous to the one identified in the *Blount* opinion.[459] One commenter emphasized the importance of restoring public confidence in the investment activities of all public pension funds.[460] Indeed, at its core, the rulemaking addresses practices that undermine the integrity of the market for advisory services, as underscored by another commenter.[461]

Allocative efficiency is enhanced when government clients award advisory business to advisers that compete based on price, performance and service and not the influence of pay to play, which in turn enables advisory firms, particularly smaller advisory firms, to compete on merit, rather than their ability or willingness to make contributions.[462] In addition, taking into account the effects of analogous practices in the underwriting of municipal securities prior to MSRB rule G–37,[463] we believe a merit-based competitive process may result in the allocation of public pension monies to different advisers who may well deliver better investment performance and lower advisory fees than those advisers

[450] *See, e.g.,* SIFMA Letter ("While SIFMA believes that addressing practices that potentially undermine the merit-based selection of investment advisers is an important and laudable effort, the SEC appears to have underestimated the compliance costs the Proposed Rule will impose on covered parties."); ICI Letter ([I]n relying on the estimates for compliance with the MSRB rules, the Commission significantly underestimates the compliance and recordkeeping burdens associated with the proposed rule."); Davis Polk Letter ("We believe that the Commission may have substantially underestimated the number of investment advisers that will be affected by the Proposed Rule and its costs and market effects in concluding that many of the aspects of the Rule would impose only minimal additional costs and burdens on investors and investment advisers."). The commenters who addressed our estimates, however, did so in general terms and did not provide specific suggestions as to how they should be modified. See the discussion below regarding changes from the proposed rule that we believe mitigate some of the costs.

[451] Common Cause Letter.

[452] Bloomberg Letter.

[453] Weber Letter ("I have seen money managers awarded contracts with our fund which involved payments to individuals who served as middlemen, creating needless expense for the fund. These middlemen were political contributors to the campaigns of board members who voted to contract for money management services with the companies who paid them as middlemen."). *See also* Pohndorf Letter (noting that when the sole trustee of a major pension fund changed several years ago, a firm managing some of the fund's assets "began to receive invitations to fundraising events for the new trustee with suggested donation amounts"); Tobe Letter (suggesting the negative effects of pay to play activities on the Kentucky Retirement System's investment performance).

[454] *See, e.g.,* DiNapoli Letter; Bloomberg Letter.

[455] According to the most recently available US census data, as of 2008, there are 2,550 State and local government employee retirement systems. *http://www.census.gov/govs/retire/*. *See also* Fund Democracy/Consumer Federation Letter ("These practices adversely affect the economic interests of millions of America's public servants.").

[456] Comment Letter of John C. Emmel (Sept. 18, 2009) ("one more step to foster a level playing field for investors * * * where advisors' priorities trump those of the investing public"); Comment Letter of George E. Kozel (Aug. 31, 2009) ("Kozel Letter") ("Their interests lie in obtaining the highest fees not in producing benefits for the pensioners. * * *").

[457] *See* DiNapoli Letter (advocating for a "level playing field for investors and investment advisers that protects the integrity of the decision-making process [for hiring an investment adviser]"); Bloomberg Letter ("Pay to play practices clearly undermine the open competitive process by which government contracts are to be awarded.").

[458] *See supra* note 453.

[459] *See Blount,* 61 F.3d at 945–46 (discussing the harms of pay to play: "Moreover, there appears to be a collective action problem tending to make the misallocation of resources persist."). *See also* text accompanying notes 291–294 of this release. Collective action problems are a class of market failures calling for a regulatory response, and exist, for example, where participants may prefer to abstain from an unsavory practice (such as pay to play), but nonetheless participate out of concern that, even if they abstain, their competitors will continue to engage in the practice profitably and without adverse consequences.

[460] Thompson Letter. *See also* Bloomberg Letter.

[461] Common Cause Letter ("Pay-to-play has not only the potential to compromise an investment adviser's ethical and legal duties under the Investment Advisers Act of 1940, but in several high profile cases across the nation, has already done so, negatively impacting the public perception of government decision making and, in some cases, costing the taxpayer millions of dollars and placing billions of dollars in pension funds at risk."). *See also* Dempsey Letter (noting applause for efforts "to stop the 'pay-to-play' practice which only serves to undermine public trust in investment advisors and regulators").

[462] *See* Comment Letter of Budge Collins (Sept. 30, 2009) (the rule would "level the playing field for the rest of us who have never made contributions to elected officials who sit on investment management committees").

[463] One commenter cited a study containing evidence that before rule G–37 was adopted, underwriters' pay to play practices distorted underwriting fees as well as which firms were hired by government issuers. *See* Butler Letter.

whose selection was influenced by pay to play.

As adopted, the rule contains a prohibition against advisers directly or indirectly compensating a third party to solicit government entities on its behalf, unless the third-party solicitor is a "regulated person" subject to pay to play restrictions. This exception enables advisers and pension plans (and their beneficiaries) to continue to benefit from the services of third-party solicitors, such as the placement of interests in private funds, while at the same time benefitting from a Commission rule that prohibits pay to play practices.[464]

Our rule may also benefit pension plans by preventing harms that can result when an adviser is not negotiating at arm's length with a government official. For example, as a result of pay to play, an adviser may obtain greater ancillary benefits, such as "soft dollars," from the advisory relationship, which may be directed for the benefit of the adviser, potentially at the expense of the pension plan, thereby using a pension plan asset for the adviser's own purposes.[465] Additionally, taxpayers may benefit from our rule because they might otherwise bear the financial burden of bailing out a government pension fund that has ended up with a shortfall due to poor performance or excessive fees that might result from pay to play.[466]

In addition to the general benefits of addressing pay to play practices by investment advisers noted above, we believe the specific provisions of the rule, including the two-year time out, the ban on using third parties to solicit government business, and the restrictions on soliciting and coordinating contributions and payments will likely result in similar benefits to those that have resulted from MSRB rules G–37 and G–38, on which our rule is closely modeled. The MSRB rules have prohibited municipal securities dealers from participating in pay to play practices since 1994.[467] As we have stated previously, we believe these rules have significantly curbed pay to play practices in the municipal securities market, and are likely to be similarly effective in deterring pay to play activities by investment advisers.[468]

Applying the rule to government entity investments in certain pooled investment vehicles or where a pooled investment vehicle is an investment option in a government-sponsored plan or program will extend the same benefits regardless of whether an adviser subject to the rule is providing advice directly to the government entity or is managing assets for the government entity indirectly through a pooled investment vehicle. By addressing distortions in the process by which investment decisions are made regarding public investments, we are providing important protections to public pension plans and their beneficiaries, as well as participants in other important plans or programs sponsored by government entities. Other investors in a pooled investment vehicle also will be better protected from, among other things, the effects of fraud that may result from an adviser's participation in pay to play activities, such as higher advisory fees.

Finally, the amendments to rule 204–2 will benefit the public plans and their beneficiaries and participants in State plans or programs as well as investment advisers that keep the required records. The public pension plans, beneficiaries, and participants will benefit from these amendments because the records required to be kept will provide Commission staff with information to review an adviser's compliance with rule 206(4)-5 and thereby may promote improved compliance. Advisers will benefit from the amendments to the recordkeeping rule as these records will assist the Commission in enforcing the rule against, for example, a competitor whose pay to play activities, if not uncovered, could adversely affect the competitive position of a compliant adviser.

B. Costs

We acknowledge that the rule and rule amendments will impose costs on advisers that provide or seek to provide advisory services to government clients directly, or indirectly through pooled investment vehicles. We discuss these costs below, along with a number of modifications we have made to the proposed rule and proposed amendments that will reduce costs.

1. Compliance Costs Related to Rule 206(4)–5

Rule 206(4)–5 requires an adviser with government clients to incur costs to monitor contributions made by the adviser and its covered associates and to establish procedures to comply with the rule. The initial and ongoing compliance costs imposed by the rule will vary significantly among firms, depending on a number of factors. Our estimated compliance costs, discussed below, take into account different ways a firm might comply with the rule. These factors include the number of covered associates of the adviser, the degree to which compliance procedures are automated (including policies and procedures that could require pre-clearance), the extent to which an adviser has a pre-existing policy under its code of ethics or compliance program,[469] and whether the adviser is affiliated with a broker-dealer firm that is subject to MSRB rules G–37 and G–38. A smaller adviser, for example, will likely have a small number of covered associates, and thus expend less resources to comply with the rule and rule amendments than a larger adviser.

Although a larger adviser is likely to spend more resources to comply with the rule, based on staff observations, a larger adviser is more likely to have an affiliated broker-dealer that is required to comply with MSRB rules G–37 and G–38.[470] As we learned from a broker-

[464] Commenters, both on the Proposing Release and our 1999 proposal, argued that treating third-party solicitors as covered associates would create significant compliance challenges because these solicitors were not controlled by advisers. *See supra* note 264 and accompanying text.

[465] *See supra* note 55 and accompanying text.

[466] *See* Kozel Letter (supporting the Commission's proposal and asserting that the persons who engage in pay to play practices know that any shortfalls would be covered by taxpayers); Bloomberg Letter ("Because the City is legally obligated to make up any short fall in the pension system assets to ensure full payment of pension benefits, pay to play practices can potentially harm all New Yorkers."). *See also* Common Cause Letter; 1997 Survey, *supra* note 8 ("[t]he investment of plan assets is an issue of immense consequence to plan participants, taxpayers, and to the economy as a whole" as a low rate of return will require additional funding from the sponsoring government, which "can place an additional strain on the sponsoring government and may require tax increases").

[467] MSRB rule G–37 was approved by the Commission and adopted by the MSRB in 1994. *See supra* note 66.

[468] *See supra* notes 101–107 and accompanying text.

[469] One commenter stated that many investment advisers already have pay to play policies and procedures in place within the framework of their codes of ethics. *See* IAA Letter (advocating for regulation that would address pay to play practices through an adviser's code of ethics, as an alternative to the approach taken in proposed rule 206(4)-5).

[470] According to registration information available from Investment Adviser Registration Depository ("IARD") as of April 1, 2010, there are 1,332 SEC-registered investment advisers (or 11.48% of the total 11,607 registered advisers) that indicate in Item 5.D.(9) of Form ADV that they have State or municipal government clients. Of those 1,332 advisers, 113 (or 85.0%) of the largest 10% have one or more affiliated broker-dealers or are, themselves, also registered as a broker-dealer. 204 of the largest 20% (or 76.7%) have one or more affiliated broker-dealers or are, themselves, also registered as a broker-dealer. Conversely, only 40 (or 30.1%) of the smallest 10% have one or more affiliated broker-dealers or are, themselves, also registered as a broker-dealer; and only 67 of the smallest 20% (or 25.2%) have one or more affiliated broker-dealers or are, themselves, also registered as a broker-dealer. With respect to broker-dealer affiliates, however, we note that our IARD data does not indicate whether the affiliated broker-dealer is a municipal securities dealer subject to MSRB rules

dealer with an investment adviser affiliate that commented on our 1999 proposal, "the more the Rule mirrors G–37, the more firms can borrow from or build upon compliance procedures already in place. * * *"[471] Accordingly, we believe some advisers with broker-dealer affiliates may spend fewer resources to comply with the rule and rule amendments. We recognize, as some commenters pointed out, that MSRB rules G–37 and G–38 compliance systems may not be easily extensible in all cases, and we acknowledge that the range of efficiencies created in these circumstances will vary.[472] A prominent concern of these commenters related to a proposed recordkeeping amendment which would have required advisers to keep records of solicitations—something that is not required under MSRB recordkeeping rule G–8. As previously discussed, we are not adopting that proposed amendment, which may address the concern noted by commenters.

We anticipate that advisory firms subject to rule 206(4)-5 will develop compliance procedures to monitor the political contributions made by the adviser and its covered associates.[473] We estimate that the costs imposed by the rule will be higher initially, as firms establish and implement procedures and systems to comply with the rule and rule amendments. We expect that compliance expenses would then decline to a relatively constant amount in future years, and annual expenses are likely to be lower for small advisers as the systems and processes should be less complex than for a large adviser.

We estimate that approximately 1,697 investment advisers registered with the Commission may be affected by the rule and rule amendments.[474] Of the 1,697 advisers, we estimate that approximately 1,271 advisers have fewer than five covered associates that would be subject to the rule (each, a "smaller firm"); approximately 304 advisers have between five and 15 covered associates (each, a "medium firm"); and approximately 122 advisers have more than 15 covered associates that would be subject to the prohibitions of the rule (each, a "larger firm").[475]

One commenter disagreed with us basing our cost estimates on an assumption that most registered advisers would have fewer than five covered associates because the commenter expects most advisers to require all or most of their employees to receive approval prior to making any political contributions in order to avoid inadvertently triggering the rule.[476] Although the rule does not require this approach and the changes we have made to the rule (*e.g.,* modified definition of covered associate) should help address the concerns of this commenter that led to the assertion, we recognize that some advisers may voluntarily restrict all of their employees' political contributions in such a manner. This type of pre-screening process could be perceived by the individuals subject to them as costs imposed on their ability to express their support for certain candidates for elected office and government officials. We also received a comment that our estimates should take into account turnover of personnel.[477] Our cost estimate assumes a certain level of turnover; although these categories are based on an adviser's number of covered associates, we have not calculated per-covered associate costs associated with this rulemaking. The categories of smaller, medium and larger advisers are based on an estimated number of covered associates, but are not intended to represent a static population of covered associates within each category. For instance, in estimating the ongoing burdens on advisers to comply with the rule, we implicitly incorporated a greater degree of turnover at larger advisers in estimating that they would incur 1,000 hours annually as compared to the estimated 10 hours for a small adviser.

Advisers that are unregistered in reliance on the exemption available under section 203(b)(3) of the Advisers Act [15 U.S.C. 80b–3(b)(3)] would be subject to rule 206(4)–5.[478] Based on our review of registration information on IARD and outside sources and reports, we estimate that there are approximately 2,000 advisers that are unregistered in reliance on section 203(b)(3).[479] Applying the same

G–37 and G–38. Also, as one commenter asserted, private fund managers may be among the larger advisers, based on assets under management, but they are unlikely to have an affiliated broker-dealer that has already adopted similar procedures to comply with MSRB rules G–37 and G–38 because most private fund managers are not involved in municipal underwriting. MFA Letter. We acknowledge that a private fund manager generally would be less likely to have an affiliated broker-dealer from which it can borrow or build upon compliance procedures; however, we also expect that a private fund manager would use less resources than other large registered advisers to comply with the rule because a private fund manager is not subject to rule 206(4)–7, the Advisers Act compliance rule, and would likely have fewer employees and covered associates than a larger organization.

[471] Comment Letter of US Bancorp Piper Jaffray Inc. (now, "Piper Jaffray & Co.") (Nov. 15, 1999).

[472] SIFMA Letter. *See also* ICI Letter.

[473] Investment advisers registered with the Commission are required to adopt and implement policies and procedures reasonably designed to prevent violation by the adviser or its supervised persons of the Advisers Act and the rules the Commission has adopted thereunder. *See* rule 206(4)–7.

[474] This estimate is based on registration information from IARD as of April 1, 2010, applying the same methodology as in the Proposing Release. As previously noted, according to responses to Item 5.D(9) of Part 1 of Form ADV, 1,332 advisers have clients that are State or municipal government entities, which represents 11.48% of all advisers registered with us. 10,275 advisers have not responded that they have clients that are State or municipal government entities. Of those, however, responses to Item 5.D(6) of Part 1 of Form ADV indicate that 2,486 advisers have some clients that are other pooled investment vehicles. Estimating that the same percentage of these advisers advise pools with government entity investors as advisers that have direct government entity clients—*i.e.,*11.48%. 285 of these advisers would be subject to the rule (2,486 × 11.48% = 285). Out of the 10,275 that have not responded that they have clients that are State or municipal government entities, after backing out the 2,486 which have clients that are other pooled investment vehicles, responses to Item 5.D(4) of Part 1 of Form ADV indicate that 699 advisers have some clients that are registered investment companies. Estimating that roughly the same percentage of these advisers advise pools with government entity investors as advisers that have direct government entity clients—*i.e.,*11.48%. 80 of these advisers would be subject to the rule (699 × 11.48% = 80). Although we limited the application of rule 206(4)–5 with respect to registered investment companies to those that are investment options of a plan or program of a government entity, we continue to estimate that 80 advisers would have to comply with the recordkeeping provisions because of the difficulty in further delineating this estimated number. Therefore, we estimate that the total number of advisers subject to the rule would be: 1,332 advisers with State or municipal clients + 285 advisers with other pooled investment vehicle clients + 80 advisers with registered investment company clients = 1,697 advisers subject to rule. We expect certain additional advisers may incur compliance costs associated with rule 206(4)–5. We anticipate some advisers may be subject to the rule because they solicit government entities on behalf of other investment advisers. Additionally, some advisers that do not currently have government clients may seek to obtain them in the future. In doing so, they likely would conduct due diligence to confirm they would not be prohibited from receiving compensation for providing investment advisory services to the government client.

[475] This estimate is based on registration information from IARD as of April 1, 2010. These estimates are based on IARD data, specifically the responses to Item 5.B.(1) of Form ADV, that 997 (or 74.9%) of the 1,332 registered investment advisers that have government clients have fewer than five employees who perform investment advisory functions, 239 (or 17.9%) have five to 15 such employees, and 96 (or 7.2%) have more than 15 such employees. We then applied those percentages to the 1,697 advisers we believe will be subject to the proposed rule for a total of 1,271 smaller, 304 medium and 122 larger firms.

[476] *See* MFA Letter.

[477] ICI Letter.

[478] The amendments to rules 204–2 and 206(4)–3, however, only apply to advisers that are registered, or required to be registered, with the Commission.

[479] This number is based on our review of registration information on IARD as of April 1, 2010, IARD data from the peak of hedge fund adviser registration in 2005, and a distillation of

Continued

principles we used with respect to registered investment advisers, we estimate that 230 of those advisers manage pooled investment vehicles in which government client assets are invested and would therefore be subject to the rule.[480] For purposes of this analysis, it is assumed that each unregistered advisory firm that would be subject to the rule would either be a smaller firm or a medium firm in terms of number of covered associates because it is unlikely that an adviser that operates outside of public view and is limited to fewer than 15 clients[481] would have a large number of advisory personnel that would be covered associates. One commenter agreed that most of these unregistered advisers would be small, although the commenter based its assessment on assets under management, not on the adviser's likely number of covered associates.[482]

Some commenters asserted that our estimated number of advisers subject to the proposed rule was too low.[483] One claimed that the number of advisory firms exempted from registration in reliance on Section 203(b)(3) may be "over two times our estimate," but provided statistics about the number of unregistered pooled investment vehicles, not the number of advisers to those pools.[484] Other commenters did not provide empirical data or suggest alternative formulas by which to recalculate our estimate. Additionally, another seemed to misunderstand our estimates.[485]

As we stated in the Proposing Release,[486] although the time needed to comply with the rule will vary significantly from adviser to adviser, as discussed in detail below, the Commission staff estimates that firms with government clients will spend between 8 hours and 250 hours to establish policies and procedures to comply with the rule. Commission staff further estimates that ongoing compliance with the rule will require between 10 and 1,000 hours annually. In addition, advisory firms may incur one-time costs to establish or enhance current systems to assist in their compliance with the rule. These costs would vary widely among firms. Small advisers may not incur any system costs if they determine a system is unnecessary due to the limited number of employees they have or the limited number of government entity clients they have. Large firms likely already have devoted significant resources into automating compliance and reporting and the new rule could result in enhancements to these existing systems. We believe such system costs could range from the tens of thousands of dollars for simple reporting systems, to hundreds of thousands of dollars for complex systems used by the large advisers.

Initial compliance procedures would likely be designed, and ongoing administration of them performed, by compliance managers and compliance clerks. We estimate that the hourly wage rate for compliance managers is $294, including benefits, and for compliance clerks, $59 per hour, including benefits.[487] To establish and implement adequate compliance procedures, we estimate that the rule would impose initial compliance costs of approximately $2,352 per smaller firm,[488] approximately $29,407 per medium firm,[489] and approximately $58,813 per larger firm.[490] It is estimated that the rule would impose annual, ongoing compliance expenses of approximately $2,940 per smaller firm,[491] $117,625 per medium firm,[492] and $235,250 per larger firm.[493]

In establishing these estimates, which are calculated in the same manner as those we included in the Proposing Release, we took into consideration comments in 1999 that suggested our cost estimates were too low.[494] Our staff, in developing the estimates contained in the Proposing Release, also engaged in conversations with industry professionals regarding broker-dealer compliance with rules G–37 and G–38 and representatives of investment advisers that have pay to play policies in place.[495] We significantly increased our cost estimates from the 1999 proposal as a result. Some commenters on the proposed rule asserted that our projected costs are too low, but did not provide empirical data or formulas for us to review.[496] One commenter indicated that, "as a practical matter, although there may be significant differences in the number of hours dedicated to ongoing annual compliance between firms of different sizes, the estimated number of hours needed to develop initial compliance procedures will be similar for all firms, regardless of size. The initial effort of designing and implementing new policies and procedures and educating personnel will require similar effort and upfront fixed costs."[497] We disagree. Although there are some aspects of implementing

numerous third-party sources including news organizations and industry trade groups.

[480] 11.48% of 2000 is 230. *See supra* note 474.

[481] *See* section 203(b)(3) of the Advisers Act [15 U.S.C. 80b–3(b)(3)] (advisers who rely on this exception from registration must have fewer than 15 clients in a 12-month period) .

[482] 3PM Letter.

[483] *See* Davis Polk Letter; MFA Letter; 3PM Letter.

[484] 3PM Letter. *See also* Davis Polk Letter (citing to 3PM Letter on this proposition).

[485] Davis Polk Letter (suggesting that we failed to take into account the costs likely to be borne by unregistered investment advisers). *See supra* notes 479 and 480 and accompanying text; Proposing Release, nn.219–20 and accompanying text (providing an estimate of the number of unregistered advisers we expect to be subject to this rule, and that must develop compliance systems).

[486] *See* Proposing Release, at section III.B.

[487] Our hourly wage rate estimate for a compliance manager and compliance clerk is based on data from the *Securities Industry Financial Markets Association's Management & Professional Earnings in the Securities Industry 2009,* modified by Commission staff to account for an 1800-hour work-year and multiplied by 5.35 (in the case of compliance managers) or 2.93 (in the case of compliance clerks) to account for bonuses, firm size, employee benefits and overhead. The calculations discussed in this release are updated from those included in the Proposing Release to incorporate data from the most recently updated version of this publication.

[488] The per firm cost estimate is based on our estimate that development of initial compliance procedures for smaller firms would take 8 hours of compliance manager time (at $294 per hour). Accordingly, the per firm cost estimate is $2,352 (8 × $294).

[489] With respect to our estimated range of 8–250 hours, we assume a medium firm would take 125 hours to develop initial compliance procedures, and such a firm would likely have support staff. We also anticipate that a compliance manager would do approximately 75% of the work because he or she is responsible for implementing the policy for the entire firm. Accordingly, the per firm cost estimate is based on our estimate that development of initial compliance procedures for medium firms would take 93.75 hours of compliance manager time, at $294 per hour (or $27,563), and 31.25 hours of clerical time, at $59 per hour (or $1,844), for a total estimated cost of $29,407.

[490] With respect to our estimated range of 8–250 hours, we assume a larger firm would take 250 hours to develop initial compliance procedures, and such a firm would likely have support staff. We also anticipate that a compliance manager would do approximately 75% of the work because he/she is responsible for implementing the policy for the entire firm. Accordingly, the per firm cost estimate is based on our estimate that development of initial compliance procedures for larger firms would take 187.50 hours of compliance manager time, at $294 per hour (or $55,125), and 62.5 hours of clerical time, at $59 per hour (or $3,688), for a total estimated cost of $58,813.

[491] The per firm cost estimate is based on our estimate that ongoing compliance procedures for smaller firms would take 10 hours of compliance manager time, at $294 per hour, for a total estimated cost of $2,940 per year.

[492] The per firm cost estimate is based on our estimate that ongoing compliance procedures for medium firms would take 375 hours of compliance manager time, at $294 per hour (or $110,250), and 125 hours of clerical time, at $59 per hour (or $7,375), for a total estimated cost of $117,625 per year.

[493] The per firm cost estimate is based on our estimate that ongoing compliance procedures for larger firms would take 750 hours of compliance manager time, at $294 per hour (or $220,500) and 250 hours of clerical time, at $59 per hour (or $14,750), for a total cost of $235,250 per year.

[494] *See* Proposing Release, at n.226 and accompanying text.

[495] *Id.* at section III.B.

[496] *See, e.g.,* ICI Letter; MFA Letter; SIFMA Letter.

[497] *See* Davis Polk Letter.

a compliance program that would be similar among all firms regardless of their number of covered associates, we expect most costs will vary significantly among firms of different sizes as they engage in such activities as developing and monitoring reporting mechanisms to track covered associate contributions, revising their codes of ethics, training their employees, and performing routine quality control tests.

In the Proposing Release, we estimated that 75% of larger advisory firms, 50% of medium firms, and 25% of smaller firms that are subject to the rule may also engage outside legal services to assist in drafting policies and procedures, based on staff observations. In addition, we also estimated the cost associated with such an engagement would include fees for approximately three hours of outside legal review for a smaller firm, 10 hours for a medium firm, and 30 hours for a larger firm. One commenter suggested that we had underestimated both the percentage of advisers that would engage outside counsel and the number of hours that outside counsel would spend lending their assistance, but did not provide alternative estimates.[498] Based on our staff's experience administering the compliance program rule, we continue to believe that our estimates for the number of firms that will retain outside counsel for review of policies and procedures are appropriate. Based on this comment, however, we have revisited the number of hours we estimated outside counsel would spend reviewing policies and procedures and have increased these estimates. We now estimate the cost associated with such an engagement would include fees for approximately eight hours of outside legal review for a smaller firm, 16 hours for a medium firm, and 40 hours for a larger firm, at a rate of $400 per hour.[499] Consequently, for a smaller firm we estimate a total of $3,200 in outside legal fees for each of the estimated 318 advisers that would seek assistance, for a medium firm we estimate a total of $6,400 for the estimated 152 advisers that would seek assistance, and for each of the 92 larger firms we estimate a total of $16,000. Thus, we estimate that approximately 562 investment advisers will incur these additional costs, for a total cost of $3,462,400[500] among advisers affected by the rule amendments.[501]

One commenter suggested that, due to the complexity of, and variation among, State and local laws, it might be more difficult than we had accounted for in the proposal for an adviser to determine with certainty who could be a covered official, and as a result, a greater number of advisers would seek the help of outside counsel to make this determination than we estimated.[502] Although the commenter did not provide an estimate of how many firms might seek such assistance, we believe that the additional guidance we have provided in the discussion of officials will address this commenter's concerns and result in fewer consultations with outside counsel than anticipated. In addition, it is our understanding from discussions with those involved in advising on compliance with MSRB rules G–37 and G–38 that a small percentage of persons subject to the rule seek legal assistance to make these determinations. Our rule uses substantially similar definitions of "official" of a "government entity" to those used in the MSRB rules; therefore we expect that the percentage of advisory firms that would retain legal counsel to make these determinations would be similarly small. Moreover, we anticipate that the advisers that are most likely to need assistance identifying officials of government entities are larger advisers, whose businesses tend to be national in scope and whose clients are located throughout the country. If all 122 of the larger advisory firms we estimate are subject to the rule retain legal counsel at a rate of $400 per hour, for approximately 20 hours per year, those advisers would incur an estimated total of $976,000 in legal fees.[503]

In the Proposing Release, we estimated that approximately five advisers annually would apply to the Commission for an exemption from the rule, based on staff discussions with the FINRA staff responsible for reviewing exemptive applications submitted under MSRB rule G–37, and that outside counsel would spend 16 hours preparing and submitting an application. We received criticism that these approximations were too low.[504] Given that the advisory industry is much larger than the municipal securities industry, and in light of the number of comment letters we received that expressed concern about inadvertent violations of the rule that would not qualify for the exception for returned contributions, our staff estimates that approximately seven advisers annually would apply to the Commission for an exemption from the rule. Although we may initially receive more than seven applications a year for an exemption, over time, we expect the number of applications we receive will significantly decline to an average of approximately seven annually. We continue to believe that a firm that applies for an exemption will hire outside counsel to prepare an exemptive request, but based on commenters concerns have raised the number of hours counsel will spend preparing and submitting an application from 16 hours to 32 hours, at a rate of $400 per hour.[505] As a result, each application will cost approximately $12,800, and the total estimated cost for seven applications annually will be $89,600.

2. Other Costs Related to Rule 206(4)–5

The prohibitions of the rule may also impose other costs on advisers, covered associates, third-party solicitors, and political officials.

(a) Two-Year Time Out

An adviser that becomes subject to the prohibitions of the rule would no longer be eligible to receive advisory fees from its government client. This would result in a direct loss to the adviser of revenues and profits relating to that government client, although another adviser that the government client subsequently chose to retain would see an increase in revenues and profits. The two-year time out could also limit the number of advisers able to provide services to potential government entity clients. An adviser that triggers the two-year time out may be obligated to provide (uncompensated) advisory services for a reasonable period of time until the government client finds a successor to ensure its withdrawal did not harm the client, or the contractual arrangement between the adviser and the government client might obligate the adviser to continue to perform under the contract at no fee. An adviser that

[498] *Id.*

[499] In the Proposing Release we estimated the hourly cost of outside counsel to be $400 based on our consultation with advisers and law firms who regularly assist them in compliance matters. We did not receive comment on this estimate and continue to believe that it is an accurate estimate.

[500] (318 × $3,200 = $1,017,600) + (152 × $6,400 = $972,800) + (92 × $16,000 = $1,472,000) = $3,462,400.

[501] One commenter asserted that a greater number of firms would seek assistance of counsel, regardless of size, but did not provide data to support its assertion. Davis Polk Letter.

[502] Caplin & Drysdale Letter. *See also* IAA Letter; MFA Letter.

[503] $400 × 20 = $8,000, and $8,000 × 122 = $976,000.

[504] *See* Davis Polk Letter; ICI Letter.

[505] The hourly cost estimate of $400 is based on our consultation with advisers and law firms who regularly assist them in compliance matters.

provides uncompensated advisory services to a government client would, at a minimum, incur the direct cost of providing uncompensated services, and may incur opportunity costs if the adviser is unable to pursue other business opportunities for a period of time.

Advisers to government clients, as well as covered associates of the adviser, also may be less likely to make contributions to government officials, including candidates, potentially resulting in less funding for these officials. Under the rule, advisers and covered associates will be subject to new limitations on the amounts and to whom they can contribute without triggering the rule's time out provision. In addition, these same persons will be prohibited from soliciting others to contribute or from coordinating contributions to government officials, including candidates, or payments to political parties in certain circumstances. These limitations and prohibitions, including if a firm chooses to adopt policies or procedures that are more restrictive than the rule, could be perceived by the individuals subject to them as costs imposed on their ability to express their support for certain candidates for elected office and government officials.[506] In addition to these costs, the rule's impact on advisers' and employees' contributions will introduce some inefficiency into the allocation of contributions to candidates and officials as the rule impacts contributions regardless of whether they are being made for the purpose of engaging in pay to play.

We have made several modifications to the rule from the proposal that will reduce these costs or burdens. We are creating a new exception to the two-year time out for contributions made by a natural person more than six months prior to becoming a covered associate unless he or she, after becoming a covered associate, solicits clients on behalf of the investment adviser.[507] This modification will decrease the burdens on both employees and employers in terms of tracking and limiting employee contributions prior to becoming employed or promoted by an investment adviser. In terms of narrowing the scope of "covered investment pools," we included a registered investment company in the definition of covered investment pool, for purposes of all three of the rule's pay to play prohibitions, only if it is an investment option of a plan or program of a government entity.[508] As noted above, we believe this approach strikes the right balance between applying the rule in those contexts in which advisers to registered investment companies are more likely to engage in pay to play conduct while recognizing the compliance challenges and costs that may result from a broader application of the rule. We are also broadening the exception to the rule's time out provision in several respects that should further decrease the compliance costs associated with the two-year time out and will lower any perceived costs on covered associates' ability to express their support for candidates. We are increasing the aggregate contribution amount eligible for the exception for certain returned contributions from $250 to $350 to any one official per election,[509] and we are increasing the number of times an adviser is permitted to rely on the returned contributions exception from two to three per calendar year for advisers with more than 50 employees.[510] Furthermore, we are making the same adjustment from $250 to $350 for contributions eligible for the *de minimis* exception,[511] and we are adopting a *de minimis* exception for contributions not exceeding $150 made by individuals who are not entitled to vote for the candidate.[512]

Several commenters highlighted the costs of the two-year time out to the adviser and government entity client, as well as pension fund beneficiaries, stating that the time out could force termination of long-standing relationships and may result in a permanent termination of the advisory relationship.[513] We acknowledge that advisers subject to the time out may lose a government client's business beyond the two-year period and are sensitive to the concerns of commenters regarding the operation of the rule on public pension funds, including the burdens they may face in replacing managers and the possibility that some managers may no longer seek to manage public plan assets as a result of the rule. We believe that these costs are necessary to accomplish our goal of addressing pay to play and are justified by the benefits of rule 206(4)–5. As discussed above, rule 206(4)–5 is modeled on the pay to play rules adopted by the MSRB, which have significantly curbed pay to play practices in the municipal securities market. We believe that adopting a two-year time out similar to the time out applicable under the MSRB rules is appropriate, and that the fiduciary relationship advisers have with public pension plans argues for a strong prophylactic rule. Finally, while we have designed the rule to reduce its impact,[514] investment advisers are best positioned to protect government clients by developing and enforcing robust compliance programs designed to prevent contributions from triggering the two-year time out.

Commenters also noted, particularly, the potential harm of the two-year time out to government clients and to other investors in a fund that holds illiquid securities when a government investor redeems its interests in the fund as a result of the fund adviser's triggering contribution.[515] As we note above, however, our rule does not require an adviser that has triggered the time out to redeem the interests of a government investor or cancel its commitment. The adviser may have multiple options available from which to select to comply with the rule in light of its fiduciary obligations and the disclosure it has made to investors. The adviser could instead comply with the rule by waiving or rebating the portion of its fees or any performance allocation or carried interest attributable to the government client.[516]

Most of the comments we received about the costs of this aspect of the proposed rule, however, focused on the costs of an inadvertent violation.[517] We understand that there will be costs, sometimes quite significant, as a result

[506] One commenter suggested that the proposed rule would inhibit individuals who work for an investment adviser from running for office because, if they were successful, it may cost their former employer business. Caplin & Drysdale Letter. We have addressed this comment by making it clear that an individual can contribute to his or her own campaign without triggering the rule. *See supra* note 139.

[507] Rule 206(4)–5(b)(2).

[508] Rule 206(4)–5(f)(3) and (f)(8).

[509] Rule 206(4)–5(b)(3).

[510] *Id.*

[511] Rule 206(4)–5(b)(1).

[512] *See id.*

[513] *See, e.g.,* ICI Letter ("[E]xisting State and local government clients may be harmed by the forced termination of a mutually beneficial business relationship, despite receiving free services for a period of time, because the government client is subject to the costs associated with selecting a new adviser, and plan beneficiaries are subject to the costs associated with portfolio commissions and other restructuring costs. Consequently, our members believe that the two-year ban will operate as a permanent ban because a government entity will be unlikely to go through the process of identifying and hiring a replacement adviser, and then return to the original adviser after the ban ends."). *See also* IAA Letter; NASP Letter; SIFMA Letter.

[514] *See, e.g.,* section II.B.2(a)(6) of this Release (discussing the *de minimis* exceptions to the two-year time out); section II.B.2(f) of this Release (discussing the rule's exemptive provision).

[515] CT Treasurer Letter; NY City Bar Letter.

[516] *See supra* note 385 and accompanying text.

[517] *See, e.g.,* IAA Letter ("We are concerned that the Commission has not considered the significance of the sanctions imposed as a result of an adviser's inadvertent violation of the rule.").

of inadvertent violations. However, with these potential costs in mind, we have taken additional steps to decrease the likelihood of inadvertent violations of the rule. First, as discussed above, we shortened the look back with respect to most covered associates. We expect this new exception will provide an additional mechanism for advisers to avoid the cost of a time out as a result of an inadvertent violation and will largely address commenters' concerns about the screening burdens for new or promoted employees that this aspect of the proposal would have imposed on advisers.[518] Second, as discussed above, we are increasing to $350 the amount eligible for an exception for certain returned contributions from what we had proposed, we are increasing the number of times an adviser is permitted to rely on the returned contributions exception, and we are also adopting an additional *de minimis* exception for certain contributions not exceeding $150. Last, we note that an adviser's implementation of a strong compliance program will reduce the likelihood, and therefore costs, of inadvertent violations.

One commenter asserted that the proposed rule would put advisers at a competitive disadvantage to other providers of advisory services to government plans that would not be subject to it, such as banks and insurance companies.[519] As we stated earlier, we believe that the concerns that we are trying to address with the rule justify its adoption, notwithstanding the potential competitive effects that advisers may face as a result of the limits on our jurisdiction. We also do not view competition by means of engaging in practices such as pay to play as an interest that we need to protect.

(b) Third-Party Solicitor Ban

Under our proposal, advisers would have been prohibited from compensating any third party to solicit government entities for advisory services, other than "related persons."[520] As a result, advisers that rely on third-party solicitors to obtain government clients would have had to bear the expense of hiring and training in-house staff in order to continue their solicitation activities,[521] a result that commenters said would be particularly costly for small and new investment advisers.[522] In addition, third-party solicitors might also have experienced substantial negative consequences under the proposed rule.[523] We heard from many commenters on this issue, offering various perspectives on how the costs would outweigh the benefits of the proposed prohibition.[524] A few commenters asserted that this proposal would have a significant adverse effect on efficient capital formation in that it would make it more difficult for private equity and venture capital managers to obtain funding that they in turn can invest in portfolio companies.[525] As other commenters pointed out, this aspect of our proposed rule might also have placed a significant burden on public pension plans,[526] particularly smaller plans because third-party solicitors provide services that plans may value, including serving as placement agent for alternative investments and serving a screening function with respect to those investments presented to the pension plan.[527]

[518] IAA Letter ("Under the Proposal, investment advisers would be required to screen for and eliminate potential employment candidates based upon contributions made for a period of up to twenty-four months before the person would begin employment with the adviser. This requirement * * * would be extremely costly and burdensome to implement."); Wells Fargo Letter ("The "look back" provision is too draconian. * * * [A] compliance system [will be] costly to develop and arduous to implement * * * [and] it would also impose severe limitations on the career opportunities of those newly entering the investment advisory world who are weighed down by political contributions that were completely innocuous when made.").

[519] NY City Bar Letter.

[520] Proposed rule 206(4)–5(a)(2)(i)(a).

[521] *See, e.g.,* Comment Letter of Greenhill & Co., LLC (Oct. 2, 2009) ("The elimination of placement agents would add a significant administrative and cost burden to fund sponsors seeking investors."). *See also* Alta Letter; Atlantic-Pacific Letter; Braxton Letter; Benedetto Letter; CA Assoc. of County Retirement Letter; Capstone Letter; EVCA Letter; GA Firefighters Letter; Glovista Letter; IL Fund Association Letter; MN Board Letter; Myers Letter; NCPERS Letter; NYC Teachers Letter; PA Public School Retirement Letter; Reed Letter; Myers Letter; TX Public Retirement Letter; WI Board Letter; Credit Suisse Letter ("Moreover, by performing these functions, placement agents enable investment advisers to focus on their core expertise, investment management, and to avoid the necessity of developing the costly in-house resources necessary to raise capital directly.").

[522] *See, e.g.,* MFA Letter ("[M]anagers that engage placement agents, particularly small and offshore managers, would lose the ability to market their services to government clients or incur significantly higher costs to hire internal marketing personnel; and managers that hire internal personnel could spend substantial amounts to register as a broker-dealer."). *See also* SIFMA Letter; IAA Letter; Seward & Kissel Letter; Sadis & Goldberg Letter; WI Board Letter; GA Firefighters Letter; MN Board Letter; IL Fund Association Letter; NYC Teachers Letter; TX Public Retirement Letter; PA Public School Retirement Letter; Ehrmann Letter; Finn Letter; Savanna Letter; Atlantic-Pacific Letter; Peterson Letter; Devon Letter; Chaldon Letter; Meridian Letter; Benedetto Letter; Capstone Letter; Braxton Letter; Littlejohn Letter; Alta Letter; Charles River Letter; Reed Letter; Glovista Letter; Blackstone Letter; Park Hill Letter.

[523] Proposing Release, at 89. *See also* Thomas Letter ("The ban would very likely cripple many legitimate placement agents—most of whom are currently regulated by the SEC and FINRA—as the public pension plans are the largest source of capital for alternative investments."); Comment Letter of the Managing Partner of Bridge 1 Advisors, LLC Robert G. McGroarty (Sept. 24, 2009) ("Bridge 1 Letter"); SIFMA Letter.

[524] *See, e.g.,* Davis Polk Letter ("While we strongly support the underlying purpose of the Proposed Rule, we believe that this ban on all third-party solicitors is overly expansive and the costs inflicted on both investment advisers and government clients from lack of access to the valuable services provided by most third-party solicitors outweigh any expected benefits to be gained from its adoption."); Capstone Letter (suggesting that many placement agent firms are small businesses helping investment managers that are, themselves, minority- or women-owned small businesses, and that, together, they are creating jobs and helping other businesses by efficiently directing capital); Monument Letter (making a similar comment regarding the minority and female ownership of placement agents); Glantz Letter; Comment Letter of Indian Harbor Partner Robert W. Stone (Aug. 13, 2009) ("Indian Harbor Letter"); Kurmanaliyeva Letter; M Advisory Letter (adding that the investment management industry as a whole will incur "dramatic job losses"); Parenteau Letter.

[525] Alta Letter; Benedetto Letter; Comment Letter of Berkshire Property Advisors, LLC (Sept. 29, 2009) ("Berkshire Letter"); Bridge 1 Letter; Comment Letter of Hampshire Real Estate Companies (Sept. 29, 2009); Comment Letter of Thomas J. Mizo on behalf of HFF Securities L.P. (Sept. 24, 2009); M Advisory Letter; Monument Group Letter; Comment Letter of Psilos Group Managers, LLC (Sept. 28, 2009).

[526] *See, e.g.,* Park Hill Letter ("The Commission has commented that if the Placement Agent Ban is adopted, Public Pension Investors can seek to engage placement agents themselves in order to continue to have access to their services in helping to find the best Fund Sponsors. However, that would impose costs on Public Pension Investors that they do not currently incur. Moreover, as the Commission has acknowledged in its cost-benefit analysis, if the Placement Agent Ban were adopted, Fund Sponsors who do not have in-house marketing staffs would be disproportionately disadvantaged relative to larger firms that have those internal resources in the competition for obtaining access to Public Pension Investors and other institutional investors."); Thomas Letter ("A ban on placement agents would have significant unintended consequences for public pension plans. * * * [For instance, the] incremental effort by investment staffs to perform due diligence on promising but possibly ill-prepared investment managers will raise the cost and lessen the overall pension fund portfolio performance."); Comment Letter of Austin F. Whitman (Sept. 21, 2009) ("Without access to placement agents, government pensions would be significantly disadvantaged relative to their private sector peers, with limited access (and benefit from) the services described above."); ABA Letter. *But see* Fund Democracy/Consumer Federation Letter ("The proposed ban would simply replace the indirect cost of placement agents incurred by pension plan sponsors with the direct cost of hiring their own placement agents—without the conflict of interest and potential for abuse that relying on advisers' placement agents creates.").

[527] *See, e.g.,* Ogburn Letter; Schmitz Letter (highlighting the valuable "pre-vetting" function of placement agents, especially in light of pension funds' budgetary pressures and lean staffs); Savanna Letter (discussing the "pre-screening" effect that reputable placement agent client selection provides for pension professionals); Atlantic-Pacific Letter; Indian Harbor Letter; Peterson Letter; Rubenstein Letter; Comment Letter of Réal Desrochers (Aug. 20,

Continued

Others argued, for similar reasons as those expressed above, that it would also harm public pension plans to ban payments to third parties because it would decrease competition by reducing the number of advisers competing for government business[528] and limit the universe of investment opportunities presented to public pension funds.[529]

We believe our decision to modify the proposed rule to permit advisers to make payments to certain "regulated persons" to solicit government clients on their behalf,[530] as described in more detail above, should alleviate many of these concerns, including those from private equity and venture capital managers on capital formation.[531] In particular, we believe the concerns expressed by private equity and venture capital managers regarding the effects of the rule on capital formation have been substantially addressed by the modification for payments to "regulated persons." We expect advisers that engage the services of regulated person solicitors will incur limited costs to initially confirm and subsequently monitor the solicitor's eligibility to be a "regulated person." Nevertheless, we expect this exception to the third-party solicitor ban will substantially reduce the costs commenters associated with this aspect of the proposal.

We acknowledge, however, that the third-party solicitor ban will nonetheless have a substantial negative impact on persons who provide third-party solicitation services that are not regulated persons, including State-registered advisers.[532] If their businesses consist solely of soliciting government entities on behalf of investment advisers, the rule could result in these persons instead being employed directly by regulated persons, shifting the focus of their solicitation activities, seeking to change their business model to shift their source of payment from investment advisers to pension plans, or going out of business.[533] In addition, we acknowledge that the third-party solicitor ban may adversely affect both competition and allocative efficiency in the market for advisory services where third-party solicitors that are not regulated persons participate. We have carefully considered these effects. As discussed above, however, we do not have regulatory authority to oversee the activities of State-registered advisers through examination and our recordkeeping rules. Nor do we have authority over the states to oversee their enforcement of their rules, as we do with FINRA. As a result, we have not included State-registered advisers in the definition of regulated person.[534]

In addition, some commenters suggested that the third-party prohibition could have a negative impact on the efficient allocation of capital for government plans, particularly small ones, and advisers that seek to manage these assets directly (not through a covered investment pool).[535]These small government plans may, as a result of the rule's ban on payments to third parties, have fewer managers to select from to the extent that larger advisers choose not to participate in this market. In addition, both government plans and advisers that seek these government clients may have to hire internal staff, respectively, to identify potential advisers and potential government clients to the extent these functions are not internalized. However, these commenters did not discuss the potentially significant costs that exist today of hiring third-party solicitors, and that eliminating the cost of pay to play may, in fact, provide greater access to pension plans by those advisers that are currently unable to afford the costs of direct or indirect political contributions or third-party solicitor fees.[536] We expect that prohibiting pay to play will reduce the costs to plans and their beneficiaries that may result when adviser selection is based on political contributions rather than investment considerations.[537]

3. Costs Related to the Amendments to Rule 204–2

The amendments to rule 204–2 require SEC-registered advisers with government clients to maintain certain records of campaign contributions by certain advisory personnel and records of the regulated persons the adviser pays or agrees to pay to solicit government entities on its behalf.[538] Records are a critical complement to rule 206(4)–5. In particular, such records are necessary for examiners to inspect advisers for compliance with the terms of the rule.

As described below, for purposes of the Paperwork Reduction Act of 1995 ("PRA"),[539] we have estimated that Commission-registered advisers would incur approximately 3,394 additional hours annually to comply with the

2009) (noting that from the perspective of a former pension fund investment officer, "[t]he skill sets of certain placement agents streamlined what they brought to our attention and made our internal process much more efficient."); Devon Letter; Thomas Letter; Myers Letter; PRIM Board Letter ("[T]he Commission should strongly resist the politically expedient suggestion that an outright ban on the use of placement agents is somehow good for plan sponsors; nothing could be further than the truth."); Meridian Letter; Comment Letter of Norman G. Benedict (Sept. 30, 2009) (indicating that, from the perspective of a retired public pension chief investment officer, placement agents provide an essential and invaluable service, particularly with providing access to private equity fund investments, which often yielded higher returns than more traditional, publicly traded securities); Berkshire Letter; Comment Letter of The British Private Equity and Venture Capital Association (Sept. 18, 2009) ("BVCA Letter") ("Placement agents are not just a crude middleman in the fundraising process"); CT Treasurer Letter; Credit Suisse Letter (describing four key functions its placement agent group performs); Portfolio Advisors Letter (noting that among the valuable services provided are: "(1) Helping new fund sponsors to become more established among the institutional investor community; (ii) helping sponsors to complete RFPs, provide information and respond to questions, which, in turn, gives the public pension plans and other investors a broader pool of investment options; and (iii) serving as intermediaries in uniting capital with fund sponsors who can put the money to work by investing in businesses and creating value"); George Letter; Comment Letter of Rahul Mehta (Sept. 11, 2009); Touchstone Letter; SIFMA Letter.

[528] *See, e.g.,* Seward & Kissel Letter; Meridian Letter; SIFMA Letter; Comment Letter of Oakpoint Advisors (Aug. 26, 2009); Comment Letter of SeaCrest Investment Management, LLC (Sept. 25, 2009).

[529] *See, e.g.,* Braxton Letter (stressing not only the increased costs that public pension funds will likely face, but also the likely reduction in creative investment strategies and opportunities available as a result of smaller and emerging funds being forced out of the market); BVCA Letter; CT Treasurer Letter; SIFMA Letter; IAA Letter; Strategic Capital Letter; Alta Letter; Benedetto Letter; Glantz Letter; Kurmanaliyeva Letter; Park Hill Letter.

[530] *See* Rule 206(4)–5(a)(2)(i).

[531] Our decision not to adopt the "related person" exception contained in the proposed rule does not diminish our belief. As we noted above, we believe our modification of the ban to allow advisers to pay "regulated persons" to solicit government entities on their behalf will still allow advisers to use employees of certain related companies—*i.e.,* of those related companies that qualify as "regulated persons"—as solicitors.

[532] As we note above, State-registered advisers are subject neither to our oversight nor to the recordkeeping rules we are adopting today.

[533] *See supra* note 523.

[534] *See supra* note 325 and accompanying text.

[535] *See, e.g.,* 3PM Letter; Bryant Law Letter.

[536] At least one commenter agreed. *See* Butler Letter ("[W]e find some evidence that the pay to play practices by underwriters [before rule G–37 was adopted] distorted not only the fees, but which firms were allocated business. The current proposal mentions that pay to play practices may create an uneven playing field among investment advisers by hurting smaller advisers that cannot afford to make political contributions. We find evidence that is consistent with this view [in our research on pay to play by municipal underwriters]. During the pay to play era, municipal bonds were underwritten by investment banks with larger underwriting market shares compared to afterward. One interpretation of this result is that smaller underwriters were passed over in favor of larger underwriters (who presumably had deeper pockets for political contributions).").

[537] *See supra* notes 452 & 453 and accompanying text (describing commenters' observations about some of the pay to play costs to plans and their beneficiaries).

[538] Unregistered advisers that would be subject to rule 206(4)–5 would not be subject to the amendments to rule 204–2.

[539] 44 U.S.C. 3501.

amendments to rule 204–2.[540] Based on this estimate, we anticipate that advisers would incur an aggregate cost of approximately $200,246 per year for the total hours advisory personnel would spend in complying with the recordkeeping requirements.[541] In addition, we expect advisory firms may incur one-time costs to establish or enhance current systems to assist in their compliance with the amendments to rule 204–2. For purposes of the PRA, we have estimated that some small and medium firms will incur start-up costs, on average, of $10,000, and larger firms will incur, on average, $100,000. As a result, the amendments to rule 204–2 are estimated to increase the PRA non-labor cost burden by $20,080,000.[542]

We received a number of specific comments on this aspect of the proposal, many of which included assertions about cost burdens associated with maintaining records related to unsuccessful solicitations, and urged us to reconsider the benefits to be gained from such a requirement in light of the costs.[543] We were persuaded by these commenters to eliminate provisions of the proposed amendments to the recordkeeping rule that would have required advisers to maintain a list of government entities that the adviser solicits.[544] Instead, an adviser must only retain records of existing government entity clients and investors as well as records of regulated persons that the adviser pays or agrees to pay to solicit government entities on its behalf for a five-year period. Additionally, we have narrowed the scope of the amended rule to apply only to advisers with government entity clients; an adviser is only required to make and keep these records if it provides investment advisory services to a government entity or a government entity is an investor in any covered investment pool to which the investment adviser provides investment advisory services.[545] We have also limited the rule to provide that only records of contributions, not payments, to government officials and candidates are required to be kept under the rule. Additionally, because rule 206(4)–5 applies to an adviser to a registered investment company only if it is an investment option of a participant-directed plan or program of a government entity,[546] such investment advisers will only have to identify government entities that provide plan or program participants the option of investing in the fund, which addresses many commenters' concerns about recordkeeping burdens that would have been imposed on advisers to registered investment companies under the proposed rule.[547]

We anticipate that commenters' general concerns that we may have underestimated the burdens we presented in our proposal will be offset by what we believe will be a reduction in burdens as a result of the various modifications from our proposal described above. In addition, we have revised the rule to require advisers to maintain a list of regulated persons that solicit on an adviser's behalf, but expect advisers to already have this information in the normal course of business, including in some instances, to comply with existing requirements of rule 206(4)–3.

V. Paperwork Reduction Act

A. Rule 204–2

The amendment to rule 204–2 contains a "collection of information" requirement within the meaning of the PRA. In the Proposing Release, the Commission solicited comment on the proposed amendment to the collection of information requirement.[548] The Commission also submitted the proposed amendment's collection of information requirement to the Office of Management and Budget ("OMB") for review in accordance with 44 U.S.C. 3507(d) and 5 CFR 1320.11 under control number 3235–0278. The title for the collection of information is "Rule 204–2 under the Investment Advisers Act of 1940." Rule 204–2 contains a currently approved collection of information number under OMB control number 3235–0278. An agency may not sponsor, or conduct, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Section 204 of the Advisers Act provides that investment advisers registered or required to be registered with the Commission must make and keep certain records for prescribed periods, and make and disseminate certain reports. Rule 204–2 sets forth the requirements for maintaining and preserving specified books and records. This collection of information is mandatory. The collection of information under rule 204–2 is necessary for the Commission staff to use in its examination and oversight program, and the information generally is kept confidential.[549] The respondents are investment advisers registered or required to be registered with us.

Today's amendments to rule 204–2 require every investment adviser registered or required to be registered that provides advisory services to (or pays or agrees to pay regulated persons to solicit) government entities to maintain certain records of contributions made by the adviser or any of its covered associates and regarding regulated persons the adviser pays or agrees to pay for soliciting government entities on its behalf. The amendments require such an adviser to make and keep the following records: (i) The names, titles, and business and residence addresses of all covered associates of the investment adviser; (ii) all government entities to which the investment adviser provides or has provided investment advisory services, or which are or were investors in any covered investment pool to which the investment adviser provides or has provided investment advisory services, as applicable, in the past five years, but not prior to the effective date of the rule; (iii) all direct or indirect contributions made by the investment adviser or any of its covered associates to an official of a government entity, or payments to a political party of a State or political subdivision thereof, or to a political action committee; and (iv) the name and business address of each regulated person to whom the investment adviser provides or agrees to provide, directly or indirectly, payment to solicit a government entity for investment advisory services on its behalf, in accordance with rule 206(4)–5(a)(2)(i).

The adviser's records of contributions and payments are required to be listed

[540] *See infra* note 559 and accompanying text.

[541] We expect that the function of recording and maintaining records of political contributions would be performed by a compliance clerk at a cost of $59 per hour. *See supra* note 487. Therefore, the total costs would be $200,246 (3,394 hours × $59 per/hour).

[542] ($10,000 × 788) + ($100,000 × 122) = $7,880,000 + $12,200,000 = $20,080,000.

[543] MassMutual Letter ("[T]he requirement to maintain records of each governmental entity being solicited would require a diverse financial services company like MassMutual to undertake significant legacy software system modifications or build an entirely new system to track each instance of a "solicitation," which could include phone calls, meetings, or responses to governmental requests. This system would then need to aggregate data across multiple business lines, many with existing systems that may not have the ability to share this data in a useful format. All of these are costly and time consuming activities to meet a requirement that appears to add little value to the Commission's efforts to ensure compliance with the Proposed Rule."). *See also* Davis Polk Letter; Dechert Letter; Holl Letter; SIFMA Letter; Skadden Letter.

[544] *See* proposed rule 204–2(a)(18)(i)(B).

[545] Rule 204–2(a)(18)(iii). *See* NASP Letter ("Many advisers do not have governmental clients but will still have to collect the information or attestations which would increase compliance costs while providing no public benefit at all.")

[546] *See supra* note 353 and accompanying text.

[547] *See, e.g.,* ICI Letter.

[548] *See* Proposing Release, at section IV.

[549] *See* section 210(b) of the Advisers Act [15 U.S.C. 80b–10(b)].

in chronological order identifying each contributor and recipient, the amounts and dates of each contribution or payment, and whether such contribution or payment was subject to the exception for certain returned contributions pursuant to rule 206(4)–5(b)(2). An investment adviser is only required to make and keep current the records referred to in (i) and (iii) above if it provides investment advisory services to a government entity or a government entity is an investor in any covered investment pool to which the adviser provides investment advisory services. The records required by amended rule 204–2 are required to be maintained in the same manner, and for the same period of time, as other books and records under rule 204–2(a). This collection of information will be found at 17 CFR 275.204–2. Advisers that are exempt from Commission registration under section 203(b)(3) of the Advisers Act are not subject to the recordkeeping requirements.

The amendments to rule 204–2 that we are adopting today differ from our proposed amendments in several respects. We have tailored certain of the requirements from our proposal. First, we have limited the rule to provide that only records of contributions, not payments, to government officials, including candidates, are required to be kept under the rule. Second, investment advisers to registered investment companies only have to identify—and keep records regarding—government entities that invest in a fund as part of a plan or program of a government entity, including any government entity that selects the fund as an investment option for participants in the plan or program.[550] Third, we are not adopting provisions of the proposed amendments to the recordkeeping rule that would have required advisers to maintain a list of all government entities that they have solicited. In addition, we have revised the rule so that only those advisers that have government entity clients must make and keep certain required records, unlike the proposal, which would have required all registered advisers to maintain records of contributions and covered associates. We are also adopting a requirement that advisers maintain records of regulated persons they pay to solicit government entities on their behalf, to reflect that rule 206(4)-5 permits advisers to compensate these solicitors.

As noted above, we requested comment on the PRA analysis contained in the Proposing Release. Although a few commenters expressed general concerns that the paperwork burdens associated with our proposed amendments to rule 204–2 might be understated, commenters representing advisers to registered investment companies suggested that the proposal significantly underestimated the burden attributed to these covered investment pools.[551] With respect to registered investment companies, commenters noted that the proposed recordkeeping requirements required advisers to identify government investors in registered investment companies regardless of whether the fund was part of a plan or program of a government entity, and as a result the proposed amendments to the recordkeeping rule would have been difficult to comply with as fund shareholder records do not necessarily identify government investors.

As a result of these comments, we recognize that we may have underestimated the recordkeeping burden for advisers to registered investment companies that would have been subject to proposed rule 206(4)-5. However, we believe that our change to the definition of "covered investment pool" from the proposal to only include those registered investment companies that are an investment option of a plan or program of a government entity addresses the recordkeeping concerns commenters expressed regarding these covered investment pools and lowers recordkeeping burdens by limiting the records relating to registered investment companies that an investment adviser must keep under the rule.[552] In addition, the other changes we highlight above—other than the requirement to keep records regarding regulated persons—would lessen the recordkeeping requirements relative to our proposal and thereby diminish our burden estimates. We anticipate that commenters' general concerns that we may have underestimated the burdens we presented in our proposal, as well as the burden associated with the additional requirement to maintain a list of regulated persons that solicit on an adviser's behalf, will be offset by what we believe will be a reduction in burdens as a result of the various modifications from proposed amendments to the recordkeeping rule, as described above. Moreover, notwithstanding the fact that the amendments we are adopting reduce advisers' recordkeeping obligations relative to our proposal, we are increasing our estimates to address the additional investment advisers who have registered with us since our proposal was issued.

Prior to today's amendments, the approved collection of information for rule 204–2, set to expire on March 31, 2011, was based on an average of 181.15 burden hours each year, per Commission-registered adviser, for a total of 1,954,109 burden hours. In addition, the currently-approved collection of information for Rule 204–2 includes a non-labor cost estimate of $13,551,390. The total burden is based on an estimate of 10,787 registered advisers.

Commission records indicate that currently there are approximately 11,607 registered investment advisers subject to the collection of information imposed by rule 204–2.[553] As a result of the increase in the number of advisers registered with the Commission since the current total burden was approved, the total burden has increased by 148,543 hours.[554] In addition, the total non-labor cost burden has increased to $14,581,509 as a result of this increase in the number of registered advisers.[555]

In our Proposing Release, we estimated that approximately 1,764 Commission-registered advisers provide, or seek to provide, advisory services to government clients and to certain pooled investment vehicles in which government entities invest, and would thus be affected by the rule amendments.[556] One commenter argued that this estimate was too low because it underestimates the number of investment advisers unregistered in reliance on Section 203(b)(3) of the Advisers Act and estimated to be subject to the Proposed Rule.[557] Unregistered

[550] Under our proposal, investment advisers to registered investment companies would have had to identify and keep records regarding government entities that invest in the funds regardless of whether they were part of a plan or program of a government entity. For a discussion of this modification, see section II.B. of this Release.

[551] *See* ICI Letter ("[I]n relying on the estimates for compliance with the MSRB rules, the Commission significantly underestimates the compliance and recordkeeping burdens associated with the proposed rule.").

[552] *See* Rule 204–2(a)(18)(i)(B).

[553] This figure is based on registration information from IARD as of April 1, 2010. The figures we relied on in our Proposing Release were based on registration information from IARD as of July 1, 2009. *See* Proposing Release, at section IV.

[554] 11,607 − 10,787 = 820. 820 additional advisers × 181.15 hours = 148,543 hours.

[555] We estimate that non-labor costs attributed to rule 204–2 will increase in the same proportion as the increase in the estimated hour burden for the rule. (2,102,652 hours/1,954,109 hours) × $13,551,390 currently approved non-labor cost estimate = $14,581,509.

[556] *See* Proposing Release, at section IV.

[557] Davis Polk Letter ("The cost benefit analysis is based solely on an estimated 1,764 registered investment advisers and does not account for the costs and burdens of compliance attributable to investment advisers exempt from registration. The

advisers are not subject to rule 204–2's recordkeeping requirements. As a result, they are not included in our estimates for purposes of this analysis. We continue to believe our estimates are appropriate, although we have revised this number for purposes of both our cost-benefit analysis above and our PRA analysis to reflect both an increase in the number of registered advisers since the proposal and the modification from our proposal to not require records of unsuccessful solicitations. We now estimate that approximately 1,697 registered advisers provide advisory services to government clients and to certain pooled investment vehicles in which government entities invest, and would thus be affected by the rule amendments.[558]

Under the amendments, each respondent is required to retain the records in the same manner and for the same period of time as currently required under rule 204–2. The amendments to rule 204–2 are estimated to increase the burden by approximately 2 hours per Commission-registered adviser with government clients annually for a total increase of 3,394 hours.[559] The revised annual aggregate burden for all respondents to the recordkeeping requirements under rule 204–2 thus would be 2,106,046 hours.[560] The revised average burden per Commission-registered adviser would be 181.45 hours.[561]

Additionally, as we noted in the Proposing Release and reiterate above, we expect advisory firms may incur one-time costs to establish or enhance current systems to assist in their compliance with the amendments to rule 204–2. These costs would vary widely among firms. Small advisers may not incur any system costs if they determine a system is unnecessary due to the limited number of employees they have or the limited number of government entity clients they have. Large firms likely already have devoted significant resources into automating compliance and reporting and the new rule could result in enhancements to these existing systems.

As a result of these one-time costs, we estimate that there will be an increase to the total non-labor cost burden. We estimated above that the non-labor cost burden has increased to $14,581,509 as a result of the increase in the number of registered advisers since the collection was last approved.[562] We believe the one-time costs could vary substantially among smaller, medium, and larger firms as smaller and medium firms may be able to use non-specialized software, such as a spreadsheet, or off-the-shelf compliance software to keep track of the information required by the rule while larger firms are more likely to have proprietary systems. Based on IARD data we estimate that there are approximately 1,271 smaller firms, 304 medium firms, and 122 larger firms.[563] We estimate that one half of the smaller and medium firms will not incur these one-time start up costs because they will use existing tools for compliance. We expect the other half of smaller and medium firms will incur one-time start up costs on average of $10,000, in the event they have a greater number of employees and government clients, and larger firms, that likely have the most employees and government clients, will incur one-time start up costs on average of $100,000. As a result, the amendments to rule 204–2 are estimated to increase the non-labor cost burden by $20,080,000.[564] Due to this increase, we now estimate the revised total non-labor cost burden for rule 204–2 to be $34,661,509.

B. Rule 206(4)–3

The amendment to rule 206(4)–3 contains a revised collection of information requirement within the meaning of the PRA. In the Proposing Release, the Commission published notice soliciting comment on the collection of information requirement.[565] The Commission submitted the revised collection of information requirement to OMB for review in accordance with 44 U.S.C. 3507(d) and 5 CFR 1320.11. Rule 206(4)–3 contains a currently approved collection of information under OMB control number 3235–0242. The title for the collection of information is "Rule 206(4)–3—Cash Payments for Client Solicitations." As noted above, an agency may not sponsor, or conduct, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Section 206(4) of the Advisers Act provides that it shall be unlawful for any investment adviser to engage in any act, practice, or course of business which is fraudulent, deceptive, or manipulative. Rule 206(4)–3 generally prohibits investment advisers from paying cash fees to solicitors for client referrals unless certain conditions are

estimated number of investment advisers unregistered in reliance on section 203(b)(3) of the Advisers Act (2,000) and estimated to be subject to the Proposed Rule (231), appears to be low. In its comment letter, the Third Party Marketers Association notes that the number of advisory firms exempted from registration may be 'over two times the estimate of the Commission. * * *'" (citations omitted)). The Davis Polk Letter does not offer any of its own estimates for the number of unregistered advisers, and the 3PM Letter references statistics regarding the number of funds, not the number of advisers.

[558] This estimate is based on registration information from IARD as of April 1, 2010, applying the same methodology as in the Proposing Release. As previously noted, according to responses to Item 5.D(9) of Part 1 of Form ADV, 1,332 advisers have clients that are State or municipal government entities, which represents 11.48% of all advisers registered with us. 10,275 advisers have not responded that they have clients that are State or municipal government entities. Of those, however, responses to Item 5.D(6) of Part 1 of Form ADV indicate that 2,486 advisers have some clients that are other pooled investment vehicles. Estimating that the same percentage of these advisers advise pools with government entity investors as advisers that have direct government entity clients—*i.e.,*11.48%. 285 of these advisers would be subject to the rule (2,486 × 11.48% = 285). Out of the 10,275 that have not responded that they have clients that are State or municipal government entities, after backing out the 2,486 which have clients that are other pooled investment vehicles, responses to Item 5.D(4) of Part 1 of Form ADV indicate that 699 advisers have some clients that are registered investment companies. Estimating that roughly the same percentage of these advisers advise pools with government entity investors as advisers that have direct government entity clients—*i.e.,*11.48%. 80 of these advisers would be subject to the rule (699 × 11.48% = 80). Although we limited the application of rule 206(4)–5 with respect to registered investment companies to those that are investment options of a plan or program of a government entity, we continue to estimate that 80 advisers would have to comply with the recordkeeping provisions because of the difficulty in further delineating this estimated number. Therefore, we estimate that the total number of advisers subject to the rule would be: 1,332 advisers with State or municipal clients + 285 advisers with other pooled investment vehicle clients + 80 advisers with registered investment company clients = 1,697 advisers subject to rule. We expect certain additional advisers may incur compliance costs associated with rule 206(4)–5. We anticipate some advisers may be subject to the rule because they solicit government entities on behalf of other investment advisers. In the Proposing Release, our estimates included an estimated burden attributable to advisers that do not currently have government clients but that may begin to seek them. The revision to the recordkeeping rule that eliminated the requirement to maintain records of government entities that an adviser solicits has eliminated the need for this additional burden estimate.

[559] 2 × 1,697 = 3,394.

[560] 1,954,109 (current approved burden) + 148,543 (burden for additional registrants) + 3,394 (burden for proposed amendments) = 2,106,046 hours.

[561] 2,106,046 (revised annual aggregate burden) divided by 11,607 (total number of registrants) = 181.45.

[562] *See supra* note 555.

[563] This estimate is based on registration information from IARD as of April 1, 2010. These estimates are based on IARD data, specifically the responses to Item 5.B.(1) of Form ADV, that 997 (or 74.9%) of the 1,332 registered investment advisers that have government clients have fewer than five employees who perform investment advisory functions, 239 (or 17.9%) have five to 15 such employees, and 96 (or 7.2%) have more than 15 such employees. We then applied those percentages to the 1,697 advisers we believe will be subject to the proposed rule for a total of 1,271 smaller, 304 medium and 122 larger firms.

[564] [$10,000 × 788] + [$100,000 × 122] = $7,880,000 + $12,200,000 = $20,080,000.

[565] *See* Proposing Release, at section IV.

met. The rule requires that an adviser pay all solicitors' fees pursuant to a written agreement that the adviser is required to retain. This collection of information is mandatory. The Commission staff uses this collection of information in its examination and oversight program, and the information generally is kept confidential.[566]

The Commission is adopting amendments to rule 206(4)–3 under the Advisers Act. The amendments to rule 206(4)–3, which are identical to our proposed amendments, require every investment adviser that relies on the rule and that provides or seeks to provide advisory services to government entities to also abide by the limitations provided in rule 206(4)–5. This collection of information is found at 17 CFR 275.206(4)–3. Advisers that are exempt from Commission registration under section 203(b)(3) of the Advisers Act would not be subject to rule 206(4)–3.

We requested comment on the PRA analysis contained in Proposing Release. We received no comment on this portion of our analysis. In addition, we have not modified our amendments to rule 206(4)–3 relative to our proposal.

The current approved collection of information for rule 206(4)–3, set to expire on March 31, 2011, is based on an estimate that 20 percent of the 10,817 Commission-registered advisers (or 2,163 advisers) rely on the rule, at an average of 7.04 burden hours each year, per respondent, for a total of 15,228 burden hours ($7.04 \times 2{,}163$).

Commission records indicate that currently there are approximately 11,607 registered investment advisers,[567] 20 percent of which (or 2,321) are likely subject to the collection of information imposed by rule 206(4)–3. As a result of the increase in the number of advisers registered with the Commission since the current total burden was approved, the total burden has increased by 1,112.32 hours (158 additional advisers[568] $\times$ 7.04 hours). We estimate that approximately 20 percent of the Commission-registered advisers that use rule 206(4)–3 (or 464 advisers)[569] provide, or seek to provide, advisory services to government clients.[570] Under the amendments, each respondent would be prohibited from certain solicitation activities, subject to the exception for "regulated persons," with respect to government clients, activities that otherwise would have been covered by rule 206(4)–3.[571] Thus, they would not need to enter into and retain the written agreement required under rule 206(4)–3 with respect to those third parties they are prohibited from paying to solicit government entities.

In the Proposing Release, we estimated a decrease to the burden due to the prohibition on paying third party solicitors to be 20% of the annual burden. As a result of the revised ban on using third parties, we now estimate that the amendments to rule 206(4)–3 will only decrease the burden by 15 percent,[572] or approximately 1.06 hour,[573] per Commission-registered adviser that uses the rule and has or is seeking government clients annually, for a total decrease of 491.84 hours.[574] The revised annual aggregate burden for all respondents to the recordkeeping requirements under rule 206(4)–3 thus would be 15,848.48 hours.[575] The revised average burden per Commission-registered adviser would be 6.83 hours.[576]

C. Rule 206(4)–7

As a result of the adoption of rule 206(4)–5, rule 206(4)–7 contains a revised collection of information requirement within the meaning of the PRA. In the Proposing Release, the Commission estimated that registered advisers would spend between 8 hours and 250 hours to establish policies and procedures to comply with rule 206(4)–5.[577] Rule 206(4)–7 contains a currently approved collection of information under OMB control number 3235–0585. The title for the collection of information is "Investment Advisers Act Rule 206(4)–7, Compliance procedures and practices." As noted above, an agency may not sponsor, or conduct, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Section 206(4) of the Advisers Act provides that it shall be unlawful for any investment adviser to engage in any act, practice, or course of business which is fraudulent, deceptive, or manipulative. Rule 206(4)–7, in part, requires registered investment advisers to adopt and implement written policies and procedures reasonably designed to prevent violation of the Federal securities laws. This collection of information is mandatory. The purpose of the information collection requirement is to ensure that registered advisers maintain comprehensive, written internal compliance programs. It also assists the Commission's staff in its examination and oversight program. Information obtained in our examination and oversight program generally is kept confidential.[578]

As we previously noted, we expect that registered investment advisers subject to rule 206(4)–5 will modify their compliance programs to address new obligations under that rule. The current approved collection of information for rule 206(4)–7, set to expire on March 31, 2011, is based on 10,817 registered advisers that were subject to the rule at an average burden of 80 hours each year per respondent for a total of 865,360 burden hours.

Commission records indicate that currently there are approximately 11,607 registered investment advisers.[579] As a result of the increase in the number of advisers registered with the Commission since the current total burden was approved, the total burden has increased by 63,200 hours (790×80 hours). In addition, although the time needed to comply with rule 206(4)–5 will vary significantly from adviser to adviser, as discussed in detail below, the Commission staff estimates that firms with government clients will spend between 8 hours and 250 hours to implement policies and procedures to comply with the rule, depending on the

[566] Section 210(b) of the Advisers Act [15 U.S.C. 80b–10(b)].

[567] This figure is based on registration information from IARD as of April 1, 2010. The figures we relied on in our Proposing Release were based on registration information from IARD as of July 1, 2009.

[568] 2,321 (20% of current registered investment advisers)—2,163 (20% of registered investment advisers when burden estimate was last approved by OMB) = 158.

[569] $2{,}321 \times 20$ percent = 464.

[570] In light of the 11.48% of registered investment advisers that indicate they have State or municipal government clients, we conservatively estimate that 20% of the advisers who rely on rule 206(4)–3 are soliciting government entities to be advisory clients or to invest in covered investment pools those advisers manage. *See supra* note 558.

[571] Rule 206(4)–3(a).

[572] In our proposal, which would have banned the use of third-party solicitors altogether, we estimated a 20 percent decrease in the burden under rule 206(4)–3. But, to account for the regulated persons exception to the third-party solicitor ban in adopted rule 206(4)–5, we have modified our estimate to only a 15 percent decrease. That is because our staff estimates that one quarter (or 5 percent) of the proposal's estimated burden reduction relating to entering into and retaining the written agreement required under rule 206(4)–3 will be retained as investment advisers engage third parties that are regulated persons to solicit on their behalf.

[573] 7.04×15 percent = 1.06.

[574] $464 \times 1.06 = 491.84$.

[575] 15,228 (current approved burden) + 1,112.32 (burden for additional registrants)—491.84 (reduction in burden for amendments) = 15,848.48 hours.

[576] 15,848.48 (revised annual aggregate burden) divided by 2,321 (total number of registrants who rely on rule) = 6.83.

[577] *See* Proposing Release, at section III.B.

[578] Section 210(b) of the Advisers Act [15 U.S.C. 80b–10(b)].

[579] This figure is based on registration information from IARD as of April 1, 2010.

firm's number of covered associates.[580] Of the 1,697 registered advisers that we estimate may be affected by rule 206(4)–5,[581] we estimate that approximately 1,271 are smaller firms, 304 are medium firms, and 122 are larger firms.[582] We anticipate that smaller firms will spend 8 hours, medium firms will spend 125 hours, and larger firms will spend 250 hours,[583] for a total of 78,668 hours,[584] to implement policies and procedures. Our estimates take into account our staff's observation that some registered advisers have established policies regarding political contributions, which can be revised to reflect the new requirements. The revised annual aggregate burden for all respondents to comply with rule 206(4)–7 thus would be 1,007,228 hours.[585]

D. Rule 0–4

Rule 0–4 under the Advisers Act,[586] entitled "General Requirements of Papers and Applications," prescribes general instructions for filing an application seeking exemptive relief with the Commission. The requirements of rule 0–4 are designed to provide the Commission with the necessary information to assess whether granting the orders of exemption is necessary and appropriate, in the public interest and consistent with the protection of investors and the intended purposes of the Act. In light of the adoption of rule 206(4)–5, which contains a provision for seeking an exemptive order from the Commission, we are revising the collection of information requirement for rule 0–4. Rule 0–4 contains a currently approved collection of information under OMB control number 3235–0633. As noted above, an agency may not sponsor, or conduct, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The current approved collection of information contains an estimated total annual hour burden of one hour for administrative purposes because most of the work of preparing an application is performed by outside counsel and, therefore, imposes minimal, if any, hourly burden on respondents. Because we expect that all, or substantially all, of the work of preparing an application for an exemptive order under rule 206(4)–5 will also be performed by outside counsel, we continue to believe that the current estimate of one hour, in the unlikely event the adviser does perform an administrative role, is sufficient. As a result, we are not increasing our estimated hourly burden in connection with the adoption of rule 206(4)–5.

The current approved collection of information also contains an estimated total annual cost burden of $355,000, which is attributed to outside counsel legal fees. In the Proposing Release, we estimated that approximately five advisers annually would apply to the Commission for an exemption from rule 206(4)–5.[587] We also estimated that an advisory firm that applies for an exemption would hire outside counsel to prepare their exemptive requests, and that counsel would spend 16 hours preparing and submitting an application for review at a rate of $400 per hour, for a per application cost of $6,400 and a total estimated cost for five applications annually of $32,000.

The Commission requested public comment on these estimates in the Proposing Release, and we received comments indicating that our estimate of five exemptive application submissions per year is too low.[588] We did not receive comments on our cost estimates. Given that the advisory industry is much larger than the municipal securities industry, and in light of the number of comment letters we received that expressed concern about inadvertent violations of the rule that would not qualify for the exception for returned contributions, our staff estimates that approximately seven advisers annually would apply to the Commission for an exemption from the rule. Although we may initially receive more than seven applications a year for an exemption, over time, we expect the number of applications we receive will significantly decline to an average of approximately seven annually. We continue to believe that a firm that applies for an exemption will hire outside counsel to prepare an exemptive request, but based on commenters' concerns have raised the number of hours counsel will spend preparing and submitting an application from 16 hours to 32 hours, at a rate of $400 per hour.[589] As a result, each application will cost approximately $12,800, and the total estimated cost for seven applications annually will be $89,600. The total estimated annual cost burden to applicants of filing all applications has therefore increased to $444,600.[590]

VI. Final Regulatory Flexibility Analysis

The Commission has prepared the following Final Regulatory Flexibility Analysis regarding rule 206(4)–5 and the amendments to rules 204–2 and 206(4)–3 in accordance with section 3(a) of the Regulatory Flexibility Act.[591] We prepared an Initial Regulatory Flexibility Analysis ("IRFA") in conjunction with the Proposing Release in August 2009.[592] The Proposing Release included, and solicited comment, on the IRFA.

A. Need for the Rule

Investment advisers that seek to influence the award of advisory contracts by government entities, by making or soliciting political contributions to those officials who are in a position to influence the awards, violate their fiduciary obligations. These practices—known as "pay to play"—distort the process by which investment advisers are selected and, as discussed in greater detail above, can harm advisers' public pension plan clients, and thereby beneficiaries of those plans, which may receive inferior advisory services and pay higher fees.[593] In addition, the most qualified adviser may not be selected, potentially leading to inferior management, diminished returns, or greater losses for the public pension plan. Pay to play is a significant problem in the management of public funds by investment advisers. Moreover, we believe that advisers' participation in pay to play is inconsistent with the high standards of ethical conduct required of them under the Advisers Act. The rule and rule amendments we are adopting today are designed to prevent fraud, deception, and manipulation by reducing or eliminating adviser participation in pay to play practices.

Rule 206(4)–5, the "pay to play" rule, prohibits an investment adviser registered (or required to be registered)

[580] *See* section IV.B.1. of this Release (describing the cost estimates associated with compliance with rule 206(4)–5).

[581] *See supra* note 558. Advisers that are unregistered in reliance on the exemption available under section 203(b)(3) of the Advisers Act [15 U.S.C. 80b–3(b)(3)] are not subject to rule 206(4)–7 and, therefore, are not reflected in this burden estimate pursuant to the PRA.

[582] *See supra* note 475.

[583] *See supra* notes 489–491.

[584] (1,271 × 8 = 10,168) + (304 × 125 = 38,000) + (122 × 250 = 30,500) = 78,668.

[585] 865,360 (current approved burden) + 63,200 (burden for additional registrants) + 78,668 (burden attributable to rule 206(4)–5) = 1,007,228 hours.

[586] 17 CFR 275.0–4.

[587] *See* Proposing Release, at Section III.B.

[588] *See* Davis Polk Letter; ICI Letter.

[589] The hourly cost estimate of $400 is based on our consultation with advisers and law firms who regularly assist them in compliance matters.

[590] $355,000 + $89,600 = $444,600.

[591] 5 U.S.C. 604(b).

[592] *See* Proposing Release, at section V.

[593] *See* section I of this Release, for more information about the need for the Commission to take action to prevent pay to play practices.

with the Commission, or unregistered in reliance on the exemption available under section 203(b)(3) of the Advisers Act, from providing advisory services for compensation to a government client for two years after the adviser, or any of its covered associates, makes a contribution to public officials (and candidates) such as State treasurers, comptrollers, or other elected executives or administrators who can influence the selection of the adviser.[594] In addition, the rule we are adopting prohibits an adviser and its covered associates from soliciting contributions for an elected official or candidate or payments to a political party of a State or locality where the adviser is providing or seeking to provide advisory services to a government entity,[595] and from providing or agreeing to provide, directly or indirectly, payment to any third party, other than a "regulated person," engaged to solicit advisory business from any government entity on behalf of the adviser.[596] Further, the prohibitions in the rule also apply to advisers to certain investment pools in which a government entity invests or that are investment options of a plan or program of a government entity.[597] The amendment we are adopting to rule 204–2 is designed to provide Commission staff with records to review compliance with rule 206(4)–5, and the amendment to rule 206(4)–3 clarifies the application of the cash solicitation rule as a result of the adoption of rule 206(4)–5.[598]

B. Significant Issues Raised by Public Comment

In the Proposing Release, we requested comment on the IRFA, in particular, on the number of small entities, particularly small advisers, to which the rule and rule amendments would apply and the effect on those entities, including whether the effects would be economically significant; and how to quantify the number of small advisers, including those that are unregistered, that would be subject to the proposed rule and rule amendments. We received a number of comments related to the impact of our proposal on small advisers. The commenters argued that the proposed rule, particularly the provision that would have prohibited advisers from directly or indirectly compensating any third party to solicit government business on its behalf, would be disproportionately expensive for, and would impose an undue regulatory burden on, smaller firms.[599]

C. Small Entities Subject to Rule

Under Commission rules, for the purposes of the Advisers Act and the Regulatory Flexibility Act, an investment adviser generally is a small entity if it: (i) Has assets under management having a total value of less than $25 million; (ii) did not have total assets of $5 million or more on the last day of its most recent fiscal year; and (iii) does not control, is not controlled by, and is not under common control with another investment adviser that has assets under management of $25 million or more, or any person (other than a natural person) that had $5 million or more on the last day of its most recent fiscal year.[600]

The Commission estimates that as of April 2010 there are approximately 708 small SEC-registered investment advisers.[601] Of these 708 advisers, 61 indicate on Form ADV that they have State or local government clients, and would, therefore, be affected by the rule.[602] The rule also applies to those advisers that are exempt from registration with the Commission in reliance on section 203(b)(3) of the Advisers Act. As noted above, based on our review of registration information on IARD and outside sources and reports, we estimate that there are approximately 2,000 advisers that are unregistered in reliance on section 203(b)(3).[603] Applying the same principles we used with respect to registered investment advisers, we estimate that 230 of those advisers manage pooled investment vehicles in which government client assets are invested and would therefore be subject to the rule.[604] Based on the current number of registered advisers subject to the rule that are small entities, we estimate that approximately 4 percent of unregistered advisers,[605] or nine, would be subject to the rule are small entities.[606]

D. Projected Reporting, Recordkeeping, and Other Compliance Requirements

The rule imposes certain reporting, recordkeeping and compliance requirements on advisers, including small advisers. The rule imposes a new compliance requirement by: (i) Prohibiting an adviser from providing investment advisory services for compensation to government clients for two years after the adviser or any of its covered associates makes a contribution to certain elected officials or candidates; (ii) prohibiting an adviser from providing or agreeing to provide, directly or indirectly, payment to any third party, other than a "regulated person," engaged to solicit advisory business from any government entity on behalf of the adviser; and (iii) prohibiting an adviser or any of its covered associates from soliciting contributions for an elected official or candidate or payments to a political party of a State or locality where the adviser is providing or seeking to provide advisory services to a government entity.

The rule amendments impose new recordkeeping requirements by requiring an adviser to maintain certain records about its covered associates, its advisory clients, government entities invested in certain pooled investment vehicles managed by the adviser, its solicitors, and its political contributions, as well as the political contributions of its covered associates.[607] An investment adviser that does not provide or seek to provide advisory services to a government entity, or to a covered investment pool

[594] Rule 206(4)–5(a)(1).

[595] Rule 206(4)–5(a)(2)(ii).

[596] Rule 206(4)–5(a)(2)(i). "Regulated person" is defined in rule 206(4)–5(f)(9).

[597] Rule 206(4)–5(c).

[598] For a more detailed discussion of the prohibitions contained in rule 206(4)–5, see section II.B.2 of this Release. For a more detailed discussion of the amendments to rules 204–2 and 206(4)–3, see sections II.D and II.E, respectively, of this Release.

[599] *See supra* note 522.

[600] 17 CFR 275.0–7(a).

[601] This estimate is based on registration information from IARD as of April 1, 2010. We have estimated the number of small advisers by reference to advisers' responses to Item 12.A, B and C of Part 1 of Form ADV.

[602] This estimate is based on registration information from IARD as of April 1, 2010. We have estimated the number of small advisers with State or local government clients by reference to advisers' responses to Item 5.D(9) of Part 1 of Form ADV.

[603] This number is based on our review of registration information on IARD as of April 1, 2010, IARD data from the peak of hedge fund adviser registration in 2005, and a distillation of numerous third-party sources including news organizations and industry trade groups.

[604] 11.48% of 2000 is 230. *See supra* note 474.

[605] 61 registered small entities subject to the rule/1,697 registered advisers subject to the rule = 3.6%.

[606] $230 \times 4\% = 9.2$. Because these advisers are not registered with us, we do not have more precise data about them, and we are not aware of any databases that compile information regarding how many advisers that are exempt from registration with the Commission in reliance on section 203(b)(3) of the Advisers Act have State or local government clients, and how many of these advisers would be small entities for purposes of this analysis. We sought comments on this issue, but none of the comments we received provided any estimates or empirical data. However, we address above commenters who generally questioned our estimates. *See* supra notes 482–484 and accompanying text. We expect certain additional advisers may incur compliance costs associated with rule 206(4)–5. Some advisers may be subject to the rule because they solicit government entities on behalf of other investment advisers.

[607] *See supra* notes 559–564 and accompanying text (providing the revised estimated hour burden and non-labor cost burden to comply with amended rule 204–2, for purposes of the PRA).

in which a government entity invests, is not subject to rule 206(4)–5 and certain recordkeeping requirements under amended rule 204–2.

As noted above, we believe that a limited number of small advisers [608] will have to comply with rule 206(4)–5 and the amendments to rules 204–2 and 206(4)–3. To the extent small advisers tend to have fewer clients and fewer employees that would be covered associates for purposes of the rule, the rule should impose lower costs on small advisers as compared to large advisers because variable costs, such as the requirement to make and keep records relating to contributions, should be lower due to the likelihood that there would be fewer records to make and keep.[609] Moreover, as discussed above, the rule and amendments were modified from what we had proposed in several ways that we expect will substantially minimize compliance burdens on small advisers.

E. Agency Action To Minimize Effect on Small Entities

The Regulatory Flexibility Act directs the Commission to consider significant alternatives that would accomplish the stated objective, while minimizing any significant impact on small entities.[610] In considering whether to adopt rule 206(4)–5 and the amendments to rules 204–2 and 206(4)–3, the Commission considered the following alternatives: (i) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (ii) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule and rule amendments for such small entities; (iii) the use of performance rather than design standards; and (iv) an exemption from coverage of the rule and rule amendments, or any part thereof, for such small entities.

Regarding the first alternative, the Commission is not adopting different compliance or reporting requirements for small advisers as it may be inappropriate to do so under the circumstances. The proposal is designed to reduce or eliminate adviser participation in pay to play, a practice that can distort the process by which investment advisers are selected to manage public pension plans that can harm public pension plan clients and cause advisers to violate their fiduciary obligations. To establish different requirements for small advisers could diminish the protections the rule and rule amendments would provide to public pension plan clients and their beneficiaries.

Regarding the second alternative, we considered whether further clarification, consolidation, or simplification of the compliance requirements would be feasible or necessary, and would reduce compliance requirements. As a result, we have simplified the compliance requirements by limiting the recordkeeping obligations to better reflect the activities of an adviser or a covered associate that could result in the adviser being subject to the two-year time out, including not requiring advisers to maintain records of unsuccessful solicitations of government entities and payments (as opposed to contributions) by advisers or covered associates to government officials.[611] Moreover, we are amending rule 206(4)–3, the cash solicitation rule, to clarify that the requirements of new rule 206(4)–5 apply to solicitation activities involving government clients.[612]

Regarding the third alternative, we considered using performance rather than design standards with respect to pay to play practices of investment advisers to be neither consistent with the objectives for this rulemaking nor sufficient to protect investors in accordance with our statutory mandate of investor protection. Design standards, which we have employed, provide a baseline for advisory conduct as it relates to contributions and other pay to play activities, which is consistent with a rule designed to prohibit pay to play. The use of design standards also is important to ensure consistent application of the rule among investment advisers to which the rule and rule amendments will apply.

Regarding the fourth alternative, exempting small entities could compromise the overall effectiveness of the rule and related rule amendments. Banning pay to play practices benefits clients of both small and large advisers, and it would be inconsistent to specify different requirements for small advisers.

As discussed above, several commenters suggested alternative approaches to our rule.[613] Such alternatives include, for example: (i) That we require advisers to disclose their contributions to State and local officials; (ii) that we require advisers to include in their codes of ethics a policy that prohibits contributions made for the purpose of influencing the selection of the adviser; (iii) that we require advisers to adopt policies and procedures reasonably designed to prevent and detect contributions designed to influence the selection of an adviser; (iv) that we mandate preclearance of employee contributions; and (v) that we allow an adviser to customize sanctions based on the severity of the violation.[614] While it may be true that some of these approaches could diminish the compliance burdens on advisers, including small advisers, as we explain above, we considered these alternative approaches and do not believe they would appropriately address the kind of conduct at which our rule is directed.[615]

We are sensitive to the burdens our rule amendments will have on small advisers. We believe that the rule we are adopting today contains a number of modifications from what we had proposed that will alleviate many of the commenters' concerns regarding small advisers. Most notably, as described above, we have created an exception to the third-party solicitor ban for "regulated persons," which will, for instance, allow advisers to continue to use third party placement agents to sell interests in covered investment pools they manage instead of incurring additional costs to hire internal marketing staff, a result that could have disproportionally affected small advisers.[616] Moreover, as discussed above, we have modified the exceptions to the rule's two-year time out provisions in certain respects to reduce the likelihood of an inadvertent or minor violation of the rule, including a shortened look back of six months for certain new covered associates whose contributions are less likely to involve pay to play and a new *de minimis* exception for contributions to officials for whom a covered associate is not entitled to vote.[617] We have also limited certain recordkeeping requirements we had proposed in order to achieve our

[608] *See* section VI.C of this Release.

[609] However, as noted above, many larger advisers with broker-dealer affiliates may spend fewer resources to comply with the proposed rule and rule amendments because they may be able to rely on compliance procedures and systems that the broker-dealer already has in place to comply with MSRB rules G–37 and G–38. *See supra* section IV.B.

[610] As noted above, we considered two alternatives to certain aspects of proposed rule 206(4)–5: A disclosure obligation and a two-year time out for third-party solicitors. We do not believe either alternative would accomplish our stated objective of curtailing pay to play activities and thereby address potential harms from those activities. *See* Proposing Release, at section II.A.2, including nn.133 and 134 and accompanying text.

[611] *See supra* note 423 and accompanying text.

[612] *See* section II.D. of this Release.

[613] *See generally* section II.B.2(a) of this Release.

[614] *See id.*

[615] *See id.*

[616] *See* section II.B.2(b) of this Release.

[617] *See* sections II.B.2(a)(5) and (6) of this Release.

goals in a way that balances the costs and benefits of the rule, including not requiring records of unsuccessful solicitations or payments (that are not contributions) by advisers or covered associates to government officials.[618]

VII. Effects on Competition, Efficiency and Capital Formation

We are adopting amendments to rule 204–2 pursuant to our authority under sections 204 and 211. Section 204 requires the Commission, when engaging in rulemaking pursuant to that authority, to consider whether the rule is "necessary or appropriate in the public interest or for the protection of investors."[619] Section 202(c) of the Advisers Act requires the Commission, when engaging in rulemaking that requires it to consider or determine whether an action is necessary or appropriate in the public interest, to consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation.[620]

In the Proposing Release, we solicited comment on whether, if adopted, the proposed amendments to rule 204–2 would promote efficiency, competition and capital formation. We further encouraged commenters to provide empirical data to support their views on any burdens on efficiency, competition or capital formation that might result from adoption of the proposed amendments. We did not receive any empirical data in this regard concerning the proposed amendments. We received some general comments, addressed below, asserting that the proposed amendments to require registered advisers to maintain books and records relating to investment advisory services they provide to government entities would have an adverse impact on competition.

We are amending rule 204–2 to require a registered adviser to make and keep a list of its covered associates, the government entities to which the adviser directly or indirectly provides advisory services, the "regulated person" solicitors the adviser retains, and the contributions made by the firm and its covered associates, as applicable, to government officials and candidates.[621] The amendments are designed to provide our examiners important information about the adviser and its covered associates' contributions to government officials, the government entities to which the adviser directly or indirectly provides advisory services, and the solicitors it retains. These amendments may also benefit advisers as records required under the amended rule will assist the Commission in enforcing the rule against, for example, an adviser whose pay to play activities, if not uncovered, could adversely affect the competitive position of a compliant adviser.

Although we believe that the amendments to the Advisers Act recordkeeping rule will require advisers to incur both one-time costs to establish and enhance current systems to assist in their compliance with the amendments and ongoing costs to maintain records, these costs will be borne by all registered advisers that have government entity clients or that pay regulated entities to solicit government clients on their behalf. As the amendments to the recordkeeping rule do not disproportionally affect any particular group of advisers with government entity clients and do not materially increase the compliance burden on advisers under rule 204–2, we do not believe that they will affect competition across registered investment advisers. Some commenters asserted that certain asset managers that provide advice to government entities but are not subject to the Advisers Act recordkeeping rule, such as banks and advisers that are exempt from registration under the Act, may be at a competitive advantage to registered advisers that must incur the costs of keeping records under the rule.[622] While we acknowledge these entities could potentially obtain a competitive advantage for this reason, we do not believe the costs attributable to the amendments to rule 204–2 will have a significant impact on registered advisers such that the advantage gained by asset managers not subject to the Advisers Act recordkeeping rule will be substantial.[623] Moreover, exempt advisers or persons that do not meet the definition of investment adviser are not subject to rule 204–2.[624] Finally, we also note that banks may be subject to laws and rules that do not apply to registered advisers.

We believe that the amendments to rule 204–2 may, to a limited extent, affect efficiency and capital formation with respect to the allocation of public pension plan assets. The amendments to rule 204–2 will allow our staff to examine for compliance with rule 206(4)–5. Authority to examine records may improve registered investment advisers' compliance with rule 206(4)–5, which may reduce the adverse effects of political contributions on the selection of investment advisers. While the amendments to the rule will not affect the aggregate amount of pension fund assets available for investment, limiting the effects of political contributions on the investment adviser selection process should improve the mechanism by which capital is formed and allocated to investment opportunities.

VIII. Statutory Authority

The Commission is adopting new rule 206(4)–5 and amending rule 206(4)–3 of the Advisers Act pursuant to the authority set forth in sections 206(4) and 211(a) of the Investment Advisers Act of 1940 [15 U.S.C. 80b–6(4), 80b–11(a)].

The Commission is amending rule 204–2 of the Advisers Act pursuant to the authority set forth in sections 204 and 211(a) of the Advisers Act [15 U.S.C. 80b–4 and 80b–11(a)].

List of Subjects in 17 CFR Part 275

Reporting and recordkeeping requirements; Securities.

■ For the reasons set out in the preamble, Title 17 Chapter II of the Code of Federal Regulations is amended as follows.

PART 275—RULES AND REGULATIONS, INVESTMENT ADVISERS ACT OF 1940

■ 1. The authority citation for Part 275 continues to read in part as follows:

Authority: 15 U.S.C. 80b–2(a)(11)(G), 80b–2(a)(17), 80b–3, 80b–4, 80b–4a, 80b–6(4), 80b–6a, and 80b–11, unless otherwise noted.

* * * * *

■ 2. Section 275.204–2 is amended by adding paragraph (a)(18) and by revising paragraph (h)(1) to read as follows:

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[618] *See* sections II.D and III.B.3. of this Release.

[619] 15 U.S.C. 80b–4.

[620] 15 U.S.C. 80b–2(c). In contrast, we are adopting rule 206(4)–5 and amendments to rule 206(4)–3 pursuant to our authority set forth in sections 206(4) and 211. For a discussion of the effects of these amendments on competition, efficiency and capital formation, see sections IV, V, and VI of this Release.

[621] Rule 204–2(a)(18)(i).

[622] SIFMA Letter ("The books and records requirement under the Proposed Rule are under inclusive. * * * As an initial matter, the books and records requirements apply only to some of the advisers covered by the Proposed Rule—although the Proposed Rule applies to a substantial number of entities who are exempt from registration under the Advisers Act, the Proposed Rule's additional books and records only modify the rules that apply to registered investment advisers.").

[623] In addition, we note that advisers not subject to the amendments to rule 204–2 may nonetheless maintain some of the required records as part of a strong compliance program.

[624] *See* section 204 of the Advisers Act, 15 U.S.C. 80b–4 (that provides the Commission authority to prescribe recordkeeping for advisers, other than those specifically exempted from registration).

§ 275.204–2 Books and records to be maintained by investment advisers.

(a) * * *

(18)(i) Books and records that pertain to § 275.206(4)–5 containing a list or other record of:

(A) The names, titles and business and residence addresses of all covered associates of the investment adviser;

(B) All government entities to which the investment adviser provides or has provided investment advisory services, or which are or were investors in any covered investment pool to which the investment adviser provides or has provided investment advisory services, as applicable, in the past five years, but not prior to September 13, 2010;

(C) All direct or indirect contributions made by the investment adviser or any of its covered associates to an official of a government entity, or direct or indirect payments to a political party of a State or political subdivision thereof, or to a political action committee; and

(D) The name and business address of each regulated person to whom the investment adviser provides or agrees to provide, directly or indirectly, payment to solicit a government entity for investment advisory services on its behalf, in accordance with § 275.206(4)–5(a)(2).

(ii) Records relating to the contributions and payments referred to in paragraph (a)(18)(i)(C) of this section must be listed in chronological order and indicate:

(A) The name and title of each contributor;

(B) The name and title (including any city/county/State or other political subdivision) of each recipient of a contribution or payment;

(C) The amount and date of each contribution or payment; and

(D) Whether any such contribution was the subject of the exception for certain returned contributions pursuant to § 275.206(4)–5(b)(2).

(iii) An investment adviser is only required to make and keep current the records referred to in paragraphs (a)(18)(i)(A) and (C) of this section if it provides investment advisory services to a government entity or a government entity is an investor in any covered investment pool to which the investment adviser provides investment advisory services.

(iv) For purposes of this section, the terms "contribution," "covered associate," "covered investment pool," "government entity," "official," "payment," "regulated person," and "solicit" have the same meanings as set forth in § 275.206(4)–5.

* * * * *

(h)(1) Any book or other record made, kept, maintained and preserved in compliance with §§ 240.17a–3 and 240.17a–4 of this chapter under the Securities Exchange Act of 1934, or with rules adopted by the Municipal Securities Rulemaking Board, which is substantially the same as the book or other record required to be made, kept, maintained and preserved under this section, shall be deemed to be made, kept, maintained and preserved in compliance with this section.

* * * * *

■ 3. Section 275.206(4)–3 is amended by adding paragraph (e) and removing the authority citation at the end of the section to read as follows:

§ 275.206(4)–3 Cash payments for client solicitations.

* * * * *

(e) *Special rule for solicitation of government entity clients.* Solicitation activities involving a government entity, as defined in § 275.206(4)–5, shall be subject to the additional limitations set forth in that section.

■ 4. Section 275.206(4)–5 is added to read as follows:

§ 275.206(4)–5 Political contributions by certain investment advisers.

(a) *Prohibitions.* As a means reasonably designed to prevent fraudulent, deceptive or manipulative acts, practices, or courses of business within the meaning of section 206(4) of the Act (15 U.S.C. 80b–6(4)), it shall be unlawful:

(1) For any investment adviser registered (or required to be registered) with the Commission, or unregistered in reliance on the exemption available under section 203(b)(3) of the Advisers Act (15 U.S.C. 80b–3(b)(3)) to provide investment advisory services for compensation to a government entity within two years after a contribution to an official of the government entity is made by the investment adviser or any covered associate of the investment adviser (including a person who becomes a covered associate within two years after the contribution is made); and

(2) For any investment adviser registered (or required to be registered) with the Commission, or unregistered in reliance on the exemption available under section 203(b)(3) of the Advisers Act (15 U.S.C. 80b–3(b)(3)) or any of the investment adviser's covered associates:

(i) To provide or agree to provide, directly or indirectly, payment to any person to solicit a government entity for investment advisory services on behalf of such investment adviser unless such person is a regulated person or is an executive officer, general partner, managing member (or, in each case, a person with a similar status or function), or employee of the investment adviser; and

(ii) To coordinate, or to solicit any person or political action committee to make, any:

(A) Contribution to an official of a government entity to which the investment adviser is providing or seeking to provide investment advisory services; or

(B) Payment to a political party of a State or locality where the investment adviser is providing or seeking to provide investment advisory services to a government entity.

(b) *Exceptions.*

(1) *De minimis* exception. Paragraph (a)(1) of this section does not apply to contributions made by a covered associate, if a natural person, to officials for whom the covered associate *was* entitled to vote at the time of the contributions and which in the aggregate do not exceed $350 to any one official, per election, or to officials for whom the covered associate was not entitled to vote at the time of the contributions and which in the aggregate do not exceed $150 to any one official, per election.

(2) Exception for certain new covered associates. The prohibitions of paragraph (a)(1) of this section shall not apply to an investment adviser as a result of a contribution made by a natural person more than six months prior to becoming a covered associate of the investment adviser unless such person, after becoming a covered associate, solicits clients on behalf of the investment adviser.

(3) Exception for certain returned contributions.

(i) An investment adviser that is prohibited from providing investment advisory services for compensation pursuant to paragraph (a)(1) of this section as a result of a contribution made by a covered associate of the investment adviser is excepted from such prohibition, subject to paragraphs (b)(3)(ii) and (b)(3)(iii) of this section, upon satisfaction of the following requirements:

(A) The investment adviser must have discovered the contribution which resulted in the prohibition within four months of the date of such contribution;

(B) Such contribution must not have exceeded $350; and

(C) The contributor must obtain a return of the contribution within 60 calendar days of the date of discovery of such contribution by the investment adviser.

(ii) In any calendar year, an investment adviser that has reported on its annual updating amendment to Form ADV (17 CFR 279.1) that it has more than 50 employees is entitled to no more than three exceptions pursuant to paragraph (b)(3)(i) of this section, and an investment adviser that has reported on its annual updating amendment to Form ADV that it has 50 or fewer employees is entitled to no more than two exceptions pursuant to paragraph (b)(3)(i) of this section.

(iii) An investment adviser may not rely on the exception provided in paragraph (b)(3)(i) of this section more than once with respect to contributions by the same covered associate of the investment adviser regardless of the time period.

(c) *Prohibitions as applied to covered investment pools.* For purposes of this section, an investment adviser to a covered investment pool in which a government entity invests or is solicited to invest shall be treated as though that investment adviser were providing or seeking to provide investment advisory services directly to the government entity.

(d) *Further prohibition.* As a means reasonably designed to prevent fraudulent, deceptive or manipulative acts, practices, or courses of business within the meaning of section 206(4) of Advisers Act (15 U.S.C. 80b–6(4)), it shall be unlawful for any investment adviser registered (or required to be registered) with the Commission, or unregistered in reliance on the exemption available under section 203(b)(3) of the Advisers Act (15 U.S.C. 80b–3(b)(3)), or any of the investment adviser's covered associates to do anything indirectly which, if done directly, would result in a violation of this section.

(e) *Exemptions.* The Commission, upon application, may conditionally or unconditionally exempt an investment adviser from the prohibition under paragraph (a)(1) of this section. In determining whether to grant an exemption, the Commission will consider, among other factors:

(1) Whether the exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Advisers Act (15 U.S.C. 80b);

(2) Whether the investment adviser:

(i) Before the contribution resulting in the prohibition was made, adopted and implemented policies and procedures reasonably designed to prevent violations of this section; and

(ii) Prior to or at the time the contribution which resulted in such prohibition was made, had no actual knowledge of the contribution; and

(iii) After learning of the contribution:

(A) Has taken all available steps to cause the contributor involved in making the contribution which resulted in such prohibition to obtain a return of the contribution; and

(B) Has taken such other remedial or preventive measures as may be appropriate under the circumstances;

(3) Whether, at the time of the contribution, the contributor was a covered associate or otherwise an employee of the investment adviser, or was seeking such employment;

(4) The timing and amount of the contribution which resulted in the prohibition;

(5) The nature of the election (*e.g,* Federal, State or local); and

(6) The contributor's apparent intent or motive in making the contribution which resulted in the prohibition, as evidenced by the facts and circumstances surrounding such contribution.

(f) *Definitions.* For purposes of this section:

(1) *Contribution* means any gift, subscription, loan, advance, or deposit of money or anything of value made for:

(i) The purpose of influencing any election for Federal, State or local office;

(ii) Payment of debt incurred in connection with any such election; or

(iii) Transition or inaugural expenses of the successful candidate for State or local office.

(2) *Covered associate* of an investment adviser means:

(i) Any general partner, managing member or executive officer, or other individual with a similar status or function;

(ii) Any employee who solicits a government entity for the investment adviser and any person who supervises, directly or indirectly, such employee; and

(iii) Any political action committee controlled by the investment adviser or by any person described in paragraphs (f)(2)(i) and (f)(2)(ii) of this section.

(3) *Covered investment pool* means:

(i) An investment company registered under the Investment Company Act of 1940 (15 U.S.C. 80a) that is an investment option of a plan or program of a government entity; or

(ii) Any company that would be an investment company under section 3(a) of the Investment Company Act of 1940 (15 U.S.C. 80a–3(a)), but for the exclusion provided from that definition by either section 3(c)(1), section 3(c)(7) or section 3(c)(11) of that Act (15 U.S.C. 80a–3(c)(1), (c)(7) or (c)(11)).

(4) *Executive officer* of an investment adviser means:

(i) The president;

(ii) Any vice president in charge of a principal business unit, division or function (such as sales, administration or finance);

(iii) Any other officer of the investment adviser who performs a policy-making function; or

(iv) Any other person who performs similar policy-making functions for the investment adviser.

(5) *Government entity* means any State or political subdivision of a State, including:

(i) Any agency, authority, or instrumentality of the State or political subdivision;

(ii) A pool of assets sponsored or established by the State or political subdivision or any agency, authority or instrumentality thereof, including, but not limited to a "defined benefit plan" as defined in section 414(j) of the Internal Revenue Code (26 U.S.C. 414(j)), or a State general fund;

(iii) A plan or program of a government entity; and

(iv) Officers, agents, or employees of the State or political subdivision or any agency, authority or instrumentality thereof, acting in their official capacity.

(6) *Official* means any person (including any election committee for the person) who was, at the time of the contribution, an incumbent, candidate or successful candidate for elective office of a government entity, if the office:

(i) Is directly or indirectly responsible for, or can influence the outcome of, the hiring of an investment adviser by a government entity; or

(ii) Has authority to appoint any person who is directly or indirectly responsible for, or can influence the outcome of, the hiring of an investment adviser by a government entity.

(7) *Payment* means any gift, subscription, loan, advance, or deposit of money or anything of value.

(8) *Plan or program of a government entity* means any participant-directed investment program or plan sponsored or established by a State or political subdivision or any agency, authority or instrumentality thereof, including, but not limited to, a "qualified tuition plan" authorized by section 529 of the Internal Revenue Code (26 U.S.C. 529), a retirement plan authorized by section 403(b) or 457 of the Internal Revenue Code (26 U.S.C. 403(b) or 457), or any similar program or plan.

(9) *Regulated person* means:

(i) An investment adviser registered with the Commission that has not, and whose covered associates have not,

within two years of soliciting a government entity:

(A) Made a contribution to an official of that government entity, other than as described in paragraph (b)(1) of this section; and

(B) Coordinated or solicited any person or political action committee to make any contribution or payment described in paragraphs (a)(2)(ii)(A) and (B) of this section; or

(ii) A "broker," as defined in section 3(a)(4) of the Securities Exchange Act of 1934 (15 U.S.C. 78c(a)(4)) or a "dealer," as defined in section 3(a)(5) of that Act (15 U.S.C. 78c(a)(5)), that is registered with the Commission, and is a member of a national securities association registered under section 15A of that Act (15 U.S.C. 78o–3), provided that:

(A) The rules of the association prohibit members from engaging in distribution or solicitation activities if certain political contributions have been made; and

(B) The Commission, by order, finds that such rules impose substantially equivalent or more stringent restrictions on broker-dealers than this section imposes on investment advisers and that such rules are consistent with the objectives of this section.

(10) *Solicit* means:

(i) With respect to investment advisory services, to communicate, directly or indirectly, for the purpose of obtaining or retaining a client for, or referring a client to, an investment adviser; and

(ii) With respect to a contribution or payment, to communicate, directly or indirectly, for the purpose of obtaining or arranging a contribution or payment.

By the Commission.

Dated: July 1, 2010.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2010–16559 Filed 7–13–10; 8:45 am]

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