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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, December 7, 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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The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 431

#### Waiver of Acceptable Mission Risk Restriction for Reentry and a Reentry Vehicle

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of waiver.

**SUMMARY:** This notice of waiver concerns two petitions for waiver submitted to the FAA by Space Exploration Technologies Corp. (SpaceX): A petition to waive the requirement that a waiver petition be submitted at least sixty days before the proposed effective date; and a petition to waive the restriction that the combined risk to the public from the launch and reentry of a reentry vehicle not exceed an expected average number of 0.00003 casualties ( $E_c \leq 30 \times 10^{-6}$ ) from debris. The first petition is unnecessary because, as explained below, SpaceX demonstrated good cause for its late filing. The FAA grants the second petition and waives the restriction that the combined risk to the public from the launch and reentry of a reentry vehicle not exceed an expected average number of 0.00003 casualties ( $E_c \leq 30 \times 10^{-6}$ ) from debris.

**FOR FURTHER INFORMATION CONTACT:** For technical questions concerning this waiver, contact Philip Brinkman, Licensing Program Lead, Commercial Space Transportation—Licensing and Safety Division, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267-7715; e-mail: [phil.brinkman@faa.gov](mailto:phil.brinkman@faa.gov). For legal questions concerning this waiver, contact Laura Montgomery, Senior Attorney for Commercial Space Transportation, AGC-200, Office of the Chief Counsel, Regulations Division,

Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267-3150.

#### SUPPLEMENTARY INFORMATION:

##### Background

On October 11, 2010, SpaceX submitted a waiver petition to the Federal Aviation Administration's (FAA's) Office of Commercial Space Transportation (AST) requesting two waivers with respect to a reentry license for Dragon, a reentry vehicle, to be carried aboard Falcon 9 flight 002. First, SpaceX requested a waiver of 14 CFR 404.3(b)(5), which requires that a waiver petition be submitted at least sixty days before the proposed effective date of the waiver. Second, SpaceX requested a waiver of 14 CFR 431.35(b)(1)(i),<sup>1</sup> which prohibits a mission involving a reentry vehicle when the total expected average number of casualties ( $E_c$ ) for that mission exceeds  $30 \times 10^{-6}$ .

The FAA licenses the launch of a launch vehicle, reentry of a reentry vehicle, and the operation of a launch or reentry site under authority granted to the Secretary of Transportation in the Commercial Space Launch Act of 1984, as amended, codified in 49 U.S.C. Subtitle IX, chapter 701 (Chapter 701), and delegated to the FAA Administrator. The Associate Administrator for Commercial Space Transportation exercises licensing authority under Chapter 701.

SpaceX is a private commercial space flight company. It has entered into a Space Act Agreement with the National Aeronautics and Space Administration (NASA) as part of NASA's Commercial Orbital Transportation Services (COTS) program. The COTS program is designed to stimulate efforts by the private sector to demonstrate safe, reliable, and cost-effective space transportation to the International Space Station.

The petition addresses an upcoming demonstration flight that SpaceX plans to undertake as part of the COTS program. At the time of the filing of the petition, the launch was scheduled for November 8, 2010. SpaceX's Falcon 9 launch vehicle will launch a reentry vehicle, named Dragon, into orbit. Once

<sup>1</sup> Even though Dragon is a reentry vehicle and not a reusable launch vehicle, 14 CFR 435.35 incorporates and applies section 431.35 to all reentry vehicles.

Dragon is in orbit, it will be subjected to a ground-implemented health check. The health check is designed to check time-dependent variables to ensure the health and functionality of the propellant, power, and avionics subsystems. If Dragon passes the health check, a ground operator will issue a remote command to reenter, which will initiate Dragon's reentry and ultimately result in Dragon splashing down in the ocean off the coast of Southern California. If Dragon fails the health check, the ground operator will issue a remote command that will disable Dragon's reentry, leaving Dragon in orbit.

While planning for this mission, SpaceX calculated that  $21 \times 10^{-6}$  is the expected average number of casualties ( $E_c$ ) to which the public will be exposed by vehicle or vehicle debris impact hazards associated with the launch of Falcon 9 and reentry of Dragon. Because this  $E_c$  was less than the  $30 \times 10^{-6}$  limit imposed by 14 CFR 431.35(b)(1)(i), SpaceX believed that it complied with the regulations.

The FAA informed SpaceX that the FAA assessed the risk for the launch of Falcon 9 and reentry of Dragon as  $47 \times 10^{-6}$ . The  $E_c$  for the launch of Falcon 9 is  $19 \times 10^{-6}$ , and by adding an  $E_c$  of  $7 \times 10^{-6}$  to account for the nominal reentry of Dragon and an  $E_c$  of  $21 \times 10^{-6}$  to account for the possibility that Dragon will initiate a failed attempt at reentry, the FAA obtained a total  $E_c$  value of  $47 \times 10^{-6}$  for the launch of Falcon 9 and reentry of Dragon. Because the FAA's calculations resulted in a total  $E_c$  value that exceeded the  $30 \times 10^{-6}$  limit imposed by section 431.35(b)(1)(i), the FAA informed SpaceX that it would need to obtain a waiver.

In response, SpaceX filed two petitions for a waiver. First, SpaceX requested a waiver of the requirement that a petition be submitted at least sixty days before the proposed effective date of the waiver. Second, SpaceX requested a waiver of the restriction that the total  $E_c$  for a launch and reentry not exceed  $30 \times 10^{-6}$ . In its waiver request, SpaceX emphasized that it had attempted to ensure public safety by adopting the following risk mitigation measures for Dragon:

1. Dragon's thermal protection system has been modified so that if it enters facing down it will burn and demise.



2. Dragon can keep orbiting in order to increase the probability of initiating a safe reentry.

3. Dragon will automatically vent its propellants if it is not able to reenter as planned. Venting occurs autonomously, but SpaceX has the ability to issue a back-up command from the ground.

4. In the case of a failed or degraded deorbit burn, Dragon automatically drains propellants and subsequently deploys its parachutes.

5. A ground command received through one of three receivers and through multiple RF links, via TDRSS and multiple ground stations, can command the venting of any remaining fuel and the draining of battery power to reduce the possibility of explosion or toxic fumes when Dragon lands.

6. Dragon has the ability to autonomously guide itself to a pre-determined site located more than 780 km from the coastline.

7. Dragon has the ability to monitor its safety-critical systems in real-time.

8. Dragon has over 100% margin on both power and propellant budgets.

9. Dragon has a space-grade Inertial Measurement Unit and space-grade flight computer, both of which have extensive flight heritage including use on the International Space Station.

10. Dragon has redundant drogue parachutes and dual redundant main parachutes.

11. The vehicle's thrusters are plumbed such that Dragon can deorbit and reenter with the loss of any two entire propulsion modules.

12. The vehicle has backup capabilities within all of its major subsystems.

#### Waiver Criteria

Chapter 701 allows the FAA to waive a license requirement if the waiver (1) will not jeopardize public health and safety, safety of property, (2) will not jeopardize national security and foreign policy interests of the United States, and (3) will be in the public interest. 49 U.S.C. 70105(b)(3) (2010); 14 CFR 404.5(b) (2010).

#### Section 404.3 Waiver Petition

Section 404.3(b)(5) requires that a petition for a waiver be submitted at least sixty days before the proposed effective date of the waiver. However, this section also provides that a petition may be submitted late if the petitioner shows good cause. *Id.* (b)(5).

Here, SpaceX submitted its waiver petition on October 11, 2010, which was less than sixty days from its planned November 8, 2010, launch date. However, in its petition, SpaceX explained that it initially calculated the

risk for the launch of Falcon 9 and the reentry of Dragon in a different manner than the FAA, and was not aware that a waiver would be required until so informed by the FAA. Once the FAA informed SpaceX that it needed to obtain a waiver, SpaceX proceeded to apply for the waiver "in a timely fashion." As such, the FAA has found that SpaceX had good cause for submitting its waiver petition less than sixty days from the planned November 8, 2010, launch date. Therefore, SpaceX's late submission does not violate section 404.3(b)(5), and a waiver of that section is unnecessary.

#### Section 431.35(b)(1)(i) Waiver Petition

Section 431.35(b)(1)(i) prohibits a launch and reentry mission if the total  $E_c$  for that mission exceeds  $30 \times 10^{-6}$ . For reasons described below, the FAA waives this restriction to allow SpaceX to conduct a mission whose total  $E_c$  is  $47 \times 10^{-6}$ , where launch and reentry are each less than  $30 \times 10^{-6}$ . In deciding whether or not to issue a waiver, the FAA had to analyze whether the waiver: (1) Would jeopardize public health and safety or safety of property; (2) would jeopardize national security and foreign policy interests of the United States; and (3) was in the public interest. *See* 49 U.S.C. 70105(b)(3); 14 CFR 404.5(b).

##### A. Public Health and Safety and Safety of Property

In order to determine whether granting a waiver would jeopardize public health and safety or safety of property, the FAA considered: (1) Whether section 431.35 requires that the  $E_c$  calculations account for the possibility of a random uncontrolled reentry that occurs as a result of a reentry vehicle ceasing to function upon arrival in orbit; (2) whether granting a waiver would be consistent with the safety rationale underlying section 431.35; and (3) whether there were any other factors that would impact the waiver decision in this case.

##### i. Random Uncontrolled Reentry

At the outset, the FAA first addressed whether to account for random uncontrolled reentry not associated with a licensed reentry. Section 431.35 could apply to two types of random uncontrolled reentry: (1) A random uncontrolled reentry occurring as a result of a failed reentry attempt; and (2) a random uncontrolled reentry occurring as a result of a reentry vehicle ceasing to function upon arrival in orbit.

The preamble to the final rule provides ambiguous guidance on this matter. *Commercial Space Transportation Reusable Launch*

*Vehicle and Reentry Licensing Regulations, Final Rule*, 65 FR 56618 (Sep. 19, 2000). When discussing the possibility of requiring contingency abort locations for reentries, the preamble states that an applicant would have to show that an uncontrolled random reentry would not exceed acceptable risk criteria for the mission. *Id.* at 56641. Another part of the preamble states that risk to public safety from a reentry that is "essentially random or otherwise non-nominal" would be assessed as part of the licensing process and an applicant would have to demonstrate that such a reentry would not exceed acceptable risk criteria for the mission. *Id.* at 56623 n.2. As a result of this waiver petition, the FAA has had to address to which of the two possible random reentry scenarios this assessment must apply.

One possible interpretation of the preamble is that section 431.35 requires that the  $E_c$  calculations account for the possibility of a random uncontrolled reentry that occurs as a result of a reentry vehicle ceasing to function upon arrival in orbit. However, this interpretation would be problematic because Chapter 701 limits the FAA's licensing of reentry to scenarios involving purposeful reentry. *See* 49 U.S.C. 70102(12) (defining "reentry" as a purposeful act); *see also* 65 FR at 56624 (clarifying that, under Chapter 701, section 431.35 is intended to regulate scenarios in which "survivability by design is combined with the purposeful act of reentry"). Because a random uncontrolled reentry arising out of a reentry vehicle ceasing to function upon arrival in orbit is not purposeful and is thus not licensed, an interpretation that section 431.35 applies to this type of reentry would conflict with Chapter 701.

The better approach is to limit the risk associated with a random uncontrolled reentry to that caused by a failed reentry attempt. Because an attempt at a reentry is a purposeful act and thus requires a license, the FAA should account for the risk associated with a random uncontrolled reentry that occurs as a result of a failed attempt. *See* 49 U.S.C. at 70102(12); 65 FR at 56624.

Under the above rationale, the total  $E_c$  for the reentry of Dragon is the  $E_c$  for nominal reentry ( $7 \times 10^{-6}$ ) plus the  $E_c$  for the possibility of a failed attempt at reentry ( $21 \times 10^{-6}$ ), which results in a total reentry  $E_c$  of  $28 \times 10^{-6}$ . When the  $E_c$  for the launch of Falcon 9 ( $19 \times 10^{-6}$ ) is added to the reentry  $E_c$  of Dragon, the combined  $E_c$  for the Falcon 9 launch and Dragon reentry comes out to  $47 \times 10^{-6}$ .

ii. Consistency With Rationale for Section 431.35

The next matter that the FAA addressed was whether granting a waiver in this case would be consistent with the safety rationale underlying section 431.35. In the preamble to the notice of proposed rulemaking (NPRM), the FAA explained that, when it was drafting section 431.35, it decided to use a single aggregate risk threshold for a mission involving the launch and reentry of a reentry vehicle. *Commercial Space Transportation Reusable Launch Vehicle and Reentry Licensing Regulations*, NPRM, 64 FR 19626, 19635 (Apr. 21, 1999). However, the FAA also acknowledged that there could be circumstances where it would be appropriate to separate launch from reentry risk, such as where different operators were involved and could be apportioned allowable risk thresholds, or where intervening events or time made reentry risks sufficiently independent of launch risks as to warrant separate consideration. *Id.*

Here, the health check of Dragon, a different vehicle than the Falcon 9 launch vehicle, that will take place once Dragon is in orbit is an intervening event that makes the launch risk associated with the launch of Falcon 9 independent of the reentry risk associated with the reentry of Dragon. The health check will permit SpaceX to reevaluate Dragon's condition after the launch has taken place, and to make a fresh determination about whether Dragon should be permitted to reenter. If, after conducting a post-launch health check of Dragon, SpaceX finds safety concerns associated with reentry, SpaceX will be able to issue a command to disable Dragon's reentry. As such, because the reentry of Dragon is based on the results of an in-orbit health check that will be conducted independently of the launch, the risks associated with the launch of Falcon 9 and reentry of Dragon are sufficiently independent to warrant separate consideration in this case.

Evaluating these risks separately, the  $E_c$  for the launch of Falcon 9 is  $19 \times 10^{-6}$ , which is within the  $30 \times 10^{-6}$  limit imposed by section 431.35(b)(1)(i). Likewise, the  $E_c$  for the reentry of Dragon is  $28 \times 10^{-6}$ , which is also within the  $30 \times 10^{-6}$  limit that the FAA applies to launch hazards. Accordingly, the FAA has determined that granting a waiver in this case would be consistent with the safety rationale underlying section 431.35.

iii. Other Factors Impacting the Waiver Decision

Dragon's mitigation measures were another factor that influenced the FAA's analysis with regard to whether a waiver would jeopardize public health and safety and safety of property. As stated above, the Dragon capsule employs numerous risk mitigation measures to reduce the risk to the public from the launch of Falcon 9 and reentry of Dragon.

The FAA has taken particular notice of the way in which Dragon's electrical power system (batteries), flight computer, and propulsion system will reduce risk to the public. For instance, Dragon has more than four times the propellant needed for a safe reentry in the target area. The additional propellant increases the probability that Dragon will land in its nominal target area instead of a population center. Dragon also has three parachutes, which decrease risk to the public because only one of these parachutes is necessary for a low impact landing. The additional parachutes reduce the chance that Dragon will crash into the ground while attempting to land.

SpaceX has also designed the Dragon reentry vehicle to vent propellants in the case of an aborted or off-nominal reentry. This mitigation measure greatly reduces the risk to the public because it allows Dragon to safely dispose of hazardous propellant materials if something should go wrong with the mission.

As a result of Dragon's mitigation measures, as well as the other considerations discussed above, the FAA has determined that granting a waiver in this case would not jeopardize public health and safety or safety of property.

*B. National Security and Foreign Policy Implications*

The FAA has identified no national security or foreign policy implications associated with granting this waiver.

*C. Public Interest*

Two of the public policy goals of Chapter 701 are: (1) To promote economic growth and entrepreneurial activity through use of the space environment; and (2) to encourage the United States private sector to provide launch and reentry vehicles and associated services. 49 U.S.C. 70101(b)(1) and (2). Here, granting this waiver is consistent with the public interest goals articulated by Chapter 701.

A goal of the COTS program's mission is to ultimately develop the capability to

resupply the International Space Station. SpaceX's demonstration launch of Falcon 9 and reentry of Dragon is a step toward achieving that goal. This demonstration launch is important in light of the fact that the U.S. Government is ending the Space Shuttle Program and NASA plans to rely upon its COTS Program to develop a robust domestic commercial space transportation capability. This capability will provide the United States with the ability to resupply the International Space Station. As such, granting SpaceX's waiver request will be consistent with Chapter 701's policy goals by: (1) Promoting SpaceX's entrepreneurial activity in the space environment; and (2) encouraging a private U.S. company to develop and launch a launch vehicle (Falcon 9) and a reentry vehicle (Dragon).

**Summary and Conclusion**

A waiver will not jeopardize public health and safety or safety of property because: (1) The risk associated with the launch of Falcon 9 and the risk associated with the reentry of Dragon are each under an  $E_c$  of  $30 \times 10^{-6}$ ; and (2) the Dragon capsule employs numerous risk mitigation measures including an in-orbit health check. The waiver also will not jeopardize national security and foreign policy interests of the United States. A waiver is in the public interest because it furthers the statutory goals of Chapter 701. For the foregoing reasons, the FAA has waived the restriction that the combined risk to the public from the launch of Falcon 9 and reentry of Dragon cannot exceed an expected average number of 0.00003 casualties ( $30 \times 10^{-6}$ ) from debris.

Issued in Washington, DC, on November 30, 2010.

**Kenneth Wong,**

*Commercial Space Transportation, Licensing and Safety Division Manager.*

[FR Doc. 2010-30402 Filed 12-3-10; 8:45 am]

**BILLING CODE 4910-13-P**

**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

**14 CFR Part 431**

**Office of Commercial Space Transportation; Waiver of Autonomous Reentry Restriction for a Reentry Vehicle**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of waiver.

**SUMMARY:** This notice of waiver concerns two petitions for waiver submitted to the Federal Aviation Administration (FAA) by Space Exploration Technologies Corp. (SpaceX): A petition to waive the requirement that a waiver petition be submitted at least sixty days before the proposed effective date of the waiver, and a petition to waive the requirement that SpaceX only initiate reentry of its reentry vehicle, the Dragon Spacecraft (Dragon), by command. The first petition is unnecessary because, as explained below, SpaceX demonstrated good cause for its late filing. The FAA finds that waiving the requirement for SpaceX ground operators to initiate Dragon's reentry to Earth is in the public interest and will not jeopardize public health and safety, safety of property, and national security and foreign policy interests of the United States.

**FOR FURTHER INFORMATION CONTACT:** For technical questions concerning this waiver contact Howard Searight, Aerospace Engineer, AST-200, Office of Commercial Space Transportation (AST), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267-7927; e-mail:

[howard.searight@faa.gov](mailto:howard.searight@faa.gov). For legal questions concerning this waiver contact Laura Montgomery, Senior Attorney for Commercial Space Transportation, AGC-200, Office of the Chief Counsel, Regulations Division, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267-3150; e-mail: [laura.montgomery@faa.gov](mailto:laura.montgomery@faa.gov).

**SUPPLEMENTARY INFORMATION:**

*Background:* On September 23, 2010, SpaceX requested two waivers from the FAA's Office of Commercial Space Transportation (AST) for the reentry of Dragon, a reentry vehicle, to be launched on Falcon 9 flight 002. First, SpaceX requested a waiver of procedural requirements for waivers set forth at 14 CFR 404.3. Second, SpaceX requested a waiver of 14 CFR 431.43(e)<sup>1</sup> to allow autonomous reentry.<sup>2</sup>

<sup>1</sup> Even though Dragon is a reentry vehicle and not a reusable launch vehicle, 14 CFR 435.33 incorporates and applies section 431.43 to all reentry vehicles.

<sup>2</sup> SpaceX stated that autonomous reentry would only be used in off-nominal circumstances, and the regulation prevents autonomous reentry only for nominal circumstances, thus rendering a waiver unnecessary. This interpretation of the regulation conflicts with the regulation's requirement that an operator only initiate reentry by command as described in the preamble to the proposed rule. There, the FAA expressed its concern that authorizing reentry of totally autonomous vehicles would not fulfill adequately its public safety

The FAA licenses, in relevant part, the launch of a launch vehicle, and reentry of a reentry vehicle under authority granted to the Secretary of Transportation by 49 U.S.C. Subtitle IX, chapter 701 (Chapter 701), and delegated to the FAA's Administrator and Associate Administrator for Commercial Space Transportation.

SpaceX is a private commercial space flight company. It entered into a Space Act Agreement with the National Aeronautics and Space Administration (NASA) as part of NASA's Commercial Orbital Transportation Services (COTS) program. The COTS program is designed to stimulate efforts within the private sector to demonstrate safe, reliable, and cost-effective space transportation to the International Space Station.

SpaceX's petition for waiver concerns an upcoming demonstration flight that it plans to undertake as part of the COTS program. At the time of the filing of the petition, the launch for that flight was scheduled to take place on November 8, 2010. During the flight, SpaceX's Falcon 9 vehicle will launch the Dragon reentry vehicle into orbit. Dragon is a reentry vehicle whose capability SpaceX plans to demonstrate for NASA. Ultimately, SpaceX intends to use Dragon to transport cargo and people to and from the International Space Station.

Once Dragon is in orbit, a ground-implemented health check will be carried out by telemetry. SpaceX has designed the Dragon capsule to remain in orbit until SpaceX ground operators transmit a reentry command. A ground operator can issue commands to either enable or disable the reentry of Dragon based on the health of the vehicle. Dragon is also able to conduct an autonomous health check. Propellant and power levels are the key variables used by ground operators in determining whether to issue commands to reenter or stay in orbit, and the same variables would be used by the vehicle in its onboard health check. The onboard health check is designed to check time-dependent variables to ensure the health and functionality of the propellant, power and avionics sub-systems. Based on these evaluations, Dragon is able to determine whether it is healthy. On the ground, the reentry team can read the

responsibility. Without active control, those systems and conditions necessary for safe reentry would not be verified before reentry was initiated *Commercial Space Transportation Reusable Launch Vehicle and Reentry Licensing Regulations*, 64 FR 19626, 19645 (Apr. 21, 1999) (*Reentry NPRM*). Because it was the FAA's intent that the regulations ensure human control capability upon reentry, SpaceX's petition is a request for a waiver.

raw data and establish for themselves whether Dragon is healthy. Dragon's onboard health check is designed to replicate the decision-making process of the ground operators with respect to time-dependent failures, which are, in Dragon's case, the full depletion of power and propellant. If Dragon's communications failed and the vehicle passed the onboard health check, Dragon would reenter autonomously.

Once Dragon passes a ground-implemented health check, ground operators will issue a reentry command. After ground operators issue the reentry command, Dragon will wait until the point in space at which the reentry burn initiation is planned before initiating reentry. Dragon will reenter, deploy three parachutes and splash down. A nominal Dragon reentry splashes down in the Pacific Ocean off the coast of southern California with some propellants on board.

If an anomaly occurs after the issuance of the reentry command, ground operators can issue a command that disables reentry. SpaceX is concerned with what would happen if its ground operators were unable to communicate a reentry command to a healthy Dragon due to failed or disabled communications. In this circumstance, SpaceX proposes that the FAA permit the autonomous reentry of a healthy Dragon at the nominal landing location in order to maximize public safety. This scenario may play out in different ways. If ground operators needed more time to complete a health check than that available during one orbit, they could disable reentry by command. Dragon would then not reenter, even if its autonomous health check would otherwise allow it to. If a health check proved satisfactory, ground operators could re-enable reentry, and Dragon would reenter. If Dragon never received a command, it could rely on the results of its own continuous autonomous health check, and, if those results were positive, reenter.

Dragon has several safety features that would allow for a safe autonomous reentry in the event of a communications failure, including: (1) The vehicle automatically reduces itself to its lowest energy level in the case of an off-nominal burn; (2) the vehicle has the ability to autonomously guide itself to the same pre-determined landing site, located more than 780 kilometers from the coastline; (3) the vehicle has the ability to monitor its safety-critical systems in real-time; (4) the vehicle has over 100% margin on both power and propellant budgets; (5) the vehicle has a space-grade inertial measurement unit (IMU); (6) the vehicle

has a space-grade flight computer; and (7) the vehicle has redundant drogue parachutes and dual redundant main parachutes.

*Waiver Criteria:* Chapter 701 allows the FAA to waive a requirement for an individual license applicant if the FAA decides that the waiver will not jeopardize public health and safety, safety of property, and national security and foreign policy interests of the United States and is in the public interest. 49 U.S.C. 70105(b)(3) (2010); 14 CFR 404.5(b) (2010).

#### Section 404.3 Waiver Petition

Section 404.3(b)(5) requires that a petition for waiver be submitted at least sixty days before the proposed effective date of the waiver. However, this section also provides that a petition may be submitted late if the petitioner shows good cause. *Id.* (b)(5).

Here, SpaceX submitted its waiver petition on September 23, 2010, which was less than sixty days before the November 8, 2010 launch date planned at the time of the filing of the petition. However, in its petition, SpaceX explained that it initially interpreted the applicable regulations differently than the FAA, and was not aware that a waiver would be required. Once the FAA informed SpaceX that it needed to obtain a waiver, SpaceX proceeded to apply for the waiver in a timely fashion. As such, the FAA has found that SpaceX had good cause for submitting its waiver petition less than sixty days from its launch date. Therefore, SpaceX's late submission does not violate 404.3(b)(5), and a waiver of that section is unnecessary.

#### Section 431.43(e) Waiver Petition

Section 431.43(e) requires, in pertinent part, any operator of a reusable launch vehicle that enters Earth orbit to issue a command enabling reentry flight of the vehicle. It further states that reentry flight cannot be initiated autonomously under nominal circumstances without prior enable. 14 CFR 431.43(e).

For reasons described below, the FAA waives the requirement of 14 CFR 431.43(e), and allows SpaceX to autonomously initiate reentry flight of Dragon in the event that SpaceX ground operators lose communication with Dragon, and Dragon is healthy. In this context, communication loss means Dragon fails to send a reentry request to SpaceX's ground operators, or the ground operators are unable to send a command enabling reentry of Dragon. The onboard health check is designed to check time-dependent variables to ensure the health and functionality of

the propellant, power and avionics subsystems.

In deciding whether or not to waive the requirement that Dragon's operator issue a command to enable reentry of the vehicle, the FAA must analyze whether the waiver: (1) Is in the public interest; (2) will not jeopardize public health and safety or safety of property; and (3) will not jeopardize national security and foreign policy interests of the United States. 49 U.S.C. 70105(b)(3); 14 CFR 404.5(b). The FAA will grant this waiver because SpaceX satisfies the criteria.

##### A. Public Interest

The change proposed by SpaceX is consistent with the statutory goal of seeking improvements to safety. 49 U.S.C. 70101(a)(12) and (b)(2)(C). Granting SpaceX's waiver is in the public interest because a guided reentry is safer than a random reentry, and therefore Dragon's proposed autonomous reentry capability enhances the overall safety of the mission.

##### B. Public Health and Safety

Although the FAA's regulation prohibits autonomous reentry, a waiver is warranted in SpaceX's case because an autonomous reentry of a healthy Dragon that has lost ground communications is safer than a random reentry. The preamble to the Reentry NPRM acknowledges that some RLV operators were contemplating totally autonomous reentry capability, and expressed a concern that autonomous reentry was not adequately safe. Specifically, the FAA was concerned about system anomalies or other non-compliant conditions that would not be verified before initiation of reentry in the absence of active human control. *Reentry NPRM*, 64 FR at 19645. The FAA retained flexibility in granting waivers to allow the use of autonomous systems. *Commercial Space Transportation Reusable Launch Vehicle and Reentry Licensing Regulations*, 65 FR 56618, 56641 (Sept. 19, 2000) (*Reentry Rule*). In requiring the capability for human intervention, the FAA did not intend to foreclose the use of autonomous systems or autonomous decision-making. *Id.* SpaceX's proposed approach addresses the concern underlying the regulatory requirements and poses less risk than that associated with Dragon being left in orbit to reenter randomly at some later time. SpaceX's mitigation measures are of additional importance to the FAA's decision to grant a waiver.

The FAA's reason for requiring commanded reentry was to make sure that an operator had the chance to verify

that there were no system anomalies or other non-compliant conditions. Under SpaceX's proposed plan, the operator would employ two means of detecting any such anomalies. Ground operators and Dragon's own continuous autonomous health check would both perform health checks to determine whether conditions prohibited reentry.

To determine the effect of granting SpaceX's waiver on public safety, the FAA performed a risk analysis of potential reentry outcomes. The risks of leaving the vehicle in orbit or attempting a reentry (whether autonomous or commanded) are best compared by applying conditional probabilities, where an undesired event is assumed to happen, to each possibility. For purposes of comparison, in the two cases discussed below, the FAA assumes that Dragon fails to expel its propellant, and its parachutes fail to deploy, resulting in an explosive impact.

In a random reentry scenario, Dragon has lost communications and is unable to reenter autonomously. The FAA assumed a 100% probability of leaving the vehicle in orbit with a full propellant load. The vehicle would continue circling the Earth until it reentered randomly due to natural orbital decay. The FAA assumed the impact probability in a given latitude band was equivalent to the dwell time of the vehicle in orbit over that latitude band. The FAA computed the population density as a function of latitude by dividing the population within each latitude band under Dragon by the Earth's surface area within each latitude band. The FAA applied a sheltering model based on surveys and socioeconomic factors, including population density and distribution and the types of homes people live in, all of which affect expected casualties. The conditional risk computed for a random reentry produced an expected average number of casualties ( $E_c$ ) of approximately  $23 \times 10^{-3}$ .

In an autonomous reentry scenario, Dragon has lost communications and is attempting an autonomous reentry. The FAA assumed a 100% probability of reentry burn failure at any time from burn initiation to burn cutoff, assuming a uniform failure rate. In this scenario, Dragon remains orbital for two-thirds of its burn. Two-thirds of the conditional random reentry risk calculated above results in an  $E_c$  of approximately  $15 \times 10^{-3}$ . The remaining risk results from an assumed failure during the last third of the reentry burn when the vehicle is no longer in orbit. This results in a flight corridor extending from the Atlantic to the Pacific crossing over the continental

United States and Northern Mexico. The conditional risk along this flight corridor is approximately  $E_c 13 \times 10^{-3}$ . The FAA multiplied  $13 \times 10^{-3}$  by one-third, to account for the fact that this failure mode is only applicable to one-third of the burn, which results in an  $E_c$  of  $41 \times 10^{-4}$ . The total conditional risk associated with an autonomous reentry, where a burn failure is assumed, is  $19 \times 10^{-3}$ . Thus, there is theoretically 20% less risk in an attempt to reenter Dragon than there is in leaving it in orbit given a communications failure.

Also of importance to the FAA's decision to grant a waiver, Dragon is equipped with a number of mitigating features. First, the vehicle automatically safes itself in the case of an off-nominal burn. This means that if Dragon conducted its reentry burn, but computed that the desired landing spot would not be achieved, it would vent the rest of its fuel, thereby reducing the possibility of explosion or dispersion of toxic fumes on impact. Second, the vehicle has the ability to autonomously guide itself to its planned landing location in the Pacific Ocean, some 780 kilometers from the coastline. This internal capability allows Dragon to act independently, based on programmed instructions and information regarding its location, if communications with the ground are lost. Third, the vehicle has the ability to monitor its safety-critical systems in real-time. This means Dragon has near-immediate awareness of the operability of its on-board systems that allow it to operate safely, and this awareness enables Dragon to react in time to conduct a reentry. Fourth, the vehicle has a space-grade IMU and flight computer. This means Dragon is equipped with a system that provides information on where Dragon is, which is pertinent to its guidance capabilities, and the IMU and flight computer are designed and tested to operate in the rigorous conditions of space.

#### *C. National Security and Foreign Policy Implications*

The FAA has not identified any national security or foreign policy implications associated with granting this waiver.

**Summary and Conclusion:** A waiver is in the public interest because it accomplishes the goals of Chapter 701 and decreases risk to the public. The waiver will not jeopardize public health and safety or safety of property because allowing autonomous reentry of a healthy Dragon vehicle that has lost all communications presents less risk than a random reentry. A waiver will not jeopardize national security and foreign policy interests of the United States. For

the foregoing reasons, the FAA has waived the requirement of 14 CFR 431.43(e) for a commanded reentry, and allows SpaceX to autonomously initiate reentry flight of Dragon in the event that all communication between ground operators and Dragon has been lost, and Dragon is healthy.

Issued in Washington, DC on November 30, 2010.

**Kenneth Wong,**

*Licensing and Safety Division Manager.*

[FR Doc. 2010-30399 Filed 12-3-10; 8:45 am]

**BILLING CODE 4910-13-P**

## LIBRARY OF CONGRESS

### Copyright Royalty Board

#### 37 CFR Part 386

[Docket No. 2010-10 CRB Satellite COLA]

#### Cost of Living Adjustment to Satellite Carrier Compulsory License Royalty Rates

**AGENCY:** Copyright Royalty Board, Library of Congress.

**ACTION:** Final rule.

**SUMMARY:** The Copyright Royalty Judges announce a cost of living adjustment (“COLA”) of 1.2% in the royalty rates paid by satellite carriers under the satellite carrier compulsory license of the Copyright Act. The COLA is based on the change in the Consumer Price Index from October 2009 to October 2010.

**DATES:** *Effective Date:* January 1, 2011.

*Applicability Dates:* These rates are applicable for the period January 1, 2011, through December 31, 2011.

**FOR FURTHER INFORMATION CONTACT:** Richard Strasser, Senior Attorney, or Gina Giuffreda, Attorney Advisor. Telephone: (202) 707-7658. E-mail: *crb@loc.gov*.

**SUPPLEMENTARY INFORMATION:** The satellite carrier compulsory license establishes a statutory copyright licensing scheme for the retransmission of distant television programming by satellite carriers. 17 U.S.C. 119. Congress created the license in 1988 and has reauthorized the license for additional five-year periods, most recently with the passage of the Satellite Television Extension and Localism Act of 2010, (“STELA”), Public Law 111-175, which was signed into law by the President on May 27, 2010.

Program Suppliers and Joint Sports Claimants (collectively, the “Copyright Owners”) and DIRECTV, Inc., DISH Network, LLC, and National

Programming Service, LLC (collectively, the “Satellite Carriers”) submitted a voluntary agreement proposing rates for the section 119 compulsory license for the period 2010-2014 and requested that the proposed rates be applied to all satellite carriers, distributors, and copyright owners without holding a rate proceeding. See 17 U.S.C.

119(c)(1)(D)(ii)(I). After publishing the proposed rates in the **Federal Register** and receiving no objections, the Judges adopted the rates as final in 37 CFR part 386. 75 FR 53198 (August 31, 2010).

Section 119(c)(2) requires the Judges annually to adjust these rates “to reflect any changes occurring in the cost of living adjustment (for all consumers and for all items) published \* \* \* before December 1 of the preceding year” with such rates being effective on January 1 of each year. 17 U.S.C. 119(c)(2). The Judges are required to publish in the **Federal Register** “[n]otification of the adjusted fees \* \* \* at least 25 days before January 1.” *Id.* Today’s notice fulfills this obligation.

The change in the cost of living as determined by the CPI-U during the period from the most recent index published before December 1, 2009, to the most recent index published before December 1, 2010, is 1.2%.<sup>1</sup> Rounding to the nearest cent, the royalty rates for the secondary transmission of broadcast stations by satellite carriers for private home viewing and viewing in commercial establishments are 25 cents and 51 cents, respectively.

#### List of Subjects in 37 CFR Part 386

Copyright, Satellite, Television.

#### Final Regulations

■ For the reasons set forth in the preamble, part 386 of title 37 of the Code of Federal Regulations is amended as follows:

#### PART 386—ADJUSTMENT OF ROYALTY FEES FOR SECONDARY TRANSMISSIONS BY SATELLITE CARRIERS

■ 1. The authority citation for part 386 continues to read as follows:

**Authority:** 17 U.S.C. 119(c), 801(b)(1).

■ 2. Section 386.2 is amended by revising paragraphs (b)(1)(ii) and (b)(2)(ii) as follows:

#### § 386.2 Royalty fee for secondary transmission by satellite carriers.

\* \* \* \* \*

<sup>1</sup> The most recent CPI-U figures are published in November of each year and use the period 1982-1984 to establish a reference base of 100. The index for October 2009 was 216.177, while the figure for October 2010 was 218.711.

(b)(1) \* \* \*

(ii) 2011: 25 cents per subscriber per month;

\* \* \* \* \*

(2) \* \* \*

(ii) 2011: 51 cents per subscriber per month;

\* \* \* \* \*

Dated: November 30, 2010.

**James Scott Sledge,**

*Chief U.S. Copyright Royalty Judge.*

[FR Doc. 2010-30416 Filed 12-3-10; 8:45 am]

**BILLING CODE 1410-72-P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA-R04-OAR-2009-0561-201053(c); FRL-9235-4]

#### Approval and Promulgation of Implementation Plans; North Carolina: Greensboro-Winston-Salem-High Point; Determination of Attaining Data for the 1997 Fine Particulate Matter Standard; Correction

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule; correcting amendment.

**SUMMARY:** On January 4, 2010, EPA published a final rule determining that the Greensboro-Winston-Salem-High Point nonattainment area (hereafter referred to as the “Greensboro Area”) has attaining data for the 1997 fine particulate matter (PM<sub>2.5</sub>) National Ambient Air Quality Standard (NAAQS). This action corrects a typographical error in the regulatory language in paragraph (e) of EPA’s January 4, 2010, final rule.

**DATES:** This action is effective December 6, 2010.

**ADDRESSES:** Copies of the documentation used in the action being corrected are available for inspection during normal business hours at the following location: U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960. The Regional Office’s official hours of business are Monday through Friday, 8:30 to 4:30, excluding Federal holidays.

**FOR FURTHER INFORMATION CONTACT:**

Ms. Lynorae Benjamin, Chief, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960.

Ms. Benjamin can be reached at 404-562-9040, or via electronic mail at benjamin.lynorae@epa.gov.

**SUPPLEMENTARY INFORMATION:** This action corrects a typographical error in the regulatory language for an entry that appears in paragraph (e) of North Carolina’s Identification of Plan at 40 CFR 52.1781. The final action, which determined that the Greensboro Area has attaining data for the 1997 PM<sub>2.5</sub> NAAQS, was approved by EPA on January 4, 2010 (75 FR 56). However, EPA inadvertently cited 40 CFR 52.1004(c) as the section of the Code of Federal Regulations (CFR) that suspends the requirements for areas attaining the 1997 PM<sub>2.5</sub> NAAQS to submit an attainment demonstration, associated reasonably available control measures, a reasonable further progress plan, contingency measures, and other planning state implementation plans related to attainment of the PM<sub>2.5</sub> NAAQS. The correct citation is 40 CFR 51.1004(c). Therefore, EPA is correcting this typographical error by inserting 51.1004(c) into paragraph (e) of 40 CFR 52.1781.

EPA has determined that today’s action falls under the “good cause” exemption in section 553(b)(3)(B) of the Administrative Procedure Act (APA) which, upon finding “good cause,” authorizes agencies to dispense with public participation where public notice and comment procedures are impracticable, unnecessary, or contrary to the public interest. Public notice and comment for this action are unnecessary because today’s action to correct an inadvertent error contained in paragraph (e) of 40 CFR 52.1781 of the rulemaking and has no substantive impact on EPA’s January 4, 2010, approval. In addition, EPA can identify no particular reason why the public would be interested in being notified of the correction, or in having the opportunity to comment on the correction prior to this action being finalized, since this correction action does not change the meaning of EPA’s analysis or action to approve the addition of paragraph (e) to 40 CFR 52.1781.

EPA also finds that there is good cause under APA section 553(d)(3) for this correction to become effective on the date of publication of this action. Section 553(d)(3) of the APA allows an effective date less than 30 days after publication “as otherwise provided by the agency for good cause found and published with the rule.” 5 U.S.C. 553(d)(3). The purpose of the 30-day waiting period prescribed in APA section 553(d)(3) is to give affected

parties a reasonable time to adjust their behavior and prepare before the final rule takes effect. Today’s rule, however, does not create any new regulatory requirements such that affected parties would need time to prepare before the rule takes effect. Rather, today’s action merely corrects a typographical error in paragraph (e) of a prior rulemaking by correcting the citation as identified above in 40 CFR 52.1781 in a revision, which EPA approved on January 4, 2010. For these reasons, EPA finds good cause under APA section 553(d)(3) for this correction to become effective on the date of publication of this action.

#### Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a “significant regulatory action” and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001). This action merely corrects a typographical error in paragraph (e) of a prior rulemaking by correcting the citation as identified above in 40 CFR 52.1781, which EPA approved on January 4, 2010, and imposes no additional requirements beyond those imposed by State law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule merely corrects an inadvertent error in paragraph (e) of a prior rule, and does not impose any additional enforceable duty beyond that required by State law, it 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).

This rule also does not have Tribal implications because it will not have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This rule also does not have Federalism implications because it does 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 (64 FR 43255, August 10, 1999). This rule merely corrects a typographical error in paragraph (e) of a prior rulemaking by correcting the citation as identified above in 40 CFR 52.1781 in a revision, which EPA approved on January 4, 2010, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act (CAA). This rule also is not subject to Executive Order 13045 "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because it is not economically significant. In addition, this rule does not involve technical standards, thus the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule also does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

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 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 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 CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 4, 2011. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule 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. This action may not be challenged later in proceedings to enforce its requirements. (See CAA section 307(b)(2).)

#### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Particulate matter.

Dated: November 17, 2010.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

■ 40 CFR part 52 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 II—North Carolina

■ 2. Section 52.1781 is amended by revising paragraph (e) to read as follows:

#### § 52.1781 Control strategy: Sulfur oxides and particulate matter.

\* \* \* \* \*

(e) *Determination of Attaining Data.* EPA has determined, as of January 4, 2010, the Greensboro-Winston-Salem-High Point, North Carolina, nonattainment area has attaining data for the 1997 PM<sub>2.5</sub> NAAQS. This determination, in accordance with 40 CFR 51.1004(c), suspends the requirements for this area to submit an attainment demonstration, associated reasonably available control measures, a reasonable further progress plan, contingency measures, and other planning SIPs related to attainment of the standard for as long as this area continues to meet the 1997 PM<sub>2.5</sub> NAAQS.

\* \* \* \* \*

[FR Doc. 2010-30482 Filed 12-3-10; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA-R04-OAR-2009-0751-201054(c); FRL-9235-5]

#### Approval and Promulgation of Implementation Plans; North Carolina: Hickory-Morganton-Lenoir; Determination of Attaining Data for the 1997 Fine Particulate Matter Standard; Correction

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule; correcting amendment.

**SUMMARY:** On January 5, 2010, EPA published a final rule determining that the Hickory-Morganton-Lenoir nonattainment area (hereafter referred to as the "Hickory Area") has attaining data for the 1997 fine particulate matter (PM<sub>2.5</sub>) National Ambient Air Quality Standard (NAAQS). This action corrects a typographical error in the regulatory

language in paragraph (f) of EPA's January 5, 2010, final rule.

**DATES:** This action is effective December 6, 2010.

**ADDRESSES:** Copies of the documentation used in the action being corrected are available for inspection during normal business hours at the following location: U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Ms. Lynorae Benjamin, Chief, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960. Ms. Benjamin can be reached at 404-562-9040, or via electronic mail at [benjamin.lynorae@epa.gov](mailto:benjamin.lynorae@epa.gov).

**SUPPLEMENTARY INFORMATION:** This action corrects a typographical error in the regulatory language for an entry that appears in paragraph (f) of North Carolina's Identification of Plan at 40 CFR 52.1781. The final action, which determined that the Hickory Area has attaining data for the 1997 PM<sub>2.5</sub> NAAQS, was approved by EPA on January 5, 2010 (75 FR 230). However, EPA inadvertently cited 40 CFR 52.1004(c) as the section of the Code of Federal Regulations (CFR) that suspends the requirements for areas attaining the 1997 PM<sub>2.5</sub> NAAQS to submit an attainment demonstration, associated reasonably available control measures, a reasonable further progress plan, contingency measures, and other planning State implementation plans related to attainment of the PM<sub>2.5</sub> NAAQS. The correct citation is 40 CFR 51.1004(c). Therefore, EPA is correcting this typographical error by inserting 51.1004(c) into paragraph (f) of 40 CFR 52.1781.

EPA has determined that today's action falls under the "good cause" exemption in section 553(b)(3)(B) of the Administrative Procedure Act (APA) which, upon finding "good cause," authorizes agencies to dispense with public participation where public notice and comment procedures are impracticable, unnecessary, or contrary to the public interest. Public notice and comment for this action are unnecessary because today's action to correct an inadvertent error contained in paragraph (f) of 40 CFR 52.1781 of the rulemaking and has no substantive impact on EPA's January 5, 2010,



approval. In addition, EPA can identify no particular reason why the public would be interested in being notified of the correction, or in having the opportunity to comment on the correction prior to this action being finalized, since this correction action does not change the meaning of EPA's analysis or action to approve the addition of paragraph (f) to 40 CFR 52.1781.

EPA also finds that there is good cause under APA section 553(d)(3) for this correction to become effective on the date of publication of this action. Section 553(d)(3) of the APA allows an effective date less than 30 days after publication "as otherwise provided by the agency for good cause found and published with the rule." 5 U.S.C. 553(d)(3). The purpose of the 30-day waiting period prescribed in APA section 553(d)(3) is to give affected parties a reasonable time to adjust their behavior and prepare before the final rule takes effect. Today's rule, however, does not create any new regulatory requirements such that affected parties would need time to prepare before the rule takes effect. Rather, today's action merely corrects a typographical error in paragraph (f) of a prior rulemaking by correcting the citation as identified above in 40 CFR 52.1781 in a revision, which EPA approved on January 5, 2010. For these reasons, EPA finds good cause under APA section 553(d)(3) for this correction to become effective on the date of publication of this action.

#### Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001). This action merely corrects a typographical error in paragraph (f) of a prior rulemaking by correcting the citation as identified above in 40 CFR 52.1781, which EPA approved on January 5, 2010, and imposes no additional requirements beyond those imposed by State law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule merely corrects an inadvertent error in paragraph (f) of a prior rule, and does not impose any additional enforceable duty beyond that required by State law, it 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).

This rule also does not have Tribal implications because it will not have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This rule also does not have Federalism implications because it does 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 (64 FR 43255, August 10, 1999). This rule merely corrects a typographical error in paragraph (f) of a prior rulemaking by correcting the citation as identified above in 40 CFR 52.1781 in a revision which EPA approved on January 5, 2010, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act (CAA). This rule also is not subject to Executive Order 13045 "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because it is not economically significant. In addition, this rule does not involve technical standards, thus the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule also does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. section 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 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 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 CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 4, 2011. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule 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. This action may not be challenged later in proceedings to enforce its requirements. (*See* CAA section 307(b)(2).)

#### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Particulate matter.

Dated: November 17, 2010.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

■ 40 CFR part 52 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 II—North Carolina

■ 2. Section 52.1781 is amended by revising paragraph (f) to read as follows:

#### § 52.1781 Control strategy: Sulfur oxides and particulate matter.

\* \* \* \* \*

(f) *Determination of Attaining Data.* EPA has determined, as of January 5, 2010, the Hickory-Morganton-Lenoir, North Carolina, nonattainment area has attaining data for the 1997 PM<sub>2.5</sub> NAAQS. This determination, in accordance with 40 CFR 51.1004(c), suspends the requirements for this area to submit an attainment demonstration, associated reasonably available control measures, a reasonable further progress plan, contingency measures, and other planning SIPs related to attainment of the standard for as long as this area continues to meet the 1997 PM<sub>2.5</sub> NAAQS.

[FR Doc. 2010-30483 Filed 12-3-10; 8:45 am]

BILLING CODE 6560-50-P



## COUNCIL ON ENVIRONMENTAL QUALITY

40 CFR Parts 1500, 1501, 1502, 1503, 1504, 1505, 1506, 1507, and 1508

### Final Guidance for Federal Departments and Agencies on Establishing, Applying, and Revising Categorical Exclusions Under the National Environmental Policy Act

**AGENCY:** Council on Environmental Quality.

**ACTION:** Notice of availability.

**SUMMARY:** The Council on Environmental Quality (CEQ) is issuing its final guidance on categorical exclusions. This guidance provides methods for substantiating categorical exclusions, clarifies the process for establishing categorical exclusions, outlines how agencies should engage the public when establishing and using categorical exclusions, describes how agencies can document the use of categorical exclusions, and recommends periodic agency review of existing categorical exclusions. A categorical exclusion is a category of actions that a Federal agency determines does not normally result in individually or cumulatively significant environmental effects. This guidance clarifies the rules for establishing, applying, and revising categorical exclusions. It applies to categorical exclusions established by Federal agencies in accordance with CEQ regulations for implementing the procedural provisions of the National Environmental Policy Act. The guidance was developed to assist agencies in making their implementation of the National Environmental Policy Act (NEPA) more transparent and efficient.

**DATES:** The guidance is effective December 6, 2010.

**FOR FURTHER INFORMATION CONTACT:** The Council on Environmental Quality (ATTN: Horst Greczmiel, Associate Director for National Environmental Policy Act Oversight), 722 Jackson Place, NW., Washington, DC 20503. Telephone: (202) 395-5750.

**SUPPLEMENTARY INFORMATION:** This guidance applies to categorical exclusions established by Federal agencies in accordance with § 1507.3 of the CEQ Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act, 40 CFR parts 1500-1508.

Enacted in 1970, the National Environmental Policy Act (NEPA), 42 U.S.C. 4321-4370, is a fundamental tool used to harmonize our environmental, economic, and social aspirations and is a cornerstone of our Nation's efforts to

protect the environment. NEPA recognizes that many Federal activities affect the environment and mandates that Federal agencies consider the environmental impacts of their proposed actions before deciding to adopt proposals and take action.<sup>1</sup> Many Federal actions do not normally have significant effects on the environment. When agencies identify categories of activities that do not normally have the potential for individually or cumulatively significant impacts, they may establish a categorical exclusion for those activities. The use of categorical exclusions can reduce paperwork and delay, so that more resources are available to assess proposed actions that are likely to have the potential to cause significant environmental effects in an environmental assessment (EA) or environmental impact statement (EIS). This guidance clarifies the rules for establishing categorical exclusions by describing: (1) How to establish or revise a categorical exclusion; (2) how to use public involvement and documentation to help define and substantiate a proposed categorical exclusion; (3) how to apply an established categorical exclusion; (4) how to determine when to prepare documentation and involve the public when applying a categorical exclusion; and (5) how to conduct periodic reviews of categorical exclusions to assure their continued appropriate use and usefulness.

On February 18, 2010, the Council on Environmental Quality announced three proposed draft guidance documents to modernize and reinvigorate NEPA, in conjunction with the fortieth anniversary of the statute's enactment.<sup>2</sup> This guidance document is the first of those three to be released in final form. With respect to the other two guidance documents, one addresses when and how Federal agencies should consider greenhouse gas emissions and climate change in their proposed actions, and the other addresses when agencies need to monitor commitments made in EAs and EISs, and how agencies can appropriately use mitigated "Findings of No Significant Impact." The **Federal Register** notice announcing the draft categorical exclusion guidance and requesting public comments was

<sup>1</sup> A discussion of NEPA applicability is beyond the scope of this guidance. For more information see CEQ, *The Citizen's Guide to the National Environmental Policy Act*, available at [ceq.hss.doe.gov/nepa/Citizens\\_Guide\\_Dec07.pdf](http://ceq.hss.doe.gov/nepa/Citizens_Guide_Dec07.pdf).

<sup>2</sup> For more information on this announcement, see <http://www.whitehouse.gov/administration/eop/ceq/initiatives/nepa>.

published on February 23, 2010.<sup>3</sup> CEQ appreciates the thoughtful responses to its request for comments on the draft guidance. Commenters included private citizens, corporations, environmental organizations, trade associations, and State agencies. CEQ received fifty-eight comments, which are available online at <http://www.whitehouse.gov/administration/eop/ceq/initiatives/nepa/comments> and at <http://www.nepa.gov>. The comments that suggested editorial revisions and requested clarification of terms are addressed in the text of the final guidance. Comments that raised policy or substantive concerns are grouped into thematic issues and addressed in the following sections of this notice.

### Process for Developing and Using Categorical Exclusions

Many commenters expressed support for CEQ's categorical exclusion guidance and for the timely and efficient use of categorical exclusions in the NEPA environmental review process to inform agency decisionmaking. Some commenters favored guidance that would limit the use of categorical exclusions. Others expressed concern that this guidance will discourage the appropriate use of categorical exclusions or make the NEPA process more difficult for agencies, and thereby delay agency decisionmaking.

This guidance was developed to provide for the consistent, proper, and appropriate development and use of categorical exclusions by Federal agencies. It reinforces the process required to establish categorical exclusions by explaining methods available to substantiate categorical exclusions. It also seeks to ensure opportunities for public involvement and increasing transparency when Federal agencies establish categorical exclusions and subsequently use those categorical exclusions to satisfy their NEPA obligations for specific proposed actions. Additionally, this guidance affords Federal agencies flexibility in developing and implementing categorical exclusions while ensuring that categorical exclusions are administered in compliance with NEPA and the CEQ Regulations. When appropriately established and applied, categorical exclusions expedite the environmental review process for proposals that normally do not require additional analysis and documentation in an EA or an EIS.

<sup>3</sup> National Environmental Policy Act (NEPA) Draft Guidance, Establishing, Applying, and Revising Categorical Exclusions under the National Environmental Policy Act, 75 FR 8045, Feb. 23, 2010.

### Applicability and Limitations

Some commenters expressed concern that the guidance creates additional limitations and constraints on the establishment of categorical exclusions, while others expressed unqualified support for using text that constrains the scope of the actions to which a categorical exclusion could apply. The discussion in the guidance of physical, temporal, or environmental factors that would constrain the use of a categorical exclusion is consistent with NEPA and past CEQ guidance.

Federal agencies that identify physical, temporal, or environmental constraints in the definition of a proposed category of actions may be able to better ensure that a new or revised categorical exclusion is neither too broadly nor too narrowly defined. Some information regarding implementation of mitigation measures that are an integral part of the proposed actions and how those actions will be carried out may be necessary to adequately understand and describe the category of actions and their projected impacts. A better and more comprehensive description of a category of actions provides clarity and transparency for proposed projects that could be categorically excluded from further analysis and documentation in an EA or an EIS.

### Public Involvement

Some commenters expressed concern over the timeliness and burden of NEPA reviews when there is greater public involvement. The final guidance makes it clear that CEQ strongly encourages public involvement in the establishment and revision of categorical exclusions. As the guidance explains, engaging the public in the environmental aspects of Federal decisionmaking is a key policy goal of NEPA and the CEQ Regulations. Public involvement is not limited to the provision of information by agencies; it should also include meaningful opportunities for the public to provide comment and feedback on the information made available. Considering recent advances in information technology, agencies should consider employing additional measures to involve the public beyond simply publishing a **Federal Register** notice as required when an agency seeks to establish new or revised categorical exclusions.<sup>4</sup>

The perceived environmental effects of the proposed category of actions are

a factor that an agency should consider when it decides whether there is a need for public involvement in determining whether to apply a categorical exclusion. Accordingly, the guidance clarifies that agencies have flexibility when applying categorical exclusions to focus their public involvement on those proposed actions and issues the agency expects to raise environmental issues and concerns that are important to the public.

In the final guidance, CEQ uses the terms “encourage” and “recommend” interchangeably. The language of the guidance relating to public engagement reflects CEQ’s authority under NEPA and the CEQ regulations to guide agency development and implementation of agency NEPA procedures. It also reflects the importance of allowing agencies to use their expertise to determine the appropriate level of engagement with the public.

### Substantiating and Documenting Categorical Exclusions

Some commenters raised the concern that the requirement to substantiate and document categorical exclusions would be burdensome and cause delay. One commenter recommended that the guidance should encourage consultation with State agencies, other Federal agencies with special expertise, and other stakeholders. Another commenter suggested that the guidance permit agencies to consult with industry project proponents that possess information that would be useful in substantiating a categorical exclusion. Along the same lines, another commenter stated that agencies should be encouraged to seek information from the most relevant and reliable sources possible.

The guidance has been revised to reflect that, when substantiating and documenting the environmental effects of a category of actions, a Federal agency need not be limited to its own experiences. Instead, the agency should consider information and records from other private and public entities, including other Federal agencies that have experience with the actions covered in a proposed categorical exclusion. The guidance acknowledges that the reliability of scientific information varies according to its source and the rigor with which it was developed, and that it is the responsibility of the agency to determine whether the information reflects accepted knowledge, accurate findings, and experience with the environmental effects relevant to the actions that would be included in the proposed categorical exclusion.

The guidance addresses the concerns over timeliness and undue burdens by explaining that the amount of information required to substantiate a proposed new or revised categorical exclusion should be proportionate to the type of activities included in the proposed category of actions. Actions that potentially have little or no impact should not require extensive information or documentation. Determining the extent of substantiation and documentation is ultimately the responsibility of the agency and will vary depending on the nature of the proposed action and the effects associated with the action. The guidance encourages agencies to make use of agency Web sites to provide further clarity and transparency to their NEPA procedures. It also recommends using modern technology to maintain and facilitate the use of documentation in future evaluations and benchmarking.

### Extraordinary Circumstances

Several commenters requested clearer and more detailed guidance on the application of extraordinary circumstances. Extraordinary circumstances are appropriately understood as those factors or circumstances that will help an agency identify the situations or environmental settings when an otherwise categorically-excludable action merits further analysis and documentation in an EA or an EIS. Specific comments noted that the determination that an extraordinary circumstance will require additional environmental review in an EA or an EIS should depend not solely on the existence of the extraordinary circumstance but rather on an analysis of its impacts. CEQ agrees with this perspective. For example, when an agency uses a protected resource, such as historic property or threatened and endangered species, as an extraordinary circumstance, the guidance clarifies that whether additional review and documentation of a proposed action’s potential environmental impacts in an EA or an EIS is required is based on the potential for significantly impacting that protected resource. However, CEQ recognizes that some agency NEPA procedures require additional analysis based solely on the existence of an extraordinary circumstance. In such cases, the agencies may define their extraordinary circumstances differently, so that a particular situation, such as the presence of a protected resource, is not considered an extraordinary circumstance per se, but a factor to consider when determining if there are extraordinary circumstances, such as a significant impact to that resource. This

<sup>4</sup> See 40 CFR 1506.6(a) (requiring agencies to make diligent efforts to involve the public in preparing and implementing their NEPA procedures).

way of structuring NEPA procedures is also appropriate. What is important is that situations or circumstances that may warrant additional analysis and documentation in an EA or an EIS are fully considered before a categorical exclusion is used.

The guidance was also revised to clarify how agencies can use the factors set out in the CEQ Regulations to determine significance. The Federal agencies are ultimately responsible for the determination of specific extraordinary circumstances for a category of actions, as well as the determination of whether to use the significance factors set out in the CEQ Regulations when establishing extraordinary circumstances.<sup>5</sup> Agency determinations are informed by the public and CEQ during the development of the categorical exclusions.

### Documenting the Use of Categorical Exclusions

Commenters were most concerned over the potential for delay and the creation of administrative burdens for projects and programs. The guidance makes it clear that the documentation prepared when categorically excluding an action should be as concise as possible to avoid unnecessary delays and administrative burdens for projects and programs. The guidance explains that each agency should determine the circumstances in which it is appropriate to prepare additional documentation. It also explains that for some activities with little risk of significant environmental effects, there may be no practical need for, or benefit from, preparing any documentation beyond the existing record supporting the underlying categorical exclusion and any administrative record for that activity. The guidance makes it clear that the extent of the documentation prepared is the responsibility of the agency and should be tailored to the type of action involved, the potential for extraordinary circumstances, and compliance requirements of other laws, regulations, and policies.

### Cumulative Impacts

Some commenters were concerned that the guidance overlooked the importance of cumulative effects. As specifically set out in the CEQ Regulations and the final guidance, the consideration of the potential cumulative impacts of proposed actions is an important and integral aspect of the NEPA process. The guidance makes

it clear that both individual and cumulative impacts must be considered when establishing categorical exclusions. With regard to the cumulative impacts of actions that an agency has categorically excluded, the guidance recommends that agencies consider the frequency with which the categorically-excluded actions are applied. For some types of categorical exclusions, it may also be appropriate for the agency to track and periodically assess use of the categorical exclusion to ensure that cumulative impacts do not rise to a level that would warrant further NEPA analysis and documentation.

### Monitoring

Commenters voiced concerns that the guidance would create a new requirement for monitoring. The final guidance makes it clear that any Federal agency program charged with complying with NEPA should develop and maintain sufficient capacity to ensure the validity of NEPA reviews that predict that there will not be significant impacts. The amount of effort and the methods used for assessing environmental effects should be proportionate to the potential effects of the action that is the subject of a proposed categorical exclusion and should ensure that the use of categorical exclusions does not inadvertently result in significant impacts.

As the guidance explains, agencies seeking to substantiate new or revised categorical exclusions can rely on the information gathered from monitoring actions the agency took in the past, as well as from monitoring the effects of impact demonstration projects. Relying solely on completed EAs and Findings of No Significant Impact (FONSI) is not sufficient without information validating the FONSI which was projected in advance of implementation. The guidance makes it clear that FONSI cannot be relied on as a basis for establishing a categorical exclusion unless the absence of significant environmental effects has been verified through credible monitoring of the implemented activity or other sources of corroborating information. The intensity of monitoring efforts for particular categories of actions or impact demonstration projects is appropriately left to the judgment of the agencies. Furthermore, the guidance explains that in some cases monitoring may not be appropriate and agencies can evaluate other information.

### Review of Existing Categorical Exclusions

Several commenters advocated "grandfathering" existing categorical

exclusions. Two other commenters voiced support for the periodic review of agency categorical exclusions and specifically requested that the guidance call for rigorous review of existing categorical exclusions. Two commenters requested that the guidance explicitly provide for public participation during the review process. Several verbal comments focused on the recommended seven year review period and suggested alternative review periods ranging from two to ten years. Several commenters also requested that the guidance describe with greater clarity how the periodic review should be implemented.

CEQ believes it is extremely important to review the categorical exclusions already established by the Federal agencies. The fact that an agency's categorical exclusions were established years ago is all the more reason to review them to ensure that changes in technology, operations, agency missions, and the environment do not call into question the continued use of these categorical exclusions. The guidance also explains the value of such a review. Reviewing categorical exclusions can serve as the impetus for clarifying the actions covered by an existing categorical exclusion. It can also help agencies identify additional extraordinary circumstances and consider the appropriate documentation when using certain categorical exclusions. The guidance states that the review should focus on categorical exclusions that no longer reflect current environmental circumstances or an agency's policies, procedures, programs, or mission.

This guidance recommends that agencies develop a process and timeline to periodically review their categorical exclusions (and extraordinary circumstances) to ensure that their categorical exclusions remain current and appropriate, and that those reviews should be conducted at least every seven years. A seven-year cycle allows the agencies to regularly review categorical exclusions to avoid the use of categorical exclusions that are outdated and no longer appropriate. If the agency believes that a different timeframe is appropriate, the agency should articulate a sound basis for that conclusion, explaining how the alternate timeframe will still allow the agency to avoid the use of categorical exclusions that are outdated and no longer appropriate. As described in the guidance, agencies should use their Web sites to notify the public and CEQ about how and when their reviews of existing categorical exclusions will be conducted. CEQ will perform oversight of agencies' reviews, beginning with

<sup>5</sup> See 40 CFR 1508.27 (defining "significantly" for NEPA purposes in terms of several context and intensity factors for agencies to consider).

those agencies currently reassessing or experiencing difficulties with implementing their categorical exclusions, as well as with agencies facing challenges to their application of categorical exclusions.

### The Final Guidance

The final guidance is provided here and is available on the National Environmental Policy Act Web site (<http://www.nepa.gov>) specifically at [ceq.hss.doe.gov/ceq\\_regulations/guidance.html](http://ceq.hss.doe.gov/ceq_regulations/guidance.html). For reasons stated in the preamble, above, CEQ issues the following guidance on establishing, applying, and revising categorical exclusions.

### MEMORANDUM FOR HEADS OF FEDERAL DEPARTMENTS AND AGENCIES

FROM: NANCY H. SUTLEY  
Chair

Council on Environmental Quality  
SUBJECT: *Final Guidance for Federal Departments and Agencies on Establishing, Applying, and Revising Categorical Exclusions under the National Environmental Policy Act*

The Council on Environmental Quality (CEQ) is issuing this guidance for Federal departments and agencies on how to establish, apply, and revise categorical exclusions in accordance with section 102 of the National Environmental Policy Act (NEPA), 42 U.S.C. 4332, and the CEQ Regulations for Implementing the Procedural Provisions of NEPA (CEQ Regulations), 40 CFR Parts 1500–1508.<sup>6</sup> This guidance explains the requirements of NEPA and the CEQ Regulations, describes CEQ policies, and recommends procedures for agencies to use to ensure that their use of categorical exclusions is consistent with applicable law and regulations.<sup>7</sup> The guidance is based on

<sup>6</sup> The Council on Environmental Quality (CEQ) Regulations for Implementing the Procedural Provisions of NEPA (CEQ Regulations), available on [www.nepa.gov](http://www.nepa.gov) at [ceq.hss.doe.gov/ceq\\_regulations/regulations.html](http://ceq.hss.doe.gov/ceq_regulations/regulations.html). This guidance applies only to categorical exclusions established by Federal agencies in accordance with section 1507.3 of the CEQ Regulations, 40 CFR 1507.3. It does not address categorical exclusions established by statute, as their use is governed by the terms of specific legislation and subsequent interpretation by the agencies charged with the implementation of that statute and NEPA requirements. CEQ encourages agencies to apply their extraordinary circumstances to categorical exclusions established by statute when the statute is silent as to the use and application of extraordinary circumstances.

<sup>7</sup> This guidance is not a rule or regulation, and the recommendations it contains may not apply to a particular situation based upon the individual facts and circumstances. This guidance does not change or substitute for any law, regulation, or any other legally binding requirement and is not legally

NEPA, the CEQ Regulations, legal precedent and agency NEPA experience and practice. It describes:

- How to establish or revise a categorical exclusion;
- How to use public involvement and documentation to help define and substantiate a proposed categorical exclusion;
- How to apply an established categorical exclusion, and determine when to prepare documentation and involve the public;<sup>8</sup> and
- How to conduct periodic reviews of categorical exclusions to assure their continued appropriate use and usefulness.

This guidance is designed to afford Federal agencies flexibility in developing and implementing categorical exclusions, while ensuring that categorical exclusions are administered to further the purposes of NEPA and the CEQ Regulations.<sup>9</sup>

### I. Introduction

The CEQ Regulations provide basic requirements for establishing and using categorical exclusions. Section 1508.4 of the CEQ Regulations defines a “categorical exclusion” as

a category of actions which do not individually or cumulatively have a significant effect on the human environment and which have been found to have no such effect in procedures adopted by a Federal agency in implementation of these regulations (§ 1507.3) and for which, therefore, neither an environmental assessment nor an environmental impact statement is required.<sup>10</sup>

Categories of actions for which exclusions are established can be limited by their terms. Furthermore, the application of a categorical exclusion can be limited by “extraordinary circumstances.” Extraordinary circumstances are factors or circumstances in which a normally excluded action may have a significant environmental effect that then requires further analysis in an environmental

enforceable. The use of non-mandatory language such as “guidance,” “recommend,” “may,” “should,” and “can,” is intended to describe CEQ policies and recommendations. The use of mandatory terminology such as “must” and “required” is intended to describe controlling requirements under the terms of NEPA and the CEQ regulations, but this document does not establish legally binding requirements in and of itself.

<sup>8</sup> The term “public” in this guidance refers to any individuals, groups, entities or agencies external to the Federal agency analyzing the proposed categorical exclusion or proposed activity.

<sup>9</sup> 40 CFR 1507.1 (noting that CEQ Regulations intend to allow each agency flexibility in adapting its NEPA implementing procedures to requirements of other applicable laws).

<sup>10</sup> *Id.* at § 1508.4.

assessment (EA) or an environmental impact statement (EIS).<sup>11</sup>

Categorical exclusions are not exemptions or waivers of NEPA review; they are simply one type of NEPA review. To establish a categorical exclusion, agencies determine whether a proposed activity is one that, on the basis of past experience, normally does not require further environmental review. Once established, categorical exclusions provide an efficient tool to complete the NEPA environmental review process for proposals that normally do not require more resource-intensive EAs or EISs. The use of categorical exclusions can reduce paperwork and delay, so that EAs or EISs are targeted toward proposed actions that truly have the potential to cause significant environmental effects.<sup>12</sup>

When determining whether to use a categorical exclusion for a proposed activity, a Federal agency must carefully review the description of the proposed action to ensure that it fits within the category of actions described in the categorical exclusion. Next, the agency must consider the specific circumstances associated with the proposed activity, to rule out any extraordinary circumstances that might give rise to significant environmental effects requiring further analysis and documentation in an EA or an EIS.<sup>13</sup> In other words, when evaluating whether to apply a categorical exclusion to a proposed activity, an agency must consider the specific circumstances associated with the activity and may not end its review based solely on the determination that the activity fits within the description of the categorical exclusion; rather, the agency must also consider whether there are extraordinary circumstances that would warrant further NEPA review. Even if a proposed activity fits within the definition of a categorical exclusion and does not raise extraordinary circumstances, the CEQ Regulations make clear that an agency can, at its discretion, decide “to prepare an environmental assessment \* \* \* in order to assist agency planning and decisionmaking.”<sup>14</sup>

Since Federal agencies began using categorical exclusions in the late 1970s,

<sup>11</sup> *Id.*

<sup>12</sup> *See id.* at §§ 1500.4(p) (recommending use of categorical exclusions as a tool to reduce paperwork), 1500.5(k) (recommending categorical exclusions as a tool to reduce delay).

<sup>13</sup> 40 CFR 1508.4 (requiring Federal agencies to adopt procedures to ensure that categorical exclusions are not applied to proposed actions involving extraordinary circumstances that might have significant environmental effects).

<sup>14</sup> 40 CFR 1501.3(b).

the number and scope of categorically-excluded activities have expanded significantly. Today, categorical exclusions are the most frequently employed method of complying with NEPA, underscoring the need for this guidance on the promulgation and use of categorical exclusions.<sup>15</sup> Appropriate reliance on categorical exclusions provides a reasonable, proportionate, and effective analysis for many proposed actions, helping agencies reduce paperwork and delay. If used inappropriately, categorical exclusions can thwart NEPA's environmental stewardship goals, by compromising the quality and transparency of agency environmental review and decisionmaking, as well as compromising the opportunity for meaningful public participation and review.

## II. Establishing and Revising Categorical Exclusions

### A. Conditions Warranting New or Revised Categorical Exclusions

Federal agencies may establish a new or revised categorical exclusion in a variety of circumstances. For example, an agency may determine that a class of actions—such as payroll processing, data collection, conducting surveys, or installing an electronic security system in a facility—can be categorically excluded because it is not expected to have significant individual or cumulative environmental effects. As discussed further in Section III.A.1, below, agencies may also identify potential new categorical exclusions after the agencies have performed NEPA reviews of a class of proposed actions and found that, when implemented, the actions resulted in no significant environmental impacts. Other categories of actions may become appropriate for categorical exclusions as a result of mission changes. When agencies acquire new responsibilities through legislation or administrative restructuring, they should propose new categorical exclusions after they, or other agencies, gain sufficient experience with the new activities to make a reasoned determination that any resulting environmental impacts are not significant.<sup>16</sup>

<sup>15</sup> See CEQ reports to Congress on the status and progress of NEPA reviews for Recovery Act funded projects and activities, available on <http://www.nepa.gov> at [ceq.hss.doe.gov/ceq\\_reports/recovery\\_act\\_reports.html](http://ceq.hss.doe.gov/ceq_reports/recovery_act_reports.html).

<sup>16</sup> When legislative or administrative action creates a new agency or restructures an existing agency, the agency should determine if its decisionmaking processes have changed and ensure that its NEPA implementing procedures align the

Agencies sometimes employ “tiering” to incorporate findings from NEPA environmental reviews that address broad programs or issues into reviews that subsequently deal with more specific and focused proposed actions.<sup>17</sup> Agencies may rely on tiering to make predicate findings about environmental impacts when establishing a categorical exclusion. To the extent that mitigation commitments developed during the broader review become an integral part of the basis for subsequently excluding a proposed category of actions, care must be taken to ensure that those commitments are clearly presented as required design elements in the description of the category of actions being considered for a categorical exclusion.

If actions in a proposed categorical exclusion are found to have potentially significant environmental effects, an agency can abandon the proposed categorical exclusion, or revise it to eliminate the potential for significant impacts. This can be done by: (1) Limiting or removing activities included in the categorical exclusion; (2) placing additional constraints on the categorical exclusion's applicability; or (3) revising or identifying additional applicable extraordinary circumstances. When an agency revises an extraordinary circumstance, it should make sure that the revised version clearly identifies the circumstances when further environmental evaluation in an EA or an EIS is warranted.

### B. The Text of the Categorical Exclusion

In prior guidance, CEQ has generally addressed the crafting of categorical exclusions, encouraging agencies to “consider broadly defined criteria which characterize types of actions that, based on the agency's experience, do not cause significant environmental effects,” and to “offer several examples of activities frequently performed by that agency's personnel which would normally fall in these categories.”<sup>18</sup> CEQ's prior guidance also urges agencies to consider whether the cumulative effects of multiple small actions “would cause sufficient environmental impact to take the actions out of the categorically-excluded class.”<sup>19</sup> This guidance expands on CEQ's earlier guidance, by advising agencies that the text of a

NEPA review and other environmental planning processes with agency decisionmaking.

<sup>17</sup> 40 CFR 1502.4(d), 1502.20, 1508.28.

<sup>18</sup> Council on Environmental Quality, “Guidance Regarding NEPA Regulations,” 48 FR 34,263, 34,265, Jul. 28, 1983, available on <http://www.nepa.gov> at [ceq.hss.doe.gov/nepa/regs/1983/1983guid.htm](http://ceq.hss.doe.gov/nepa/regs/1983/1983guid.htm).

<sup>19</sup> *Id.*

proposed new or revised categorical exclusion should clearly define the eligible category of actions, as well as any physical, temporal, or environmental factors that would constrain its use.

Some activities may be variable in their environmental effects, such that they can only be categorically excluded in certain regions, at certain times of the year, or within a certain frequency. For example, because the status and sensitivity of environmental resources varies across the nation or by time of year (e.g., in accordance with a protected species' breeding season), it may be appropriate to limit the geographic applicability of a categorical exclusion to a specific region or environmental setting. Similarly, it may be appropriate to limit the frequency with which a categorical exclusion is used in a particular area. Categorical exclusions for activities with variable impacts must be carefully described to limit their application to circumstances where the activity has been shown not to have significant individual or cumulative environmental effects. Those limits may be spatial (restricting the extent of the proposed action by distance or area); temporal (restricting the proposed action during certain seasons or nesting periods in a particular setting); or numeric (limiting the number of proposed actions that can be categorically excluded in a given area or timeframe). Federal agencies that identify these constraints can better ensure that a categorical exclusion is neither too broadly nor too narrowly defined.

When developing a new or revised categorical exclusion, Federal agencies must be sure the proposed category captures the entire proposed action. Categorical exclusions should not be established or used for a segment or an interdependent part of a larger proposed action. The actions included in the category of actions described in the categorical exclusion must be stand-alone actions that have independent utility. Agencies are also encouraged to provide representative examples of the types of activities covered in the text of the categorical exclusion, especially for broad categorical exclusions. These examples will provide further clarity and transparency regarding the types of actions covered by the categorical exclusion.

### C. Extraordinary Circumstances

Extraordinary circumstances are appropriately understood as those factors or circumstances that help a Federal agency identify situations or environmental settings that may require

an otherwise categorically-excludable action to be further analyzed in an EA or an EIS. Often these factors are similar to those used to evaluate intensity for purposes of determining significance pursuant to section 1508.27(b) of the CEQ Regulations.<sup>20</sup> For example, several agencies list as extraordinary circumstances the potential effects on protected species or habitat, or on historic properties listed or eligible for listing in the National Register of Historic Places.

When proposing new or revised categorical exclusions, Federal agencies should consider the extraordinary circumstances described in their NEPA procedures to ensure that they adequately account for those situations and settings in which a proposed categorical exclusion should not be applied. An extraordinary circumstance requires the agency to determine how to proceed with the NEPA review. For example, the presence of a factor, such as a threatened or endangered species or a historic resource, could be an extraordinary circumstance, which, depending on the structure of the agency's NEPA implementing procedures, could either cause the agency to prepare an EA or an EIS, or cause the agency to consider whether the proposed action's impacts on that factor require additional analysis in an EA or an EIS. In other situations, the extraordinary circumstance could be defined to include both the presence of the factor and the impact on that factor. Either way, agency NEPA implementing procedures should clearly describe the manner in which an agency applies extraordinary circumstances and the circumstances under which additional analysis in an EA or an EIS is warranted.

Agencies should review their existing extraordinary circumstances concurrently with the review of their categorical exclusions. If an agency's existing extraordinary circumstances do not provide sufficient parameters to limit a proposed new or revised categorical exclusion to actions that do not have the potential for significant environmental effects, the agency should identify and propose additional extraordinary circumstances or revise those that will apply to the proposed categorical exclusion. If extensive extraordinary circumstances are needed to limit a proposed categorical exclusion, the agency should also consider whether the proposed categorical exclusion itself is appropriate. Any new or revised extraordinary circumstances must be

issued together with the new or revised categorical exclusion in draft form and then in final form according to the procedures described in Section IV.

### III. Substantiating a New or Revised Categorical Exclusion

Substantiating a new or revised categorical exclusion is basic to good decisionmaking. It serves as the agency's own administrative record of the underlying reasoning for the categorical exclusion. A key issue confronting Federal agencies is how to substantiate a determination that a proposed new or revised categorical exclusion describes a category of actions that do not individually or cumulatively have a significant effect on the human environment.<sup>21</sup> Provided below are methods agencies can use to gather and evaluate information to substantiate proposed new or revised categorical exclusions.

#### A. Gathering Information To Substantiate a Categorical Exclusion

The amount of information required to substantiate a categorical exclusion depends on the type of activities included in the proposed category of actions. Actions that are reasonably expected to have little impact (for example, conducting surveys or purchasing small amounts of office supplies consistent with applicable acquisition and environmental standards) should not require extensive supporting information.<sup>22</sup> For actions that do not obviously lack significant environmental effects, agencies must gather sufficient information to support establishing a new or revised categorical exclusion. An agency can substantiate a categorical exclusion using the sources of information described below, either alone or in combination.<sup>23</sup>

<sup>21</sup> See *id.* at §§ 1508.7, 1508.8, 1508.27.

<sup>22</sup> Agencies should still consider the environmental effects of actions that are taken on a large scale. Agency-wide procurement and personnel actions could have cumulative impacts. For example, purchasing paper with higher recycled content uses less natural resources and will have lesser environmental impacts. See "Federal Leadership in Environmental, Energy, and Economic Performance," E.O. No. 13,514, 74 FR 52,117, Oct. 8, 2009.

<sup>23</sup> Agencies should be mindful of their obligations under the Information Quality Act to ensure the quality, objectivity, utility, and integrity of the information they use or disseminate as the basis of an agency decision to establish a categorical exclusion. See Information Quality Act, Pub. L. No. 106-554, section 515 (2000), 114 Stat. 2763, 2763A-153 (codified at 44 U.S.C. 3516 (2001)); see also "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, Republication," 60 FR 8452, Feb. 22, 2002, available at <http://www.whitehouse.gov/omb/inforeg/infopoltech.html>. Additional laws and regulations that establish obligations that apply or may apply

#### 1. Previously Implemented Actions

An agency's assessment of the environmental effects of previously implemented or ongoing actions is an important source of information to substantiate a categorical exclusion. Such assessment allows the agency's experience with implementation and operating procedures to be taken into account in developing the proposed categorical exclusion.

Agencies can obtain useful substantiating information by monitoring and/or otherwise evaluating the effects of implemented actions that were analyzed in EAs that consistently supported Findings of No Significant Impact. If the evaluation of the implemented action validates the environmental effects (or lack thereof) predicted in the EA, this provides strong support for a proposed categorical exclusion. Care must be taken to ensure that any mitigation measures developed during the EA process are an integral component of the actions considered for inclusion in a proposed categorical exclusion.

Implemented actions analyzed in an EIS can also be a useful source of substantiating information if the implemented action has independent utility to the agency, separate and apart from the broader action analyzed in the EIS. The EIS must specifically address the environmental effects of the independent proposed action and determine that those effects are not significant. For example, when a discrete, independent action is analyzed in an EIS as part of a broad management action, an evaluation of the actual effects of that discrete action may support a proposed categorical exclusion for the discrete action. As with actions previously analyzed in EAs, predicted effects (or lack thereof) should be validated through monitoring or other corroborating evidence.

Agencies can also identify or substantiate new categorical exclusions and extraordinary circumstances by using auditing and implementation data gathered in accordance with an Environmental Management System or other systems that track environmental performance and the effects of particular actions taken to attain that performance.<sup>24</sup>

to the processes of establishing and applying categorical exclusions (such as the Federal Records Act) are beyond the scope of this guidance.

<sup>24</sup> An EMS provides a systematic framework for a Federal agency to monitor and continually improve its environmental performance through audits, evaluation of legal and other requirements, and management reviews. The potential for EMS to support NEPA work is further described in CEQ's

<sup>20</sup> *Id.* at § 1508.27(b).

Agencies should also consider appropriate monitoring or other evaluation of the environmental effects of their categorically-excluded actions, to inform periodic reviews of existing categorical exclusions, as discussed in Section VI, below.

## 2. Impact Demonstration Projects

When Federal agencies lack experience with a particular category of actions that is being considered for a proposed categorical exclusion, they may undertake impact demonstration projects to assess the environmental effects of those actions. As part of a demonstration project, the Federal agency should monitor the actual environmental effects of the proposed action during and after implementation. The NEPA documentation prepared for impact demonstration projects should explain how the monitoring and analysis results will be used to evaluate the merits of a proposed categorical exclusion. When designing impact demonstration projects, an agency must ensure that the action being evaluated accurately represents the scope, the operational context, and the environmental context of the entire category of actions that will be described in the proposed categorical exclusion. For example, if the proposed categorical exclusion would be used in regions or areas of the country with different environmental settings, a series of impact demonstration projects may be needed in those areas where the categorical exclusion would be used.

## 3. Information From Professional Staff, Expert Opinions, and Scientific Analyses

A Federal agency may rely on the expertise, experience, and judgment of its professional staff as well as outside experts to assess the potential environmental effects of applying proposed categorical exclusions, provided that the experts have knowledge, training, and experience relevant to the implementation and environmental effects of the actions described in the proposed categorical exclusion. The administrative record for the proposed categorical exclusion should document the experts' credentials (*e.g.*, education, training, certifications, years of related experience) and describe how the experts arrived at their conclusions.

Scientific analyses are another good source of information to substantiate a

new or revised categorical exclusion. Because the reliability of scientific information varies according to its source and the rigor with which it was developed, the Federal agency remains responsible for determining whether the information reflects accepted knowledge, accurate findings, and experience relevant to the environmental effects of the actions that would be included in the proposed categorical exclusion. Peer-reviewed findings may be especially useful to support an agency's scientific analysis, but agencies may also consult professional opinions, reports, and research findings that have not been formally peer-reviewed. Scientific information that has not been externally peer-reviewed may require additional scrutiny and evaluation by the agency. In all cases, findings must be based on high-quality, accurate technical and scientific information.<sup>25</sup>

## 4. Benchmarking Other Agencies' Experiences

A Federal agency cannot rely on another agency's categorical exclusion to support a decision not to prepare an EA or an EIS for its own actions. An agency may, however, substantiate a categorical exclusion of its own based on another agency's experience with a comparable categorical exclusion and the administrative record developed when the other agency's categorical exclusion was established. Federal agencies can also substantiate categorical exclusions by benchmarking, or drawing support, from private and public entities that have experience with the actions covered in a proposed categorical exclusion, such as State and local agencies, Tribes, academic and professional institutions, and other Federal agencies.

When determining whether it is appropriate to rely on another entity's experience, an agency must demonstrate that the benchmarked actions are comparable to the actions in a proposed categorical exclusion. The agency can demonstrate this based on: (1) Characteristics of the actions; (2) methods of implementing the actions; (3) frequency of the actions; (4) applicable standard operating procedures or implementing guidance (including extraordinary circumstances); and (5) timing and context, including the environmental settings in which the actions take place.

## B. Evaluating the Information Supporting Categorical Exclusions

After gathering substantiating information and determining that the category of actions in the proposed categorical exclusion does not normally result in individually or cumulatively significant environmental effects, a Federal agency should develop findings that demonstrate how it made its determination. These findings should account for similarities and differences between the proposed categorical exclusion and the substantiating information. The findings should describe the method and criteria the agency used to assess the environmental effects of the proposed categorical exclusion. These findings, and the relevant substantiating information, should be maintained in an administrative record that will support: Benchmarking by other agencies (as discussed in Section III.A.4, above); applying the categorical exclusions (as discussed in Section V.A, below); and periodically reviewing the continued viability of the categorical exclusion (as discussed in Section VI, below). These findings should also be made available to the public, at least in preliminary form, as part of the process of seeking public input on the establishment of new or revised categorical exclusions, though the final findings may be revised based on new information received from the public and other sources.

## IV. Procedures for Establishing a New or Revised Categorical Exclusion

Pursuant to section 1507.3(a) of the CEQ Regulations, Federal agencies are required to consult with the public and with CEQ whenever they amend their NEPA procedures, including when they establish new or revised categorical exclusions. An agency can only adopt new or revised NEPA implementing procedures after the public has had notice and an opportunity to comment, and after CEQ has issued a determination that the procedures are in conformity with NEPA and the CEQ regulations. Accordingly, an agency's process for establishing a new or revised categorical exclusion should include the following steps:

- Draft the proposed categorical exclusion based on the agency's experience and substantiating information;
- Consult with CEQ on the proposed categorical exclusion;
- Consult with other Federal agencies that conduct similar activities to coordinate with their current procedures, especially for programs

Guidebook, "Aligning National Environmental Policy Act Processes with Environmental Management Systems" (2007), available on [http://www.nepa.gov/at/ceq.hss.doe.gov/publications/nepa\\_and\\_ems.html](http://www.nepa.gov/at/ceq.hss.doe.gov/publications/nepa_and_ems.html).

<sup>25</sup> See 40 CFR 1500.1(b), 1502.24.



requesting similar information from members of the public (e.g., applicants);

- Publish a notice of the proposed categorical exclusion in the **Federal Register** for public review and comment;
- Consider public comments;
- Consult with CEQ on the public comments received and the proposed final categorical exclusion to obtain CEQ's written determination of conformity with NEPA and the CEQ Regulations;
- Publish the final categorical exclusion in the **Federal Register**;
- File the categorical exclusion with CEQ; and
- Make the categorical exclusion readily available to the public through the agency's Web site and/or other means.

#### A. Consultation With CEQ

The CEQ Regulations require agencies to consult with CEQ prior to publishing their proposed NEPA procedures in the **Federal Register** for public comment. Agencies are encouraged to involve CEQ as early as possible in the process and to enlist CEQ's expertise and assistance with interagency coordination to make the process as efficient as possible.<sup>26</sup>

Following the public comment period, the Federal agency must consider the comments received and consult again with CEQ to discuss substantive comments and how they will be addressed. CEQ shall complete its review within thirty (30) days of receiving the final text of the agency's proposed categorical exclusion. For consultation to successfully conclude, CEQ must provide the agency with a written statement that the categorical exclusion was developed in conformity with NEPA and the CEQ Regulations. Finally, when the Federal agency publishes the final version of the categorical exclusion in the **Federal Register** and on its established agency Web site, the agency should notify CEQ of such publication so as to satisfy the requirements to file the final categorical exclusion with CEQ and to make the final categorical exclusion readily available to the public.<sup>27</sup>

#### B. Seeking Public Involvement When Establishing or Revising a Categorical Exclusion

Engaging the public in the environmental aspects of Federal decisionmaking is a key aspect of NEPA

and the CEQ Regulations.<sup>28</sup> At a minimum, the CEQ Regulations require Federal agencies to make any proposed amendments to their categorical exclusions available for public review and comment in the **Federal Register**,<sup>29</sup> regardless of whether the categorical exclusions are promulgated as regulations through rulemaking, or issued as departmental directives or orders.<sup>30</sup> To maximize the value of comments from interested parties, the agency's **Federal Register** notice should:

- Describe the proposed activities covered by the categorical exclusion and provide the proposed text of the categorical exclusion;
- Summarize the information in the agency's administrative record that was used to substantiate the categorical exclusion, including an evaluation of the information and related findings;<sup>31</sup>
- Define all applicable terms;
- Describe the extraordinary circumstances that may limit the use of the categorical exclusion; and
- Describe the available means for submitting questions and comments about the proposed categorical exclusion (for example, e-mail addresses, mailing addresses, Web site addresses, and names and phone numbers of agency points of contact).

<sup>26</sup> National Environmental Policy Act of 1969, § 2 *et seq.*, 42 U.S.C. 4321 *et seq.*; *see, e.g.*, 40 CFR 1506.6(a) (requiring agencies to make diligent efforts to involve the public in preparing and implementing their NEPA procedures); 40 CFR 1507.3(a) (requiring each agency to consult with CEQ while developing its procedures and before publishing them in the **Federal Register** for comment; providing that an agency's NEPA procedures shall be adopted only after an opportunity for public review; and providing that, once in effect, the procedures must be made readily available to the public).

<sup>27</sup> *See* 40 CFR 1507.3 (outlining procedural requirements for agencies to establish and revise their NEPA implementing regulations), 1506.6(a) (requiring agencies to involve the public in rulemaking, including public notice and an opportunity to comment).

<sup>28</sup> NEPA and the CEQ Regulations do not require agency NEPA implementing procedures, of which categorical exclusions are a key component, to be promulgated as regulations through rulemaking. Agencies should ensure they comply with all appropriate agency requirements for issuing and revising their NEPA implementing procedures.

<sup>31</sup> This step is particularly beneficial when the agency determines that the public will view a potential impact as significant, as it provides the agency the opportunity to explain why it believes that impact to be presumptively insignificant. Whenever practicable, the agency should include a link to a Web site containing all the supporting information, evaluations, and findings. Ready access to all supporting information will likely minimize the need for members of the public to depend on Freedom of Information Act requests and enhance the NEPA goals of outreach and disclosure. Agencies should consider using their regulatory development tools to assist in maintaining access to supporting information, such as establishing an online docket using <http://www.regulations.gov>.

When establishing or revising a categorical exclusion, agencies should also pursue additional opportunities for public involvement beyond publication in the **Federal Register** in cases where there is likely to be significant public interest and additional outreach would facilitate public input. The extent of public involvement can be tailored to the nature of the proposed categorical exclusion and the degree of expected public interest.

CEQ encourages Federal agencies to engage interested parties such as public interest groups, Federal NEPA contacts at other agencies, Tribal governments and agencies, and State and local governments and agencies. The purpose of this engagement is to share relevant data, information, and concerns. Agencies can involve the public by using the methods noted in section 1506.6 of the CEQ Regulations, as well as other public involvement techniques such as focus groups, e-mail exchanges, conference calls, and Web-based forums.

CEQ also strongly encourages Federal agencies to post updates on their official Web sites whenever they issue **Federal Register** notices for new or revised categorical exclusions. An agency Web site may serve as the primary location where the public learns about agency NEPA implementing procedures and their use, and obtains efficient access to updates and supporting information. Therefore, agencies should ensure that their NEPA implementing procedures and any final revisions or amendments are easily accessed through the agency's official Web site including when an agency is adding, deleting, or revising the categorical exclusions and/or the extraordinary circumstances in its NEPA implementing procedures.

#### V. Applying an Established Categorical Exclusion

When applying a categorical exclusion to a proposed action, Federal agencies face two key decisions: (1) Whether to prepare documentation supporting their determination to use a categorical exclusion for a proposed action; and (2) whether public engagement and disclosure may be useful to inform determinations about using categorical exclusions.

##### A. When To Document Categorical Exclusion Determinations

In prior guidance, CEQ has "strongly discourag[e]d" procedures that would require the preparation of additional paperwork to document that an activity has been categorically excluded," based on an expectation that "sufficient information will usually be available

<sup>26</sup> 40 CFR 1507.3(a) (requiring agencies with similar programs to consult with one another and with CEQ to coordinate their procedures).

<sup>27</sup> *Id.*



during the course of normal project development” to determine whether an EIS or an EA is needed.<sup>32</sup> Moreover, “the agency’s administrative record (for the proposed action) will clearly document the basis for its decision.”<sup>33</sup> This guidance modifies our prior guidance to the extent that it recognizes that each Federal agency should decide—and update its NEPA implementing procedures and guidance to indicate—whether any of its categorical exclusions warrant preparation of additional documentation.

Some activities, such as routine personnel actions or purchases of small amounts of supplies, may carry little risk of significant environmental effects, such that there is no practical need for, or benefit from, preparing additional documentation when applying a categorical exclusion to those activities. For those activities, the administrative record for establishing the categorical exclusion and any normal project development documentation may be considered sufficient.

For other activities, such as decisions to allow various stages of resource development after a programmatic environmental review, documentation may be appropriate to demonstrate that the proposed action comports with any limitations identified in prior NEPA analysis and that there are no potentially significant impacts expected as a result of extraordinary circumstances. In such cases, the documentation should address proposal-specific factors and show consideration of extraordinary circumstances with regard to the potential for localized impacts. It is up to agencies to decide whether to prepare separate NEPA documentation in such cases or to include this documentation in other project-specific documents that the agency is preparing.

In some cases, courts have required documentation to demonstrate that a Federal agency has considered the environmental effects associated with extraordinary circumstances.<sup>34</sup> Documenting the application of a categorical exclusion provides the agency the opportunity to demonstrate why its decision to use the categorical exclusion is entitled to deference.<sup>35</sup>

<sup>32</sup> “Guidance Regarding NEPA Regulations,” 48 FR 34,263, 34,265, Jul. 28, 1983, available on <http://www.nepa.gov/ceq.hss.doe.gov/nepa/regs/1983/1983guid.htm>.

<sup>33</sup> *Id.*

<sup>34</sup> See, e.g., *California v. Norton*, 311 F.3d 1162, 1175–78 (9th Cir. 2002).

<sup>35</sup> The agency determination that an action is categorically excluded may itself be challenged under the Administrative Procedure Act, 5 U.S.C. 501 *et seq.*

Documentation may be necessary to comply with the requirements of other laws, regulations, and policies, such as the Endangered Species Act or the National Historic Preservation Act. When that is the case, all resource analyses and the results of any consultations or coordination should be incorporated by reference in the administrative record developed for the proposed action. Moreover, the nature and severity of the effect on resources subject to additional laws or regulations may be a reason for limiting the use of a categorical exclusion and therefore should, where appropriate, also be addressed in documentation showing how potential extraordinary circumstances were considered and addressed in the decision to use the categorical exclusion.

For those categorical exclusions for which an agency determines that documentation is appropriate, the documentation should cite the categorical exclusion being used and show that the agency determined that: (1) The proposed action fits within the category of actions described in the categorical exclusion; and (2) there are no extraordinary circumstances that would preclude the proposed action from being categorically excluded. The extent of the documentation should be tailored to the type of action involved, the potential for extraordinary circumstances and environmental effects, and any applicable requirements of other laws, regulations, and policies. If lengthy documentation is needed to address these aspects, an agency should consider whether it is appropriate to apply the categorical exclusion in that particular situation. In all circumstances, any documentation prepared for a categorical exclusion should be concise.

#### *B. When To Seek Public Engagement and Disclosure*

Most Federal agencies do not routinely notify the public when they use a categorical exclusion to meet their NEPA responsibilities. There are some circumstances, however, where the public may be able to provide an agency with valuable information, such as whether a proposal involves extraordinary circumstances or potentially significant cumulative impacts that can help the agency decide whether to apply a categorical exclusion. CEQ therefore encourages Federal agencies to determine—and specify in their NEPA implementing procedures—those circumstances in which the public should be engaged or notified before a categorical exclusion is used.

Agencies should utilize information technology to provide the public with access to information about the agency’s NEPA compliance. CEQ strongly recommends that agencies post key information about their NEPA procedures and implementation on a publicly available Web site. The Web site should include:

- The text of the categorical exclusions and applicable extraordinary circumstances;
- A synopsis of the administrative record supporting the establishment of each categorical exclusion with information on how the public can access the entire administrative record;
- Those categorical exclusions which the agency determines are and are not likely to be of interest to the public;<sup>36</sup> and
- Information on agencies’ use of categorical exclusions for proposed actions, particularly in those situations where there is a high level of public interest in a proposed action.

Where an agency has documented a categorical exclusion, it should also consider posting that documentation online. For example, in 2009, the Department of Energy adopted a policy to post documented categorical exclusion determinations online.<sup>37</sup> By adopting a similar policy, other agencies can significantly increase the quality and transparency of their decisionmaking when using categorical exclusions.

## **VI. Periodic Review of Established Categorical Exclusions**

The CEQ Regulations direct Federal agencies to “continue to review their policies and procedures and in consultation with [CEQ] to revise them as necessary to ensure full compliance with the purposes and provisions of [NEPA].”<sup>38</sup> Many agencies have categorical exclusions that were established many years ago. Some Federal agencies have internal procedures for identifying and revising categorical exclusions that no longer reflect current environmental circumstances, or current agency policies, procedures, programs, or mission. Where an agency’s categorical exclusions have not been regularly

<sup>36</sup> Many agencies publish two lists of categorical exclusions: (1) Those which typically do not raise public concerns due to the low risk of potential environmental effects, and (2) those more likely to raise public concerns.

<sup>37</sup> See Department of Energy, Categorical Exclusion Determinations, available at [http://www.gc.energy.gov/NEPA/categorical\\_exclusion\\_determinations.htm](http://www.gc.energy.gov/NEPA/categorical_exclusion_determinations.htm).

<sup>38</sup> 40 CFR 1507.3.

reviewed, they should be reviewed by the agency as soon as possible.

There are several reasons why Federal agencies should periodically review their categorical exclusions. For example, a Federal agency may find that an existing categorical exclusion is not being used because the category of actions is too narrowly defined. In such cases, the agency should consider amending its NEPA implementing procedures to expand the description of the category of actions included in the categorical exclusion. An agency could also find that an existing categorical exclusion includes actions that raise the potential for significant environmental effects with some regularity. In those cases, the agency should determine whether to delete the categorical exclusion, or revise it to either limit the category of actions or expand the extraordinary circumstances that limit when the categorical exclusion can be used. Periodic review can also help agencies identify additional factors that should be included in their extraordinary circumstances and consider whether certain categorical exclusions should be documented.

Agencies should exercise sound judgment about the appropriateness of categorically excluding activities in light of evolving or changing conditions that might present new or different environmental impacts or risks. The assumptions underlying the nature and impact of activities encompassed by a categorical exclusion may have changed over time. Different technological capacities of permitted activities may present very different risk or impact profiles. This issue was addressed in CEQ's August 16, 2010 report reviewing the Department of the Interior's Minerals Management Service's application of NEPA to the permitting of deepwater oil and gas drilling.<sup>39</sup>

Agencies should review their categorical exclusions on an established timeframe, beginning with the categorical exclusions that were established earliest and/or the categorical exclusions that may have the greatest potential for significant environmental impacts. This guidance recommends that agencies develop a process and timeline to periodically

review their categorical exclusions (and extraordinary circumstances) to ensure that their categorical exclusions remain current and appropriate, and that those reviews should be conducted at least every seven years. A seven-year cycle allows the agencies to regularly review categorical exclusions to avoid the use of categorical exclusions that are outdated and no longer appropriate. If the agency believes that a different timeframe is appropriate, the agency should articulate a sound basis for that conclusion, explaining how the alternate timeframe will still allow the agency to avoid the use of categorical exclusions that are outdated and no longer appropriate. The agency should publish its process and time period, along with its articulation of a sound basis for periods over seven years, on the agency's Web site and notify CEQ where on the Web site the review procedures are posted. We recognize that due to competing priorities, resource constraints, or for other reasons, agencies may not always be able to meet these time periods. The fact that a categorical exclusion has not been evaluated within the time established does not invalidate its use for NEPA compliance, as long as such use is consistent with the defined scope of the exclusion and has properly considered any potential extraordinary circumstances.

In establishing this review process, agencies should take into account factors including changed circumstances, how frequently the categorical exclusions are used, the extent to which resources and geographic areas are potentially affected, and the expected duration of impacts. The level of scrutiny and evaluation during the review process should be commensurate with a categorically-excluded activity's potential to cause environmental impacts and the extent to which relevant circumstances have changed since it was issued or last reviewed. Some categorical exclusions, such as for routine purchases or contracting for office-related services, may require minimal review. Other categorical exclusions may require a more thorough reassessment of scope, environmental effects, and extraordinary circumstances, such as when they are tied to programmatic EAs or EISs that analyzed activities whose underlying circumstances have since changed.

To facilitate reviews, the Federal agency offices charged with overseeing their agency's NEPA compliance should develop and maintain sufficient capacity to periodically review their existing categorical exclusions to ensure

that the agency's prediction of no significant impacts is borne out in practice.<sup>40</sup> Agencies can efficiently assess changed circumstances by utilizing a variety of methods such as those recommended in Section III, above, for substantiating new or revised categorical exclusions. These methods include benchmarking, monitoring of previously implemented actions, and consultation with professional staff. The type and extent of monitoring and other information that should be considered in periodic reviews, as well as the particular entity or entities within the agency that would be responsible for gathering this information, will vary depending upon the nature of the actions and their anticipated effects. Consequently, agencies should utilize the expertise, experience, and judgment of agency professional staff when determining the appropriate type and extent of monitoring and other information to consider. This information will help the agency determine whether its categorical exclusions are used appropriately, or whether a categorical exclusion needs to be revised. Agencies can also use this information when they engage stakeholders in developing proposed revisions to categorical exclusions and extraordinary circumstances.

Agencies can also facilitate reviews by keeping records of their experiences with certain activities in a number of ways, including tracking information provided by agency field offices.<sup>41</sup> In such cases, a Federal agency could conduct its periodic review of an established categorical exclusion by soliciting information from field offices about the observed effects of implemented actions, both from agency personnel and the public. On-the-ground monitoring to evaluate environmental effects of an agency's categorically-excluded actions, where appropriate, can also be incorporated into an agency's procedures for conducting its oversight of ongoing projects and can be included as part of regular site visits to project areas.

Agencies can also conduct periodic review of existing categorical exclusions through broader program reviews. Program reviews can occur at various levels (for example, field office, division office, headquarters office) and on various scales (for example, geographic location, project type, or areas identified in an interagency agreement). While a

<sup>39</sup> Council on Environmental Quality, *Report Regarding the Mineral Management Service's National Environmental Policy Act Policies, Practices, and Procedures as They Relate to Outer Continental Shelf Oil and Gas Exploration*, available at [ceq.hss.doe.gov/current\\_developments/docs/CEQ\\_Report\\_Reviewing\\_MMS\\_OCS\\_NEPA\\_Implementation.pdf](http://ceq.hss.doe.gov/current_developments/docs/CEQ_Report_Reviewing_MMS_OCS_NEPA_Implementation.pdf) (Aug. 2010) at 18–20 (explaining that MMS NEPA review for the Macondo Exploratory Well relied on categorical exclusions established in the 1980s, before deepwater drilling became widespread).

<sup>40</sup> 40 CFR 1507.2.

<sup>41</sup> Council on Environmental Quality, *The NEPA Task Force Report to the Council on Environmental Quality—Modernizing NEPA Implementation*, p. 63 (Sept. 2003), available on <http://www.nepa.gov> at [ceq.hss.doe.gov/ntf/report/index.html](http://ceq.hss.doe.gov/ntf/report/index.html).

Federal agency may choose to initiate a program review specifically focused on categorical exclusions, it is possible that program reviews with a broader focus may yield information relevant to categorical exclusions and may thus substitute for reviews specifically focused on categorical exclusions. However, the substantial flexibility that agencies have in how they structure their review procedures underscores the importance of ensuring that the review procedures are clear and transparent.

In working with agencies on reviewing their existing categorical exclusions, CEQ will look to the actual impacts from activities that have been subject to categorical exclusions, and will consider the extent and scope of agency monitoring and/or other substantiating evidence. As part of its oversight role and responsibilities under NEPA, CEQ will contact agencies following the release of this guidance to ascertain the status of their reviews of existing categorical exclusions. CEQ will make every effort to align its oversight with reviews being conducted by the agency and will begin with those agencies that are currently reassessing their categorical exclusions, as well as with agencies that are experiencing difficulties or facing challenges to their application of categorical exclusions.

Finally, it is important to note that the rationale and supporting information for establishing or documenting experience with using a categorical exclusion may be lost if an agency has inadequate procedures for recording, retrieving, and preserving documents and administrative records. Therefore, Federal agencies will benefit from a review of their current practices for maintaining and preserving such records. Measures to ensure future availability could include greater centralization of records, use of modern storage systems and improvements in the agency's electronic and hard copy filing systems.<sup>42</sup>

## VII. Conclusion

This guidance will help to guide CEQ and the agencies when an agency seeks to propose a new or revised categorical exclusion. It should also guide the agencies when categorical exclusions are used for proposed actions, when reviewing existing categorical exclusions, or when proposing new categorical exclusions. Questions regarding this guidance should be

directed to the CEQ Associate Director for NEPA Oversight.

**Nancy H. Sutley,**  
*Chair.*

[FR Doc. 2010-30017 Filed 12-3-10; 8:45 am]

**BILLING CODE 3125-W0-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 660

[Docket No. 100218107-0199-01]

RIN 0648-XY31

#### Fisheries Off West Coast States; Modifications of the West Coast Commercial and Recreational Salmon Fisheries; Inseason Actions #12 and #13

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Modification of fishing seasons, gear restrictions, and landing and possession limits; request for comments.

**SUMMARY:** NOAA Fisheries announces two inseason actions in the ocean salmon fisheries. Inseason action #12 modified the commercial fishery in the area from the U.S./Canada Border to Cape Falcon, Oregon. Inseason action #13 modified the commercial and recreational fisheries in the area from U.S./Canada Border to Cape Falcon, Oregon.

**DATES:** Inseason actions #12 and #13 were effective on August 6, 2010, and remain in effect until the closing date of the 2010 salmon season announced in the 2010 annual management measures or through additional inseason action. Comments will be accepted through December 21, 2010.

**ADDRESSES:** You may submit comments, identified by 0648-XY31, by any one of the following methods:

- *Electronic Submissions:* Submit all electronic public comments via the Federal eRulemaking Portal <http://www.regulations.gov>.
- *Fax:* 206-526-6736, Attn: Peggy Busby.
- *Mail:* 7600 Sand Point Way, NE., Building 1, Seattle, WA, 98115.

*Instructions:* No comments will be posted for public viewing until after the comment period has closed. All comments received are a part of the public record and will generally be posted to <http://www.regulations.gov> without change. All Personal Identifying

Information (for example, name, address, *etc.*) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

NMFS will accept anonymous comments (enter N/A in the required fields, if you wish to remain anonymous). You may submit attachments to electronic comments in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

**FOR FURTHER INFORMATION CONTACT:** Peggy Busby, by phone at 206-526-4323.

**SUPPLEMENTARY INFORMATION:** In the 2010 annual management measures for ocean salmon fisheries (75 FR 24482, May 5, 2010), NMFS announced the commercial and recreational fisheries in the area from the U.S./Canada Border to the U.S./Mexico Border, beginning May 1, 2010.

The Regional Administrator (RA) consulted with representatives of the Council, Washington Department of Fish and Wildlife, and Oregon Department of Fish and Wildlife on August 5, 2010. The information considered during this consultation related to Chinook and coho salmon catch to date and Chinook and coho salmon catch rates compared to quotas and other management measures established preseason.

Inseason action #12 reduced the landing and possession limit for Chinook salmon in the commercial salmon fishery from the U.S./Canada Border to Cape Falcon, Oregon. Previously, inseason action #11 (75 FR 54791, September, 9, 2010) imposed an open period landing and possession limit of 60 Chinook salmon and 50 coho per vessel. Inseason action #12 decreased the Chinook salmon landing and possession limit to 30 Chinook salmon per vessel; the open period landing and possession limit for coho was unchanged by inseason action #12. This action was taken because Chinook salmon catches increased dramatically in the previous week, and there was concern that if the landing limit was not reduced the fishery would quickly exhaust the remaining Chinook salmon quota. On August 5, 2010, the States recommended this action and the RA concurred; inseason action #12 took effect on August 6, 2010. Modification of quota and/or fishing seasons is authorized by 50 CFR 660.409 (b)(1)(i).

Inseason action #13 modified the quotas for the commercial and recreational fisheries through an inseason trade and transfer of quota; 7,000 coho were transferred from the

<sup>42</sup> Agencies should be mindful of their obligations to maintain and preserve agency records under the Federal Records Act for maintaining and preserving agency records. 44 U.S.C. 3101 *et seq.*

commercial fishery quota to the recreational fishery quota; 2,500 Chinook salmon were transferred from the recreational fishery guideline to the commercial fishery quota. This action was taken to provide additional Chinook salmon quota to the commercial fishery to extend the season and to provide additional coho quota to the recreational fishery. On August 5, 2010, the States recommended this action and the RA concurred; inseason action #13 took effect on August 6, 2010. The States and the RA met again on August 12, 2010 to consult with the Salmon Technical Team (STT). The STT modeled and reported on the impact neutral equivalents of the trade that took effect August 6, 2010. The transfer of 7,000 coho to the recreational fishery resulted in a net reduction of 5,700 coho in the commercial quota. The transfer of 2,500 Chinook salmon from the recreational fishery resulted in a net increase of 1,650 Chinook salmon in the commercial quota. Modification of quota and/or fishing seasons is authorized by 50 CFR 660.409 (b)(1)(i).

All other restrictions and regulations remain in effect as announced for the 2010 Ocean Salmon Fisheries and previous inseason actions.

The RA determined that the best available information indicated that the catch and effort data, and projections, supported the above inseason actions recommended by the States. The States manage the fisheries in State waters adjacent to the areas of the U.S. exclusive economic zone in accordance with these Federal actions. As provided by the inseason notice procedures of 50 CFR 660.411, actual notice of the described regulatory actions was given, prior to the date the action was effective, by telephone hotline number 206-526-6667 and 800-662-9825, and by U.S. Coast Guard Notice to Mariners broadcasts on Channel 16 VHF-FM and 2182 kHz.

#### Classification

The Assistant Administrator for Fisheries, NOAA (AA), finds that good cause exists for this notification to be issued without affording prior notice and opportunity for public comment under 5 U.S.C. 553(b)(B) because such notification would be impracticable. As previously noted, actual notice of the regulatory actions was provided to fishers through telephone hotline and radio notification. These actions comply with the requirements of the annual management measures for ocean salmon fisheries (75 FR 24482, May 5, 2010), the West Coast Salmon Plan, and regulations implementing the West Coast Salmon Plan 50 CFR 660.409 and

660.411. Prior notice and opportunity for public comment was impracticable because NMFS and the State agencies had insufficient time to provide for prior notice and the opportunity for public comment between the time the fishery catch and effort data were collected to determine the extent of the fisheries, and the time the fishery modifications had to be implemented in order to ensure that fisheries are managed based on the best available scientific information, thus allowing fishers access to the available fish at the time the fish were available while ensuring that quotas are not exceeded. The AA also finds good cause to waive the 30-day delay in effectiveness required under U.S.C. 553(d)(3), as a delay in effectiveness of these actions would allow fishing at levels inconsistent with the goals of the Salmon Fishery Management Plan and the current management measures.

These actions are authorized by 50 CFR 660.409 and 660.411 and are exempt from review under Executive Order 12866.

**Authority:** 16 U.S.C. 1801 *et seq.*

Dated: November 30, 2010.

**Brian W. Parker,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 2010-30506 Filed 12-3-10; 8:45 am]

**BILLING CODE 3510-22-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 660

[Docket No. 100218107-0199-01]

RIN 0648-XY83

#### Fisheries Off West Coast States; Modifications of the West Coast Commercial and Recreational Salmon Fisheries; Inseason Actions #14 and #15

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Modification of fishing seasons, gear restrictions, and landing and possession limits; request for comments.

**SUMMARY:** NOAA Fisheries announces two inseason actions in the ocean salmon fisheries. Inseason action #14 modified the commercial fishery in the area from the U.S./Canada Border to Cape Falcon, Oregon. Inseason action #15 modified the commercial and recreational fisheries in the area from

U.S./Canada Border to Cape Falcon, Oregon.

**DATES:** Inseason actions #14 and #15 were effective on September 3, 2010, and remain in effect until the closing date of the 2010 salmon season announced in the 2010 annual management measures or through additional inseason action. Comments will be accepted through December 21, 2010.

**ADDRESSES:** You may submit comments, identified by 0648-XY83, by any one of the following methods:

- **Electronic Submissions:** Submit all electronic public comments via the Federal eRulemaking Portal <http://www.regulations.gov>.

- **Fax:** 206-526-6736, Attn: Peggy Busby.

- **Mail:** 7600 Sand Point Way, NE., Building 1, Seattle, WA, 98115.

**Instructions:** No comments will be posted for public viewing until after the comment period has closed. All comments received are a part of the public record and will generally be posted to <http://www.regulations.gov> without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

NMFS will accept anonymous comments (enter N/A in the required fields, if you wish to remain anonymous). You may submit attachments to electronic comments in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

**FOR FURTHER INFORMATION CONTACT:** Peggy Busby, by phone at 206-526-4323.

**SUPPLEMENTARY INFORMATION:** In the 2010 annual management measures for ocean salmon fisheries (75 FR 24482, May 5, 2010), NMFS announced the commercial and recreational fisheries in the area from the U.S./Canada Border to the U.S./Mexico Border, beginning May 1, 2010.

The Regional Administrator (RA) consulted with representatives of the Council, Washington Department of Fish and Wildlife, and Oregon Department of Fish and Wildlife on September 2, 2010. The information considered during this consultation related to Chinook and coho salmon catch to date and Chinook and coho salmon catch rates compared to quotas and other management measures established preseason.

Inseason action #14 announced that the commercial salmon fishery from the

U.S./Canada Border to Cape Falcon, Oregon would close at 11:59 p.m., Tuesday, September 7, 2010. This action was taken to fully utilize remaining Chinook salmon quota without exceeding the available quota between the Commercial and Recreational fisheries. On September 2, 2010, the States recommended this action and the RA concurred; inseason action #14 took effect on September 3, 2010. Modification of quota and/or fishing seasons is authorized by 50 CFR 660.409(b)(1)(i).

Inseason action #15 modified the quotas for the commercial and recreational fisheries through an inseason transfer of quota; 1,000 Chinook salmon were transferred from the north of Cape Falcon recreational fishery guideline to the north of Cape Falcon commercial fishery quota. The Salmon Technical Team determined that the impact neutral effective transfer would increase the commercial quota north of Cape Falcon by 800 Chinook salmon. This action was taken to make available to the commercial fishery Chinook salmon quota that was otherwise projected to go unutilized in the recreational fishery. On September 2, 2010, the States recommended this action and the RA concurred; inseason action #15 took effect on September 3, 2010. Modification of quota and/or fishing seasons is authorized by 50 CFR 660.409(b)(1)(i).

All other restrictions and regulations remain in effect as announced for the 2010 Ocean Salmon Fisheries and previous inseason actions.

The RA determined that the best available information indicated that the catch and effort data, and projections, supported the above inseason actions recommended by the States. The States manage the fisheries in State waters adjacent to the areas of the U.S. exclusive economic zone in accordance with these Federal actions. As provided by the inseason notice procedures of 50 CFR 660.411, actual notice of the described regulatory actions was given, prior to the date the action was effective, by telephone hotline number 206-526-6667 and 800-662-9825, and by U.S. Coast Guard Notice to Mariners broadcasts on Channel 16 VHF-FM and 2182 kHz.

#### Classification

The Assistant Administrator for Fisheries, NOAA (AA), finds that good cause exists for this notification to be issued without affording prior notice and opportunity for public comment under 5 U.S.C. 553(b)(B) because such notification would be impracticable. As previously noted, actual notice of the regulatory actions was provided to fishers through telephone hotline and radio notification. These actions comply with the requirements of the annual management measures for ocean salmon fisheries (75 FR 24482, May 5, 2010), the West Coast Salmon Plan, and

regulations implementing the West Coast Salmon Plan 50 CFR 660.409 and 660.411. Prior notice and opportunity for public comment was impracticable because NMFS and the State agencies had insufficient time to provide for prior notice and the opportunity for public comment between the time the fishery catch and effort data were collected to determine the extent of the fisheries, and the time the fishery modifications had to be implemented in order to ensure that fisheries are managed based on the best available scientific information, thus allowing fishers access to the available fish at the time the fish were available while ensuring that quotas are not exceeded. The AA also finds good cause to waive the 30-day delay in effectiveness required under U.S.C. 553(d)(3), as a delay in effectiveness of these actions would allow fishing at levels inconsistent with the goals of the Salmon Fishery Management Plan and the current management measures.

These actions are authorized by 50 CFR 660.409 and 660.411 and are exempt from review under Executive Order 12866.

**Authority:** 16 U.S.C. 1801 *et seq.*

Dated: November 30, 2010.

**Brian W. Parker,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 2010-30507 Filed 12-3-10; 8:45 am]

**BILLING CODE 3510-22-P**

# Proposed Rules

Federal Register

Vol. 75, No. 233

Monday, December 6, 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 Parts 71 and 73

[NRC-1999-0005]

RIN 3150-AG41

#### Advance Notification to Native American Tribes of Transportation of Certain Types of Nuclear Waste

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Proposed rule.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations that govern packaging and transportation of radioactive material and physical protection of plants and materials. Specifically, the proposed amendments would require licensees to provide advance notification to Federally recognized Tribal governments regarding shipments of irradiated reactor fuel and certain nuclear wastes for any shipment that passes within or across their reservations. The Tribal government would be required to protect the shipment information as Safeguards Information (SGI).

**DATES:** Submit comments on the rule by February 22, 2011. Submit comments specific to the information collections aspects of this proposed rule by January 5, 2011. Comments received after the above dates 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-1999-0005 in the subject line of your comments. For instructions on submitting comments and 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 e-Rulemaking Portal:* Go to <http://www.regulations.gov> and search for documents filed under Docket ID NRC-1999-0005. Comments may be submitted electronically through this Web site. Address questions about NRC dockets to Carol Gallagher, telephone 301-492-3668; e-mail [Carol.Gallagher@nrc.gov](mailto:Carol.Gallagher@nrc.gov).

*Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

*E-mail comments to:* [Rulemaking.Comments@nrc.gov](mailto:Rulemaking.Comments@nrc.gov). If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at 301-415-1677.

*Hand deliver comments to:* 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. Federal workdays. (Telephone 301-415-1966)

*Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.

You may submit comments on the information collections by the methods indicated in the Paperwork Reduction Act Statement.

**FOR FURTHER INFORMATION CONTACT:** Merri Horn, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone 301-415-8126, e-mail, [Merri.Horn@nrc.gov](mailto:Merri.Horn@nrc.gov).

#### **SUPPLEMENTARY INFORMATION:**

- I. Submitting Comments and Accessing Information
- II. Background
- III. Discussion
  - A. What action is the NRC taking?
  - B. What is the purpose of the proposed rule?
  - C. Whom would this action affect?
  - D. Would all tribes receive advance notifications?
  - E. How and when would tribes be given the option to receive advance notifications?
  - F. Does a tribe's decision to receive advance notification affect whether shipments pass through that tribe's reservation?
  - G. How would licensees determine who the tribal contacts are?
  - H. How would advance notifications be made to tribal officials?
  - I. Would tribes be required to protect the advance notifications?
  - J. Would tribal officials need to be fingerprinted and undergo a background investigation for access to SGI?

K. When do these actions become effective?

L. What should I consider as I prepare my comments to the NRC?

- IV. Discussion of Proposed Rule by Section V. Criminal penalties
- VI. Agreement state compatibility
- VII. Plain Language
- VIII. Voluntary Consensus Standards
- IX. Environmental Impact: Categorical Exclusion
- X. Paperwork Reduction Act Statement
- XI. Regulatory Analysis
- XII. Regulatory Flexibility Certification
- XIII. Backfit Analysis

#### **I. 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](mailto:PDR.Resource@nrc.gov).

*Federal Rulemaking Web site:* Public comments and supporting materials related to this proposed rule can be found at <http://www.regulations.gov> by searching on Docket ID NRC-1999-0005.

## II. Background

Current NRC regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) require licensees to inform State governors, or the governor's designee, of certain shipments of irradiated reactor fuel and certain nuclear waste passing through or across the boundary of their States. Section 73.37 requires licensees to provide advance notifications for shipments of irradiated reactor fuel in excess of 100 grams in net weight of irradiated fuel, exclusive of cladding or other structural or packaging material, which has a total external radiation dose rate in excess of 100 rems per hour at a distance of 3 feet from any accessible surface without intervening shielding. Section 71.97 requires licensees to provide advance notice for shipments of irradiated reactor fuel in quantities less than that subject to § 73.37 and certain licensed material that is required to be transported in Type B packaging and is being transported to a disposal facility or a collection point for transport to a disposal facility. The advance notification provisions apply if the quantity of licensed material in a single package exceeds the least of the following: (1) 3000 times the  $A_1$  value of the radionuclides as specified in Appendix A, Table A-1 of 10 CFR Part 71, for special form radioactive material; (2) 3000 times the  $A_2$  value of the radionuclides as specified in Appendix A, Table A-1 of 10 CFR Part 71, for normal form radioactive material; or (3) 1000 Terabequerel (TBq) (27,000 curies). Schedule and itinerary information provided for shipments of more than 100 grams of irradiated reactor fuel is considered to be SGI under NRC regulations and must be protected under the requirements in §§ 73.21 and 73.22.

The NRC developed these advance notification regulations in 1982 to comply with the NRC Authorization Act for Fiscal Year 1980, which was enacted to deal with concerns expressed by States about their abilities to fulfill their responsibilities to protect public health and safety while waste shipments pass through their jurisdictions. Neither the Atomic Energy Act of 1954, as amended (AEA), nor the notification regulations required licensees to notify Native American Tribes of this type of shipment passing through their Tribal reservations. Tribal officials requested similar notification in the 1990s.

On December 21, 1999, the NRC published an Advance Notice of Proposed Rulemaking (ANPR) to solicit stakeholder input on a possible rulemaking that would consider requiring advance notification to Native American Tribes of transportation of certain types of nuclear waste (64 FR 71331; December 21, 1999). Information was sought on minimizing the burden to licensees, identifying the location of Tribal reservations in relationship to shipment routes, and the sharing and protecting of SGI. A total of 44 comment letters were received. Thirty-six of the letters received were from Tribes and Tribal organizations; four letters were received from private citizens; and letters were received from a licensee, an industry association, a State agency, and a Federal agency. Virtually all the commenters favored providing advance notification to Tribal governments with some disagreement on the details of the implementation. Most commenters were in favor of providing Tribal governments the same advance notification that State governments receive regarding high-level radioactive waste shipments. Commenters encouraged the NRC to provide advance notification through more up-to-date means of communication, *e.g.*, via the Internet. Tribal representatives and others encouraged the NRC to communicate directly with Tribal governments during the rulemaking process as well as when implementing procedures for advance notification. The comments received in response to the ANPR were taken into account during the development of this proposed rule.

On November 6, 2000, President Clinton issued Executive Order (EO) 13175, "Consultation and Coordination with Indian Tribal Governments." EO 13175 emphasized the importance of respecting the sovereignty of Tribal governments and working with them on a government-to-government basis.<sup>1</sup> On November 5, 2009, President Obama expressed his commitment to EO 13175 at the White House Tribal Nations Conference and Interactive Discussion with Tribal Leaders. During the conference, the President signed an Executive Memorandum on Tribal consultation for the heads of Executive Departments and Agencies, directing Cabinet agencies to take steps to develop regular and meaningful consultation with Tribal governments. The Memorandum underscored a

<sup>1</sup> These ideas were previously emphasized in a Presidential Memorandum dated April 29, 1994, entitled "Government-to-Government Relations with Native American Tribal Governments" (59 FR 22951; May 4, 1994) and Executive Orders 12875 and 12866.

commitment to regular and meaningful collaboration and consultation with Tribal officials, and sought complete and consistent implementation of EO 13175. The NRC has adopted agency practices that are consistent with the principles of consultation and cooperation with Indian Tribal governments articulated in President Clinton's April 29, 1994, guidance and EO 13175. The NRC practice is to conduct its activities in a manner that respects the rights of sovereign Tribal governments, and involves consultation and cooperation with Federally recognized Tribes on a government-to-government basis.

## III. Discussion

### A. What action is the NRC taking?

The NRC is proposing to amend its regulations to require licensees to provide to Tribal officials, or their designees, advance notice of shipments of irradiated reactor fuel under § 73.37 and other nuclear wastes listed in § 71.97 before crossing the border of Tribal reservations. For the purposes of these regulatory provisions, Tribal official is defined as the highest ranking individual that represents Tribal leadership, such as the Chief, President, or Tribal Council leadership of an Indian Tribe. This action would only affect commercial shipments being made by NRC and Agreement State licensees. This action would not include shipments made by the Department of Energy or the Department of Defense.

### B. What is the purpose of the proposed rule?

The purpose of the proposed rule is to recognize Tribal sovereignty by informing Tribes of shipments of irradiated reactor fuel and other nuclear wastes passing across their reservations and to recognize Tribal governments' interest in being informed of activities occurring on Tribal reservations.

### C. Whom would this action affect?

The proposed rule would apply to any NRC licensee that ships irradiated reactor fuel. The proposed rule would also affect any licensee that ships other nuclear wastes listed in § 71.97, namely, certain licensed material that is: (a) Required to be transported in Type B packaging; (b) being transported to or across a State boundary enroute to a disposal facility or to a collection point for transport to a disposal facility; and (c) the quantity of licensed material in a single package exceeds the least of the following: (1) 3,000 times the  $A_1$  value of the radionuclides as specified in Appendix A, Table A-1 of 10 CFR Part



71, for special form radioactive material; (2) 3,000 times the  $A_2$  value of the radionuclides as specified in Appendix A, Table A-1 of 10 CFR Part 71, for normal form radioactive material; or (3) 1,000 TBq (27,000 curies).

Finally, the proposed rule would affect any Tribe that chooses to receive the advance notifications of shipments passing within or across its Tribal reservation.

*D. Would all Tribes receive advance notifications?*

No. Given the information protection requirements involved, the NRC believes Tribes should have the option to decide whether to receive advance notifications of shipments that pass across their Tribal reservations. If a Tribe opts to receive the advance notifications, the Tribe would be obligated to protect the schedule and itineraries of the shipments under the SGI requirements in §§ 73.21 and 73.22. If a Tribe opts not to receive the advance notification, the Tribe would have no information protection obligations relating to the shipments. For the purposes of the advance notifications, an Indian Tribe is defined as an Indian or Alaska Native Tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian Tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994. There are currently 565 federally recognized Tribes.

*E. How and when would Tribes be given the option to receive advance notifications?*

After the final rule has been approved by the Commission, the NRC staff would contact each Federally recognized Tribe to provide them information on the rule. As part of the information, the Tribe would be asked if they would like to receive advance notifications of irradiated reactor fuel and other nuclear wastes listed in § 71.97 before crossing the border of the Tribal reservation. The Tribe can then notify NRC whether they would like to receive the advance notifications and certify that the SGI information will be appropriately protected. Tribes would be able to change their decision to receive or not receive the advance notifications by informing the NRC. In addition, the NRC would periodically contact all Federally recognized Tribes to give Tribes an opportunity to change their status in regards to receiving notifications.

*F. Does a Tribe's decision to receive advance notification affect whether shipments pass through that Tribe's reservation?*

No. This rulemaking would only give the Tribe a voluntary opportunity to receive advance notification of shipments that cross their reservation. A Tribe's decision to receive or not receive advance notifications does not affect shipment routes.

*G. How would licensees determine who the Tribal contacts are?*

The NRC would maintain a list of Tribal contacts as is done for State governmental contacts. The NRC would work with the Tribes to complete and maintain the list. The Tribal official would designate who is intended to represent the Tribe. The NRC staff currently intends to annually publish a list of Tribal contacts in the **Federal Register** and post it on the Web site maintained by the NRC's Office of Federal and State Materials and Environmental Management Programs.

*H. How would advance notifications be made to Tribal officials?*

The methods permitted for communication of advance notifications are detailed in § 71.97(c), "Procedures for submitting advance notification." Notifications would be made in writing. The notifications could be sent by mail or courier. SGI may not be transmitted over the phone, by e-mail, or by facsimile unless it is transmitted and received by NRC-approved secure electronic devices.

*I. Would Tribes be required to protect the advance notifications?*

Tribes would be required to protect the schedule and itinerary information contained in the advance notification as SGI as specified by §§ 73.21 and 73.22. Only individuals that have a "need-to-know" the information and have undergone both a Federal Bureau of Investigation (FBI) criminal history records check and a background check for determination of trustworthiness and reliability or have been relieved from these checks under §§ 73.57 or 73.59 may be provided access to the SGI. Basic protection requirements include storing unattended SGI in a locked security storage container. Access to the lock information, such as a combination, must be strictly controlled to prevent disclosure to an individual not authorized access to SGI. Documents containing SGI must be destroyed by burning, shredding, or any other method that precludes reconstruction by means available to the public at large. The specific

requirements for the protection of SGI are located in § 73.22. Failure to comply with these regulatory requirements could result in civil or criminal penalties.

The NRC is specifically inviting comment as to the best method for informing the Tribes of the obligations of possessing SGI. The obligations would include how to handle and protect SGI and who could be provided access to the information, as well as potential civil or criminal penalties that could result in failure to comply with the regulatory requirements. Possible mechanisms include an information packet, a Webinar, or a training course.

*J. Would Tribal officials need to be fingerprinted and undergo a background investigation for access to SGI?*

Section 149 of the AEA requires fingerprinting and submission of fingerprints to the Attorney General for identification and criminal history records check for any individual permitted access to SGI, unless the Commission, by rule, has relieved that individual from the fingerprinting, identification, and criminal history records check requirements. The Commission may relieve individuals from these regulatory requirements "if the Commission finds that such action is consistent with its obligations to promote the common defense and security and protect the health and safety of the public." As allowed by Section 149 of the AEA, NRC enacted § 73.58 to relieve specific categories of individuals from fingerprinting and criminal history record checks prior to receiving SGI. The categories of individuals covered by this regulation include the governor of a State or his or her designated State employee representative; Federal, State, or local law enforcement personnel; and representatives of foreign government organizations that are involved in planning for, or responding to, nuclear or radiological emergencies or security incidents who the Commission approves for access to SGI.

The United States has a unique legal relationship with Indian Tribal governments as set forth in the Constitution of the United States, treaties, statutes, Executive Orders, and court decisions. Indian Tribes exercise inherent sovereign powers over their members and territory. The United States recognizes the right of Indian Tribes to self-government and supports Tribal sovereignty and self-determination. As a result, the NRC has determined that exempting Tribal officials, Tribal official designees, or Tribal law enforcement personnel is



analogous to exempting the State governor, State governor designees, or State law enforcement personnel from the fingerprinting and background check requirements. Furthermore, some Tribes have emergency response responsibilities similar to States. Revising the regulation would permit the Commission and licensees to more efficiently provide SGI relating to advance notification of shipments to Tribes who determine this information would enable them to be more effective in their day-to-day efforts to ensure the protection of nuclear materials and respond to emergencies within their territories. Therefore, the Commission has determined that the proposed rule helps the Commission fulfill its obligations to promote the common defense and security and to protect the health and safety of the public.

The Tribal official, Tribal official designee, and Tribal law enforcement personnel are considered trustworthy and reliable to receive SGI by virtue of their occupational status and have either already undergone a background or criminal history check as a condition of their employment, or are subject to direct oversight by Government authorities in their day-to-day job functions. Under the proposed rule, if the Tribe decides to participate in the advance notification of shipment program, the Tribal official, Tribal official designee, or Tribal law enforcement personnel that needs to know this SGI information to perform their job function, may have access to SGI information regarding advance notification of shipments affecting their territories without undergoing fingerprinting or a criminal history check.

At this time, the NRC is not proposing to provide relief to Tribal officials, Tribal official's designees, or Tribal law enforcement officials for access to all types of SGI because the scope of this rule is limited to advance notifications. Therefore, the relief being proposed in this rulemaking is only for receipt of the SGI contained in advance shipment notifications. The NRC invites comments on whether the proposed relief should be applied generally to access other types of SGI.

The proposed rule would add Tribal official, his or her designee, and Tribal law enforcement personnel for the purpose of advance notifications to the list of categories of individuals that are granted relief from the fingerprinting, identification and criminal history records checks, and other elements of background checks. Those individuals granted access to SGI are required to abide by the requirements in §§ 73.21

and 73.22 for proper management and protection of SGI.

*K. When do these actions become effective?*

The NRC is recommending that the final rule be effective one year after publication in the **Federal Register**. This would provide time for NRC to work with the Tribes and develop the list of Tribal contacts, provide training on protection of SGI to the Tribes, and provide time for licensees to develop procedures and conduct training on the new requirements.

*L. What should I consider as I prepare my comments to the NRC?*

When submitting your comments, remember to:

i. Identify the rulemaking (RIN 3150-AG41; [NRC-1999-0005]).

ii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iii. Describe any assumptions and provide any technical information and/or data that you used.

iv. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

v. Provide specific examples to illustrate your concerns, and suggest alternatives.

vi. Explain your views as clearly as possible.

vii. Make sure to submit your comments by the identified comment period deadline.

viii. The NRC is particularly interested in your comments concerning (a) the best method for informing the Tribes of the obligations of possessing SGI (Section III I.); (b) whether the proposed relief should be applied generally to access other types of SGI (Section III J.); (c) the compatibility designations for the proposed rule (Section V); (d) the use of plain language (Section VI); (e) the environmental assessment (Section VIII); (f) the information collection requirements (Section IX); and (g) the draft regulatory analysis (Section X).

#### **IV. Discussion of Proposed Rule by Section**

##### *Section 71.4 Definitions*

Definition for *Indian Tribe* is proposed based on the term as defined in Executive Order 13175. The definition of *Tribal official* describes the highest ranking individual that represents Tribal leadership, such as the Chief, President, or Tribal Council leadership.

##### *Section 71.97 Advance Notification of Shipment of Irradiated Reactor Fuel and Nuclear Waste*

Current paragraph (a) would be renumbered as paragraph (a)(1) and revised to reflect shipments within or across the State boundary instead of through or across. This change is made for consistency of rule language. Paragraph (a)(2) would be added to require licensees to provide advance notification to Tribal officials or their designee of the shipment of licensed material within or across the boundary of the Tribe's reservation.

Paragraph (c) would be revised to require notifications to be made to the office of each appropriate Tribal official or his/her designee. Paragraph (c) would also be revised to indicate how the list of Tribal officials would be made available.

Paragraph (d) would be revised to include arrival at Tribal reservation boundaries.

Paragraph (e) would be revised to require that revision notices be provided to Tribal officials or their designee if schedule information previously provided will not be met.

Paragraph (f) would be revised to require that cancellation notices be provided to each Tribal official or his/her designee that had previously been notified of an advance shipment.

##### *Section 73.2 Definitions*

Definition for *Indian Tribe* is proposed based on the terms as defined in Executive Order 13175. The definition for *Tribal official* is added to describe the highest ranking individual that represents Tribal leadership, such as the Chief, President, or Tribal Council leadership.

##### *Section 73.21 Protection of Safeguards Information: Performance Requirements*

Paragraph (a)(2) would be revised to include Tribal law enforcement agencies in the list of agencies whose information protection procedures are presumed to meet the general performance requirements for the protection of SGI.

##### *Section 73.37 Requirements for Physical Protection of Irradiated Reactor Fuel in Transit*

Paragraph (f) would be revised to require that advance notification of irradiated fuel shipments be provided to participating Tribes if a shipment crosses Tribal reservation boundaries.

*Section 73.59 Relief From Fingerprinting, Identification and Criminal History Records Checks and Other Elements of Background Checks for Designated Categories of Individuals*

New paragraph (l) would be added to include Tribal official, Tribal official's designee, and Tribal law enforcement personnel that receive the advance notifications to the categories of individuals that are relieved from the requirement for fingerprinting, identification and criminal records checks, and other elements of background checks.

**V. Criminal Penalties**

For the purpose of Section 223 of the AEA, the Commission is proposing to amend 10 CFR parts 71 and 73 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement.

**VI. Agreement State Compatibility**

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997, and published in the **Federal Register** (62 FR 46517; Sept. 3, 1997), this proposed rule would be a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among the Agreement States and the NRC requirements. The NRC staff analyzed the proposed rule in accordance with the procedure established within Part III, "Categorization Process for NRC Program Elements," of Handbook 5.9 to Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs" (a copy of which may be

viewed at <http://www.nrc.gov/reading-rm/doc-collections/management-directives/>).

NRC program elements (including regulations) are placed into four compatibility categories (see the Draft Compatibility Table in this section). In addition, the NRC program elements can also be identified as having particular health and safety significance or as being reserved solely to the NRC. Compatibility Category A are those program elements that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. An Agreement State should adopt Category A program elements in an essentially identical manner to provide uniformity in the regulation of agreement material on a nationwide basis. Compatibility Category B are those program elements that apply to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. Compatibility Category C are those program elements that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. An Agreement State should adopt the essential objectives of the Category C program elements. Compatibility Category D are those program elements that do not meet any of the criteria of Category A, B, or C, above, and, thus, do not need to be adopted by Agreement States for purposes of compatibility.

Health and Safety (H&S) are program elements that are not required for compatibility but are identified as having a particular health and safety role (i.e., adequacy) in the regulation of agreement material within the State. Although not required for compatibility, the State should adopt program elements in the H&S category based on those of the NRC that embody the essential objectives of the NRC program elements because of particular health and safety considerations.

Compatibility Category NRC are those program elements that address areas of regulation that cannot be relinquished to Agreement States under the AEA, or provisions of 10 CFR. These program elements are not adopted by Agreement States. The following table lists the parts and sections that would be revised and their corresponding compatibility categorization under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs."

The NRC invites comment on the compatibility category designations in the proposed rule and suggests that commenters refer to Handbook 5.9 of Management Directive 5.9 for more information (a copy of which may be viewed at <http://www.nrc.gov/reading-rm/doc-collections/management-directives/>). The NRC notes that, like the rule text, the compatibility category designations can change between the proposed rule and final rule, based on comments received and Commission decisions regarding the final rule. The NRC encourages anyone interested in commenting on the compatibility category designations to do so during the comment period.

DRAFT COMPATIBILITY TABLE FOR PROPOSED RULE

Section	Change	Subject	Compatibility	
			Existing	New
<b>Part 71</b>				
71.4 .....	New .....	Definition Indian Tribe .....	— .....	B
71.4 .....	New .....	Definition Tribal official .....	— .....	B
71.97 .....	Amend .....	Advance notification of shipment of irradiated reactor fuel and nuclear waste.	B .....	B
<b>Part 73</b>				
73.2 .....	New .....	Definition Indian Tribe .....	— .....	NRC
73.2 .....	New .....	Definition Tribal official .....	— .....	NRC
73.21 .....	Amend .....	Protection of Safeguards Information: Performance Requirements .....	NRC .....	NRC
73.37 .....	Amend .....	Requirements for physical protection of irradiated reactor fuel in transit ...	NRC .....	NRC
73.59 .....	Amend .....	Relief from fingerprinting, identification and criminal history records checks and other elements of background checks for designated categories of individuals.	NRC .....	NRC

## VII. Plain Language

The Presidential Memorandum "Plain Language in Government Writing" published June 10, 1998 (63 FR 31883), directed that the Government's documents be in clear and accessible language. The NRC requests comments on this proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent as indicated under the **ADDRESSES** heading of this document.

## VIII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this proposed rule, the NRC would require that advance notification be provided to Tribal governments for shipments of irradiated reactor fuel and other nuclear wastes listed in § 71.97 that pass within or across Tribal reservations. The NRC is not aware of any voluntary consensus standards that address the subject matter of this proposed rule. The NRC will consider using a voluntary consensus standard if an appropriate standard is identified. If a voluntary consensus standard is identified for consideration, the submittal should explain why the standard should be used.

## IX. Environmental Impact: Categorical Exclusion

The NRC has determined that this proposed rule is the type of action described in categorical exclusion 10 CFR 51.22(c)(3). Therefore neither an environmental impact statement nor an environmental assessment has been prepared for this proposed rule.

## X. Paperwork Reduction Act Statement

This proposed rule contains new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This rule has been submitted to the Office of Management and Budget (OMB) for review and approval of the information collection requirements.

*Type of submission, new or revision:* Revised.

*The title of the information collection:* 10 CFR Parts 71 and 73, "Advance Notification to Native American Tribes of Transportation of Certain Types of Nuclear Waste."

*The form number if applicable:* NA.

*How often the collection is required:* On occasion; each time a shipment of irradiated reactor fuel or certain other nuclear wastes listed in § 71.97 is made that crosses Tribal reservation borders.

*Who will be required or asked to report:* Licensees that are shipping irradiated reactor fuel or certain other nuclear wastes listed in § 71.97.

*An estimate of the number of annual responses:* 386 (380 responses plus 6 record keepers).

*The estimated number of annual respondents:* 18.

*An estimate of the total number of hours needed annually to complete the requirement or request:* 163 (6.4 recordkeeping hours plus 156.4 third party hours) all of which is associated with Part 73.

*Abstract:* The NRC is proposing to amend its regulations to put in place a new requirement for licensees to provide advance notification to participating Tribes of any shipments of irradiated reactor fuel or certain other nuclear wastes listed in § 71.97 that pass within or across Tribal reservations.

The NRC is seeking public comment on the potential impact of the information collections contained in this proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?
2. Is the estimate of burden accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

A copy of the OMB clearance package may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O-1F21, Rockville, MD 20852. The OMB clearance package and rule are available at the NRC worldwide Web site <http://www.nrc.gov/public-involve/doc-comment/omb/index.html> for 60 days after the signature date of this notice.

Send comments on any aspect of these proposed information collections, including suggestions for reducing the burden and on the above issues, by January 5, 2011 to the Information Services Branch (T-5F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to [INFCOLLECTS.Resource@NRC.gov](mailto:INFCOLLECTS.Resource@NRC.gov) and to the Desk Officer Christine J. Kymn, Office of Information and

Regulatory Affairs, NEOB-10202, (3150-0008, 0002), Office of Management and Budget, Washington, DC 20503. Comments on the proposed information collections may also be submitted via the Federal eRulemaking Portal at <http://www.regulations.gov>, Docket Number NRC-1999-0005. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date. You may also e-mail comments to Christine J. Kymn at [Christine.J.Kymn@omb.eop.gov](mailto:Christine.J.Kymn@omb.eop.gov) or comment by telephone at 202-395-4638.

## Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

## XI. Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission.

The Commission requests public comment on the draft regulatory analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the **ADDRESSES** heading of this document. The analysis is available for inspection in the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O-1F21, Rockville, MD 20852 and can be found at <http://www.regulations.gov> by searching on Docket ID NRC-1999-0005.

## XII. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule would not, if promulgated, have a significant economic impact on a substantial number of small entities. The amendments will apply to reactor licensees and a few licensees who possess large sources of byproduct materials. The majority, if not all, of these licensees are not "small entities" under either the Regulatory Flexibility Act or NRC's size standards (10 CFR 2.810).

## XIII. Backfit Analysis

The NRC has determined that the backfit rule, which is found in the regulations at 10 CFR 50.109, 70.76, 72.62, 76.76, and in 10 CFR Part 52, does not apply to this proposed rule

because this amendment would not involve any provisions that would impose backfits as defined in 10 CFR chapter I. Therefore, a backfit analysis is not required.

#### List of Subjects

##### 10 CFR Part 71

Criminal penalties, Hazardous materials transportation, Import, Nuclear materials, Packaging and containers, Reporting and recordkeeping requirements.

##### 10 CFR Part 73

Criminal penalties, Export, Hazardous materials transportation, Import, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements, Security measures.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553; the NRC is proposing to adopt the following amendments to 10 CFR parts 71 and 73.

#### PART 71—PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

1. The authority citation for part 71 continues to read as follows:

**Authority:** Secs. 53, 57, 62, 63, 81, 161, 182, 183, 68 Stat. 930, 932, 933, 935, 948, 953, 954, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2077, 2092, 2093, 2111, 2201, 2232, 2233, 2297f); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. No. 109–58, 119 Stat. 594 (2005). Section 71.97 also issued under sec. 301, Pub. L. 96–295, 94 Stat. 789–790.

2. In § 71.4, new definitions for *Indian Tribe* and *Tribal official* are added in alphabetical order to read as follows:

##### § 71.4 Definitions.

\* \* \* \* \*

*Indian Tribe* means an Indian or Alaska Native Tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian Tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a.

\* \* \* \* \*

*Tribal official* means the highest ranking individual that represents Tribal leadership, such as the Chief, President, or Tribal Council leadership.

\* \* \* \* \*

3. In § 71.97, paragraphs (a), (c)(1), (c)(3), (d)(4), (e), and (f)(1) are revised to read as follows:

##### § 71.97 Advance notification of shipment of irradiated reactor fuel and nuclear waste.

(a)(1) As specified in paragraphs (b), (c), and (d) of this section, each licensee shall provide advance notification to the governor of a State, or the governor's designee, of the shipment of licensed material, within or across the boundary of the State, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

(2) As specified in paragraphs (b), (c), and (d) of this section, each licensee shall provide advance notification to the Tribal official of participating Tribes referenced in paragraph (c)(3)(iii) of this section, or the official's designee, of the shipment of licensed material, within or across the boundary of the Tribe's reservation, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

\* \* \* \* \*

(c) *Procedures for submitting advance notification.* (1) The notification must be made in writing to:

(i) The office of each appropriate governor or governor's designee;

(ii) The office of each appropriate Tribal official or Tribal official's designee; and

(iii) The Director, Division of Security Policy, Office of Nuclear Security and Incident Response.

\* \* \* \* \*

(3) A notification delivered by any other means than mail must reach the office of the governor or of the governor's designee or the Tribal official or Tribal official's designee at least 4 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur.

(i) A list of the names and mailing addresses of the governors' designees receiving advance notification of transportation of nuclear waste was published in the **Federal Register** on June 30, 1995 (60 FR 34306).

(ii) The list of governor's designees and Tribal official's designees of participating Tribes will be published annually in the **Federal Register** on or about June 30th to reflect any changes in information.

(iii) A list of the names and mailing addresses of the governors' designees and Tribal officials' designees of participating Tribes is available on request from the Director, Division of Intergovernmental Liaison and Rulemaking, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear

Regulatory Commission, Washington, DC 20555–0001.

\* \* \* \* \*

(d) \* \* \*

(4) The 7-day period during which arrival of the shipment at State boundaries or Tribal reservation boundaries is estimated to occur;

\* \* \* \* \*

(e) *Revision notice.* A licensee who finds that schedule information previously furnished to a governor or governor's designee or a Tribal official or Tribal official's designee, in accordance with this section, will not be met, shall telephone a responsible individual in the office of the governor of the State or of the governor's designee or the Tribal official or the Tribal official's designee and inform that individual of the extent of the delay beyond the schedule originally reported. The licensee shall maintain a record of the name of the individual contacted for 3 years.

(f) *Cancellation notice.* (1) Each licensee who cancels an irradiated reactor fuel or nuclear waste shipment for which advance notification has been sent shall send a cancellation notice to the governor of each State or to the governor's designee previously notified, each Tribal official or to the Tribal official's designee previously notified, and to the Director, Division of Security Policy, Office of Nuclear Security and Incident Response.

\* \* \* \* \*

#### PART 73—PHYSICAL PROTECTION OF PLANTS AND MATERIALS

4. The authority citation for part 73 continues to read as follows:

**Authority:** Secs. 53, 161, 149, 68 Stat. 930, 948, as amended, sec. 147, 94 Stat. 780 (42 U.S.C. 2073, 2167, 2169, 2201); sec. 201, as amended, 204, 88 Stat. 1242, as amended, 1245, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 5841, 5844, 2297f); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. 109–58, 119 Stat. 594 (2005).

Section 73.1 also issued under secs. 135, 141, Pub. L. 97–425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 73.37(f) also issued under sec. 301, Pub. L. 96–295, 94 Stat. 789 (42 U.S.C. 5841 note). Section 73.57 is issued under sec. 606, Pub. L. 99–399, 100 Stat. 876 (42 U.S.C. 2169).

5. In § 73.2, new definitions for *Indian Tribe* and *Tribal official* are added in alphabetical order to read as follows:

##### § 73.2 Definitions.

\* \* \* \* \*

*Indian Tribe* means an Indian or Alaska Native Tribe, band, nation, pueblo, village, or community that the

Secretary of the Interior acknowledges to exist as an Indian Tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a.

\* \* \* \* \*

*Tribal official* means the highest ranking individual that represents Tribal leadership, such as the Chief, President, or Tribal Council leadership.

\* \* \* \* \*

6. In § 73.21, paragraph (a)(2) is revised to read as follows:

**§ 73.21 Protection of Safeguards Information: Performance Requirements.**

(a) \* \* \*

(2) Information protection procedures employed by Federal, State, Tribal, and local law enforcement agencies are presumed to meet the general performance requirement in paragraph (a)(1) of this section.

\* \* \* \* \*

7. In § 73.37, paragraphs (f) and (g) are revised to read as follows:

**§ 73.37 Requirements for physical protection of irradiated reactor fuel in transit.**

\* \* \* \* \*

(f) Prior to the transport of spent fuel within or across a State or Tribal reservation, a licensee subject to this section shall notify the governor or the governor's designee and the Tribal official of each participating Tribe referenced in § 71.97(c)(3) of this chapter or the Tribal official's designee. The licensee shall comply with the following criteria in regard to a notification:

(1) The notification must be in writing and sent to the office of each appropriate governor or the governor's designee and each appropriate Tribal official or the Tribal official's designee. A notification delivered by mail must be postmarked at least 7 days before transport of a shipment within or across the State or Tribal reservation. A notification delivered by messenger must reach the office of the governor or the governor's designee and any Tribal official or Tribal official's designee at least 4 days before transport of a shipment within or across the State or Tribal reservation. A list of the mailing addresses of governors and governors' designees and Tribal officials and Tribal officials' designees is available upon request from the Director, Division of Intergovernmental Liaison and Rulemaking, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

(2) The notification must include the following information:

(i) The name, address, and telephone number of the shipper, carrier and receiver.

(ii) A description of the shipment as specified by the Department of Transportation in 49 CFR 172.202 and 172.203(d).

(iii) A listing of the routes to be used within the State or Tribal reservation.

(iv) A statement that the information described in paragraph (f)(3) of this section is required by NRC regulations to be protected in accordance with the requirements of §§ 73.21 and 73.22.

(3) The licensee shall provide the following information on a separate enclosure to the written notification:

(i) The estimated date and time of departure from the point of origin of the shipment.

(ii) The estimated date and time of entry into the governor's State or Tribal reservation.

(iii) For the case of a single shipment whose schedule is not related to the schedule of any subsequent shipment, a statement that schedule information must be protected in accordance with the provisions of §§ 73.21 and 73.22 until at least 10 days after the shipment has entered or originated within the State or Tribal reservation.

(iv) For the case of a shipment in a series of shipments whose schedules are related, a statement that schedule information must be protected in accordance with the provisions of §§ 73.21 and 73.22 until 10 days after the last shipment in the series has entered or originated within the State or Tribal reservation and an estimate of the date on which the last shipment in the series will enter or originate within the State or Tribal reservation.

(4) A licensee shall notify by telephone or other means a responsible individual in the office of the governor or in the office of the governor's designee and the office of the Tribal official or in the office of the Tribal official's designee of any schedule change that differs by more than 6 hours from the schedule information previously furnished in accordance with paragraph (f)(3) of this section, and shall inform that individual of the number of hours of advance or delay relative to the written schedule information previously furnished.

(g) State officials, State employees, Tribal officials, Tribal employees, and other individuals, whether or not licensees of the Commission, who receive schedule information of the kind specified in paragraph (f)(3) of this section shall protect that information against unauthorized disclosure as specified in §§ 73.21 and 73.22.

8. In § 73.59, new paragraph (l) is added to read as follows:

**§ 73.59 Relief from fingerprinting, identification and criminal history records checks and other elements of background checks for designated categories of individuals.**

\* \* \* \* \*

(l) Tribal official or the Tribal official's designated representative, and Tribal law enforcement personnel to whom access has been granted for the purpose of advance notification of shipments under provisions of § 73.37(f).

Dated at Rockville, Maryland this 1st day of December 2010.

For the Nuclear Regulatory Commission,  
**Annette Vietti-Cook,**

*Secretary of the Commission.*

[FR Doc. 2010-30478 Filed 12-3-10; 8:45 am]

BILLING CODE 7590-01-P

**NATIONAL CREDIT UNION ADMINISTRATION**

**12 CFR Parts 701, 704, and 741**

RIN 3133-AD74

**Corporate Credit Unions**

**AGENCY:** National Credit Union Administration (NCUA).

**ACTION:** Notice of extension of comment period.

**SUMMARY:** On November 18, 2010, the NCUA Board issued a proposed rule amending its corporate credit union rule. 75 FR 73000 (November 29, 2010). NCUA has received a request to extend the comment period set in the proposed rule and has determined to extend the comment period for an additional 30 days.

**DATES:** Comments must now be received by January 28, 2011.

**ADDRESSES:** You may submit comments by any of the following methods (Please send comments by one method only): Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. NCUA Web site: <http://www.ncua.gov/Resources/RegulationsOpinionsLaws/ProposedRegulations.aspx>. Follow the instructions for submitting comments.

*E-mail:* Address to [regcomments@ncua.gov](mailto:regcomments@ncua.gov). Include "[Your name] Comments on "Notice of Proposed Rulemaking for Part 704—Corporate Credit Unions" in the e-mail subject line.

*Fax:* (703) 518-6319. Use the subject line described above for e-mail.

*Mail:* Address to Mary Rupp, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428. Hand Delivery/Courier: Same as mail address.

*Public Inspection:* All public comments are available on the agency's Web site at <http://www.ncua.gov/Resources/RegulationsOpinionsLaws/ProposedRegulations.aspx> as submitted, except as may not be possible for technical reasons. Public comments will not be edited to remove any identifying or contact information. Paper copies of comments may be inspected in NCUA's law library at 1775 Duke Street, Alexandria, Virginia 22314, by appointment weekdays between 9 a.m. and 3 p.m. To make an appointment, call (703) 518–6546 or send an e-mail to [OGCMail@ncua.gov](mailto:OGCMail@ncua.gov).

**FOR FURTHER INFORMATION CONTACT:** Jacqueline Lussier, Staff Attorney, Office of General Counsel; Elizabeth Wirick, Staff Attorney, Office of General Counsel; and Lisa Henderson, Staff Attorney, Office of General Counsel, at the address above or telephone (703) 518–6540; or David Shetler, Deputy Director, Office of Corporate Credit Unions, at the address above or telephone (703) 518–6640.

**SUPPLEMENTARY INFORMATION:** On November 18, 2010, the NCUA Board issued proposed amendments to its rule governing corporate credit unions (corporates) contained in part 704. The amendments include internal control and reporting requirements for corporates similar to those required for banks under the Federal Deposit Insurance Act and the Sarbanes-Oxley Act. The amendments require each corporate to establish an enterprise-wide risk management committee staffed with at least one risk management expert. The amendments provide for the equitable sharing of Temporary Corporate Credit Union Stabilization Fund expenses among all members of corporates, including both credit union and noncredit union members. The amendments increase the transparency of decision-making by requiring corporates conduct all board of director votes as recorded votes and include the votes of individual directors in the meeting minutes. The amendments permit corporates to charge their members reasonable one-time or periodic membership fees as necessary to facilitate retained earnings growth. For senior corporate executives who are dual employees of corporate credit union service organizations (CUSOs), the amendments require disclosure of certain compensation

received from the corporate CUSO. In addition, this proposal would amend parts 701 and 741 to limit natural person credit unions to membership in one corporate credit union at any particular time and provide that a natural person credit union may not make any investment in a corporate credit union of which the natural person credit union is not also a member. 75 FR 73000 (November 29, 2010).

NCUA requested comments on its proposal and set a 30-day comment period, originally scheduled to end on December 29, 2010. NCUA has received a request to extend the comment period. The NCUA Board believes a 30-day extension will facilitate the submission of comments without causing undue delay to the rulemaking process. Accordingly, the comment period is extended and comments must now be received by January 28, 2011.

By the National Credit Union Administration Board on November 29, 2010.

**Mary F. Rupp,**

*Secretary of the Board.*

[FR Doc. 2010–30426 Filed 12–3–10; 8:45 am]

**BILLING CODE 7535–01–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 65

[Docket No.: FAA–2010–1060]

#### Policy Clarifying Definition of “Actively Engaged” for Purposes of Inspector Authorization

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed policy; extension of comment period.

**SUMMARY:** This action extends the comment period for a Notice of Proposed Policy that was published on November 5, 2010. The proposed policy would clarify the term “actively engaged” for the purposes of application for and renewal of an inspection authorization. The proposed policy would amend the Flight Standards Management System Order 8900.1.

**DATES:** The comment period for the Notice of Proposed Policy published on November 5, 2010 (75 FR 68249) was scheduled to close on December 6, 2010, and is extended to January 17, 2011.

**ADDRESSES:** You may send comments identified by docket number FAA–2010–1060 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow

the online instructions for sending your comments electronically.

- *Mail:* Send Comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

- *Hand Delivery:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- *Fax:* (202) 493–2251.

**FOR FURTHER INFORMATION CONTACT:** Ed Hall, Aircraft Maintenance General Aviation Branch, AFS–350, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (804) 222–7494 ext. 240; e-mail: [ed.hall@faa.gov](mailto:ed.hall@faa.gov).

#### SUPPLEMENTARY INFORMATION:

##### Comments Invited

The FAA invites interested persons to submit written comments, data, or views concerning this proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, please send only one copy of written comments, or if you are filing comments electronically, please submit your comments only one time.

The FAA will file in the docket all comments received, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposal. Before acting on this proposal, the FAA will consider all comments received on or before the closing date for comments and any late-filed comments if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of comments received.

##### Availability of This Proposed Policy

You can get an electronic copy using the Internet by—

- (1) Searching the Federal eRulemaking Portal (<http://www.regulations.gov>);
- (2) Visiting the FAA's Regulations and Policies Web page at [http://www.faa.gov/regulations\\_policies/](http://www.faa.gov/regulations_policies/); or
- (3) Accessing the Government Printing Office's Web page at <http://www.gpoaccess.gov/fr/index.html>.

You can also get a copy by sending a request to the Federal Aviation Administration, Office of Rulemaking,

ARM-1, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267-9680. Make sure to identify the docket number or notice number of this proposal.

### Background

On November 5, 2010 the FAA published a Notice of Proposed Policy, entitled Policy Clarifying Definition of "Actively Engaged" for the Purpose of Inspector Authorization. (75 FR 68249, Docket No. FAA-2010-1060.)

Comments to that document were to be received on or before December 6, 2010.

By letter dated November 16, 2010, the Experimental Aircraft Association (EAA) requested an extension of the comment period to January 17, 2011. By letter dated November 22, 2010, the Aircraft Owners and Pilots Association (AOPA) requested a 60-day extension of the comment period. Both petitioners stated the additional time is necessary to fully investigate the proposal's potential negative impact on the industry and because of the impact of upcoming holidays on their opportunity to provide meaningful comments.

### Extension of Comment Period

In accordance with § 11.47(c) of Title 14, Code of Federal Regulations, the FAA has reviewed the petitions for extension by EAA and AOPA. The FAA agrees with the petitioners that an opportunity for meaningful comment is in the public interest. However, the FAA does not support extending the comment period by 60 days. This proposed policy does not constitute a significant change from current FAA policy regarding inspector authorization but is merely a clarification of that policy as stated in the Notice of Proposed Policy.

The FAA supports an extension to January 17, 2011 to allow additional time to investigate and develop meaningful comments in light of the holiday schedule. The FAA has determined that an extension of the comment period is consistent with the public interest, and that good cause exists for taking this action.

Accordingly, the comment period for this Notice of Proposed Policy is extended until January 17, 2011. Absent unusual circumstances, the FAA does not anticipate any further extension of the comment period.

Issued in Washington, DC, on December 2, 2010.

### Carol Giles,

Manager, Aircraft Maintenance Division of Flight Standards Service.

[FR Doc. 2010-30604 Filed 12-3-10; 8:45 am]

BILLING CODE 4910-13-P

## SECURITIES AND EXCHANGE COMMISSION

### 17 CFR Part 275

[Release No. IA-3118; File No. S7-23-07]

RIN 3235-AJ96

### Temporary Rule Regarding Principal Trades With Certain Advisory Clients

**AGENCY:** Securities and Exchange Commission.

**ACTION:** Proposed rule.

**SUMMARY:** The Securities and Exchange Commission is proposing to amend rule 206(3)-3T under the Investment Advisers Act of 1940, a temporary rule that establishes an alternative means for investment advisers who are registered with the Commission as broker-dealers to meet the requirements of section 206(3) of the Investment Advisers Act when they act in a principal capacity in transactions with certain of their advisory clients. The amendment would extend the date on which rule 206(3)-3T will sunset from December 31, 2010 to December 31, 2012.

**DATES:** Comments must be received on or before December 20, 2010.

**ADDRESSES:** Comments may be submitted by any of the following methods:

#### Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/proposed.shtml>); or
- Send an e-mail to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number S7-23-07 on the subject line; or
- Use the Federal eRulemaking Portal (<http://www.regulations.gov>). Follow the instructions for submitting comments.

#### 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 S7-23-07. This file number should be included on the subject line if e-mail is used. To help us 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/proposed.shtml>). Comments are also available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549 on official business days between the hours of 10

a.m. and 3 p.m. All comments received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

#### FOR FURTHER INFORMATION CONTACT:

Brian M. Johnson, Attorney-Adviser, Devin F. Sullivan, Senior Counsel, Matthew N. Goldin, Branch Chief, or Sarah A. Bessin, Assistant Director, at (202) 551-6787 or [IArules@sec.gov](mailto:IArules@sec.gov), Office of Investment Adviser Regulation, Division of Investment Management, U.S. Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549-5041.

**SUPPLEMENTARY INFORMATION:** The Securities and Exchange Commission is proposing an amendment to temporary rule 206(3)-3T [17 CFR 275.206(3)-3T] under the Investment Advisers Act of 1940 [15 U.S.C. 80b] that would extend the date on which the rule will sunset from December 31, 2010 to December 31, 2012.

### I. Background

On September 24, 2007, we adopted, on an interim final basis, rule 206(3)-3T, a temporary rule under the Investment Advisers Act of 1940 (the "Advisers Act") that provides an alternative means for investment advisers who are registered with us as broker-dealers to meet the requirements of section 206(3) of the Advisers Act when they act in a principal capacity in transactions with certain of their advisory clients.<sup>1</sup> The purpose of the rule was to permit broker-dealers to sell to their advisory clients, in the wake of *Financial Planning Association v. SEC* (the "FPA Decision"),<sup>2</sup> certain securities held in the proprietary accounts of their firms that might not be available on an agency basis—or might be available on an agency basis only on less attractive terms<sup>3</sup>—while protecting clients from

<sup>1</sup> Rule 206(3)-3T [17 CFR 275.206(3)-3T]. All references to rule 206(3)-3T and the various sections thereof in this release are to 17 CFR 275.206(3)-3T and its corresponding sections. See also *Temporary Rule Regarding Principal Trades with Certain Advisory Clients*, Investment Advisers Act Release No. 2653 (Sep. 24, 2007) [72 FR 55022 (Sep. 28, 2007)] ("2007 Principal Trade Rule Release").

<sup>2</sup> 482 F.3d 481 (DC Cir. 2007). In the FPA Decision, handed down on March 30, 2007, the Court of Appeals for the DC Circuit vacated (subject to a subsequent stay until October 1, 2007) rule 202(a)(11)-1 under the Advisers Act. Rule 202(a)(11)-1 provided, among other things, that fee-based brokerage accounts were not advisory accounts and were thus not subject to the Advisers Act. For further discussion of fee-based brokerage accounts, see 2007 Principal Trade Rule Release, Section I.

<sup>3</sup> See 2007 Principal Trade Rule Release at nn.19-20 and Section VI.C.



conflicts of interest as a result of such transactions.<sup>4</sup>

As initially adopted on an interim final basis, rule 206(3)–3T was set to expire on December 31, 2009. In December 2009, however, we adopted rule 206(3)–3T as a final rule in the same form in which it was adopted on an interim final basis in 2007, except that we extended the rule's sunset period by one year to December 31, 2010.<sup>5</sup> We deferred final action on rule 206(3)–3T in December 2009 because we needed additional time to understand how, and in what situations, the rule was being used.<sup>6</sup>

On July 21, 2010, President Obama signed into law the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act").<sup>7</sup> Under section 913 of the Dodd-Frank Act, we are required to conduct a study, and provide a report to Congress, concerning the obligations of broker-dealers and investment advisers, including the standards of care applicable to those intermediaries and their associated persons.<sup>8</sup> We intend to deliver the report concerning this study, as required by the Dodd-Frank Act, no later than January 21, 2011.<sup>9</sup>

Our staff has observed the use of the rule by entities that are investment advisers also registered with us as broker-dealers.<sup>10</sup> Of the firms contacted

by our staff, some firms indicated that they were relying on the rule. As discussed more fully below, our staff observed several compliance issues. The staff is pursuing those matters where appropriate, including referrals to the Division of Enforcement.

## II. Discussion

We are proposing to amend rule 206(3)–3T only to extend the rule's expiration date by two additional years. If the rule is amended, absent further action by the Commission, the rule will expire on December 31, 2012.

As noted above, under section 913 of the Dodd-Frank Act, we are required to conduct a study and provide a report to Congress concerning the obligations of broker-dealers and investment advisers, including the standard of care applicable to those intermediaries.<sup>11</sup> We are required to deliver the report concerning this study no later than six months after the enactment of the Dodd-Frank Act, in January 2011.<sup>12</sup>

Section 913 of the Dodd-Frank Act also authorizes us to promulgate rules concerning, among other things, the legal or regulatory standards of care for broker-dealers, investment advisers, and persons associated with these intermediaries for providing personalized investment advice about securities to retail customers. In enacting any rules pursuant to this authority, we are required to consider the findings, conclusions, and recommendations of the mandated study. The study and our consideration of the need for further rulemaking pursuant to this authority are part of our broader consideration of the regulatory requirements applicable to broker-dealers and investment advisers in connection with the Dodd-Frank Act.<sup>13</sup>

As part of this study and any rulemaking that may follow, we expect to consider the issues raised by principal trading, including the restrictions in section 206(3) of the Advisers Act and our experiences with, and observations regarding, the operation of rule 206(3)–3T. We will not, however, complete our

consideration of these issues before December 31, 2010, rule 206(3)–3T's current expiration date.

We believe that firms' compliance with the substantive provisions of rule 206(3)–3T as currently in effect provides sufficient protections to advisory clients to warrant the rule's continued operation for an additional limited period of time while we conduct the study mandated by the Dodd-Frank Act and consider more broadly the regulatory requirements applicable to broker-dealers and investment advisers.<sup>14</sup>

If we permit rule 206(3)–3T to expire on December 31, 2010, after that date investment advisers also registered as broker-dealers who currently rely on rule 206(3)–3T would be required to comply with section 206(3)'s transaction-by-transaction written disclosure and consent requirements without the benefit of the alternative means of complying with these requirements currently provided by rule 206(3)–3T. This could limit the access of non-discretionary advisory clients of advisory firms that are also registered as broker-dealers to certain securities.<sup>15</sup> In addition, certain of these firms have informed us that, if rule 206(3)–3T were to expire on December 31, 2010, they would be required to make substantial changes to their disclosure documents, client agreements, procedures, and systems.

As noted above, our staff has observed the use of the rule by entities that are investment advisers and are also registered as broker-dealers.<sup>16</sup> Of the firms contacted by our staff, some indicated that they were relying on the rule. Significantly, among those advisers, our staff did not identify instances of "dumping," a particular concern underlying section 206(3) of the Advisers Act.<sup>17</sup> However, our staff did

<sup>4</sup> As a consequence of the FPA Decision, broker-dealers offering fee-based brokerage accounts with an advisory component became subject to the Advisers Act with respect to those accounts, and the client relationship became fully subject to the Advisers Act. These broker-dealers — to the extent they wanted to continue to offer fee-based accounts and met the requirements for registration — had to: Register as investment advisers, if they had not done so already; act as fiduciaries with respect to those clients; disclose all material conflicts of interest; and otherwise fully comply with the Advisers Act, including the restrictions on principal trading contained in section 206(3) of the Act. See 2007 Principal Trade Rule Release, Section I.

<sup>5</sup> See *Temporary Rule Regarding Principal Trades with Certain Advisory Clients*, Investment Advisers Act Release No. 2965 (Dec. 23, 2009) [74 FR 69009 (Dec. 30, 2009)] ("Extension Release") and *Temporary Rule Regarding Principal Trades with Certain Advisory Clients*, Investment Advisers Act Release No. 2965A (Dec. 31, 2009) [75 FR 742 (Jan. 6, 2010)] (making a technical correction to the Extension Release).

<sup>6</sup> See Extension Release, Section II.C.

<sup>7</sup> Public Law 111–203, 124 Stat. 1376 (2010).

<sup>8</sup> See generally section 913 of the Dodd-Frank Act and *Study Regarding Obligations of Brokers, Dealers, and Investment Advisers*, Investment Advisers Act Release No. 3058 (July 27, 2010) [75 FR 44996 (July 30, 2010)].

<sup>9</sup> See section 913(d)(1) of the Dodd-Frank Act (requiring us to submit the study to Congress no later than six months after the date of enactment of the Dodd-Frank Act).

<sup>10</sup> Rule 206(3)–3T is available only to an investment adviser that is a broker-dealer registered under section 15 of the Securities Exchange Act of 1934 [15 U.S.C. 78o]. Rule 206(3)–3T(a)(7).

<sup>11</sup> See *supra* note 8 and accompanying text.

<sup>12</sup> See *supra* note 9 and accompanying text.

<sup>13</sup> The study mandated by section 913 of the Dodd-Frank Act is one of several studies and other actions relevant to the regulation of broker-dealers and investment advisers mandated by that Act. See, e.g., section 914 of the Dodd-Frank Act (requiring the Commission to review and analyze the need for enhanced examination and enforcement resources for investment advisers); section 919 of the Dodd-Frank Act (authorizing the Commission to issue rules designating documents or information that shall be provided by a broker or dealer to a retail investor before the purchase of an investment product or service by the retail investor).

<sup>14</sup> For a discussion of some of the benefits underlying rule 206(3)–3T, see 2007 Principal Trade Rule Release, Section VI.C.

<sup>15</sup> See *id.*

<sup>16</sup> The Office of Compliance Inspections and Examinations conducted examinations regarding compliance with rule 206(3)–3T. The staff's observations discussed in this release are from these examinations.

<sup>17</sup> Congress intended section 206(3) to address concerns that an adviser might engage in principal transactions to benefit itself or its affiliates, rather than the client. In particular, Congress was concerned that advisers might use advisory accounts to "dump" unmarketable securities or those the advisers fear may decline in value. See *Investment Trusts and Investment Companies: Hearings on S. 3580 Before the Subcomm. of the Comm. on Banking and Currency, 76th Cong., 3d Sess. 320, 322 (1940)* ("[i]f a fellow feels he has a sour issue and finds a client to whom he can sell it, then that is not right. \* \* \*") (statement of



observe certain compliance issues, including but not limited to instances in which firms:

- Did not comply with section 206(3) or rule 206(3)-3T for certain transactions that were executed on a principal basis;<sup>18</sup>
- Demonstrated weaknesses relating to compliance monitoring of electronic systems to identify principal trades and to validate compliance with rule 206(3)-3T's disclosure and consent provisions;<sup>19</sup>
- Failed to test periodically the adequacy of their compliance programs;
- Had inadequate policies and procedures concerning rule 206(3)-3T;<sup>20</sup>
- Did not provide disclosures or provided disclosures that appeared to be potentially confusing, misleading, or incomplete;<sup>21</sup>
- Failed to obtain transaction-by-transaction consent;
- Provided written confirmations that appeared to be potentially confusing or incomplete;<sup>22</sup> and
- Maintained books and records in a manner that did not enable the staff meaningfully to assess compliance with rule 206(3)-3T.<sup>23</sup>

David Schenker, Chief Counsel, Securities and Exchange Commission Investment Trust Study).

<sup>18</sup> For example, the staff observed instances in which transactions in underwritten securities were not identified as being executed in a principal capacity, even when these securities passed through a firm's inventory. In addition, the staff observed instances in which firms executed principal transactions in reliance on rule 206(3)-3T in securities that were ineligible for trading pursuant to the rule.

<sup>19</sup> For example, in some instances, automated compliance systems erroneously permitted advisory client transactions to be executed on a principal basis for clients that had not authorized such transactions.

<sup>20</sup> See 2007 Principal Trade Rule Release, Section II.B.8 (" \* \* \* an adviser relying on rule 206(3)-3T as an alternative means of complying with section 206(3) must have adopted and implemented written policies and procedures reasonably designed to comply with the requirements of the rule."); Rule 206(4)-7(a) [17 CFR 275.206(4)-7(a)] (requiring an investment adviser registered with us to adopt and implement written policies and procedures reasonably designed to prevent violations of the Advisers Act (and the rules thereunder) by the adviser or any of its supervised persons).

<sup>21</sup> Such observations were made with respect to prospective written disclosures, transaction-by-transaction disclosures, and client annual reports. For example, the staff observed instances in which firms placed limitations on clients' ability to revoke their permission to execute transactions on a principal basis. The staff also observed instances in which annual summary reports were not sent to clients or were incomplete.

<sup>22</sup> For example, the staff observed instances in which confirmations did not clearly state that the client's consent was given prior to execution.

<sup>23</sup> For example, in some instances, the staff was unable to verify whether oral transaction-by-transaction disclosures were, in fact, provided. The staff also observed instances in which it was unable

We find it important that the staff found no instances of "dumping" by advisers the staff observed were relying on rule 206(3)-3T.<sup>24</sup> However, we remain concerned about the compliance issues observed by the staff. As noted above, the staff is pursuing those matters where appropriate, including referrals to the Division of Enforcement. If the rule is extended, the staff will monitor compliance and continue to take appropriate action to help ensure that firms are complying with the rule's conditions, including referring firms to the Division of Enforcement if warranted. We further encourage all firms that rely on rule 206(3)-3T to evaluate whether they have any of the compliance issues discussed in this Release, and if so, to take steps to address them.

In light of these and other considerations discussed in this Release, we believe that it would be premature to require these firms to restructure their operations and client relationships before we complete our study and our broader consideration of the regulatory requirements applicable to broker-dealers and investment advisers. To the extent our consideration of these issues leads to new rules concerning principal trading, these firms would again be required to restructure their operations and client relationships, potentially at substantial expense.

As part of our broader consideration of the regulatory requirements applicable to broker-dealers and investment advisers, we intend to carefully consider principal trading by advisers, including whether rule 206(3)-3T should be substantively modified, supplanted, or permitted to expire. In making these determinations, we expect to consider, among other things, the results of the study required by section 913 of the Dodd-Frank Act, relevant comments received in connection with the study and any potential rulemaking that may follow, the results of our staff's evaluation of the operation of rule 206(3)-3T, any relevant comments we receive in connection with this proposal, and comments we received in response to the 2007 Principal Trade Rule Release.

We expect to revisit the relief provided in rule 206(3)-3T following the completion of our study. Although we anticipate that will occur prior to the proposed amended expiration date for the temporary rule, we want to ensure that we have sufficient time to complete

any potential rulemaking process prior to the rule's expiration.

### III. Request for Comment

We request comment on our proposal to extend rule 206(3)-3T for two additional years.

- Is it appropriate to extend rule 206(3)-3T for a limited period of time in its current form while we complete our study and our broader consideration of the regulatory requirements applicable to broker-dealers and investment advisers? Or should we allow the rule to expire?
- Given the compliance issues observed, is extending the rule appropriate?
- Is two years an appropriate period of time to extend the rule? Or should we extend the rule for a different period of time? If so, for how long?

### IV. Paperwork Reduction Act

Rule 206(3)-3T contains "collection of information" requirements within the meaning of the Paperwork Reduction Act of 1995.<sup>25</sup> The Office of Management and Budget ("OMB") approved the burden estimates presented in the 2007 Principal Trade Rule Release,<sup>26</sup> first on an emergency basis and subsequently on a regular basis. OMB approved the collection of information with an expiration date of March 31, 2011. 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 title for the collection of information is: "Temporary rule for principal trades with certain advisory clients, rule 206(3)-3T" and the OMB control number for the collection of information is 3235-0630. As noted in the Extension Release, the 2007 Principal Trade Rule Release solicited comments on our PRA estimates, but we did not receive comment on them.<sup>27</sup>

The amendment to the rule we are proposing today—to extend rule 206(3)-3T for two years—does not affect the burden estimates contained in the 2007 Principal Trade Rule Release. Therefore, as was the case when we extended rule 206(3)-3T in December 2009, we are not revising our Paperwork Reduction Act burden and cost estimates submitted to OMB.

We request comment on whether the estimates and underlying assumptions that are more fully described in the 2007 Principal Trade Rule Release continue

<sup>25</sup> 44 U.S.C. 3501 *et seq.*

<sup>26</sup> See 2007 Principal Trade Rule Release, Section V.B&C.

<sup>27</sup> See Extension Release, Section IV.

to establish whether certain transactions were, in fact, subject to section 206(3).

<sup>24</sup> See *supra* note 17.

to be reasonable.<sup>28</sup> Have circumstances changed since that time such that these estimates should be modified or revised? Persons submitting comments should direct the comments to the Office of Management and Budget, Attention: Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Washington, DC 20503, and should send a copy to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549-1090, with reference to File No. S7-23-07.

#### V. Cost-Benefit Analysis

Other than proposing to extend rule 206(3)-3T's sunset period for two years, we are not otherwise proposing to modify the rule from the form in which we initially adopted it on an interim final basis in September 2007 or as final in December 2009. We discussed the benefits provided by rule 206(3)-3T in both the 2007 Principal Trade Rule Release and the Extension Release.

In summary, as explained in the 2007 Principal Trade Rule Release and the Extension Release,<sup>29</sup> we believe the principal benefit of rule 206(3)-3T is that it maintains investor choice and protects the interests of investors who formerly held an estimated \$300 billion in fee-based brokerage accounts. A resulting second benefit of the rule is that non-discretionary advisory clients of advisory firms that are also registered as broker-dealers have easier access to a wider range of securities which, in turn, should continue to lead to increased liquidity in the markets for these securities and promote capital formation in these areas. A third benefit of the rule is that it provides the protections of the sales practice rules of the Securities Exchange Act of 1934 ("Exchange Act")<sup>30</sup> and the relevant self-regulatory organizations because an adviser relying on the rule must also be a registered broker-dealer. Another benefit of rule 206(3)-3T is that it provides a lower cost alternative for an adviser to engage in principal transactions. We did not receive comments directly addressing with supporting data the cost-benefit analysis we presented in the 2007 Principal Trade Rule Release and we continue to believe those benefits apply today.

In addition to the general benefits described in those releases, there also are benefits to extending the rule for an

additional two years. If we do not extend the rule in its current form, firms currently relying on the rule would be required to restructure their operations and client relationships on or before the rule's current expiration date—potentially only to have to do so again shortly thereafter (first when the rule expires or is modified, and again if we adopt a new approach after the study mandated by the Dodd-Frank Act, discussed above, is complete). By extending the rule for two years, non-discretionary advisory clients who have had access to certain securities because of their advisers' reliance on the rule to trade on a principal basis would continue to have access to those securities without disruption. Firms relying on the rule would continue to be able to offer clients and prospective clients access to certain securities on a principal basis as well and would not need during this two-year period to incur the cost of adjusting to a new set of rules or abandoning the systems established to comply with the current rule. In other words, extension would avoid disruption to clients and firms during the period while we complete the study mandated by section 913 of the Dodd-Frank Act and our broader consideration of the regulatory requirements applicable to broker-dealers and investment advisers.

We also described the costs associated with rule 206(3)-3T, including the operational costs associated with complying with the rule, in the 2007 Principal Trade Rule Release and the Extension Release. We presented estimates of the costs of each of the rule's disclosure elements, including: Prospective disclosure and consent; transaction-by-transaction disclosure and consent; transaction-by-transaction confirmations; and the annual report of principal transactions. We also provided estimates for the following related costs of compliance with rule 206(3)-3T: (i) The initial distribution of prospective disclosure and collection of consents; (ii) systems programming costs to ensure that trade confirmations contain all of the information required by the rule; and (iii) systems programming costs to aggregate already-collected information to generate compliant principal transactions reports. We did not receive comments directly addressing with supporting data the cost-benefit analysis we presented in the 2007 Principal Trade Rule Release and we believe the amendments we are proposing today would not materially affect those costs.<sup>31</sup>

<sup>31</sup> In the 2007 Principal Trade Rule Release, we estimated the total overall costs, including

We recognize that if today's amendment is adopted, firms relying on the rule would incur the costs associated with complying with the rule for two additional years.

We request comment on all aspects of the cost-benefit analysis, including the accuracy of the potential costs and benefits identified and assessed in this Release, the 2007 Principal Trade Rule Release and the Extension Release, as well as any other costs or benefits that may result from the proposal.

#### VI. Promotion of Efficiency, Competition, and Capital Formation

Section 202(c) of the Advisers Act mandates that the Commission, when engaging in rulemaking that requires it to consider or determine whether an action is necessary or appropriate in the public interest, consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation.<sup>32</sup>

We explained in the 2007 Principal Trade Rule Release and the Extension Release the manner in which rule 206(3)-3T, in general, would promote these aims. We continue to believe that this analysis generally applies today.

As noted in the Extension Release, we received comments on the 2007 Principal Trade Rule Release from commenters who opposed the limitation of the temporary rule to investment advisers that are also registered as broker-dealers, as well as to accounts that are subject to both the Advisers Act and Exchange Act as providing a competitive advantage to investment advisers that are also registered broker-dealers.<sup>33</sup> Based on our experience with the rule to date, just as we noted in the Extension Release, we have no reason to believe that broker-dealers (or affiliated but separate investment advisers and broker-dealers) are put at a competitive disadvantage to advisers that are themselves also registered as broker-dealers;<sup>34</sup> however we intend to continue to evaluate the effects of the rule on efficiency, competition and capital formation as we complete the study mandated by section 913 of the Dodd-Frank Act and our broader consideration of the regulatory requirements applicable to broker-dealers and investment advisers.

estimated costs for all eligible advisers and eligible accounts, relating to compliance with rule 206(3)-3T to be \$37,205,569. See 2007 Principal Trade Rule Release, Section VI.D.

<sup>32</sup> 15 U.S.C. 80b-2(c).

<sup>33</sup> See Extension Release, Section VI; Comment Letter of the Financial Planning Association (Nov. 30, 2007).

<sup>34</sup> See Extension Release, Section VI.

<sup>28</sup> See 2007 Principal Trade Rule Release, Section V.

<sup>29</sup> See *id.*, Section VI; Extension Release, Section V.

<sup>30</sup> 15 U.S.C. 78 *et seq.*

We anticipate no new effects on efficiency, competition and capital formation would result from the two-year extension. However, during that time, we would continue to assess the rule's operation and impact along with intervening developments.

We request comment on whether the proposal, if adopted, would promote efficiency, competition, and capital formation. Commenters are requested to provide empirical data to support their views.

## VII. Initial Regulatory Flexibility Act Analysis

The Commission has prepared the following Initial Regulatory Flexibility Analysis ("IRFA") regarding the proposed amendment to rule 206(3)-3T in accordance with section 3(a) of the Regulatory Flexibility Act.<sup>35</sup>

### A. Reasons for Proposed Action

We are proposing to extend rule 206(3)-3T for two years in its current form because we believe that it would be premature to require firms relying on the rule to restructure their operations and client relationships before we complete our study and our broader consideration of the regulatory requirements applicable to broker-dealers and investment advisers.

### B. Objectives and Legal Basis

The objective of the proposed amendment to rule 206(3)-3T, as discussed above, is to permit firms currently relying on rule 206(3)-3T to limit the need to modify their operations and relationships on multiple occasions, both before and potentially after we complete our study and any related rulemaking.

We are proposing to amend rule 206(3)-3T pursuant to sections 206A and 211(a) of the Advisers Act [15 U.S.C. 80b-6a and 15 U.S.C. 80b-11(a)].

### C. Small Entities Subject to the Rule

Rule 206(3)-3T is an alternative method of complying with Advisers Act section 206(3) and is available to all investment advisers that: (i) Are registered as broker-dealers under the Exchange Act; and (ii) effect trades with clients directly or indirectly through a broker-dealer controlling, controlled by or under common control with the investment adviser, including small entities. Under Advisers Act rule 0-7, for purposes of 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.<sup>36</sup>

We estimate that as of November 1, 2010, 680 SEC-registered investment advisers were small entities.<sup>37</sup> As discussed in the 2007 Principal Trade Rule Release, we opted not to make the relief provided by rule 206(3)-3T available to all investment advisers, and instead have restricted it to investment advisers that also are registered as broker-dealers under the Exchange Act.<sup>38</sup> We therefore estimate for purposes of this IRFA that 38 of these small entities (those that are both investment advisers and broker-dealers) could rely on rule 206(3)-3T.<sup>39</sup>

### D. Reporting, Recordkeeping, and Other Compliance Requirements

The provisions of rule 206(3)-3T impose certain reporting or recordkeeping requirements, and our proposal, if adopted, would extend the imposition of these requirements for an additional two years. We do not, however, expect that the proposed two-year extension would alter these requirements.

Rule 206(3)-3T is designed to provide an alternative means of compliance with the requirements of section 206(3) of the Advisers Act. Investment advisers taking advantage of the rule with respect to non-discretionary advisory accounts would be required to make certain disclosures to clients on a prospective, transaction-by-transaction and annual basis.

Specifically, rule 206(3)-3T permits an adviser, with respect to a non-discretionary advisory account, to comply with section 206(3) of the Advisers Act by, among other things: (i) Making certain written disclosures; (ii) obtaining written, revocable consent from the client prospectively authorizing the adviser to enter into principal trades; (iii) making oral or written disclosure and obtaining the client's consent orally or in writing prior to the execution of each principal transaction; (iv) sending to the client confirmation statements for each principal trade that disclose the

capacity in which the adviser has acted and indicating that the client consented to the transaction; and (v) delivering to the client an annual report itemizing the principal transactions. Advisers are already required to communicate the content of many of the disclosures pursuant to their fiduciary obligations to clients. Other disclosures are already required by rules applicable to broker-dealers.

Our proposed amendment, if adopted, only would extend the rule for two years in its current form. Advisers currently relying on the rule already should be making the disclosures described above.

### E. Duplicative, Overlapping, or Conflicting Federal Rules

We believe that there are no rules that duplicate or conflict with rule 206(3)-3T, which presents an alternative means of compliance with the procedural requirements of section 206(3) of the Advisers Act that relate to principal transactions.

We note, however, that rule 10b-10 under the Exchange Act is a separate confirmation rule that requires broker-dealers to provide certain information to their customers regarding the transactions they effect. Furthermore, FINRA rule 2230 requires broker-dealers that are members of FINRA to deliver a written notification containing certain information, including whether the member is acting as a broker for the customer or is working as a dealer for its own account. Brokers and dealers typically deliver this information in confirmations that fulfill the requirements of rule 10b-10 under the Exchange Act. Rule G-15 of the Municipal Securities Rulemaking Board also contains a separate confirmation rule that governs member transactions in municipal securities, including municipal fund securities. In addition, investment advisers that are qualified custodians for purposes of rule 206(4)-2 under the Advisers Act and that maintain custody of their advisory clients' assets must send quarterly account statements to their clients pursuant to rule 206(4)-2(a)(3) under the Advisers Act.

These rules overlap with certain elements of rule 206(3)-3T, but we designed the temporary rule to work efficiently together with existing rules by permitting firms to incorporate the required disclosure into one confirmation statement.

### F. Significant Alternatives

The Regulatory Flexibility Act directs us to consider significant alternatives that would accomplish our stated

<sup>36</sup> See 17 CFR 275.0-7.

<sup>37</sup> IARD data as of November 1, 2010.

<sup>38</sup> See 2007 Principal Trade Rule Release, Section VIII.B.

<sup>39</sup> IARD data as of November 1, 2010.

<sup>35</sup> 5 U.S.C. 603(a).

objective, while minimizing any significant adverse impact on small entities.<sup>40</sup> Alternatives in this category would include: (i) Establishing different compliance or reporting standards or timetables that take into account the resources available to small entities; (ii) clarifying, consolidating, or simplifying compliance requirements under the rule for small entities; (iii) using performance rather than design standards; and (iv) exempting small entities from coverage of the rule, or any part of the rule.

We believe that special compliance or reporting requirements or timetables for small entities, or an exemption from coverage for small entities, may create the risk that the investors who are advised by and effect securities transactions through such small entities would not receive adequate disclosure. Moreover, different disclosure requirements could create investor confusion if it creates the impression that small investment advisers have different conflicts of interest with their advisory clients in connection with principal trading than larger investment advisers. We believe, therefore, that it is important for the disclosure protections required by the rule to be provided to advisory clients by all advisers, not just those that are not considered small entities. Further consolidation or simplification of the proposals for investment advisers that are small entities would be inconsistent with the Commission's goals of fostering investor protection.

We have endeavored through rule 206(3)-3T to minimize the regulatory burden on all investment advisers eligible to rely on the rule, including small entities, while meeting our regulatory objectives. It was our goal to ensure that eligible small entities may benefit from the Commission's approach to the new rule to the same degree as other eligible advisers. The condition that advisers seeking to rely on the rule must also be registered as broker-dealers and that each account with respect to which an adviser seeks to rely on the rule must be a brokerage account subject to the Exchange Act, and the rules thereunder, and the rules of the self-regulatory organization(s) of which it is a member, reflect what we believe is an important element of our balancing between easing regulatory burdens (by affording advisers an alternative means of compliance with section 206(3) of the Act) and meeting our investor protection objectives.<sup>41</sup> Finally, we do

not consider using performance rather than design standards to be consistent with our statutory mandate of investor protection in the present context.

#### G. Solicitation of Comments

We solicit written comments regarding our analysis. We request comment on whether the rule will have any effects that we have not discussed. We request that commenters describe the nature of any impact on small entities and provide empirical data to support the extent of the impact.

Do small investment advisers believe an alternative means of compliance with section 206(3) of the Advisers Act should be available to more of them?

#### VIII. Consideration of Impact on the Economy

For purposes of the Small Business Regulatory Enforcement Fairness Act of 1996, or "SBREFA,"<sup>42</sup> we must advise OMB whether a proposed regulation constitutes a "major" rule. Under SBREFA, a rule is considered "major" where, if adopted, it results in or is likely to result in: (1) An annual effect on the economy of \$100 million or more; (2) a major increase in costs or prices for consumers or individual industries; or (3) significant adverse effects on competition, investment or innovation.

We request comment on the potential impact of the proposed amendment on the economy on an annual basis. Commenters are requested to provide empirical data and other factual support for their views to the extent possible.

#### IX. Statutory Authority

The Commission is proposing to amend rule 206(3)-3T pursuant to sections 206A and 211(a) of the Advisers Act.

#### List of Subjects in 17 CFR Part 275

Investment advisers, Reporting and recordkeeping requirements.

#### Text of Proposed Rule Amendment

For the reasons set out in the preamble, Title 17, Chapter II of the Code of Federal Regulations is proposed to be 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:

condition as disadvantaging small broker-dealers (or affiliated but separate investment advisers and broker-dealers)).

<sup>42</sup>Public Law 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C., 15 U.S.C. and as a note to 5 U.S.C. 601).

**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.

\* \* \* \* \*

#### § 275.206(3)-3T [Amended]

2. In § 275.206(3)-3T, amend paragraph (d) by removing the words "December 31, 2010" and adding in their place "December 31, 2012."

Dated: December 1, 2010.

By the Commission.

**Elizabeth M. Murphy,**  
*Secretary.*

[FR Doc. 2010-30590 Filed 12-2-10; 4:15 pm]

**BILLING CODE 8011-01-P**

#### POSTAL REGULATORY COMMISSION

#### 39 CFR Part 3055

[Docket No. RM2011-4; Order No. 600]

#### Periodic Reporting Rules

**AGENCY:** Postal Regulatory Commission.

**ACTION:** Notice of rulemaking.

**SUMMARY:** The Postal Service has filed a request for a semi-permanent waiver of periodic reporting rules concerning service performance for First-Class Mail Flats at the District level or, in the alternative, a rulemaking petition seeking deletion of this reporting requirement. This document addresses the Postal Service's filing and identifies related procedural steps, including a request for public comments.

**DATES:** *Comments are due:* December 14, 2010.

**ADDRESSES:** Submit comments electronically via the Commission's Filing Online system. Commenters who cannot submit filings electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for advice on alternatives.

**FOR FURTHER INFORMATION CONTACT:** Stephen L. Sharfman, General Counsel, at [stephen.sharfman@prc.gov](mailto:stephen.sharfman@prc.gov) or 202-789-6820.

**SUPPLEMENTARY INFORMATION:** On November 23, 2010, the Postal Service filed a request for a semi-permanent exception from periodic reporting of service performance measurement for First-Class Mail Flats at the District level pursuant to Commission Order No. 465 and 39 CFR 3055.3(a)(1).<sup>1</sup>

<sup>1</sup> United States Postal Service Request for Semi-Permanent Exception from Periodic Reporting of Service Performance Measurement or, in the Alternative, Petition for Rulemaking Concerning 39 CFR 3055.45(a), November 23, 2010 (Request); see also Docket No. RM2009-11, Order Establishing Final Rules Concerning Periodic Reporting of

<sup>40</sup> See 5 U.S.C. 603(c).

<sup>41</sup> See 2007 Principal Trade Rule Release, Section II.B.7 (noting commenters that objected to this

Alternatively, the Postal Service petitions the Commission to initiate a rulemaking to remove the requirement to report service performance measurement for First-Class Mail Flats at the District level from the Commission's rules of practice and procedure. See 39 CFR 3055.45(a). Concomitantly, the Postal Service filed a provisional notice of withdrawal from a separate request for a temporary waiver of this reporting requirement.<sup>2</sup> See Docket No. RM2011-1.

Specifically, the Postal Service requests that the Commission grant one of the following extraordinary remedies: (1) Allow a semi-permanent exception for quarterly, district-level reporting of First-Class Mail Flats under 39 CFR 3055.3(a)(1), on the basis of the undue burden that a \$4 million measurement cost would impose on the Postal Service's financial position; (2) allow a semi-permanent exception on an extraordinary basis, not under 39 CFR 3055.3(a)(1), for the same reason; or (3) amend 39 CFR 3055.45(a)(1) and (2) to delete the word "District." Request at 7.

The Commission establishes Docket No. RM2011-4 for consideration of matters related to the proposed semi-permanent exception from periodic reporting of service performance measurement identified in the Postal Service's Request.

Interested persons may submit comments on whether the Postal Service's Request is consistent with the policies of 39 U.S.C. 3652(a)(2) and 39 CFR 3055.3. Comments are due no later than December 14, 2010. The Postal Service's Request can be accessed via the Commission's Web site (<http://www.prc.gov>).

The Commission appoints Emmett Rand Costich to serve as Public Representative in the captioned proceedings.

*It is ordered:*

1. The Commission establishes Docket No. RM2011-4 for consideration of matters raised by the Postal Service's Request.

2. Comments by interested persons in these proceedings are due no later than December 14, 2010.

3. Pursuant to 39 U.S.C. 505, Emmett Rand Costich is appointed to serve as the officer of the Commission (Public Representative) to represent the interests of the general public in these proceedings.

Service Performance Measurements and Customer Satisfaction, May 25, 2010, at 22 (Order No. 465).

<sup>2</sup>Docket No. RM2011-1, United States Postal Service Notice of Provisional Partial Withdrawal of Request for Temporary Waiver, November 24, 2010.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.  
**Shoshana M. Grove,**  
*Secretary.*  
 [FR Doc. 2010-30448 Filed 12-3-10; 8:45 am]  
**BILLING CODE 7710-FW-P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA-R01-OAR-2010-0934; A-1-FRL-9235-2]

### Approval and Promulgation of Air Quality Implementation Plans; New Hampshire; Determination of Attainment of the 1997 Ozone Standard

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The EPA is proposing to determine that the Boston-Manchester-Portsmouth (SE), New Hampshire moderate 1997 8-hour ozone nonattainment area continues to attain the 1997 8-hour National Ambient Air Quality Standard (NAAQS) for ozone. This determination is based upon complete, quality-assured, certified ambient air monitoring data that show the area has monitored attainment of the 1997 8-hour ozone NAAQS for the 2007-2009 monitoring period. Preliminary data available through June 15, 2010 also are consistent with continued attainment. In addition, in accordance with the Clean Air Act, EPA is proposing to determine that this area has attained the 1997 ozone NAAQS as of June 15, 2010, its applicable attainment date.

**DATES:** Written comments must be received on or before January 5, 2011.

**ADDRESSES:** Submit your comments, identified by Docket ID Number EPA-R01-OAR-2010-0934 by one of the following methods:

1. <http://www.regulations.gov>: Follow the online instructions for submitting comments.

2. *E-mail:* [arnold.anne@epa.gov](mailto:arnold.anne@epa.gov).

3. *Fax:* (617) 918-0047.

4. *Mail:* "Docket Identification Number EPA-R01-OAR-2010-0934," Anne Arnold, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square, Suite 100 (mail code: OEP05-2), Boston, MA 02109-3912.

5. *Hand Delivery or Courier.* Deliver your comments to: Anne Arnold, Manager, Air Quality Planning Unit,

Office of Ecosystem Protection, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square, Suite 100, Boston, MA 02109-3912. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding legal holidays.

*Instructions:* Direct your comments to Docket ID No. EPA-R01-OAR-2010-0934. 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 through <http://www.regulations.gov>, or e-mail, information that you consider to be CBI or otherwise protected. 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.

*Docket:* All documents in the electronic 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 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 electronically in <http://www.regulations.gov> or in hard copy at Office of Ecosystem Protection, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square, Suite 100, Boston, MA.

EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding legal holidays.

**FOR FURTHER INFORMATION CONTACT:** Richard P. Burkhart, Air Quality Planning Unit, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square, Suite 100, Boston, MA 02109-3912, telephone number (617) 918-1664, fax number (617) 918-0664, e-mail [Burkhart.Richard@epa.gov](mailto:Burkhart.Richard@epa.gov).

**SUPPLEMENTARY INFORMATION:** Throughout this document whenever "we," "us," or "our" is used, we mean EPA.

Organization of this document. The following outline is provided to aid in locating information in this preamble.

- I. What actions is EPA taking?
- II. What is the effect of these actions?
- III. What is the background for these actions?
- IV. What is EPA's analysis of the relevant air quality data?
- V. Proposed Actions
- VI. Statutory and Executive Order Reviews

**I. What actions is EPA taking?**

EPA is proposing to determine that the Boston-Manchester-Portsmouth (SE), New Hampshire moderate 8-hour ozone nonattainment area continues to attain the 1997 8-hour NAAQS for ozone. This determination is based upon complete, quality-assured and certified ambient air monitoring data that show the area has monitored attainment of the 1997 ozone NAAQS for the 2007-2009 monitoring period. Data available through June 15, 2010, in the EPA Air Quality System (AQS) are also consistent with continued attainment. In addition, under section 181(b)(2)(A) of the Clean Air Act (CAA), EPA is proposing to determine that this area has attained the 1997 ozone NAAQS by its applicable attainment date (June 15, 2010).

**II. What is the effect of these actions?**

Under section 181(b)(2)(A) of the CAA and the provisions of EPA's ozone implementation rule (see 40 CFR Section 51.902(a)), EPA is proposing to determine that this area has attained the 1997 ozone NAAQS by its applicable attainment date of June 15, 2010. The

effect of a final determination of attainment by the area's attainment date would be to discharge EPA's obligation under section 181(b)(2)(A), and to establish that, in accordance with that section, the area would not be reclassified for failure to attain by its applicable attainment date. This proposed action, if finalized, would not constitute a redesignation to attainment under the Clean Air Act (CAA) section 107(d)(3), because we would not yet have an approved maintenance plan for the area as required under section 175A of the CAA, nor a determination that the area has met the other requirements for redesignation. The classification and designation status of the area would remain moderate nonattainment for the 1997 8-hour ozone NAAQS until such time as EPA determines that the area meets the CAA requirements for redesignation to attainment.

The further effect of this proposed action is to reaffirm EPA's prior determination of attainment for this area (See 73 FR 14387 (March 18, 2004)), and thus, pursuant to 40 CFR. 51.918, to continue the suspension of New Hampshire's obligation to make certain SIP submissions for this area.

**III. What is the background for these actions?**

On April 30, 2004 (69 FR 23857), EPA designated as nonattainment any area that was violating the 1997 8-hour ozone NAAQS based on the three most recent years (2001-2003) of air quality data. The Boston-Manchester-Portsmouth (SE), New Hampshire area was designated as a moderate ozone nonattainment area. Subsequently, on March 18, 2008, EPA published in the **Federal Register** a determination that the area was attaining the 1997 8-hour ozone standard, based on complete, quality-assured and certified data for 2004-2006. (See 73 FR 14387). That action suspended the obligation for the area to submit an attainment demonstration, a reasonable further progress plan, section 172(c)(9) contingency measures, and any other planning State Implementation Plans (SIPs) related to attainment of the 1997 8-hour ozone NAAQS for so long as the area continues to attain the 1997 ozone NAAQS. 40 CFR 51.918. Complete, certified ozone air quality data for 2007 through 2009, as well as complete,

quality-assured, but not yet certified, ozone data available in AQS, through June 15, 2010, show that the Boston-Manchester-Portsmouth (SE), New Hampshire area continues to meet the 1997 8-hour ozone standard. Additional, preliminary ozone data available through September 30, 2010, continues to show this area meets the ozone NAAQS.

**IV. What is EPA's analysis of the relevant air quality data?**

The EPA has reviewed the ambient air monitoring data for ozone, consistent with the requirements contained in 40 CFR part 50 and recorded in the Air Quality Data System (AQS) database, for Boston-Manchester-Portsmouth (SE), New Hampshire area, from 2007 through 2009. On the basis of its review, EPA proposes to conclude that the area attained the 1997 8-hour ozone standard at the end of the 2009 ozone season, based on 3 years of complete, quality-assured and State-certified 2007-2009 ozone data. Preliminary data available in the EPA Air Quality System, through June 15, 2010 are also consistent with continued attainment.

Under EPA regulations at 40 CFR part 50, the 1997 8-hour ozone standard is attained at a site when the 3-year average of the annual fourth-highest daily maximum 8-hour average ozone concentrations at an ozone monitor is less than or equal to 0.08 parts per million (ppm) (i.e., 0.084 ppm, based on the rounding convention in 40 CFR part 50, appendix I). This 3-year average is referred to as the design value. When the design value is less than or equal to 0.084 ppm at each monitoring site within the area, then the area is meeting the NAAQS. Also, the data completeness requirement is met when the average percent of days with valid ambient monitoring data is greater than 90%, and no single year has less than 75% data completeness as determined in Appendix I of 40 CFR part 50.

Table 1 shows the fourth-highest daily maximum 8-hour average ozone concentrations for the Boston-Manchester-Portsmouth (SE), New Hampshire nonattainment area monitors for the years 2007-2009, and the ozone design values for these same monitors based on 2007-2009.

TABLE 1—2007–2009 FOURTH-HIGH 8-HOUR AVERAGE OZONE CONCENTRATIONS AND 2007–2009 DESIGN VALUES (PARTS PER MILLION) IN THE BOSTON-MANCHESTER-PORTSMOUTH (SE), NEW HAMPSHIRE AREA

Location	AQS site ID	4th high 2007	4th high 2008	4th high 2009	Design value (07–09)
Manchester .....	330110020	0.074	0.064	0.060	0.066

TABLE 1—2007–2009 FOURTH-HIGH 8-HOUR AVERAGE OZONE CONCENTRATIONS AND 2007–2009 DESIGN VALUES (PARTS PER MILLION) IN THE BOSTON-MANCHESTER-PORTSMOUTH (SE), NEW HAMPSHIRE AREA—Continued

Location	AQS site ID	4th high 2007	4th high 2008	4th high 2009	Design value (07–09)
Nashua .....	330111011	0.081	0.067	0.066	0.071
Portsmouth .....	330150014	0.078	0.069	0.070	0.072
Rye .....	330150016	0.086	0.075	0.068	0.076

EPA's review of these data indicates that the Boston-Manchester-Portsmouth (SE), New Hampshire ozone nonattainment area has met the 1997 8-hour ozone NAAQS, based on 2007–2009 data. EPA believes these data, coupled with preliminary data available through June 15, 2010, indicate that the Boston-Manchester-Portsmouth (SE), New Hampshire area has also attained the standard as of its applicable attainment date of June 15, 2010. Thus, in accordance with CAA section 181(b)(2), EPA is also proposing to determine that the Boston-Manchester-Portsmouth (SE), New Hampshire area has attained the standard by its applicable attainment date.

EPA is soliciting public comment on the issues discussed in this notice or on other relevant matters pertaining to this rulemaking action. These comments will be considered before EPA takes final action. Interested parties may participate in the Federal rulemaking procedure by submitting written comments to the EPA New England Regional Office listed in the **ADDRESSES** section of this **Federal Register**.

#### V. Proposed Actions

EPA is proposing to determine that the Boston-Manchester-Portsmouth (SE), New Hampshire 1997 8-hour ozone moderate nonattainment area continues to attain the 1997 8-hour ozone standard, based on complete, quality-assured data from 2007 through 2009. Data for 2010 that are available in AQS through June 30, 2010 are consistent with continued attainment. As provided in 40 CFR Section 51.918, if EPA finalizes this determination, the requirements for New Hampshire to submit planning SIPs related to attainment of the 1997 8-hour ozone NAAQS for this area remain suspended, for so long as the area continues to attain the standard. In addition, under section 181(b)(2)(A) of the Clean Air Act and the provisions of EPA's ozone implementation rule (*see* 40 CFR 51.902(a)), EPA is proposing to determine that this area has attained the 1997 ozone NAAQS by its applicable attainment date of June 15, 2010.

#### VI. Statutory and Executive Order Reviews

These actions propose to make determinations of attainment based on air quality, and would, if finalized, result in the continued suspension of certain Federal requirements, and would not impose additional requirements beyond those imposed by State law. For that reason, these proposed actions:

- Are 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);
- Do not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Are 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.*);
- Do 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);
- Do not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Are not economically significant regulatory actions based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Are not significant regulatory actions subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Are not subject to the 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
- Do not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have Tribal implications as specified by Executive Order 13175 (65 FR 67249,

November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on Tribal governments or preempt Tribal law.

#### List of Subjects in 40 CFR Part 52

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

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

Dated: November 24, 2010.

**Ira W. Leighton,**

*Acting Regional Administrator, EPA New England.*

[FR Doc. 2010–30493 Filed 12–3–10; 8:45 am]

**BILLING CODE 6560–50–P**

#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 52

[EPA–R10–OAR–2010–0921, FRL–9235–6]

#### Approval and Promulgation of Implementation Plans; Alaska: Prevention of Significant Deterioration; Greenhouse Gas Permitting Authority and Tailoring Rule Revision

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to approve a draft revision to the State Implementation Plan (SIP), submitted by the Commissioner of the Alaska Department of Environmental Conservation (ADEC) to EPA on October 25, 2010, for parallel processing. The proposed SIP revision updates Alaska's Prevention of Significant Deterioration (PSD) program to reflect changes to the Federal PSD program relating to the permitting of greenhouse gas (GHG) emissions. EPA is proposing in this action to approve those revisions if the final SIP revision submitted by Alaska to EPA is consistent with the draft SIP revision.

**DATES:** Comments must be received on or before January 5, 2011.



**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-R10-OAR-2010-0921, by any of the following methods:

- <http://www.regulations.gov>: Follow the on-line instructions for submitting comments.

- *E-mail: R10-*

*Public Comments@epa.gov.*

- *Mail:* Scott Hedges, EPA Region 10, Office of Air, Waste and Toxics (AWT-107), 1200 Sixth Avenue, Suite 900, Seattle, WA 98101.

- *Hand Delivery/Courier:* EPA Region 10, 1200 Sixth Avenue, Suite 900, Seattle, WA 98101. Attention: Scott Hedges, Office of Air, Waste and Toxics, AWT-107. Such deliveries are only accepted during normal hours of operation, and special arrangements should be made for deliveries of boxed information.

*Instructions:* Direct your comments to Docket ID No. EPA-R10-OAR-2010-0921. 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.

*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, is not placed on the Internet and 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 during normal business hours at the Office of Air, Waste and Toxics, EPA Region 10, 1200 Sixth Avenue, Seattle, WA 98101.

**FOR FURTHER INFORMATION CONTACT:**

Scott Hedges at telephone number: (206) 553-0296, e-mail address: [hedges.scott@epa.gov](mailto:hedges.scott@epa.gov), or the above EPA, Region 10 address.

**SUPPLEMENTARY INFORMATION:**

Throughout this document wherever "we", "us" or "our" are used, we mean EPA. Information is organized as follows:

**Table of Contents**

- I. What action is EPA proposing today?
- II. What is the background for the action that EPA is proposing today?
- III. What is EPA's analysis of Alaska's proposed SIP revision?
- IV. Proposed Action
- V. Statutory and Executive Order Reviews

**I. What action is EPA proposing today?**

On October 25, 2010, ADEC submitted a draft revision to EPA for approval into the Alaska's SIP to update Alaska's PSD program to reflect changes to the Federal PSD program that would authorize the State of Alaska to regulate GHGs under its PSD program and establish appropriate emission thresholds for determining which new or modified stationary sources become subject to Alaska's PSD permitting requirements for GHG emissions. ADEC subsequently clarified in an e-mail dated November 16, 2010, that its request is limited to updating the incorporation by reference date of 40 CFR 52.21 in 18 AAC 50.040(h) in order to incorporate the new definition of "subject to regulation" in 40 CFR 52.21(49) to clarify the meaning of the definition of "regulated NSR pollutant" in the Alaska SIP so as to make the Alaska SIP consistent with Federal PSD requirements for the regulation of GHGs.

Because this draft SIP revision is not yet State-effective, Alaska requested that EPA "parallel process" the SIP revision. Under this procedure, the EPA Regional Office works closely with the State while developing new or revised regulations. Generally, the State submits a copy of the proposed regulation or other revisions before final promulgation by the State. EPA reviews this proposed State action and prepares a notice of proposed rulemaking. EPA publishes this notice of proposed

rulemaking in the **Federal Register** and solicits public comment in approximately the same time frame during which the State is completing its rulemaking action.

In this case, the regulatory revisions submitted in Alaska's October 25, 2010, proposed SIP revision have already gone through public review and were adopted by the Commissioner of ADEC on September 27, 2010. On November 8, 2010, ADEC provided EPA with a revised draft submittal following review by the Alaska Department of Law. On November 16, 2010, ADEC advised EPA that the revisions that were filed by the Alaska Lieutenant Governor on November 9, 2010, will become effective as a matter of State law on December 8, 2010, and will be submitted as a final SIP revision before December 1, 2010. Therefore, EPA is processing this proposed rulemaking prior to Alaska's submission of the final SIP revision.

EPA is proposing to approve the update to 18 AAC 50.040(h) with respect to the definition of "subject to regulation" as a revision to the Alaska SIP if the final SIP revision relating to the PSD permitting of GHGs submitted by Alaska to EPA is consistent with the proposed SIP revision. Final approval of Alaska's SIP revision will make Alaska's SIP for GHG-emitting sources consistent with Federal PSD requirements for GHG emissions, including the GHG emission thresholds for PSD applicability. If changes are made to the SIP revision after this proposal, such changes will be acknowledged in EPA's final rulemaking action and, if such changes are significant, may require a reproposal and an additional public comment period.

**II. What is the background for the action that EPA is proposing today?**

On June 3, 2010 (effective August 2, 2010), EPA promulgated a final rulemaking tailoring the applicability criteria that determine which stationary sources and modification projects become subject to permitting requirements for GHG emissions under the PSD and title V permitting programs. See "Prevention of Significant Deterioration and title V Greenhouse Gas Tailoring Rule; Final Rule," (the Tailoring Rule), 75 FR 31514 (June 3, 2010).<sup>1</sup> In particular, by amending the definition of "subject to regulation," EPA established thresholds for GHGs with a phase-in approach for PSD applicability and established the first

<sup>1</sup> The Tailoring Rule also applies to the title V program, which requires operating permits for existing sources. However, today's action does not affect Alaska's title V program.



two steps of the phase-in for the largest GHG-emitters. As EPA explained in the Tailoring Rule, the threshold limitations are necessary because without it, PSD would apply to all stationary sources that emit or have the potential to emit more than 100 or 250 tons of GHGs per year beginning on January 2, 2011. This is the date when EPA's recently promulgated Light Duty Vehicle Rule takes effect,<sup>2</sup> imposing control requirements for the first time on GHGs. If this January 2, 2011, date were to pass without the Tailoring Rule being in effect, PSD requirements would apply to GHG emissions at the 100/250 tons per year applicability levels provided under a literal reading of the Clean Air Act (CAA or the Act) as of that date. From that point forward, a source owner proposing to construct any new major source that emits at or higher than the applicability levels (and which therefore may be referred to as a "major" source) or modify any existing major source in a way that would increase GHG emissions would need to obtain a permit under the PSD program that addresses these emissions before construction or modification could begin. See 75 FR 31514.

As explained in the Tailoring Rule, many State, local and Tribal area programs will likely be able to immediately implement the approach in the Tailoring Rule without rule or statutory changes by, for example, interpreting the term "subject to regulation" that is part of the applicability provisions for PSD permitting. EPA has requested permitting authorities to confirm that they will follow this implementation approach for their programs, and if they cannot, then EPA has requested that they notify the Agency so that we can take appropriate follow-up action to narrow Federal approval of their programs before GHGs become subject to PSD permitting on January 2, 2011. Narrowing EPA's approval will ensure that for Federal purposes, sources with GHG emissions that are less than the Tailoring Rule's emission thresholds will not be obligated under Federal law to obtain PSD permits during the gap between when GHG PSD requirements go into effect on January 2, 2011 and when either (1) EPA approves a SIP revision adopting EPA's tailoring approach, or (2) if a State opts to regulate smaller GHG-emitting sources, the State demonstrates to EPA that it has adequate resources to handle permitting

for such sources. EPA expects to finalize the narrowing action prior to the January 2, 2011 deadline with respect to those States for which EPA will not have approved the Tailoring Rule thresholds in their SIPs by that time.

On August 2, 2010, Alaska provided a letter to EPA explaining that its PSD rules only apply to pollutants "subject to regulation" at the time of adoption in July 1, 2004, and that Alaska thus did not have authority to issue PSD permits that address GHG emissions. By notice dated September 2, 2010, EPA issued a proposed "Action to Ensure Authority to Issue Permits Under the Prevention of Significant Deterioration Program to Sources of Greenhouse Gas Emissions: Finding of Substantial Inadequacy and SIP Call, Proposed Rule," 75 FR 53892 (September 2, 2010) (GHG SIP Call). In that action, along with a companion proposal published at the same time, EPA took steps to ensure that in States that do not appear to have authority to issue PSD permits to GHG-emitting sources at present, either the State or EPA will have the authority to issue such permits by January 2, 2011. EPA explained in the GHG SIP Call that, although for most States, either the State or EPA is already authorized to issue PSD permits for GHG-emitting sources as of that date, our preliminary information showed that 13 States, including Alaska, have EPA-approved PSD programs that do not appear to include GHG-emitting sources and therefore do not appear to authorize these States to issue PSD permits to such sources. Therefore, EPA proposed to find that these 13 States' SIPs are substantially inadequate to comply with CAA requirements and, accordingly, proposed to issue a SIP Call to require a SIP revision that applies their SIP PSD programs to GHG-emitting sources.<sup>3</sup>

In a companion rulemaking issued on the same date, EPA proposed a Federal Implementation Plan (FIP) that would give EPA authority to apply EPA's PSD program to GHG-emitting sources in any State that is unable to submit a corrective SIP revision by its deadline. See "Action to Ensure Authority to Issue Permits Under the Prevention of Significant Deterioration Program to Sources of Greenhouse Gas Emissions: Federal Implementation Plan, Proposed Rule," 75 FR 53883 (September 2, 2010)

<sup>3</sup> As explained in the proposed GHG SIP Call (75 FR 53892, 53896), EPA intends to finalize its finding of substantial inadequacy and the SIP call for the 13 listed States by December 1, 2010. EPA requested that the States for which EPA is proposing a SIP call identify the deadline—between 3 weeks and 12 months from the date of signature of the final SIP Call—that they would accept for submitting their corrective SIP revision.

(GHG FIP). Alaska was one of the States for which EPA proposed a SIP Call and a FIP because, as discussed above, Alaska advised EPA that it did not interpret its then current PSD regulations as providing it with the authority to regulate GHGs.

Alaska's proposed SIP revision that is the subject of this rulemaking, however, addresses this authority. Therefore, if the State submits its final SIP revision to EPA prior to the final rulemaking for the GHG SIP Call, EPA will not take final action on the GHG SIP Call for Alaska. Additionally, Alaska would not be subject to the FIP if EPA finalizes today's proposed approval of the Alaska's SIP revision.

### III. What is EPA's analysis of Alaska's proposed SIP revision?

The State of Alaska is currently a SIP-approved State for the PSD program, and has incorporated EPA's 2002 New Source Review (NSR) reform revisions for PSD into its SIP. See 72 FR 45378 (August 14, 2007). However, Alaska does not interpret its PSD rules that are currently in the SIP, which generally incorporate the Federal rules by reference, to be automatically updating to include newly designated regulated air pollutants such as GHGs. As discussed above, in a letter provided to EPA on August 2, 2010, Alaska notified EPA that the State did not then have the authority to regulate GHGs under the PSD program and thus was in the process of revising its regulations (the subject of this proposed action) to provide this authority.

The proposed rules submitted by ADEC to EPA with the proposed SIP revision updates its incorporation by reference of the Federal PSD requirements at 40 CFR 51.166 and 40 CFR 52.21–40 CFR 52.22 (Prevention of Significant Deterioration of Air Quality) to include all revisions to these Federal requirements as of August 2, 2010, the effective date of the Tailoring Rule. See 18 AAC 50.040(h). ADEC has requested that EPA approve this update only with respect to the definition of "subject to regulation" in 40 CFR 52.21(b)(49) promulgated in the Tailoring Rule (effective August 2, 2010), which in turn clarifies the meaning of the State definition of "regulated NSR pollutant."<sup>4</sup> As discussed below, ADEC intends to request that EPA approve

<sup>4</sup> 18 AAC 50.040(h)(4)(C)(i) states that the definition of "regulated NSR pollutant" in 40 CFR 52.21(b)(50) is not adopted and that that term shall have the meaning assigned to it in 18 AAC 50.990. The SIP-approved version of 18 AAC 50.990(92) states that "regulated NSR pollutant" has the meaning given in 40 CFR 51.166(b)(49), which is the same definition as in 40 CFR 52.21(b)(50).

<sup>2</sup> See "Light-Duty Vehicle Greenhouse Gas Emission Standards and Corporate Average Fuel Economy Standards; Final Rule," 75 FR 25324 (May 7, 2010).

these rule revisions with respect to all other changes in a subsequent and separate SIP revision request.

As discussed above, unless EPA either approves the Alaska SIP revision authorizing the PSD permitting of GHG emissions by January 2, 2010, or unless EPA promulgates a FIP to do so, such sources will be unable to receive preconstruction permits and therefore may not be able to construct or modify in the State of Alaska after that date. Alaska's incorporation by reference of the new definition of "subject to regulation" at 40 CFR 52.21(b)(49) is consistent with EPA's regulation of GHG emissions under the Federal PSD program. Therefore, if the final SIP submitted by ADEC to EPA is consistent with the proposed SIP revision, EPA is proposing to approve this revision because Alaska's regulation is consistent with the CAA PSD requirements and its implementing regulations regarding GHGs.

#### IV. Proposed Action

Pursuant to section 110 of the CAA, EPA is proposing to approve the State of Alaska's draft SIP revision that reflects changes to the Federal PSD program as of August 2, 2010, relating to the permitting of GHGs if the final SIP revision submitted by Alaska to EPA is consistent with the proposed SIP revision. This proposed SIP revision provides Alaska with the authority to regulate GHGs under its PSD program and establishes appropriate emissions thresholds for determining PSD applicability to new and modified GHG-emitting sources in accordance with EPA's Tailoring Rule. EPA has made the preliminary determination that this SIP revision is approvable because it is in accordance with the CAA and EPA regulations regarding PSD permitting for GHGs.

Note that ADEC has made other changes to its rules for PSD permitting and other air regulations that it has not submitted as part of this draft SIP

revision (subject to this action) and does not intend to submit as part of its final SIP submission. However, ADEC does intend to submit these other rules and regulations as a subsequent SIP revision in the near future. Because of the need to approve as a SIP revision the changes relating to the PSD permitting of GHGs by January 2, 2011 or as soon thereafter as possible to ensure the State has adequate authority to issue PSD permits to subject sources emitting GHGs, once the requirements go into effect as a matter of Federal law, EPA believes it is appropriate to approve Alaska's revisions that update the Alaska PSD program to address GHG emissions as a SIP strengthening measure.

#### 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 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 CAA. Accordingly, this proposed action merely approves the State's law as meeting Federal requirements and does not impose additional requirements beyond those imposed by the State's law. For that reason, this proposed 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 Alaska, and EPA notes that it will not impose substantial direct costs on Tribal governments or preempt Tribal law.

#### List of Subjects in 40 CFR Part 52

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

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

Dated: November 19, 2010.

**Dennis J. McLerran,**  
Regional Administrator, Region 10.

[FR Doc. 2010-30479 Filed 12-3-10; 8:45 am]

**BILLING CODE 6560-50-P**

# Notices

Federal Register

Vol. 75, No. 233

Monday, December 6, 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.

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## DEPARTMENT OF AGRICULTURE

### Forest Service

#### Gallatin County Resource Advisory Committee

**AGENCY:** Forest Service, USDA.

**ACTION:** Notice of meeting.

**SUMMARY:** The Gallatin National Forest's Gallatin County Resource Advisory Committee will meet in Bozeman, Montana. The committee is meeting as authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L. 110-343) and in compliance with the Federal Advisory Committee Act. The purpose is of the meeting is to determine parameters and timeframes for the first round of projects and Public Comments.

**DATES:** The meeting will be held on December 15, 2010, and will begin at 12:30 p.m.

**ADDRESSES:** The meeting will be held at the Bozeman Public Library, Large Meeting Room, 626 East Main, Bozeman, MT. Written comments should be sent to Babete Anderson, Custer National Forest, 1310 Main Street, Billings, MT 59105. Comments may also be sent via e-mail to [branderson@fs.fed.us](mailto:branderson@fs.fed.us), or via facsimile to 406-657-6222.

All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at Custer National Forest, 1310 Main Street, Billings, MT 59105. Visitors are encouraged to call ahead to 406-657-6205 ext 239.

**FOR FURTHER INFORMATION CONTACT:** Babete Anderson, RAC coordinator, USDA, Custer National Forest, 1310 Main Street, Billings, MT 59105; (406) 657-6205 ext 239; E-mail [branderson@fs.fed.us](mailto:branderson@fs.fed.us).

Individuals who use telecommunication devices for the deaf

(TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8 a.m. and 8 p.m., Mountain Standard Time, Monday through Friday.

**SUPPLEMENTARY INFORMATION:** The meeting is open to the public. The following business will be conducted: Review first round of project proposals and Public Comments. Persons who wish to bring related matters to the attention of the Committee may file written statements with the Committee staff before or after the meeting. Public input sessions will be provided and individuals who made written request by December 10th will have the opportunity to address the Committee at those sessions.

Dated: November 29, 2010.

**Chris Worth,**

*Deputy Forest Supervisor.*

[FR Doc. 2010-30339 Filed 12-3-10; 8:45 am]

**BILLING CODE 3410-11-M**

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## DEPARTMENT OF AGRICULTURE

### Forest Service

#### Prince of Wales Resource Advisory Committee

**AGENCY:** Forest Service, USDA.

**ACTION:** Notice of meeting.

**SUMMARY:** The Prince of Wales Resource Advisory Committee will meet in Coffman Cove, Alaska, December 20, 2010. The purpose of this meeting is to discuss potential projects under the Secure Rural Schools and Community Self-Determination Act of 2008.

**DATES:** The meeting will be held December 20, 2010 from 10 a.m. to 4 p.m.

**ADDRESSES:** The meeting will be held at the Ferry Terminal 110 Stikine Way, Coffman Cove, Alaska. Send written comments to Prince of Wales Resource Advisory Committee, c/o District Ranger, USDA Forest Service, P.O. Box 500, Craig, AK 99921, or electronically to Rebecca Sakraida, RAC Coordinator at [rsakraida@fs.fed.us](mailto:rsakraida@fs.fed.us).

**FOR FURTHER INFORMATION CONTACT:** Rebecca Sakraida, RAC Coordinator Craig Ranger District, Tongass National Forest, (907) 826-1601.

**SUPPLEMENTARY INFORMATION:** The meeting is open to the public. Committee discussion is limited to Forest Service staff and Committee

members. However, public input opportunity will be provided and individuals will have the opportunity to address the Committee at that time.

**Jason C. Anderson,**

*District Ranger.*

[FR Doc. 2010-30439 Filed 12-3-10; 8:45 am]

**BILLING CODE 3410-11-P**

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## CHEMICAL SAFETY AND HAZARD INVESTIGATION BOARD

### Sunshine Act Meeting

In connection with its investigation into the April 20, 2010, explosion and fire that occurred on the BP/Transocean Deepwater Horizon oil rig, the United States Chemical Safety and Hazard Investigation Board (CSB) announces that it will be holding an all day symposium entitled "International Models of Offshore Oil Rig Regulation" on Wednesday, December 15, 2010 in Washington, DC. The meeting will bring together international regulators, union representatives and industry groups' to discuss regulation of offshore drilling operations in the wake of the Deepwater Horizon accident.

The meeting will be held from 9 a.m.-5 p.m. at the Embassy Suites Ballroom located at 1250 22nd Street Northwest in Washington, DC. The meeting is free and open to the public.

The CSB's Board Members and BP Deepwater Horizon investigation team will hear testimony from leading safety experts involved in offshore drilling activities from countries including the United Kingdom, Australia and Norway. CSB Board Members and panel participants will be available to answer questions during a public comment period. The meeting will be available via webcast. All proceedings will be videotaped and an official transcript will be published.

The CSB is an independent Federal agency charged with investigating industrial chemical accidents. The agency's board members are appointed by the president and confirmed by the Senate. CSB investigations look into all aspects of chemical accidents, including physical causes such as equipment failure as well as inadequacies in

regulations, industry standards, and safety management systems.

**Christopher W. Warner,**  
General Counsel.

[FR Doc. 2010-30672 Filed 12-2-10; 4:15 pm]

BILLING CODE 6350-01-P

## DEPARTMENT OF COMMERCE

### Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

*Agency:* U.S. Census Bureau.

*Title:* 2010 Census Count Question Resolution (CQR) Program.

*Form Number(s):* D-18(L)CQR-1, D-18(L)CQR-1(S), D-18(L)CQR-A, D-18(L)CQR-B, D-18(L)CQR-C, D-18(L)CQR-D, D-18(L)CQR-E, D-18(L)CQR-F, D-18(L)CQR-G, D-18(L)CQR-H, D-18(L)CQR-I, D-18(L)CQR-J, D-2010B CQR, D-2010B CQR(S).

*OMB Control Number:* 0607-0879.

*Type of Request:* Reinstatement of a previously approved collection.

*Burden Hours:* 7,800.

*Number of Respondents:* 1,500.

*Average Hours per Response:* 5.2 hours.

*Needs and Uses:* The primary need for implementation of the CQR Program is to ensure a way for state, local and tribal area governments to challenge the accuracy of the counts of 2010 Census housing units and group quarters (GQs). The CQR Program is not a mechanism or process to challenge or revise the population counts sent to the President by December 31, 2010, which are used to apportion the U.S. House of Representatives. The Count Question Resolution (CQR) Program will process requests for corrections to the 2010 Census count of housing units and/or GQs based on three types of challenges (1) boundary, (2) geocoding, and (3) coverage. The Census Bureau will accept challenges between June 1, 2011, and June 1, 2013.

The Census Bureau will make all corrections on the basis of appropriate documentation provided by the challenging entities and through research of the official 2010 Census records by the Census Bureau. The Census Bureau will not collect additional data for the enumeration of living quarters through the CQR Program. The Census Bureau will

respond to all challenges and will notify all affected governmental units of any corrections to their official counts as a result of a CQR Program decision.

Corrections made to the population and housing unit counts by this program will result in the issuance of new official 2010 Census counts to the officials of governmental units affected. These corrections may be used by the governmental units for future programs requiring official 2010 Census data, including requests for federal or state funding, grants, and other needs that are based on the population and/or housing and group quarters counts within a governmental unit. The Census Bureau will use these corrections to modify the decennial census file for use in annual postcensal estimates beginning in December 2012, and to create the errata information we will make available to the public on the Census Bureau's *American FactFinder* Web site at <http://factfinder.census.gov>.

The Census Bureau will issue an official 2010 Census CQR Program announcement in the **Federal Register** after we receive OMB approval to conduct the program. This announcement will provide full details to governmental entities wishing to participate in the 2010 CQR Program. Additionally, we will mail information about the CQR Program to the highest elected officials at all levels of state, Municipio, and Tribal area government in the United States and Puerto Rico.

*Affected Public:* State, Municipio, and Tribal area governments in the United States and Puerto Rico.

*Frequency:* One time.

*Respondent's Obligation:* Required to obtain a benefit.

*Legal Authority:* Title 13 U.S.C., Section 141.

*OMB Desk Officer:* Brian Harris-Kojetin, (202) 395-7314.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482-0266, Department of Commerce, Room 6616, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at [dhynek@doc.gov](mailto:dhynek@doc.gov)).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to Brian Harris-Kojetin, OMB Desk Officer either by fax (202-395-7245) or e-mail ([bharrisk@omb.eop.gov](mailto:bharrisk@omb.eop.gov)).

Dated: December 1, 2010.

**Glenna Mickelson,**

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2010-30446 Filed 12-3-10; 8:45 am]

BILLING CODE 3510-07-P

## DEPARTMENT OF COMMERCE

### International Trade Administration

[C-570-959]

#### Certain Coated Paper Suitable for High-Quality Print Graphics Using Sheet-Fed Presses From the People's Republic of China: Notice of Correction for Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**DATES:** *Effective Date:* December 6, 2010.

**FOR FURTHER INFORMATION CONTACT:** David Neubacher at (202) 482-5823 or Jennifer Meek at (202) 482-2778; AD/CVD Operations, Office 1, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

**SUPPLEMENTARY INFORMATION:** On November 17, 2010, the Department published an amended final determination and countervailing duty order on certain coated paper from the People's Republic of China. See *Certain Coated Paper Suitable for High-Quality Print Graphics Using Sheet-Fed Presses From the People's Republic of China: Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order*, 75 FR 70201 (November 17, 2010) ("Amended Final and CVD Order"). In the Amended Final and CVD Order, certain coated paper suitable for high-quality print graphics using sheet-fed presses was referred to as "coated paper" instead of "certain coated paper." The use of the term "coated paper" in the "Scope of the Order" section rather than "certain coated paper" could result in confusion with respect to the scope of the order as published. Therefore, we are hereby correcting the notice to include the term "certain coated paper" as it has appeared in prior **Federal Register** notices in relation to this investigation. See *Certain Coated Paper Suitable for High-Quality Print Graphics Using Sheet-Fed Presses from the People's Republic of China: Initiation of Countervailing Duty Investigation*, 74 FR 53703 (October 20, 2009); *Certain Coated Paper Suitable*

*For High-Quality Print Graphics Using Sheet-Fed Presses from the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Countervailing Duty Determination with Final Antidumping Duty Determination*, 75 FR 10774 (March 9, 2010); *Certain Coated Paper Suitable For High-Quality Print Graphics Using Sheet-Fed Presses from the People's Republic of China: Amended Affirmative Preliminary Countervailing Duty Determination*, 75 FR 30370 (June 1, 2010); and *Certain Coated Paper Suitable For High-Quality Print Graphics Using Sheet-Fed Presses from the People's Republic of China: Final Affirmative Countervailing Duty Determination*, 75 FR 59212 (September 27, 2010).

The scope of the order should read as follows:

The merchandise covered by this order includes certain coated paper and paperboard<sup>1</sup> in sheets suitable for high quality print graphics using sheet-fed presses; coated on one or both sides with kaolin (China or other clay), calcium carbonate, titanium dioxide, and/or other inorganic substances; with or without a binder; having a GE brightness level of 80 or higher;<sup>2</sup> weighing not more than 340 grams per square meter; whether gloss grade, satin grade, matte grade, dull grade, or any other grade of finish; whether or not surface-colored, surface-decorated, printed (except as described below), embossed, or perforated; and irrespective of dimensions ("Certain Coated Paper").

Certain Coated Paper includes: (a) Coated free sheet paper and paperboard that meets this scope definition; (b) coated groundwood paper and paperboard produced from bleached chemi-thermo-mechanical pulp ("BCTMP") that meets this scope definition; and (c) any other coated paper and paperboard that meets this scope definition.

Certain Coated Paper is typically (but not exclusively) used for printing multi-colored graphics for catalogues, books, magazines, envelopes, labels and wraps, greeting cards, and other commercial

<sup>1</sup> 'Paperboard' refers to Certain Coated Paper that is heavier, thicker and more rigid than coated paper which otherwise meets the product description. In the context of Certain Coated Paper, paperboard typically is referred to as 'cover,' to distinguish it from 'text.'

<sup>2</sup> One of the key measurements of any grade of paper is brightness. Generally speaking, the brighter the paper the better the contrast between the paper and the ink. Brightness is measured using a GE Reflectance Scale, which measures the reflection of light off of a grade of paper. One is the lowest reflection, or what would be given to a totally black grade, and 100 is the brightest measured grade.

printing applications requiring high quality print graphics.

Specifically excluded from the scope are imports of paper and paperboard printed with final content printed text or graphics.

As of 2009, imports of the subject merchandise are provided for under the following categories of the Harmonized Tariff Schedule of the United States ("HTSUS"): 4810.14.11, 4810.14.1900, 4810.14.2010, 4810.14.2090, 4810.14.5000, 4810.14.6000, 4810.14.70, 4810.19.1100, 4810.19.1900, 4810.19.2010, 4810.19.2090, 4810.22.1000, 4810.22.50, 4810.22.6000, 4810.22.70, 4810.29.1000, 4810.29.5000, 4810.29.6000, 4810.29.70, 4810.32, 4810.39 and 4810.92. While HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this order is dispositive.

This notice serves to correct the shortened name used to refer to certain coated paper suitable for high-quality print graphics using sheet-fed presses listed in the Amended Final and CVD Order.

We are issuing and publishing this notice in accordance with sections 705(c)(2), 705(d), 705(e), and 777(i)(1) of the Tariff Act of 1930, as amended.

Dated: November 30, 2010.

**Ronald K. Lorentzen,**

*Deputy Assistant Secretary for Import Administration.*

[FR Doc. 2010-30505 Filed 12-3-10; 8:45 am]

**BILLING CODE 3510-DS-P**

## COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

### Determination Under the Textile and Apparel Commercial Availability Provision of the Dominican Republic-Central America-United States Free Trade Agreement ("CAFTA-DR Agreement")

**AGENCY:** The Committee for the Implementation of Textile Agreements.

**ACTION:** Determination to add a product in unrestricted quantities to Annex 3.25 of the CAFTA-DR Agreement.

**DATES:** *Effective Date:* December 6, 2010.

**SUMMARY:** The Committee for the Implementation of Textile Agreements ("CITA") has determined that certain woven flannel fabric of polyester, rayon, and spandex, as specified below, is not available in commercial quantities in a timely manner in the CAFTA-DR countries. The product will be added to the list in Annex 3.25 of the CAFTA-

DR Agreement in unrestricted quantities.

**FOR FURTHER INFORMATION CONTACT:** Maria Dybczak, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482-3651.

**FOR FURTHER INFORMATION ON-LINE:** <http://web.ita.doc.gov/tacgi/CaftaReqTrack.nsf> under "Approved Requests," Reference number: 150.2010.10.27.Fabric.Alston&BirdforRothschild

### SUPPLEMENTARY INFORMATION:

**Authority:** The CAFTA-DR Agreement; Section 203(o)(4) of the Dominican Republic-Central America-United States Free Trade Agreement Implementation Act ("CAFTA-DR Implementation Act"), Public Law 109-53; the Statement of Administrative Action, accompanying the CAFTA-DR Implementation Act; and Presidential Proclamations 7987 (February 28, 2006) and 7996 (March 31, 2006).

### Background

The CAFTA-DR Agreement provides a list in Annex 3.25 for fabrics, yarns, and fibers that the Parties to the CAFTA-DR Agreement have determined are not available in commercial quantities in a timely manner in the territory of any Party. The CAFTA-DR Agreement provides that this list may be modified pursuant to Article 3.25(4)-(5), when the President of the United States determines that a fabric, yarn, or fiber is not available in commercial quantities in a timely manner in the territory of any Party. *See* Annex 3.25 of the CAFTA-DR Agreement; *see also* section 203(o)(4)(C) of the CAFTA-DR Implementation Act.

The CAFTA-DR Implementation Act requires the President to establish procedures governing the submission of a request and providing opportunity for interested entities to submit comments and supporting evidence before a commercial availability determination is made. In Presidential Proclamations 7987 and 7996, the President delegated to CITA the authority under section 203(o)(4) of CAFTA-DR Implementation Act for modifying the Annex 3.25 list. Pursuant to this authority, on September 15, 2008, CITA published modified procedures it would follow in considering requests to modify the Annex 3.25 list of products determined to be not commercially available in the territory of any Party to CAFTA-DR (Modifications to Procedures for Considering Requests Under the Commercial Availability Provision of the Dominican Republic-Central America-United States Free Trade Agreement, 73 FR 53200) ("CITA's procedures").

On October 27, 2010, the Chairman of CITA received a Request for a Commercial Availability Determination ("Request") from Alston & Bird for Rothschild for certain woven fabric of polyester, rayon, and spandex. On October 29, 2010, in accordance with CITA's procedures, CITA notified interested parties of the Request, which was posted on the dedicated Web site for CAFTA-DR Commercial Availability proceedings. In its notification, CITA advised that any Response with an Offer to Supply ("Response") must be submitted by November 10, 2010, and any Rebuttal Comments to a Response ("Rebuttal") must be submitted by November 17, 2010, in accordance with Sections 6 and 7 of CITA's procedures. No interested entity submitted a Response to the Request advising CITA of its objection to the Request and its ability to supply the subject product.

In accordance with section 203(o)(4)(C) of the CAFTA-DR Implementation Act, and Section 8(c)(2) of CITA's procedures, as no interested entity submitted a Response objecting to the Request and demonstrating its ability to supply the subject product, CITA has determined to add the specified fabric to the list in Annex 3.25 of the CAFTA-DR Agreement.

The subject product has been added to the list in Annex 3.25 of the CAFTA-DR Agreement in unrestricted quantities. A revised list has been posted on the dedicated Web site for CAFTA-DR Commercial Availability proceedings.

#### Specifications: Certain Woven Polyester/Rayon/Spandex Fabric

HTS Subheading(s): 5407.52.2060; 5407.53.2060; 5407.61.9935; 5407.61.9955; 5407.69.2060; 5407.69.4060; 5407.72.0060; 5407.73.2060; 5407.92.2010; 5407.92.2050; 5407.93.2010; 5407.93.2050; 5512.19.0005; 5512.19.0045; 5512.99.0005; 5512.99.0040; 5515.11.0005; 5515.11.0040; 5515.12.0040; 5515.19.0005; 5515.19.0040

Fiber Content: 60-90% polyester; 10-40% rayon; 0-3% spandex (yarns of filament and/or staple fiber; textured and/or non-textured).

Yarn Size(s): Various.

Thread Count (warp): 43 to 56 ends per cm.

Thread Count (weft): 29 to 38 filling pics per cm.

Weave Type: Woven twill.

Fabric Weight: 356 to 407 grams per sq. m.

Fabric Width: Greater than 30 centimeters.

Coloration: Piece dyed or yarn-dyed.

Finishing Processes: Napped on both sides.

**Janet E. Heinzen,**

*Acting Chairman, Committee for the Implementation of Textile Agreements.*

[FR Doc. 2010-30504 Filed 12-3-10; 8:45 am]

**BILLING CODE 3510-DS-P**

## COMMODITY FUTURES TRADING COMMISSION

### Agency Information Collection Activities Under OMB Review: Notice of Intent To Renew Collection 3038-0054, Establishing Procedures for Entities Operating as Exempt Markets

**AGENCY:** Commodity Futures Trading Commission.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and the expected costs and burden.

**DATES:** Comments must be submitted on or before January 5, 2011.

**FOR FURTHER INFORMATION CONTACT:** David Van Wagner, Chief Counsel, Division Of Market Oversight, U.S. Commodity Futures Trading Commission, 1155 21st Street, NW., Washington, DC 20581, (202) 418-5481; FAX: (202) 418-5527; e-mail: [dvanwagner@cftc.gov](mailto:dvanwagner@cftc.gov) and refer to OMB Control No. 3038-0054.

#### SUPPLEMENTARY INFORMATION:

**Title:** Establishing Procedures for Entities Operating as Exempt Markets, OMB Control No. 3038-0054. This is a request for extension of a currently approved information collection.

**Abstract:** Sections 2(h)(3) through (5) of the Commodity Exchange Act (Act) provides that exempt commercial markets (ECMs) are markets excluded from the Act's other requirements. The rules implement the qualifying conditions of the exemption. Rule 36.3(a) implements the notification requirements, and rule 36.3(b)(1) establishes information requirements for ECMs consistent with section 2(h)(5)(B) of the Act. An ECM may provide the Commission with access to transactions conducted on the facility or it can satisfy its reporting requirements by complying with the Commission's reporting requirements. The Act affirmatively vests the Commission with comprehensive anti-manipulation enforcement authority over these trading facilities. The Commission is charged with monitoring these markets for manipulation and enforcing the anti-manipulation provisions of the Act. The informational requirements imposed by proposed rules are designed to ensure that the Commission can effectively perform these functions. Section 5d of the Act establishes a category of market

exempt from Commission oversight referred to as "exempt boards of trade" (EBOTs). Rule 36.2 implements regulations that define those commodities that are eligible to trade on an EBOT. Rule 36.2(b) implements the notification requirements of section 5d of the Act. Rule 36.2(b)(1) requires EBOTs relying on this exemption to disclose to traders that the facility and trading on the facility is not regulated by the Commission. This requirement is necessary to make manifest the nature of the market and to avoid misleading the public.

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 the CFTC's regulations were published on December 30, 1981. See 46 FR 63035 (Dec. 30, 1981). The **Federal Register** notice with a 60-day comment period soliciting comments on this collection of information was published on August 27, 2010 (75 FR 52731).

**Burden statement:** The respondent burden for this collection is estimated to average 20 hours per response. These estimates include the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; and transmit or otherwise disclose the information.

**Respondents/Affected Entities:** 23.

**Estimated number of responses:** 23.

**Estimated total annual burden on respondents:** 230 hours.

**Frequency of collection:** Annually.

Send comments regarding the burden estimated or any other aspect of the information collection, including suggestions for reducing the burden, to the addresses listed below. Please refer to OMB Control No. 3038-0054 in any correspondence.

David P. Van Wagner, Chief Counsel, Division Of Market Oversight, U.S. Commodity Futures Trading Commission, 1155 21st Street, NW., Washington, DC 20581, and Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: Desk Officer for CFTC, 725  
17th Street, Washington, DC 20503.

**David Stawick,**

*Secretary of the Commission.*

[FR Doc. 2010-30474 Filed 12-3-10; 8:45 am]

**BILLING CODE 6351-01-P**

## DEPARTMENT OF EDUCATION

[CFDA No. 84.330B]

### Advanced Placement (AP) Test Fee Program

**AGENCY:** Office of Elementary and Secondary Education (OESE), Department of Education.

**ACTION:** Notice reopening the AP Test Fee fiscal year (FY) 2011 competition.

**SUMMARY:** On September 1, 2010, we published in the **Federal Register** (75 FR 53681) a notice inviting applications for the AP Test Fee FY 2011 competition. That notice established a November 17, 2010 deadline date for eligible applicants to apply for funding under this program. In order to afford as many eligible applicants as possible an opportunity to receive funding under this program, we are reopening the AP Test Fee FY 2011 competition to eligible applicants that did not apply for funds by the November 17, 2010 deadline. An eligible applicant that submitted its application by the November 17, 2010 deadline does not need to re-submit its application. All information in the September 1, 2010 notice remains the same for this notice reopening the competition, except for the following updates to Dates.

**DATES:** *Applications Available:* December 6, 2010.

*Deadline for Transmittal of Applications:* December 21, 2010.

**Note:** Applications for grants under this program must be submitted electronically using the Electronic Grant Application System (e-Application) accessible through the Department's e-Grants site. For information about how to submit your application electronically, please refer to Electronic Submission of Applications in the September 1, 2010 notice (75 FR 53682-53683). We encourage eligible applicants to submit their applications as soon as possible to avoid any problems with filing electronic applications on the last day.

*Deadline for Intergovernmental Review:* February 22, 2011.

**FOR FURTHER INFORMATION CONTACT:** Francisco Ramirez, U.S. Department of Education, 400 Maryland Avenue, SW., Room 3E224, Washington, DC 20202-6200. Telephone: (202) 260-1541 or by e-mail: [Francisco.Ramirez@ed.gov](mailto:Francisco.Ramirez@ed.gov).

If you use a telecommunications device for the deaf (TDD), call the

Federal Relay Service (FRS), toll free, at 1-800-877-8339. Individuals with disabilities can obtain a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or computer diskette) by contacting the program person listed in this section.

*Electronic Access to This Document:* You can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: <http://www.ed.gov/news/fedregister>. To use PDF you must have Adobe Acrobat Reader, which is available free at this site.

If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1-888-293-6498; or in the Washington, DC, area at (202) 512-1530.

**Note:** The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: <http://www.gpoaccess.gov/nara/index.html>.

*Program Authority:* 20 U.S.C. 6531-6537.

Dated: December 1, 2010.

**Thelma Meléndez de Santa Ana,**  
*Assistant Secretary for Elementary and Secondary Education.*

[FR Doc. 2010-30513 Filed 12-3-10; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF EDUCATION

### Submission for OMB Review; Comment Request

**AGENCY:** Department of Education.

**ACTION:** Correction notice.

**SUMMARY:** On November 26, 2010, the Department of Education published a 30-day public comment period notice in the **Federal Register** (Page 72818, Column 3) for the information collection, "William D. Ford Federal Direct Loan (Direct Loan) Program Federal Direct PLUS Loan Master Promissory Note and Endorser Addendum". The correct title for the information collection should be William D. Ford Federal Direct Loan (Direct Loan) Program Federal Direct Consolidation Loan Application and Promissory Note Documents. The abstract for the information collection package should read as follows: "The Federal Direct Consolidation Loan Application and Promissory Note serves as the means by which a borrower applies for a Direct Consolidation Loan

and promises to repay the loan. Related documents included with this collection are (1) Additional Loan Listing Sheet (provides additional space for a borrower to list loans that he or she wishes to consolidate, if there is insufficient space on the Application and Promissory Note); (2) Request to Add Loans (serves as the means by which a borrower may add other loans to an existing Direct Consolidation Loan within a specified time period); and (3) Loan Verification Certificate (serves as the means by which the U.S. Department of Education obtains the information needed to pay off the holders of the loans that the borrower wants to consolidate)." The Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management, hereby issues a correction notice as required by the Paperwork Reduction Act of 1995.

### FOR FURTHER INFORMATION CONTACT:

Stephanie Valentine at [stephanie.valentine@ed.gov](mailto:stephanie.valentine@ed.gov).

Dated: November 30, 2010.

**Darrin A. King,**

*Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management.*

[FR Doc. 2010-30460 Filed 12-3-10; 8:45 am]

**BILLING CODE 4000-01-P**

## DEPARTMENT OF EDUCATION

### Office of Special Education and Rehabilitative Services Overview Information; National Institute on Disability and Rehabilitation Research (NIDRR)—Disability and Rehabilitation Research Projects and Centers Program—Field Initiated (FI) Projects; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2011

Catalog of Federal Domestic Assistance (CFDA) Numbers: 84.133G-1 (Research) and 84.133G-2 (Development).

Dates:

*Applications Available:* December 6, 2010.

*Deadline for Transmittal of Applications:* February 4, 2011.

### Full Text of Announcement

#### I. Funding Opportunity Description

*Purpose of Program:* The purpose of the FI Projects program is to develop methods, procedures, and rehabilitation technology that maximize the full inclusion and integration into society, employment, independent living, family support, and economic and social self-sufficiency of individuals with disabilities, especially individuals with



the most severe disabilities. Another purpose of the FI Projects program is to improve the effectiveness of services authorized under the Rehabilitation Act of 1973, as amended.

NIDRR makes two types of awards under the FI Projects program: Research grants (CFDA 84.133G-1) and development grants (CFDA 84.133G-2).

In carrying out a research activity under an FI research grant, a grantee must identify one or more hypotheses or research questions and, based on the hypotheses or research questions identified, perform an intensive, systematic study directed toward producing (1) new scientific knowledge, or (2) better understanding of the subject, problem studied, or body of knowledge.

In carrying out a development activity under an FI project development grant, a grantee must use knowledge and understanding gained from research to create materials, devices, systems, or methods, including designing and developing prototypes and processes, that are beneficial to the target population. Target population means the group of individuals, organizations, or other entities expected to be affected by the project. There may be more than one target population because a project may affect those who receive services, provide services, or administer services.

**Note:** Different selection criteria are used for FI projects research grants (84.133G-1) and development grants (84.133G-2). Applicants must clearly indicate in the application whether they are applying for a research grant (84.133G-1) or a development grant (84.133G-2) and must address the selection criteria relevant for their grant type. Without exception, NIDRR will review each application based on the designation (*i.e.*, research (84.133G-1) or development (84.133G-2)) made by the applicant. Applications will be determined ineligible and will not be reviewed if they do not include a clear designation of research or development.

**Note:** This program is in concert with NIDRR's currently approved long range plan (the Plan). The Plan is comprehensive and integrates many issues relating to disability and rehabilitation research topics. The Plan, which was published in the **Federal Register** on February 15, 2006 (71 FR 8165), can be accessed on the Internet at the following site: <http://www.ed.gov/about/offices/list/osers/nidrr/policy.html>.

Through the implementation of the Plan, NIDRR seeks to (1) improve the quality and utility of disability and rehabilitation research; (2) foster an exchange of expertise, information, and training to facilitate the advancement of knowledge and understanding of the unique needs of individuals with

disabilities from traditionally underserved populations; (3) determine the best strategies and programs to improve rehabilitation outcomes for individuals with disabilities from underserved populations; (4) identify research gaps; (5) identify mechanisms of integrating research and practice; and (6) disseminate findings.

**Program Authority:** 29 U.S.C. 764.

**Applicable Regulations:** (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 80, 81, 82, 84, 85, 86, and 97. (b) The regulations for this program in 34 CFR part 350.

**Note:** The regulations in 34 CFR part 86 apply to institutions of higher education (IHEs) only.

## II. Award Information

**Type of Award:** Discretionary grants.

**Estimated Available Funds:** The Administration has requested \$111,919,000,000 for NIDRR for FY 2011, of which we intend to use an estimated \$4,000,000 for the FI Projects competition. The actual level of funding, if any, depends on final congressional action. However, we are inviting applications to allow enough time to complete the grant process if Congress appropriates funds for this program.

**Estimated Range of Awards:** \$195,000–\$200,000.

**Estimated Average Size of Awards:** \$200,000.

**Maximum Award:** We will reject any application that proposes a budget exceeding \$200,000 for a single budget period of 12 months. The Assistant Secretary for Special Education and Rehabilitative Services may change the maximum amount through a notice published in the **Federal Register**.

**Note:** The maximum amount includes direct and indirect costs.

**Estimated Number of Awards:** 20.

**Note:** The Department is not bound by any estimates in this notice.

**Maximum Project Period:** We will reject any application that proposes a project period exceeding 36 months. The Assistant Secretary for Special Education and Rehabilitative Services may change the maximum project period through a notice published in the **Federal Register**.

## III. Eligibility Information

1. **Eligible Applicants:** States; public or private agencies, including for-profit agencies; public or private organizations, including for-profit

organizations; IHEs; and Indian Tribes and Tribal organizations.

2. **Cost Sharing or Matching:** Cost sharing is required by 34 CFR 350.62 and will be negotiated at the time of the grant award.

## IV. Application and Submission Information

1. **Address To Request Application Package:** You can obtain an application package via the Internet or from the Education Publications Center (ED Pubs). To obtain a copy via the Internet, use the following address: <http://www.ed.gov/fund/grant/apply/grantapps/index.html>.

To obtain a copy from ED Pubs, write, fax, or call the following: ED Pubs, U.S. Department of Education, P.O. Box 22207, Alexandria, VA 22304. Telephone, toll free: 1-877-433-7827. FAX: (703) 605-6794. If you use a telecommunications device for the deaf (TDD), call, toll free: 1-877-576-7734.

You can contact ED Pubs at its Web site, also: <http://www.EDPubs.gov> or at its e-mail address: [edpubs@inet.ed.gov](mailto:edpubs@inet.ed.gov).

If you request an application from ED Pubs, be sure to identify this competition as follows: CFDA number 84.133G-1 or 84.133G-2.

Individuals with disabilities can obtain a copy of the application package in an accessible format (*e.g.*, braille, large print, audiotape, or computer diskette) by contacting the person or team listed under *Accessible Format* in section VIII of this notice.

2. **Content and Form of Application Submission:** Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition.

**Page Limit:** The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you limit Part III to the equivalent of no more than 50 pages, using the following standards:

- A "page" is 8.5" x 11", on one side only, with 1" margins at the top, bottom, and both sides.

- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.

- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).

- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.



The recommended page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, the page limit does apply to all of the application narrative section [Part III].

The application package will provide instructions for completing all components to be included in the application. Each application must include a cover sheet (Standard Form 424); budget requirements (ED Form 524) and narrative justification; other required forms; an abstract, Human Subjects narrative, Part III narrative; resumes of staff; and other related materials, if applicable.

Applicants should consult NIDRR's Long-Range Plan when preparing their applications. The Plan is organized around the following research domains and arenas: (1) Community Living and Participation; (2) Health and Function; (3) Technology; (4) Employment; and (5) Demographics. Applicants should indicate, for each application, the domain or arena under which they are applying. In their applications, applicants should clearly indicate whether they are applying for a research grant in the area of (1) Community Living and Participation; (2) Health and Function; (3) Technology; (4) Employment; or (5) Demographics.

### 3. Submission Dates and Times:

*Applications Available:* December 6, 2010.

*Deadline for Transmittal of Applications:* February 4, 2011.

Applications for grants under this competition must be submitted electronically using the Grants.gov Apply site (Grants.gov). For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to section IV.7. *Other Submission Requirements* of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under For Further Information Contact in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other

requirements and limitations in this notice.

4. *Intergovernmental Review:* This program is not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and Central Contractor Registry:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the Central Contractor Registry (CCR), the Government's primary registrant database;

c. Provide your DUNS number on your application; and

d. Maintain an active CRR registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from DUN and Bradstreet. A DUNS number can be created within one business day.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow 2–5 weeks for your TIN to become active.

The CCR registration process may take five or more business days to complete. If you are currently registered with the CCR, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your CCR registration on an annual basis. This may take three or more business days to complete.

In addition, if you are submitting your application via Grants.gov, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with Grants.gov as an AOR. Details on these steps are outlined in the Grants.gov 3–Step Registration Guide (*see <http://www.grants.gov/section910/Grants.govRegistrationBrochure.pdf>*).

7. *Other Submission Requirements:* Applications for grants under this competition must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

### a. *Electronic Submission of Applications.*

Applications for grants under the Field Initiated Projects program, CFDA Number 84.133G–1 (Research) or 84.133G–2 (Development), must be submitted electronically using the Governmentwide Grants.gov Apply site at <http://www.Grants.gov>. Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not e-mail an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement and submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement*.

You may access the electronic grant application for the Field Initiated Projects program—CFDA Number 84.133G–1 (Research) or 84.133G–2 (Development)—at <http://www.Grants.gov>. You must search for the downloadable application package for this competition by the CFDA number. Do not include the CFDA number's alpha suffix in your search (*e.g.*, search for 84.133, not 84.133G).

Please note the following:

- When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.

- Applications received by Grants.gov are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the Grants.gov system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the Grants.gov system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from Grants.gov, we will notify you if we are rejecting your application because it was date and time stamped by the Grants.gov system after 4:30:00 p.m., Washington, DC time, on the application deadline date.

- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.

- You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this competition to ensure that you submit your application in a timely manner to the Grants.gov system. You can also find the Education Submission Procedures pertaining to Grants.gov under News and Events on the Department's G5 system homepage at <http://www.G5.gov>.

- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.

- You must submit all documents electronically, including all information you typically provide on the following forms: Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.

- You must attach any narrative sections of your application as files in a .PDF (Portable Document) format only. If you upload a file type other than a .PDF file or submit a password-protected file, we will not review that material.

- Your electronic application must comply with any page-limit requirements described in this notice.

- After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. (This notification indicates receipt by Grants.gov only, not receipt by the Department.) The Department then will retrieve your application from Grants.gov and send a second notification to you by e-mail. This second notification indicates that the Department has received your application and has assigned your application a PR/Award number (an ED-specified identifying number unique to your application).

- We may request that you provide us original signatures on forms at a later date.

*Application Deadline Date Extension in Case of Technical Issues With the*

*Grants.gov System:* If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1-800-518-4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under For Further Information Contact in section VII of this notice and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that that problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. The Department will contact you after a determination is made on whether your application will be accepted.

**Note:** The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

*Exception to Electronic Submission Requirement:* You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the Grants.gov system because—

- You do not have access to the Internet; or
- You do not have the capacity to upload large documents to the Grants.gov system; and
- No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining

which of the two grounds for an exception prevent you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Lynn Medley, U.S. Department of Education, 400 Maryland Avenue, SW., Room 5140, Potomac Center Plaza (PCP), Washington, DC 20202-2700. FAX: (202) 245-7323.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

*b. Submission of Paper Applications by Mail.*

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center.

Attention: Applicants must identify either CFDA Number 84.133G-1 (Research) or 84.133G-2 (Development) depending on the designation of their proposed project. LBJ Basement Level 1, 400 Maryland Avenue, SW., Washington, DC 20202-4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

**Note:** The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

*c. Submission of Paper Applications by Hand Delivery.*

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center. Attention: Applicants must identify either CFDA Number 84.133G-1 (Research) or 84.133G-2 (Development) depending on the designation of their proposed project. 550 12th Street, SW., Room 7041, Potomac Center Plaza, Washington, DC 20202-4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

**Note for Mail or Hand Delivery of Paper Applications:** If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245-6288.

## V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 350.54 and 350.55 and are listed in the application package.

**Note:** There are two different sets of selection criteria for FI projects: One set to evaluate applications proposing to carry out research activities (CFDA 84.133G-1), and a second set to evaluate applications proposing to carry out development activities (CFDA 84.133G-2). Each applicant will be evaluated using the selection criteria for the type of project the applicant designates in its application.

2. *Review and Selection Process:* Additional factors we consider in selecting an application for an award are as follows:

The Secretary is interested in outcomes-oriented research or development projects that use rigorous scientific methodologies. To address this interest, applicants are encouraged to articulate goals, objectives, and expected outcomes for the proposed research or development activities. Proposals should describe how results and planned outputs are expected to contribute to advances in knowledge,

improvements in policy and practice, and public benefits for individuals with disabilities. Applicants should propose projects that are designed to be consistent with these goals. We encourage applicants to include in their applications a description of how results will measure progress towards achievement of anticipated outcomes (including a discussion of measures of effectiveness), the mechanisms that will be used to evaluate outcomes associated with specific problems or issues, and how the proposed activities will support new intervention approaches and strategies. Submission of the information identified in this section is voluntary, except where required by the selection criteria listed in the application package.

We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary also requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Special Conditions:* Under 34 CFR 74.14 and 80.12, the Secretary may impose special conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 34 CFR parts 74 or 80, as applicable; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

## VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN). We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other

requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to <http://www.ed.gov/fund/grant/apply/appforms/appforms.html>.

**Note:** NIDRR will provide information by letter to grantees on how and when to submit the performance report.

4. *Performance Measures:* NIDRR assesses the quality of its funded projects through review of grantee performance and products. Each year, NIDRR examines a portion of its grantees to determine:

- The percentage of newly awarded NIDRR projects that are multi-site, collaborative, controlled studies of interventions and programs.
- The number of accomplishments (e.g., new or improved tools, methods, discoveries, standards, interventions, programs, or devices) developed or tested with NIDRR funding that have been judged by expert panels to be of high quality and to advance the field.
- The average number of publications per award based on NIDRR-funded research and development activities in refereed journals.
- The percentage of new grants that include studies funded by NIDRR that assess the effectiveness of interventions, programs, and devices using rigorous and appropriate methods.

Each grantee must annually report on its performance through NIDRR's Annual Performance Report (APR) form. NIDRR uses APR information submitted

by grantees to assess progress on these measures.

5. *Continuation Awards*: In making a continuation award, the Secretary may consider, under 34 CFR 75.253, the extent to which a grantee has made "substantial progress toward meeting the objectives in its approved application." This consideration includes the review of a grantee's progress in meeting the targets and projected outcomes in its approved application, and whether the grantee has expended funds in a manner that is consistent with its approved application and budget. In making a continuation grant, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

## VII. Agency Contact

### FOR FURTHER INFORMATION CONTACT:

Either Lynn Medley or Marlene Spencer as follows: Lynn Medley, U.S. Department of Education, 400 Maryland Avenue, SW., Room 5140, PCP, Washington, DC 20202-2700. Telephone: (202) 245-7338 or by e-mail: [Lynn.Medley@ed.gov](mailto:Lynn.Medley@ed.gov). Marlene Spencer, U.S. Department of Education, 400 Maryland Avenue, SW., Room 5133, PCP, Washington, DC 20202-2700. Telephone: (202) 245-7532 or by e-mail: [Marlene.Spencer@ed.gov](mailto:Marlene.Spencer@ed.gov).

If you use a TDD, call the Federal Relay Service (FRS), toll free, at 1-800-877-8339.

## VIII. Other Information

*Accessible Format*: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (e.g., braille, large print, audiotope, or computer diskette) by contacting the Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue, SW., Room 5075, PCP, Washington, DC 20202-2550. Telephone: (202) 245-7363. If you use a TDD, call the FRS, toll free, at 1-800-877-8339.

*Electronic Access to This Document*: You can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: <http://www.ed.gov/news/fedregister>. To use PDF you must have Adobe Acrobat Reader, which is available free at this site.

**Note**: The official version of this document is the document published in the **Federal**

**Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: <http://www.gpoaccess.gov/nara/index.html>.

Dated: December 1, 2010.

**Alexa Posny**,

*Assistant Secretary for Special Education and Rehabilitative Services.*

[FR Doc. 2010-30515 Filed 12-3-10; 8:45 am]

**BILLING CODE 4000-01-P**

## DEPARTMENT OF EDUCATION

### Regional Advisory Committees

**AGENCY**: U.S. Department of Education, Office of Elementary and Secondary Education.

**ACTION**: Notice of establishment of 10 Regional Advisory Committees.

**SUMMARY**: The U.S. Secretary of Education (Secretary) announces the establishment of ten Regional Advisory Committees (RACs). The Federal Advisory Committee Act (FACA) (Pub. L. 92-463, as amended; 5 U.S.C., Appendix) shall govern the RACs.

### Purpose

The Secretary is establishing the RACS in order to collect information on the educational needs of each of the ten regions served by the Regional Educational Laboratories. The RACs will seek input regarding the need for the technical assistance activities described in section 203 of the Educational Technical Assistance Act and how those needs would be most effectively addressed. In order to achieve this purpose, the RACs will seek input from chief executive officers of States; chief State school officers; educators, including teachers and administrators; local educational agencies; librarians; businesses; State educational agencies; parents; and other customers within each region.

Not later than six months after each RAC is convened, the committee will submit a report based on this needs assessment to the Secretary. Each report will identify the educational needs of the region and how those needs would be most effectively addressed. The Secretary will establish priorities for the comprehensive centers to address, taking into account these regional assessments and other relevant regional surveys of educational needs, to the extent the Secretary deems appropriate.

**FOR FURTHER INFORMATION CONTACT**: U.S. Department of Education, White House Liaison Office, Washington, DC 20202, telephone: (202) 401-3677.

The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: <http://www.gpoaccess.gov/nara/index.html>.

Dated: November 29, 2010.

**Arne Duncan**,

*Secretary of Education.*

[FR Doc. 2010-30477 Filed 12-3-10; 8:45 am]

**BILLING CODE 4000-01-P**

## DEPARTMENT OF EDUCATION

### Regional Advisory Committees

**AGENCY**: U.S. Department of Education, Office of Elementary and Secondary Education.

**ACTION**: Request for nominations to serve on the Regional Advisory Committees.

**SUMMARY**: The Secretary of Education (Secretary) invites interested parties to submit nominations for individuals to serve on the Regional Advisory Committees.

**SUPPLEMENTARY INFORMATION**: The Regional Advisory Committees (RACs) will be established by the Secretary and governed by the provisions of the Federal Advisory Committee Act (FACA) (Pub. L. 92-463, as amended; 5 U.S.C., Appendix). The Secretary is establishing ten RACs, one in each region served by the Regional Educational Laboratories, in order to collect information on the educational needs of each region. The RACs will seek input regarding the need for the technical assistance activities described in section 203 of the Educational Technical Assistance Act (ETAA) and how those needs would be most effectively addressed. In order to achieve this purpose, the RACs will seek input from chief executive officers of States; chief State school officers; educators, including teachers and administrators; local educational agencies; librarians; businesses; State educational agencies; parents; and other customers. Not later than six months after each RAC is convened, it will submit a report to the Secretary. Each report will identify the educational needs of the region and how those needs would be most effectively addressed. To the extent that he deems appropriate, the Secretary will consider these reports, and other relevant regional surveys of educational needs, in establishing priorities for the comprehensive centers.

Section 206(b) of the ETAA requires that the membership of each RAC contain a balanced representation of States in the region and include not more than one representative of each State educational agency located in the region. The membership of each RAC may include the following: Representatives of local educational agencies, both rural and urban; representatives of institutions of higher education, including those that represent university-based research on education and on subjects other than education; parents; practicing educators, including classroom teachers, principals, administrators, school board members, and other local school officials; representatives of business; and researchers. Each RAC will be composed of approximately 12 members.

#### Nomination Process

Any interested person or organization may nominate one or more qualified individuals for membership. If you would like to nominate an individual or yourself for appointment to one of the RACs, please submit the following information to the Department's White House Liaison Office:

- A copy of the nominee's resume;
- A cover letter that provides the reason(s) for nominating the individual;
- Contact information for the nominee (name, title, home and business address, phone number, fax number, and e-mail address); and
- Specify the groups the nominee may qualify to represent from the following categories (list all that apply):
  - State educational agency.
  - Local educational agency (LEA).
    - Rural LEA.
    - Urban LEA.
  - Practicing educator.
    - Classroom teacher.
    - School principal.
    - Other school administrator.
    - School board member.
    - Other local school official.
  - Parent.
  - Institution of higher education.
    - University-based education research.
    - University-based research on subjects other than education.
  - Business.
  - Researchers.

In addition, the cover letter must state that the nominee (if you are nominating someone other than yourself) has agreed to be nominated and is willing to serve on one of the RACs. Nominees will be appointed based on technical qualifications, professional experience, demonstrated knowledge of issues, and

demonstrated experience, integrity, impartiality, and good judgment.

The Secretary will appoint members for the life of the Committee, which will span approximately five months. The committee will meet approximately five times during this period. Any member appointed to fill a vacancy occurring prior to the expiration of the full term for which the member's predecessor was appointed will be appointed for the remainder of such term. Members will serve without compensation. However, members may receive reimbursement for travel expenses for attending Committee meetings, including *per diem* in lieu of subsistence, as authorized by the Federal travel regulations.

Each RAC will be composed of both representatives of organizations or recognizable groups of persons and Special Government Employees (SGEs). SGE members will be chosen for their individual expertise, qualifications, and experience; they will provide advice and make recommendations based on their independent judgment and will not be speaking for or representing the views of any nongovernmental organization or recognizable group of persons.

**DATES:** Nominations for individuals to serve on the RACs must be submitted (postmarked, if sending by mail; submitted electronically; or received, if hand delivered) by January 5, 2011.

**ADDRESSES:** You may submit nominations, including attachments, by any of the following methods:

- *Electronically:* Send to: [WhiteHouseLiaison@ed.gov](mailto:WhiteHouseLiaison@ed.gov) (specify in the e-mail subject line, "Regional Advisory Committee Nomination").

- *Mail, express delivery, hand delivery, messenger, or courier service:* Submit *one* copy of the documents listed above to the following address: U.S. Department of Education, White House Liaison Office, 400 Maryland Avenue, SW., Room 7C109, Washington, DC 20202, Attn: Karen Akins. Express mail or hand delivery is encouraged to ensure timely receipt of materials.

For questions, contact Karen Akins, White House Liaison Office, at (202) 401-3677, at (202) 205-0723 (fax), or via e-mail at [WhiteHouseLiaison@ed.gov](mailto:WhiteHouseLiaison@ed.gov).

Dated: November 29, 2010.

**Arne Duncan,**  
*Secretary of Education.*

[FR Doc. 2010-30475 Filed 12-3-10; 8:45 am]

**BILLING CODE P**

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-9235-1]

### Proposed Settlement Agreement, Clean Air Act Citizen Suit

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of Proposed Settlement Agreement; 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 settlement agreement to address a lawsuit filed by the Louisiana Environmental Action Network in the United States District Court for the District of Columbia: *Louisiana Environmental Action Network v. Jackson*, No. 1:09-0133 (D. D.C.). On February 17, 2010, Plaintiff filed an amended complaint alleging that EPA failed to perform nondiscretionary duties under the Clean Air Act related to the attainment of National Ambient Air Quality Standards (NAAQS) for ozone in the Baton Rouge area. Specifically, they alleged that EPA failed to promulgate a Federal Implementation Plan to adopt regulations for the Baton Rouge area necessary to implement CAA requirements for ozone nonattainment areas that have been designated as "severe" nonattainment areas for the 1-hour ozone standard. The proposed settlement agreement establishes deadlines for EPA to take action on certain requirements related to the 1-hour and 1997 8-hour ozone standards.

**DATES:** Written comments on the proposed settlement agreements must be received by *January 5, 2011*.

**ADDRESSES:** Submit your comments, identified by Docket ID number EPA-HQ-OGC-2010-0971, online at <http://www.regulations.gov> (EPA's preferred method); by e-mail to [oei.docket@epa.gov](mailto: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:** Jan Tierney, Air and Radiation Law Office (2344A), Office of General Counsel, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone: (202) 564-5598; fax number (202) 564-5603; e-mail address: [tierney.jan@epa.gov](mailto:tierney.jan@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Additional Information About the Proposed Settlement Agreement**

The proposed settlement agreement would resolve a lawsuit seeking to compel the Agency to promulgate a Federal implementation plan addressing certain elements of a severe area 1-hour ozone SIP for Baton Rouge. In 2003, EPA reclassified the Baton Rouge area as a severe 1-hour ozone nonattainment area and established a schedule for Louisiana to submit SIP revisions to address the CAA's pollution control requirements for severe ozone nonattainment areas. The LDEQ submitted to EPA for approval certain SIP revisions relevant to severe 1-hour requirements for major sources in the Baton Rouge area, which included: (1) A June 15, 2005 submittal titled "Severe Area Rule Update," (2) a December 20, 2005, submittal titled "New Source Review State Implementation Plan," and (3) a November 9, 2007, submittal titled "General Rule Update."

Under the proposed settlement agreement, if by February 28, 2012, EPA has not taken final action redesignating the Baton Rouge area to attainment for the 1997 8-hour ozone NAAQS, EPA will sign a notice to be published in the **Federal Register**, proposing action on (1) LDEQ's June 15, 2005 submittal titled "Severe Area Rule Update," (2) LDEQ's December 20, 2005, submittal titled "New Source Review State Implementation Plan," and (3) LDEQ's November 9, 2007, submittal titled "General Rule Update." The proposed settlement also states that if by September 30, 2012, EPA has not taken final action redesignating the Baton Rouge area to attainment for the 1997 8-hour ozone NAAQS, EPA will sign a notice to be published in the **Federal Register**, taking final action on the three SIP submissions identified above. If EPA fulfills its obligations, the Parties shall jointly file with the Court in *LEAN v. Jackson* (civil action no. 1:09-01333) a motion pursuant to Fed. R. Civ. P. 41(a) to dismiss the case.

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 settlement agreements 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 settlement agreements 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 that consent to these settlement agreements should be withdrawn, the terms of the agreements will be affirmed.

**II. Additional Information About Commenting on the Proposed Settlement Agreements**

*A. How can I get a copy of the settlement agreements?*

The official public docket for this action (identified by Docket ID No. EPA-HQ-OGC-2010-0971) contains copies of the proposed settlement agreements. 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: November 29, 2010.

**Richard B. Ossias,**  
*Associate General Counsel.*

[FR Doc. 2010-30492 Filed 12-3-10; 8:45 am]

**BILLING CODE 6560-50-P**

**ENVIRONMENTAL PROTECTION AGENCY**

[ER-FRL-8993-9]

**Environmental Impacts Statements; Notice of Availability**

*Responsible Agency:* Office of Federal Activities, General Information (202) 564-1399 or <http://www.epa.gov/compliance/nepa/>.

Weekly receipt of Environmental Impact Statements.

Filed 11/22/2010 through 11/26/2010. Pursuant to 40 CFR 1506.9.

**Notice**

In accordance with Section 309(a) of the Clean Air Act, EPA is required to make its comments on EISs issued by other Federal agencies public. Historically, EPA has met this mandate by publishing weekly notices of availability of EPA comments, which includes a brief summary of EPA's comment letters, in the **Federal Register**. Since February 2008, EPA has been including its comment letters on EISs on its Web site at: <http://www.epa.gov/compliance/nepa/eisdata.html>. Including the entire EIS comment letters on the Web site satisfies the Section 309(a) requirement to make EPA's comments on EISs available to the public. Accordingly, on March 31, 2010, EPA discontinued the publication of the notice of availability of EPA comments in the **Federal Register**.

*EIS No. 20100455, Final EIS, BLM, NV, ON Line Project, (Previously Known as Ely Energy Center) Proposed 236-mile long 500 kV Electric Transmission Line from a new substation near Ely, Nevada approximately 236 mile south to the existing Harry Allen substation near Las Vegas, Clark, Lincoln, Nye and White Pine Counties, NV, Wait Period Ends: 01/03/2011, Contact: Michael Dwyer 775-293-0523.*

*EIS No. 20100456, Draft EIS, FTA, OR, Lake Oswego to Portland Transit Project, To Improve Transit Service with the Lake Oswego to Portland Transit Corridor, Clackamas and Multnomah Counties, OR, Comment Period Ends: 01/31/2011, Contact: John Witmer 206-220-7950.*

*EIS No. 20100457, Final EIS, NPS, FL, Big Cypress National Preserve Addition, General Management Plan/Wilderness Study/Off-Road Vehicle Management Plan, Implementation, Collier County, FL, Wait Period Ends: 01/03/2011, Contact: Pedro Ramos 239-695-1101.*

Dated: November 30, 2010.

**Robert W. Hargrove,**  
*Director, NEPA Compliance Division, Office of Federal Activities.*

[FR Doc. 2010-30415 Filed 12-3-10; 8:45 am]

BILLING CODE 6560-50-P

**FARM CREDIT ADMINISTRATION****Farm Credit Administration Board; Sunshine Act; Regular Meeting**

**AGENCY:** Farm Credit Administration.

**SUMMARY:** Notice is hereby given, pursuant to the Government in the Sunshine Act (5 U.S.C. 552b(e)(3)), of the regular meeting of the Farm Credit Administration Board (Board).

**DATE AND TIME:** The regular meeting of the Board will be held at the offices of the Farm Credit Administration in McLean, Virginia, on December 9, 2010, from 9 a.m. until such time as the Board concludes its business.

**FOR FURTHER INFORMATION CONTACT:** Roland E. Smith, Secretary to the Farm Credit Administration Board, (703) 883-4009, TTY (703) 883-4056.

**ADDRESSES:** Farm Credit Administration, 1501 Farm Credit Drive, McLean, Virginia 22102-5090.

**SUPPLEMENTARY INFORMATION:** Parts of this meeting of the Board will be open to the public (limited space available), and parts will be closed to the public. In order to increase the accessibility to Board meetings, persons requiring assistance should make arrangements in advance. The matters to be considered at the meeting are:

**Open Session***A. Approval of Minutes*

- November 10, 2010.

*B. New Business*

- Proposed Bookletter—Farm Credit System Investment Asset Management.

*C. Reports*

- Farmland Values and Collateral Risk Guidance.

**Closed Session\*****Reports**

- Office of Secondary Market Oversight Quarterly Report.

\*Session Closed-Exempt pursuant to 5 U.S.C. 552b(c)(8) and (9).

Dated: December 2, 2010.

**Roland E. Smith,**  
*Secretary, Farm Credit Administration Board.*

[FR Doc. 2010-30634 Filed 12-2-10; 4:15 pm]

BILLING CODE 6705-01-P

**FEDERAL DEPOSIT INSURANCE CORPORATION****Agency Information Collection Activities; Proposed Collection Renewals; Comment Request**

**AGENCY:** Federal Deposit Insurance Corporation (FDIC).

**ACTION:** Notice and request for comment.

**SUMMARY:** In accordance with requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the FDIC may not conduct or sponsor, and the respondent is not required to respond to an information collection unless it displays a currently valid Office of Management and Budget control number. The FDIC hereby gives notice that it is seeking public comment on renewal of three information collections.

**DATES:** Comments must be submitted on or before February 4, 2011.

**ADDRESSES:** Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- <http://www.FDIC.gov/regulations/laws/federal/notices.html>.
- E-mail: [comments@fdic.gov](mailto:comments@fdic.gov).

Include the name of the collection in the subject line of the message.

- *Mail:* Leneta G. Gregorie (202-898-3719), Counsel, Room F-1084, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.

- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street Building (located on F Street), on business days between 7 a.m. and 5 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB Desk Officer for the FDIC, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

**FOR FURTHER INFORMATION CONTACT:** Leneta G. Gregorie, at the FDIC address above.

**SUPPLEMENTARY INFORMATION:** Proposal to renew the following currently approved collections of information:

1. *Title:* Application for Waiver of Publication on Acceptance of Brokered Deposits for Adequately Capitalized Insured Institutions.

*OMB Number:* 3064-0099.

*Frequency of Response:* On occasion.

*Affected Public:* Any insured depository institution seeking a waiver to the prohibition on the acceptance of brokered deposits.

*Estimated Number of Respondents:* 30.



*Estimated Time per Response:* 6 hours.

*Total Annual Burden:* 180 hours.

*General Description of Collection:* Section 29 of the FDI Act prohibits undercapitalized insured depository institutions from accepting, renewing, or rolling over any brokered deposits. Adequately capitalized institutions may do so with a waiver from the FDIC, while well-capitalized institutions may accept, renew, or roll over brokered deposits without restriction.

2. *Title:* Management Official Interlocks.

*OMB Number:* 3064–0118.

*Frequency of Response:* On occasion.

*Affected Public:* Insured State nonmember banks.

*Estimated Number of Respondents:* 7.  
*Estimated Time per Response:* 4 hours.

*Total Annual Burden:* 28 hours.

*General Description of Collection:* This collection is associated with the FDIC's Management Official Interlocks regulation, 12 CFR Part 348, which implements the Depository Institution Management Interlocks Act (DIMIA). DIMIA generally prohibits bank management officials from serving simultaneously with two unaffiliated depository institutions or their holding companies but allows the FDIC to grant exemptions on request in appropriate circumstances.

3. *Title:* Foreign Branching and Investment by Insured State Nonmember Banks.

*OMB Number:* 3064–0125.

*Frequency of Response:* On occasion.

*Affected Public:* Insured state nonmember banks.

*Estimated Number of Respondents:* Recordkeeping: 50; reporting: 11.

*Estimated Time per Response:* Recordkeeping: 400 hours; reporting: 27 hours.

*Total Annual Burden:* 20,298 hours.

*General Description of Collection:* The Federal Deposit Insurance (FDI) Act requires state nonmember banks to obtain FDIC consent to establish or operate a branch in a foreign country, or to acquire and hold, directly or indirectly, stock or other evidence of ownership in any foreign bank or other entity. The FDI Act also authorizes the FDIC to impose conditions for such consent and to issue regulations related thereto. This collection is a direct consequence of those statutory requirements.

4. *Title:* Affiliate Marketing Disclosures/Consumer Opt-Out Notices.

*OMB Number:* 3064–0149.

*Frequency of Response:* On occasion.

*Affected Public:* Insured state nonmember banks.

*Number of Respondents:* 978 financial institutions and 198,450 consumers.

*Estimated Time per Response:* 18 hours: prepare and distribute notice to consumers and employee training; 5 minutes: consumer response to opt-out notice.

*Total Estimated Annual Burden:* 34,142 hours.

*General Description of Collection:* Section 624 of the Fair Credit Reporting Act generally provides that, if a person shares certain information about a consumer with an affiliate, the affiliate may not use that information to make or send solicitations to the consumer about its products or services, unless the consumer is given notice and a reasonable opportunity to opt-out of such use of the information and the consumer does not opt-out. The information collections for which the Agencies seek OMB approval are (1) Notices to consumers of the opportunity to opt-out of solicitations from affiliates, and (2) consumer responses to the opt-out notices.

*Request for Comment:*

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, 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 information collection on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Dated at Washington, DC, this 1st day of December 2010.

Federal Deposit Insurance Corporation.

**Robert E. Feldman,**

*Executive Secretary.*

[FR Doc. 2010–30508 Filed 12–3–10; 8:45 am]

**BILLING CODE 6741–01–P**

## FEDERAL DEPOSIT INSURANCE CORPORATION

### Agency Information Collection Activities: Proposed Collection Renewals; Comment Request

**AGENCY:** Federal Deposit Insurance Corporation (FDIC).

**ACTION:** Notice and request for comment.

**SUMMARY:** In accordance with requirements of the Paperwork Reduction Act of 1995 (44 U.S.C.

chapter 35), the FDIC may not conduct or sponsor, and the respondent is not required to respond to an information collection unless it displays a currently valid Office of Management and Budget control number. The FDIC hereby gives notice that it is seeking public comment on renewal of four information collections described below.

**DATES:** Comments must be submitted on or before February 4, 2011.

**ADDRESSES:** Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- <http://www.FDIC.gov/regulations/laws/federal/notices.html>.

- *E-mail:* [comments@fdic.gov](mailto:comments@fdic.gov).

Include the name of the collection in the subject line of the message.

- *Mail:* Leneta G. Gregorie (202–898–3719), Counsel, Room F–1084, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.

- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street Building (located on F Street), on business days between 7 a.m. and 5 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

**FOR FURTHER INFORMATION CONTACT:** Leneta Gregorie, at the FDIC address above.

**SUPPLEMENTARY INFORMATION:** *Proposal to renew the following currently approved collections of information:*

1. *Title:* Procedures for Monitoring Bank Secrecy Act Compliance.

*OMB Number:* 3064–0087.

*Frequency of Response:* On occasion.

*Affected Public:* Insured state nonmember banks.

*Estimated Number of Respondents:* 4,822.

*Estimated Time per Response:* 67.5 hours.

*Total Annual Burden:* 325,620 hours.

*General Description of Collection:* Respondents must establish and maintain procedures designed to assure and monitor their compliance with the requirements of the Bank Secrecy Act and the implementing regulations promulgated by the Department of Treasury at 31 CFR part 103. Respondents must also provide training for appropriate personnel.

2. *Title:* Interagency Biographical and Financial Report.

*OMB Number:* 3064–0006.



*Affected Public:* Individuals or households; businesses or others for profit.

*Estimated Number of Respondents:* 1,769.

*Frequency of Response:* On occasion.

*Estimated Annual Burden Hours per Response:* 4.

*Estimated Total Annual Burden Hours:* 7,076.

3. *Title:* Interagency Bank Merger Act Application.

*OMB Number:* 3064–0015.

*Affected Public:* Individuals or households; businesses or others for profit.

*Estimated Number of Respondents:* 275.

*Frequency of Response:* On occasion.

*Estimated Annual Burden Hours per Response:* 23.5.

*Estimated Total Annual Burden Hours:* 6,463.

4. *Title:* Interagency Notice of Change in Control.

*OMB Number:* 3064–0019.

*Affected Public:* Individuals or households; businesses or others for profit.

*Estimated Number of Respondents:* 27.

*Frequency of Response:* On occasion.

*Estimated Annual Burden Hours per Response:* 30.

*Estimated Total Annual Burden Hours:* 810.

#### Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, 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 information collection on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Dated at Washington, DC, this 1st day of December 2010.

Federal Deposit Insurance Corporation.

**Robert E. Feldman,**

*Executive Secretary.*

[FR Doc. 2010–30509 Filed 12–3–10; 8:45 am]

**BILLING CODE 6741–01–P**

#### FEDERAL ELECTION COMMISSION

##### Sunshine Act Notices

**AGENCY:** Federal Election Commission.

**DATE AND TIME:** Thursday, December 2, 2010, at 10 a.m.

**PLACE:** 999 E Street, NW., Washington, DC (Ninth Floor).

**STATUS:** This meeting will be open to the public.

#### ITEMS TO BE DISCUSSED:

Proposed Final Audit Report on Biden for President, Inc.

Proposed Final Audit Report on the Washington State Democratic Central Committee.

Proposed Final Audit Report on the Tennessee Republican Party Federal Election Account.

Proposed Final Audit Report on the Tennessee Democratic Party.

Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Shawn Woodhead Werth, Commission Secretary and Clerk, 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. 2010–30413 Filed 12–3–10; 8:45 am]

**BILLING CODE 6715–01–M**

#### FEDERAL MARITIME COMMISSION

[Docket No. 10–11]

##### Smart Garments v. Worldlink Logix Services, Inc.; Notice of Filing of Complaint and Assignment

Notice is given that a complaint has been filed with the Federal Maritime Commission (“Commission”) by Smart Garments (“SG”), hereinafter “Complainant,” against WORLDLINK LOGIX SERVICE, INC. (“WLLS”). Complainant asserts that it is a “registered partnership firm duly under Indian Law” and a manufacturer and exporter of garments. Complainant alleges that Respondent WLLS is a “freight forwarder/common carrier” incorporated in New York and licensed by the Commission.

Complainant states that it engaged Respondent as “a shipping agency” to ship two containers from Chennai, India to New York and that the cargo was delivered. Complainant alleges that such deliveries “were to be made by WLLS to the buyer, only after surrender of the original Bill of Lading.” Complainant further alleges that the “consignments were wrongfully delivered to the buyer [by WLLS], without receiving the endorsed Bill of

Lading \* \* \*.” Complainant asserts that “the shipment is still unpaid.”

Complainant alleges that Respondents violated the Shipping Act of 1984 by: (1) Giving information about the shipment without the consent of the shipper; and (2) “releasing the goods without original Bill of Lading with malafide intention to cheat and defraud”; and by doing so knowingly disclosed information about the shipment without consent of the shipper and to its detriment and failed to observe and enforce just and reasonable practices relating to or connected with the receiving, handling, sorting or delivering property in violation of Sections 10(b)(13) and 10(d)(1) of the Shipping Act, 46 U.S.C. 41103(a) and 41102(c). Complainant asserts that as a result of the unpaid shipment, it is “losing goodwill, business opportunities and loss of further orders from our prospective customers and bankers.”

Complainant seeks reparations for its lost payment, “interest on investments for past 8 [m]onths”, “[d]amages toward loss of [b]usiness, [g]oodwill and [o]pportunities”, and “[c]ompensation for mental agony.” Complainant asks the Commission to order reparations in the amount of \$84,594, and to impose any other relief as the Commission determines to be proper, fair, and just.

This proceeding has been assigned to the Office of Administrative Law Judges. Hearing in this matter, if any is held, shall commence within the time limitations prescribed in 46 CFR 502.61, and only after consideration has been given by the parties and the presiding officer to the use of alternative forms of dispute resolution. The hearing shall include oral testimony and cross-examination in the discretion of the presiding officer only upon proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record. Pursuant to the further terms of 46 CFR 502.61, the initial decision of the presiding officer in this proceeding shall be issued by November 30, 2011 and the final decision of the Commission shall be issued by March 29, 2012.

**Karen V. Gregory,**

*Secretary.*

[FR Doc. 2010–30436 Filed 12–3–10; 8:45 am]

**BILLING CODE P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

[Document Identifier: OS-0990-New; 30-day notice]

**Agency Information Collection Request. 30-Day Public Comment Request**

**AGENCY:** Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request,

including your address, phone number, OMB number, and OS document identifier, to [Sherrette.funncoleman@hhs.gov](mailto:Sherrette.funncoleman@hhs.gov), or call the Reports Clearance Office on (202) 690-5683. Send written comments and recommendations for the proposed information collections within 30 days of this notice directly to the OS OMB Desk Officer; faxed to OMB at 202-395-5806.

**Proposed Project:** Prevention and Wellness-Leveraging National Organizations- OMB No. 0990-New-Office of Public Health and Science.

**Abstract:** The Office of Public Health and Science is requesting an approval by OMB on a new collection. The American Recovery and Reinvestment Act (ARRA) Prevention and Wellness-Leveraging National Organizations is a cooperative agreement program authorized under 42 U.S.C. 300k-1, 300, section 1701 of the Public Health Service Act, as amended. The funding opportunity focuses on two categories of activities:

- Category A: Obesity prevention through improved nutrition and increased physical activity
- Category B: Tobacco prevention and control

The National Organizations who receive funding will be supporting Communities Putting Prevention to Work (CPPW)-funded communities by providing expertise and technical

assistance to help implement select MAPPs (Media, Access, Point of Purchase/Promotion, Pricing, and Social Support and Services) strategies through national organizations' systems and networks. The National Organizations will work to sustain community prevention efforts beyond Recovery Act CPPW funding and support the National Prevention Media Initiative through co-branding and augmenting HHS-developed media campaigns in communities.

The outcome measures that will be collected from funded National Organizations include approval/enactment of MAPPs-related policy, systems, and environmental change in physical activity, nutrition, and tobacco in funded communities. Since a critical component of the National Organizations is to support and assist CPPW-funded communities with their expert resources, the National Organizations and the CPPW-funded communities will share ownership of the same outcome measures. Because the National Organizations and their local affiliates have a distinct supporting role in these community-wide efforts, the output measures track the kinds of added-value to be derived from involvement of the National Organizations and its local affiliates in the community-wide efforts which should help drive the outcome measure.

**ESTIMATED ANNUALIZED BURDEN TABLE**

Forms	Type of respondent	Number of respondents	Number of responses per respondent	Average burden (in hours) per response	Total burden hours
National Organizations Measures Instrument.	Cooperative Agreement recipients—National Organizations.	10	4	2	80

**Seleda Perryman,**

*Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.*

[FR Doc. 2010-30435 Filed 12-3-10; 8:45 am]

**BILLING CODE 4150-28-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2010-N-0595]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Exports; Notification and Recordkeeping Requirements**

**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 notification and recordkeeping requirements for persons exporting human drugs, biological products, devices, animal drugs, food, and

cosmetics that may not be marketed or sold in the United States.

**DATES:** Submit either electronic or written comments on the collection of information by February 4, 2011.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezuto, Office of Information Management, Food and Drug

Administration, 1350 Piccard Dr., PI50-410B, Rockville, MD 20850, 301-796-3794, E-mail: [Jonnalynn.Capezzuto@fda.hhs.gov](mailto:Jonnalynn.Capezzuto@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, 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.

**Exports: Notification and Recordkeeping Requirements—21 CFR Part 1 (OMB Control Number 0910-0482)—Extension**

The respondents to this information collection are exporters who have notified FDA of their intent to export

unapproved products that may not be sold or marketed in the United States as allowed under section 801(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 381). In general, the notification identifies the product being exported (e.g., name, description, and in some cases, country of destination) and specifies where the notification should be sent. These notifications are sent only for an initial export; subsequent exports of the same product to the same destination (or, in the case of certain countries identified in section 802(b) of the FD&C Act (21 U.S.C. 382)) would not result in a notification to FDA.

The recordkeepers for this information collection export human drugs, biologics, devices, animal drugs, foods, and cosmetics that may not be sold in the United States and maintain records demonstrating their compliance with the requirements in section 801(e)(1) of the FD&C Act.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
1.101 (d) to (e) .....	400	3	1,200	15	18,000

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	Number of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
1.101 (b) to (c) .....	320	3	960	22	21,120

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: November 30, 2010.  
**Leslie Kux,**  
*Acting Assistant Commissioner for Policy.*  
 [FR Doc. 2010-30433 Filed 12-3-10; 8:45 am]  
**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**  
 [Docket Nos. FDA-2010-E-0032 and FDA-2010-E-0036]

**Determination of Regulatory Review Period for Purposes of Patent Extension; STELARA**

**AGENCY:** Food and Drug Administration, HHS.  
**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for *STELARA* and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological product.

**ADDRESSES:** Submit electronic comments to <http://www.regulations.gov>. Submit written petitions along with three copies and 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:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6222, Silver Spring, MD 20993-0002, 301-796-3602.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis

for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product.

Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biologic product *STELARA* (ustekinumab). *STELARA* is indicated for treatment of adult patients with severe plaque psoriasis who are candidates for phototherapy or systemic therapy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for *STELARA* (U.S. Patent No. 6,902,734 and 7,166,285) from Centocor Ortho Biotech Inc., and the Patent and Trademark Office requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated March 24, 2010, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of *STELARA* represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for *STELARA* is 3,165 days. Of this time, 2,498 days occurred during the testing phase of the regulatory review period, while 667 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* January 27, 2001. The applicant claims December 28, 2000 as the date the investigational new drug application (IND) became effective.

However, FDA records indicate that the IND effective date was January 27, 2001, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* November 29, 2007. FDA has verified the applicant's claim that the biologics license application (BLA) for *STELARA* (BLA 125261/0) was initially submitted on November 29, 2007.

3. *The date the application was approved:* September 25, 2009. FDA has verified the applicant's claim that BLA 125261/0 was approved on September 25, 2009.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 425 or 510 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by February 4, 2011. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by June 6, 2011. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written petitions. It is only necessary to send one set of comments. It is no longer necessary to send three copies of mailed comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document. Comments and petitions that have not been made publicly available on regulations.gov may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 22, 2010.

**Jane A. Axelrad,**

*Associate Director for Policy, Center for Drug Evaluation and Research.*

[FR Doc. 2010–30512 Filed 12–3–10; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2009–E–0584]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; **BESIVANCE**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for *BESIVANCE* and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

**ADDRESSES:** Submit electronic comments to <http://www.regulations.gov>. Submit written petitions along with three copies and 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:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when

the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product *BESIVANCE* (besifloxacin hydrochloride). *BESIVANCE* is indicated for treatment of bacterial conjunctivitis. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for *BESIVANCE* (U.S. Patent No. 5,447,926) from Bausch & Lomb Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 10, 2010, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of *BESIVANCE* represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for *BESIVANCE* is 2,271 days. Of this time, 1,910 days occurred during the testing phase of the regulatory review period, while 361 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* March 12, 2003. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on March 12, 2003.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* June 2, 2008. FDA has verified the applicant's claim that the new drug application (NDA) for

Besivance (NDA 22-308) was submitted on June 2, 2008.

3. *The date the application was approved:* May 28, 2009. FDA has verified the applicant's claim that NDA 22-308 was approved on May 28, 2009.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,316 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by February 4, 2011. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by June 6, 2011. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written petitions. It is only necessary to send one set of comments. It is no longer necessary to send three copies of mailed comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document.

Comments and petitions that have not been made publicly available on regulations.gov may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 22, 2010.

**Jane A. Axelrad,**

*Associate Director for Policy, Center for Drug Evaluation and Research.*

[FR Doc. 2010-30510 Filed 12-3-10; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0001]

#### Oncologic Drugs Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Oncologic Drugs Advisory Committee.

*General Function of the Committee:*

To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on February 9, 2011, from 8 a.m. to 12:30 p.m.

*Location:* FDA White Oak Campus, Building 31 Conference Center, the Great Room (rm. 1503), 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "White Oak Conference Center Parking and Transportation Information for FDA Advisory Committee Meetings." Please note that visitors to the White Oak Campus must have a valid driver's license or other picture ID, and must enter through Building 1.

*Contact Person:* Nicole Vesely, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301 847-8533, e-mail: [Nicole.vesely@fda.hhs.gov](mailto:Nicole.vesely@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512542. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* On February 9, 2011, the committee will discuss biologics license application (BLA) 125377, with the proposed trade name YERVOY (ipilimumab), submitted by Bristol-Myers Squibb Co. The proposed indication (use) for this product is for the treatment of advanced melanoma in patients who have received prior therapy.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before January 25, 2011. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11:30 a.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 14, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 18, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Nicole Vesely at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 1, 2010.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2010-30502 Filed 12-3-10; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0001]

#### Peripheral and Central Nervous System Drugs Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Peripheral and Central Nervous System Drugs Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on January 20, 2011, from 8 a.m. to 5 p.m. and on January 21, 2011, from 8 a.m. to 12 p.m.

*Location:* FDA White Oak Campus, Building 31 Conference Center, the Great Room (rm. 1503), 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You", click on "White Oak Conference Center Parking and Transportation Information for FDA Advisory Committee Meetings". Please note that visitors to the White Oak Campus must have a valid driver's license or other picture ID, and must enter through Building 1.

*Contact Person:* Diem-Kieu Ngo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX 301-847-8533, e-mail: [diem.ngo@fda.hhs.gov](mailto:diem.ngo@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512543. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* On January 20, 2011, the committee will discuss new drug application (NDA) 202-008, florbetapir F 18 injection, sponsored by Avid Radiopharmaceuticals, Inc., proposed for use in positron emission tomography (PET) imaging of  $\beta$ -amyloid (beta-amyloid) aggregates in the brain to help rule out Alzheimer's disease.

On January 21, 2011, the committee will discuss NDA 201-277, gadobutrol injection, sponsored by Bayer HealthCare Pharmaceuticals, proposed for use in diagnostic magnetic resonance imaging (MRI) in adults and children (2 years of age and older) to detect and visualize areas with disrupted blood brain barrier (BBB) and/or abnormal vascularity (abnormal blood supply and circulation) of the central nervous system. The BBB is an area consisting of specialized cells that restrict passage of certain molecules from the bloodstream into the brain.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before January 5, 2011.

Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. on January 20, 2011, and between approximately 10 a.m. and 11 a.m. on January 21, 2011. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before December 27, 2010. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by December 28, 2010.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Diem-Kieu Ngo at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 1, 2010.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2010-30501 Filed 12-3-10; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2000-N-0163; Formerly Docket No. 2000N-1219]

#### Reclassification of Category IIIA Biological Products, Bacterial Vaccines and Related Biological Products; Implementation of Efficacy Review; Final Order; and Delmont Laboratories, Inc.: Denial of Request for a Hearing, and Revocation of License

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; final order.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing a final order pursuant to the reclassification procedures under the biologics regulations; denying the request by Delmont Laboratories, Inc. (Delmont), for a hearing on FDA's proposal to revoke Delmont's license based on the proposed reclassification of its product, Polyvalent Bacterial Antigens with "No U.S. Standard of Potency," Staphage Lysate® (SPL) (hereinafter referred to as SPL) into Category II (unsafe, ineffective, or misbranded); and revoking Delmont's U.S. License No. 299. The final order finalizes the proposed order published in the **Federal Register** of May 15, 2000 (65 FR 31003) (May 2000 proposal), to reclassify Category IIIA bacterial vaccines and bacterial antigens into Category I or Category II.

**DATES:** The final order reclassifying Delmont's SPL into Category II, and Sanofi Pasteur Inc.'s (Sanofi's) Tetanus Toxoid Adsorbed and Tetanus and Diphtheria Toxoids Adsorbed For Adult Use (DECAVAC™) into Category I for both primary immunization and booster use is effective December 6, 2010. The revocation of Delmont's license (U.S. License No. 299) is effective December 6, 2010.

**FOR FURTHER INFORMATION CONTACT:** Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, 301-827-6210.

#### SUPPLEMENTARY INFORMATION:

##### I. Background on the Efficacy Review Process

In the **Federal Register** of February 13, 1973 (38 FR 4319), FDA issued procedures for the review by independent advisory panels of the safety, effectiveness, and labeling of

biological products licensed before July 1, 1972. These procedures were later codified in § 601.25 (21 CFR 601.25) (38 FR 32048 at 32052, November 20, 1973). Under § 601.25, FDA assigned responsibility for the initial review of each of the biological product categories to a separate independent advisory panel consisting of qualified experts. Each panel was charged with preparing for the Commissioner of Food and Drugs an advisory report which was to: (1) Evaluate the safety and effectiveness of the biological products for which a license had been issued; (2) review their labeling; and (3) identify the biological products that are safe, effective, and not misbranded. Each advisory panel report was also to include recommendations classifying the products reviewed into one of three categories.

- Category I, designating those biological products determined by the panel to be safe, effective, and not misbranded.

- Category II, designating those biological products determined by the panel to be unsafe, ineffective, or misbranded.

- Category III, designating those biological products determined by the panel not to fall within either Category I or Category II on the basis of the panel's conclusion that the available data were insufficient to classify such biological products, and for which further testing was therefore required. Category III products were assigned to one of two subcategories. Category IIIA products were those that would be permitted to remain on the market pending the completion of further studies. Category IIIB products were those for which the panel recommended license revocation on the basis of the panel's assessment of potential risks and benefits.

In accordance with § 601.25, after reviewing the conclusions and recommendations of the review panels, FDA would publish in the **Federal Register** a proposed order containing: (1) A statement designating the biological products reviewed into Categories I, II, IIIA or IIIB; (2) a description of the testing necessary for Category IIIA biological products; and (3) the complete panel report. Under the proposed order, FDA would propose to revoke the licenses of those products designated into Category II and Category IIIB. After reviewing public comments, FDA would publish a final order on the matters covered in the proposed order.

Two original advisory panels reviewed the four Category IIIA products that are the subject of this final order. The advisory panel for Bacterial Vaccines and Bacterial Antigens with



“no U.S. Standard of Potency” (the Original Antigen Panel) reviewed Delmont’s SPL product. The advisory panel for Bacterial Vaccines and Toxoids with Standards of Potency (the Original Toxoid Panel) reviewed Sanofi’s Tetanus Toxoid Adsorbed and Tetanus and Diphtheria Toxoids Adsorbed For Adult Use products. The above definition of Category IIIA was applied at the time of each advisory panel’s review and served as the basis for their recommendations.

In the **Federal Register** of October 5, 1982 (47 FR 44062), FDA revised § 601.25 and codified § 601.26 (21 CFR 601.26) to establish procedures to reclassify those products in Category IIIA into either Category I or Category II based on available evidence of safety and effectiveness. Under § 601.26, Category IIIA products that would be reclassified included products that an advisory panel had recommended be assigned to Category IIIA, that FDA had proposed to place into Category IIIA, or for which FDA had issued a final order reclassifying the products into Category IIIA.

Under the procedures specified in § 601.26, FDA appointed an advisory panel and used existing advisory panels to review Category IIIA products and to make recommendations to reclassify each Category IIIA product into Category I or Category II. FDA assigned the reclassification review of bacterial vaccines and bacterial antigens with “no U.S. standard of potency” to the Vaccines and Related Biological Products Advisory Committee

(VRBPAC). FDA also assigned the reclassification review of bacterial vaccines and toxoids with standards of potency to the VRBPAC.

During the reclassification review process, interested persons were permitted to attend meetings, appear before the advisory panels, and submit data to the panels for review. The advisory panels then submitted reports to FDA that recommended the reclassification of each Category IIIA product into either Category I or II. According to § 601.26, after reviewing the conclusions and recommendations of the advisory panels, FDA must publish in the **Federal Register** a proposed order containing: (1) A statement designating the products as Category I or Category II, (2) a notice of availability of the full panel report, (3) a proposal to accept or reject the findings of the advisory panels, and (4) a statement identifying those products that FDA proposes to permit to remain on the market because of a compelling medical need and because no suitable alternative exists as described in § 601.26(d)(4).

**II. Category IIIA Products Subject to This Final Reclassification Order**

FDA published the May 2000 proposal to reclassify Category IIIA bacterial vaccines and bacterial antigens into Category I or Category II. FDA based the proposed order on its review of all the evidence, and considered the findings and recommendations of the VRBPAC. The proposed order also announced FDA’s intent to revoke the biologics licenses for those bacterial

vaccines and bacterial antigens that FDA proposed reclassifying into Category II.

FDA agreed with VRBPAC’s recommendations and proposed that bacterial vaccines and toxoids with standards of potency be classified into two separate categories based upon their use as either a primary immunogen or as a booster immunogen. FDA proposed that some bacterial vaccines with standards of potency be classified into Category II for use as a primary immunogen, but into Category I for use as a booster immunogen.

FDA further proposed that bacterial vaccines and bacterial antigens with “no U.S. standard of potency” be classified into Category II for all labeled indications, agreeing with the VRBPAC’s recommendations.

*A. Category IIIA Products That FDA Had Proposed To Reclassify Into Category II*

Five manufacturers of Category IIIA products that VRBPAC recommended for reclassification into Category II were subject to the May 2000 proposal (Table 1 of this document). After publication of the May 2000 proposal, four of the five manufacturers voluntarily submitted to FDA requests for revocation of their licenses for the applicable products. Subsequently, FDA revoked these licenses. Therefore, no further action is required on these manufacturers’ products. The reclassification of the Category IIIA product of the remaining manufacturer, Delmont, is discussed in a later section of this document.

TABLE 1—CATEGORY IIIA PRODUCTS THAT FDA HAD PROPOSED TO RECLASSIFY INTO CATEGORY II

Manufacturer/License No.	Product(s)	Proposed Category II indication
Bioport Corporation, No. 1260 .....	Diphtheria and Tetanus Toxoids Adsorbed <sup>2</sup> .....	Primary immunogen.
Delmont Laboratories, Inc., No. 299 .....	Tetanus Toxoid Adsorbed <sup>2</sup> .....	All labeled indications.
	Polyvalent Bacterial Antigens with “No U.S. Standard of Potency” Staphage Lysate® (SPL).	
Hollister-Stier Laboratories LLC, No. 1272.	Polyvalent Bacterial Vaccines with “No U.S. Standard of Potency” (Bacterial Vaccines Mixed Respiratory (MRV or MRVI), Bacterial Vaccines for Treatment, Special Mixtures) <sup>3</sup> .	All labeled indications.
Sanofi Pasteur Inc., No. 1725 .....	Tetanus Toxoid <sup>4</sup> .....	Primary immunogen.
Wyeth Laboratories, Inc., No. 3 .....	Tetanus and Diphtheria Toxoids Adsorbed (Adult Use) <sup>5</sup> .....	Primary immunogen.

<sup>1</sup> FDA is not relisting in this document the licenses FDA listed in and revoked before the May 2000 proposal.

<sup>2</sup> The licenses for these products were transferred from Michigan Department of Public Health, No. 99, to BioPort Corporation, License No. 1260 on November 12, 1998. The licenses were subsequently revoked by FDA on November 20, 2000, at the request of the manufacturer (66 FR 29148 at 29149, May 29, 2001).

<sup>3</sup> The licenses for these products were transferred from Bayer, Inc., No. 8 to Hollister-Stier, LLC, No. 1272 on June 2, 1999. The licenses were subsequently revoked by FDA on August 3, 2000, at the request of the manufacturer (66 FR 29148 at 29149, May 29, 2001).

<sup>4</sup> The license for this product was transferred from Merrell-National Laboratories Division of Richardson-Merrell, Inc. (License No. 101) to Connaught Laboratories, Inc. (License No. 711) on January 3, 1978; from Connaught Laboratories, Inc. (License No. 711) to Aventis Pasteur, Inc. (License No. 1277) on December 9, 1999; and from Aventis Pasteur, Inc. (License No. 1277) to Sanofi Pasteur Inc. (License No. 1725) on December 19, 2005. The license for this product was subsequently revoked by FDA on July 16, 2009, at the request of the manufacturer.

<sup>5</sup> The license for this product was revoked by FDA on May 30, 2002, at the request of the manufacturer.



Delmont Laboratories, Inc., SPL

On August 9, 2000, Delmont submitted to FDA a response to FDA's May 2000 proposal to reclassify SPL into Category II. Information regarding Delmont's response and FDA's actions are discussed in section III of this document.

*B. Category IIIA Products That FDA Had Proposed To Reclassify Into Category I*

Four manufacturers of Category IIIA products, recommended by VRBPAC for reclassification into Category I for both primary and booster immunization, were subject to the May 2000 proposal (Table 2 of this document). After publication of the May 2000 proposal,

three of the four manufacturers voluntarily submitted to FDA requests for revocation of their licenses. FDA subsequently revoked these licenses. Therefore, no further action is required on these manufacturers' products. The reclassification of the Category IIIA products of the remaining manufacturer, Sanofi, is discussed in this section of this document.

TABLE 2—CATEGORY IIIA PRODUCTS THAT FDA HAD PROPOSED TO RECLASSIFY INTO CATEGORY I FOR BOTH PRIMARY AND BOOSTER IMMUNIZATION <sup>1</sup>

Manufacturer/License No.	Product(s)
Lederle Laboratories, Division, American Cyanamid Company, No. 17	Tetanus Toxoid. <sup>2</sup> Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed. <sup>2</sup> Diphtheria and Tetanus Toxoids Adsorbed. <sup>2</sup> Tetanus and Diphtheria Toxoids Adsorbed (Adult Use). <sup>2</sup> Tetanus Toxoid Adsorbed. <sup>2</sup>
Sanofi Pasteur Inc., License No. 1725 .....	Tetanus Toxoid Adsorbed. <sup>3</sup> Tetanus and Diphtheria Toxoids Adsorbed (Adult Use). <sup>3</sup>
Swiss Serum and Vaccine Institute Berne, No. 21 .....	Tetanus Toxoid Adsorbed. <sup>4</sup>
Wyeth Laboratories, Inc., No. 3 .....	Diphtheria and Tetanus Toxoids Adsorbed. <sup>5</sup> Tetanus Toxoid. <sup>5</sup> Tetanus Toxoid Adsorbed. <sup>5</sup> Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed. <sup>5</sup>

<sup>1</sup> FDA is not relisting in this document the licenses FDA listed in and revoked before the May 2000 proposal.

<sup>2</sup> The licenses for these products were revoked by FDA on March 4, 1994, July 24, 2002, May 10, 2002, May 10, 2002, and May 22, 2002, respectively, at the request of the manufacturer.

<sup>3</sup> The licenses for these products were transferred from Merrell-National Laboratories Division of Richardson-Merrell, Inc. (License No. 101) to Connaught Laboratories, Inc. (License No. 711) on January 3, 1978; from Connaught Laboratories, Inc. (License No. 711) to Aventis Pasteur, Inc. (License No. 1277) on December 9, 1999; and from Aventis Pasteur, Inc. (License No. 1277) to Sanofi Pasteur Inc. (License No. 1725) on December 19, 2005.

<sup>4</sup> The license for this product was revoked by FDA on August 29, 2000, at the request of the manufacturer.

<sup>5</sup> The licenses for these products were revoked by FDA on May 30, 2002, May 30, 2002, May 30, 2002, and October 15, 2002, respectively, at the request of the manufacturer.

1. Sanofi Pasteur Inc., Tetanus Toxoid Adsorbed

The Original Toxoid Panel recommended that all licensed and marketed tetanus toxoid products be classified into Category I for booster immunization (50 FR 51002, December 13, 1985). The Original Toxoid Panel reviewed Sanofi's Tetanus Toxoid Adsorbed product and recommended that the product be placed into Category I for booster use and Category IIIA for primary immunization (50 FR 51002 at 51029). FDA agreed with the Original Toxoid Panel's recommendations to classify this product into Category I for booster use and Category IIIA for primary immunization (50 FR 51002 at 51105 and 51106). The VRBPAC reviewed the Category IIIA primary immunization indication for Sanofi's Tetanus Toxoid Adsorbed. Based on additional data from a clinical study performed by the firm, the VRBPAC recommended that the product be placed into Category I for primary immunization. (See Ref. 1, at pages 19 and 20). FDA agrees with the Original Toxoid Panel's and VRBPAC's recommendations and is reclassifying Sanofi's Tetanus Toxoid Adsorbed

product into Category I for both primary immunization and booster use.

2. Sanofi Pasteur Inc., Tetanus and Diphtheria Toxoids Adsorbed (Adult Use)

The Original Toxoid Panel reviewed Sanofi's Tetanus and Diphtheria Toxoids Adsorbed (Adult Use) and recommended that the product be placed into Category I for booster immunization and Category IIIA for primary immunization (50 FR 51002 at 51040). FDA agreed with the Original Toxoid Panel's recommendations to classify this product into Category I for booster use and Category IIIA for primary immunization (50 FR 51002 at 51105 and 51106). The VRBPAC reviewed the Category IIIA primary immunization indication for Sanofi's Tetanus and Diphtheria Toxoids Adsorbed (Adult Use). Based on additional data from a human clinical study performed by the firm, the VRBPAC recommended that the product be placed into Category I for primary immunization. (See Ref. 1, at pages 21 and 22). FDA agrees with the Original Toxoid Panel's and VRBPAC's recommendations and is therefore

reclassifying Sanofi's Tetanus and Diphtheria Toxoids Adsorbed For Adult Use product into Category I for both primary immunization and booster use.

**III. Denial of a Hearing on Proposed License Revocation—Delmont Laboratories, Inc.**

*A. Notice of Opportunity for a Hearing*

On August 9, 2000, Delmont submitted to FDA a written comment opposing FDA's May 2000 proposal to reclassify its product, SPL, into Category II. Delmont proposed, instead, reclassifying SPL into Category I and submitted information supporting its proposal. FDA carefully considered the information that Delmont provided and found that the information did not support a reclassification of SPL into Category I.

Accordingly, a Notice of Opportunity for Hearing (NOOH) on a proposal to revoke the license for Delmont's SPL was published in the **Federal Register** of February 26, 2003 (68 FR 8908). In the NOOH, FDA provided a detailed analysis and discussion of the information that Delmont submitted in its response to FDA's May 2000 proposal. Further, in the NOOH, FDA

advised Delmont that a request for a hearing should identify the specific fact or facts that are genuine, substantial, and in dispute (§ 12.24(b)(1) (21 CFR 12.24(b)(1)). FDA put Delmont on notice that mere allegations or denials are not enough to obtain a hearing (§ 12.24(b)(2)). FDA also put Delmont on notice that the Commissioner would deny a hearing request if the Commissioner concluded that the data and information submitted are insufficient to justify the factual determination urged, even if accurate (§ 12.24(b)(3)).

#### B. Delmont's Hearing Request

On April 28, 2003, Delmont submitted to FDA a letter objecting to FDA's proposal to revoke its license and requested a hearing. In the letter, Delmont did not submit any evidence that raised a genuine and substantial issue of fact justifying a hearing. Instead, Delmont resubmitted data on SPL that it previously submitted to FDA and made procedural arguments for why it is entitled to a hearing. Specifically, Delmont argued that FDA applied the wrong effectiveness standard when evaluating the studies that Delmont previously submitted, and that FDA used incorrect procedures when proposing to reclassify SPL and to revoke Delmont's license.

#### C. Commissioner's Determination That Delmont Has Not Justified a Hearing

As explained in subsection 1 in this section of this document, FDA applied the correct effectiveness standard to SPL. In subsection 2 in this section of this document, we explain that SPL does not satisfy that standard. Specifically, this document explains why most of the data on which Delmont relies came from studies that do not meet that standard either because they were not human studies or were not adequately controlled studies. For the few studies that were controlled or even partially controlled, this document explains why they did not show that SPL is effective. Therefore, Delmont fails to raise a genuine and substantial issue of fact regarding the effectiveness of SPL for resolution at a hearing. Moreover, the procedural objections that Delmont raises do not create a basis for a hearing (§ 12.24(b)(1)). These arguments are discussed in subsection 3 of this section of this document.

##### 1. Biologics Effectiveness Standard

Under FDA regulations, codified from the final rule published on February 13, 1973 (38 FR 4319 at 4322), biologics manufacturers, like Delmont, whose products were licensed before 1972,

must prove that their products are effective by submitting data from "controlled clinical investigations" as defined in § 314.126 (21 CFR 314.126) ("Adequate and well-controlled studies"), unless FDA waives that requirement (§ 601.25(d)(2)). To obtain a waiver, the sponsor must show that controlled clinical investigations are "not reasonably applicable to the biological product or essential to the validity of the investigation, and that an alternative method of investigation is adequate to substantiate effectiveness" (§ 601.25(d)(2)) (emphasis added).

Delmont attempted to argue that FDA should not have applied that standard to SPL. Instead of arguing that controlled clinical investigations are not reasonably applicable to SPL or essential to the validity of SPL investigations, and instead of advancing an alternative method of investigation and explaining why it would be adequate to substantiate SPL's effectiveness, Delmont simply argued that FDA should never require data from controlled clinical investigations for biologics. The basis for its argument is the following statement in the preamble to FDA's proposed reclassification rule for Category IIIA products (46 FR 4634 at 4635, January 16, 1981): "While it is clear \* \* \* that the applicable statutory requirement for potency in the Public Health Service Act has been interpreted as requiring that a product be effective, the specific statutory criteria governing new drugs, 'adequate and well-controlled clinical studies,' have not been applied to biological drugs."

FDA's final reclassification rule for Category IIIA products (47 FR 44062 at 44067, October 5, 1982), however, confirmed that FDA "does indeed consider controlled clinical studies to be the preferred form of evidence for documenting a product's effectiveness." Furthermore, FDA clarified that "unless unusual circumstances justify a special exemption for a particular product," controlled clinical investigations are required to establish effectiveness (47 FR 44062 at 44067).

In this case, Delmont did not attempt to show that SPL meets the criteria for a special exemption, namely, that an alternative method of investigation is adequate to substantiate SPL's effectiveness, and that controlled clinical investigations are either inapplicable to SPL or not essential to the validity of the investigation. In fact, Delmont sponsored a controlled clinical trial of SPL (in patients suffering from the disease hidradenitis suppurativa), but as FDA explained at length in the February 26, 2003, NOOH, the data showed no statistically significant

difference between SPL and a placebo. Therefore, the data were inadequate to demonstrate that the product was effective. See 68 FR 8908 at 8909.

Clearly, FDA applied the correct standard when evaluating SPL.

##### 2. Application of the Standard to SPL

Since FDA's biologics review began, Delmont has submitted to FDA data on SPL at four different times: (a) Before 1978, as part of FDA's initial biologics review process; (b) between January and May 1978, to convince FDA to classify SPL into Category IIIA rather than IIIB so that Delmont could continue marketing SPL while obtaining data from effectiveness studies; (c) in 1983, as part of FDA's reclassification procedures; and (d) in 1994, to supplement its reclassification data with the results of studies that were incomplete in 1983. As discussed in turn below, none of the data are sufficient to demonstrate that SPL is effective.

###### a. Pre-1978 Data

As part of FDA's initial biologics review process, Delmont submitted data to the Original Antigen Panel. The Original Antigen Panel issued a report, which is published in the **Federal Register** of November 8, 1977 (42 FR 58266 at 58270), that analyzed in detail all the studies that Delmont had submitted, and described deficiencies in each one. Based on that analysis, the Original Antigen Panel concluded that Delmont had provided "no substantial evidence of safety or effectiveness," and "no evidence presumptive of safety" (42 FR 58266 at 58285). Consequently, the Original Antigen Panel recommended that FDA classify SPL into Category IIIB and revoke Delmont's license (42 FR 58266 at 58285). In the **Federal Register** of November 8, 1977, FDA issued a proposed order notifying Delmont that it agreed with the Original Antigen Panel's findings and that it intended to revoke Delmont's license (42 FR 58266 at 58318). As discussed in subsection b.iii of this section of this document, FDA ultimately classified SPL into category IIIA based on additional safety data that Delmont submitted (44 FR 1544 at 1548, January 5, 1979), but FDA agreed with the Original Antigen Panel's criticisms of SPL's effectiveness data (44 FR 1544 at 1546, comment 5) and ordered Delmont to complete and submit the effectiveness testing that the Original Antigen Panel had recommended (44 FR 1544 at 1548).

## b. January to May 1978 Data

## i. Delmont's Hearing Request

In response to FDA's revocation proposal (42 FR 58266), Delmont requested a hearing on whether FDA should classify SPL into Category IIIA or IIIB, and submitted to FDA additional data on January 8, 1978, February 7, 1978, March 31, 1978, and May 26, 1978. Those submissions are all currently in the public docket relating to this matter, Docket No. 2000N-1219, as attachments to Delmont's April 28, 2003, hearing request. None of the data satisfied the controlled clinical investigations standard for proving effectiveness, as discussed in subsection b.iii of this section of this document, even though FDA eventually determined that the safety data were sufficient to classify SPL into Category IIIA to allow Delmont to continue marketing SPL while obtaining effectiveness data.

## ii. Deficiencies in Delmont's Data

## (1). January 8, 1978, Submission

In a letter dated January 8, 1978 (Docket No. 2000N-1219, Item SUP1, Tab C to Delmont's April 28, 2003, hearing request), Delmont submitted to FDA additional study reports. Delmont stated that the reports "show that no risk to human safety can result from continued marketing of SPL for a limited period while further studies are conducted." As to effectiveness, however, Delmont said only that the study reports "demonstrate that further studies of SPL in accordance with FDA requirements for clinical investigations will very likely provide substantial evidence that the product is effective for its labeled indications \* \* \*." Therefore, Delmont admitted that the data it was submitting were collected from studies that were not conducted in accordance with FDA requirements for clinical investigations.

Most of those studies failed to satisfy FDA's controlled clinical investigations standard because they were preclinical studies not performed on humans, and therefore, were not clinical investigations. Specifically, those reports were as follows: "Chronic Toxicity Test of SPL in Rats" (Fujino, *et al.*) (Ref. 2); "Acute and Subacute Toxicity Tests of SPL" (Fujino, *et al.*) (mice and rats) (Ref. 3); "Teratogenicity Study of SPL in Rats and Rabbits" (Hachihiko Hirayama) (Ref. 4); "Effect of SPL on the Development of Skin Lesion in Mice after Inoculation with Herpes Simplex Virus" (Department of Microbiology, School of Medicine, Kyushu University) (Ref. 5); "Chemotactic Accumulation of

Macrophages in the Peritoneal Cavity after Inoculation of SPL and their Antitumor Activity" (Department of Microbiology, School of Medicine, Kyushu University) (mice) (Ref. 6); and "S-27: Summary of Results of Tests Conducted at Fuji-Zoki Pharmaceutical Research Division" (safety tests in mice and guinea pigs) (Ref. 7).

Two other studies that Delmont included in its January 8, 1978, submission, "Susceptibility of Staphylococcus aureus Clinical Isolates to Gratia Bacteriophage" (Shigeno, *et al.*) (Ref. 8) and "Influence of Staphage Lysates (SPL) on Immune Responses In Vitro" (Mitsuma, *et al.*) (Ref. 9), do not qualify as controlled clinical investigations because they were in vitro studies. Moreover, the limited data contained in the abstracts that Delmont submitted to FDA on these two studies limit their usefulness for any purpose. Therefore, they are not adequate to support reclassifying SPL into Category I.

Delmont also submitted two reports on studies of SPL in humans, "Immunopotiator Activity of Staphage Lysate (Mudd)" (Azuma, *et al.*) (Ref. 10) and "Immunochemotherapy for Infections—With Particular Reference to Staphage Lysate" (Tsuda, *et al.*) (Ref. 11). Neither of those qualifies as a controlled clinical investigation, for a number of reasons. First, neither study was controlled as required in FDA's 1979 final order, which included Delmont's product in Category IIIA (44 FR 1544 at 1548). A fundamental characteristic of controlled clinical investigations is that they "use a design that permits a valid comparison with a control to provide a quantitative assessment of drug effect" (§ 314.126(b)(2)). A control is necessary to "distinguish the effect of a drug from other influences, such as spontaneous change in the course of the disease, placebo effect, or biased observation" (§ 314.126(a)). While different types of controls are permitted under different conditions, neither study reports that the investigators used controls.

Second, both a protocol and a study result report should contain a clear statement of the objectives of the investigation and a summary of the methods of analysis (§ 314.126(b)(1)). Delmont did not submit the protocol for either study, and the resulting reports for the two studies did not explain how the investigators measured or analyzed the results of treating their study subjects with SPL. Although the Tsuda study report (*see* Ref. 11) contains a summary of clinical results in Table 8, which lists the investigators' assessments of subjects' responses to

SPL—either "Excellent," "Greatly improved," or "Unimproved"—the study does not state what criteria were used to reach those assessments. Moreover, as the report itself admits, "no conclusive statement can be made here because of the relatively small series studied." Clearly, the reports do not provide "sufficient details of the study design, conduct, and analysis to allow critical evaluation and a determination of whether the characteristics of an adequate and well-controlled study are present" (§ 314.126(a)).

The studies also failed to meet other characteristics of a controlled investigation. The study reports fail to show that the "method of selection of subjects provides adequate assurance that they have the disease or condition being studied or evidence of susceptibility and exposure to the condition against which prophylaxis is directed" (§ 314.126(b)(3)). In the Tsuda study (*see* Ref. 11) the diseases being studied were chronic intractable staphylococcal infections or other viral infections. In the Azuma study (*see* Ref. 10), the condition being studied was defensive capacity against infection generally. However, neither study report showed how the subjects were selected to meet these criteria. Similarly, the studies fail to show that the "method of assigning patients to treatment and control groups minimizes bias and is intended to assure comparability of the groups with respect to pertinent variables" (§ 314.126(b)(4)); fail to show that "[a]dequate measures [were] taken to minimize bias on the part of the subjects, observers, and analysts of the data" (§ 314.126(b)(5)); fail to demonstrate that the "methods of assessment of subjects' response [were] well-defined and reliable" (§ 314.126(b)(6)); and fail to provide "an analysis of the results of the study adequate to assess the effects of the drug" (§ 314.126(b)(7)). Clearly, then, these two studies do not meet the criteria for controlled clinical investigations.

Finally, Delmont submitted what it described as a protocol for "a study based on short- and long-term surveillance of patients receiving SPL therapy under the care of Arthur G. Baker, M.D." The study had not begun, and Delmont had no results to report at that time. Therefore, it did not contribute to the effectiveness assessment.

In summary, none of the submissions that Delmont included with its January 8, 1978, letter constituted controlled clinical investigations. Thus, they were insufficient to establish SPL's effectiveness at that time.

## (2). February 7, 1978, Letter

On February 7, 1978, Delmont sent to FDA additional data to support its request for a hearing on whether to classify SPL into Category IIIA or IIIB (Docket No. 2000N-1219, Item SUP1, Tab D to Delmont's April 28, 2003, hearing request). Delmont categorized much of the data and reports as safety data, but did include a set of attachments that it labeled "Effectiveness Data." Delmont divided those attachments into "Controlled Studies," and "Other Efficacy Data." The Controlled Studies section contains only a protocol for a study that was then in early stages, and does not contain a report on the results of that study. Thus, Delmont admitted that its February 7, 1978, submission did not contain effectiveness data that met the controlled clinical investigations standard.

The "Other Efficacy Data" section was divided into two subsections: "Studies in Humans" and "Studies in Animals." The first paper in the human studies subsection, Salmon G.G. and M. Symonds, "Staphage Lysate Therapy in Chronic Staphylococcal Infections," (Ref. 12), is a duplicate of a published article that Delmont had submitted to the Original Antigen Panel in 1977. The Original Antigen Panel rejected that article, stating that in the article "patients are said to have recovered because of antibody induction but no data demonstrating such responses are provided" (42 FR 58283). The next three reports were duplicates of reports that Delmont had submitted with its January 8, 1978, letter, which are deficient for the reasons discussed previously in this section of this document. Finally, Delmont submitted two summaries of case studies, "Immune Stimulation Therapy for Inflammatory Disease of the Gut," (Ref. 13) and "Immune Stimulation for Aphthous (Herpetic) Stomatitis & Rhinitis," (Ref. 14) that Dr. Dale Rank had sent to Delmont. These reports contain little information, and therefore do not "provide sufficient details of study design, conduct, and analysis to allow critical evaluation and a determination of whether the characteristics of an adequate and well-controlled study are present" (§ 314.126(a)). Moreover, the terse case reports of Dr. Rank's patients contain no indication that any type of control was used.

Therefore, none of Delmont's February 7, 1978, submissions satisfied the controlled clinical investigations standard.

## (3). March 31, 1978, Letter

On March 31, 1978, Delmont sent to FDA another letter (Docket No. 2000N-1219, Item SUP1, Tab E to Delmont's April 28, 2003, hearing request). That letter served primarily to answer questions that FDA had raised about the animal studies in Delmont's January 8, 1978, submission. The letter also included three new reports. One reported on tests in rabbits and another reported the results of in vitro assays, neither of which constituted controlled clinical investigations in humans. The letter also included a one-page "report of a double blind, placebo controlled trial for evaluation of SPL as a treatment for warts, dated March 7, 1978." The one-page summary clearly did not "provide sufficient details of study design, conduct, and analysis to allow critical evaluation and a determination of whether the characteristics of an adequate and well-controlled study are present," as § 314.126(a) requires, for many reasons. Among them are that it provided: No patient recruitment details on their diagnoses, as § 314.126(b)(3) requires; no explanation of patient inclusion and exclusion criteria (§ 314.126(b)(3)); no description of patient randomization procedures (if performed), as § 314.126(b)(4) requires; and no clinical descriptions or associated clinical measurements for the endpoints of "Excellent," "Good," and "No change," as § 314.126(b)(6) and (b)(7) require. Thus, Delmont's March 31, 1978, submissions did not satisfy the controlled clinical investigations standard.

## (4). May 26, 1978, Letter

In a letter dated May 26, 1978 (Docket No. 2000N-1219, Item SUP1, Tab F to Delmont's April 28, 2003, hearing request), Delmont submitted one last supplement to its comments on FDA's proposal to classify SPL into Category IIIB. The letter stated that "[t]his information further supports Delmont's position, set out in its January 8, 1978, comments, that SPL is safe and that an opportunity should be provided for the completion of clinical studies to provide additional information demonstrating the product's effectiveness." Thus, Delmont acknowledged that its May submissions did not demonstrate SPL's effectiveness.

The first set of documents contains case reports on 50 patients that Dr. Arthur Baker had treated with SPL. Delmont submitted those individual case reports to "show that no allergic reactions or adverse effects were observed in any of the patients who received SPL over extended periods of

time." Delmont did not include a study result report analyzing the data for effectiveness.

The second set of documents consists of protocols for two clinical studies of SPL that Dr. John Silva was conducting. One was then underway at the Department of Veterans Affairs hospital in Biloxi, MS and the second had not begun. Delmont did not submit any effectiveness data from the ongoing study. Instead, it submitted a letter from Dr. Silva stating that no allergic reactions or other adverse effects had been observed. Therefore, the information related to safety rather than efficacy.

## iii. FDA's 1979 Final Order on SPL

On January 5, 1979 (44 FR 1544), FDA published a final order formally classifying into Category IIIA those products, including Delmont's SPL, for which the data were insufficient to determine their safety and effectiveness, but which FDA would allow to remain on the market pending completion of testing. That final order confirmed that the Commissioner agreed with the Original Antigen Panel's conclusions and recommendations about all the deficiencies in the Category IIIA data (44 FR 1544 at 1546, comment 5). It further confirmed that the manufacturers of those products had to submit data from controlled clinical investigations, and that their products could not remain in category IIIA indefinitely (44 FR 1544 at 1545 to 1548).

That final order also expressly confirmed that SPL was subject to the same requirement. The order stated as follows: "Because data submitted by Delmont Laboratories, Inc., have been found to be adequate to reclassify its staphage lysate types I and [III] combined, License No. 299, from Category IIIB to IIIA, the requirements concerning *completion of testing* and labeling *apply to these products*" (44 FR 1544 at 1548) (emphasis added). The order also made clear that those testing requirements were the ones that the Original Antigen Panel had recommended; after listing all of the Category IIIA products, including SPL, the order stated that "[l]icenses remain in effect for these products *pending conformance with the Panel's recommendations and completion of testing*" (44 FR 1544 at 1548) (emphasis added). As discussed above, the Original Antigen Panel was clear that all Category IIIA products reviewed by that Panel needed further clinical investigations to establish their effectiveness.

## c. 1983 Data

In December 1982, FDA assigned the VRBPAC to follow the reclassification procedures in § 601.26 (65 FR 31003 at 31004) to reclassify the bacterial vaccines and antigens with “no U.S. standards of potency” that had been previously classified into Category IIIA, including SPL into either Category I or Category II. Under these procedures, Delmont submitted to the VRBPAC additional data on SPL. The VRBPAC held reclassification meetings in January, June, and September 1983 (65 FR 31003 at 31006).

After reviewing all of the data, VRBPAC voted to recommend placing SPL into Category II and to revoke Delmont’s license. VRBPAC’s Final Report provides VRBPAC’s detailed critique of all the data that Delmont submitted (*see* Ref. 1, at pages 47 to 54). The Final Report confirmed that the VRBPAC members voted unanimously to recommend placing SPL into Category II because the evidence was insufficient to prove effectiveness. (*See* Ref. 1, at page 55). We continue to agree with the VRBPAC’s analysis as described in that portion of the Final Report at page 55.

## d. 1994 Data

On February 28, 1994, Delmont submitted to FDA results from a study on hidradenitis suppurativa (HS) that had just begun in 1983, along with the results from some other studies. (A copy of Delmont’s February 28, 1994, submission is attached as Tab C to comments that Delmont submitted to the Docket No. 2000N–1219, Item C1 on August 9, 2000). In FDA’s February 26, 2003, NOOH, FDA published a detailed critique of Delmont’s 1994 data (68 FR 8908 at 8909). Of all the study results that Delmont submitted, only the HS study, a prospective, double-blind, placebo controlled trial, constituted a controlled clinical investigation (68 FR 8908 at 8909). The investigators in that study, however, found “[n]o significant differences between treatment groups or between the two centers” after performing efficacy analyses, and concluded that “[u]nder the conditions of the study, SPL was not demonstrated to be effective in the treatment of HS” (Delmont’s February 28, 1994, submission, at page 9). A third party that Delmont contracted with to perform a reanalysis of the data reached a more optimistic conclusion (Delmont’s February 28, 1994, submission, pages 9 to 11, and 68 FR 8908 at 8909). But it reached that conclusion only after first unblinding the patient data and performing a subset analysis on a

selected subgroup of patients based on a different method of assessing effectiveness (68 FR 8908 at 8909). Even then, the third party found no statistically significant difference between the patients treated with placebo and with SPL (68 FR 8908 at 8909).

The rest of Delmont’s 1994 data fails to satisfy the controlled clinical investigations standard, as FDA explained in its February 26, 2003, NOOH (68 FR 8908 at 8909). We continue to support the analysis described in the **Federal Register** document of February 26, 2003 (68 FR 8908).

Significantly, Delmont’s April 28, 2003, hearing request does not attempt to argue that any of the data it submitted to FDA during the reclassification process in 1983 and 1994 satisfies the controlled clinical investigations standard or otherwise is adequate to demonstrate effectiveness. Instead, Delmont’s hearing request argues that the data that it submitted to FDA in 1978 sufficiently demonstrates that SPL is effective. Delmont does not, however, discuss the specific data that it submitted in 1978 or explain why it is sufficient to prove that SPL is effective. Rather, Delmont argues that in 1978, FDA stated that Delmont’s data were sufficient to justify a hearing. What FDA actually stated, however, is that the data justified a hearing only on whether FDA should classify SPL into Category IIIA or IIIB—not Category I. In other words, FDA did not find that the data justified a hearing on whether SPL was effective—only on whether SPL was safe enough to allow Delmont to keep marketing it while Delmont conducted further effectiveness studies. Indeed, even Delmont admitted that further effectiveness studies were necessary.

Therefore, Delmont has not raised a genuine and substantial issue of fact justifying a hearing as to whether SPL is effective.

## 3. Delmont’s Procedural Objection

Delmont also argues that FDA did not follow correct procedures during the effectiveness reclassification process and that, therefore, Delmont deserves a hearing on SPL’s effectiveness. Delmont’s specific objection is that because FDA issued a NOOH before finally reclassifying SPL into Category II, FDA has violated its own procedures and has deprived Delmont of fair notice and opportunity for judicial review.

Delmont is incorrect that FDA violated its own procedures. The reclassification procedures, set forth in § 601.26, are silent as to when FDA should issue an NOOH. However, the

preamble to § 601.26 provides that the procedures for review and reclassification of the Category IIIA products were designed to be “analogous to the procedures in § 601.25 for the 1972 biologics review,” as Delmont itself admits (Delmont’s April 28, 2003, hearing request, at page 4) (46 FR 4634, January 16, 1981). Section 601.25 required FDA to issue an NOOH before issuing its final classification order. Specifically, § 601.25(g) required FDA’s final classification order to address all matters in the proposed order, and § 601.25(f)(2) required that for products that FDA proposed to classify into Category II, FDA also include a license revocation proposal in the proposed order. However, before revoking a license, FDA first had to issue an NOOH (§ 601.5(b)(1) (21 CFR 601.5(b)(1))). Therefore, under § 601.25, FDA had to issue an NOOH before issuing a final classification order because that final classification order had to include the license revocation.

Although § 601.26 is silent on this issue, as stated in the preamble, the agency did follow the process analogous to § 601.25 for this license revocation. In the proposed order issued at 65 FR 31003, May 15, 2000, FDA stated that the proposed order contained the agency’s intent to revoke the licenses of certain products that the agency proposed to reclassify into Category II. The agency further stated that, after the end of the comment period on the proposed order, if it decided to proceed with the license revocation proceeding, it would publish a NOOH on the revocation of the license of each Category II product. The agency also stated it would issue a final order on all matters covered by the proposed order (65 FR at 31005). In fact, § 601.26(e) provides for the final order to cover all matters in the proposed order. As with the procedures under § 601.25, FDA included notice of its intent to revoke certain licenses in the proposed order. In order to finalize all matters in the proposed order in the final order, it was necessary for FDA to issue the NOOH prior to the final order. Therefore, contrary to Delmont’s arguments, FDA has not violated its procedures.

In addition, Delmont is mistaken that FDA has deprived Delmont of fair notice and an opportunity for judicial review. This final order, which contains all of FDA’s reasons for denying Delmont a hearing and for revoking Delmont’s license, is final agency action that is reviewable in the courts (§ 12.28(d) (21 CFR 12.28(d))). Moreover, Delmont has had years of notice that FDA intends to reclassify SPL into Category II and to revoke its license based on that

reclassification, and has availed itself of two opportunities to comment on and object to FDA's proposal: (1) On August 9, 2000, in response to FDA's May 2000 proposal, and (2) on April 28, 2003, in response to FDA's NOOH (68 FR 8908). FDA has not deprived Delmont of fair notice, nor has FDA precluded Delmont from seeking judicial review.

#### D. Denial of Hearing Request

For the reasons stated previously in this document, the Commissioner of Food and Drugs (Commissioner) determines that Delmont has failed to raise a genuine and substantial issue of fact to justify a hearing on the proposed revocation of U.S. License No. 299 issued to Delmont Laboratories, Inc. for Polyvalent Bacterial Antigens with "no U.S. Standard of Potency" (Staphage Lysate), and, therefore, denies Delmont's request for a hearing. The Commissioner also determines that Delmont's procedural arguments do not provide a basis for a hearing.

#### IV. Categorization of Products—Final Order

The Commissioner has considered all relevant information regarding the four Category IIIA bacterial vaccines and bacterial antigens subject to reclassification and concludes that FDA's proposal for the reclassification of Category IIIA products into Category I or Category II is adopted as set forth in this section of this document and hereby formally classifies:

Category I—Biological products determined to be safe, effective, and not misbranded, and which may continue to be introduced into interstate commerce. Sanofi Pasteur Inc., U.S. License No.

1725:  
Tetanus Toxoid Adsorbed (primary and booster use), and  
Tetanus and Diphtheria Toxoids Adsorbed For Adult Use (DECAVAC™) (primary and booster use).

Category II—Biological products determined to be unsafe, ineffective, or misbranded, and which may not continue to be introduced into interstate commerce.

Delmont Laboratories Inc., U.S. License No. 299:  
Polyvalent Bacterial Antigens with "No U.S. Standard of Potency" Staphage Lysate® (SPL)

#### V. License Revocation—Final Order

For the reasons set forth in this document, under section 351 of the Public Health Service Act (42 U.S.C. 262) and 21 CFR 601.5(b)(1)(vi), the Commissioner revokes the license (U.S.

License No. 299) issued to Delmont Laboratories, Inc., for Polyvalent Bacterial Antigens with "No U.S. Standard of Potency" Staphage Lysate® (SPL).

#### VI. References

The following references have been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Final Report: Addendum to Previous Panel Reports for the Reclassification of Category IIIA Biologics, VRBPAC, 1984.
2. Fujino, Ryuichi; Yuji Sugisaki; Junko Nakagawa; Masana Komatsu; and Hachihiko Hirayama, "Chronic Toxicity Test of SPL in Rats," Fujizoki Pharmaceutical Co., Ltd., Shinjuku-ku, Tokyo.
3. Fujino, Ryuichi; Yuji Sugisaki; Junko Nakagawa; Masana Komatsu; "Acute and Subacute Toxicity Tests of SPL," Fujizoki Pharmaceutical Co., Ltd., Shinjuku-ku, Tokyo.
4. Hirayama, Hachihiko, "Teratogenicity Study of SPL in Rats and Rabbits," Fujizoki Pharmaceutical Co., Ltd., Nerima-ku, Tokyo.
5. "Effect of SPL on the Development of Skin Lesion in Mice after Inoculation with Herpes Simplex Virus," Department of Microbiology, School of Medicine, Kyushu University, Fukuoka, Japan.
6. "Chemotactic Accumulation of Macrophages in the Peritoneal Cavity after Inoculation of SPL and their Antitumor Activity," Department of Microbiology, School of Medicine, Kyushu University, Fukuoka, Japan.
7. "S-27: Summary of Results of Tests Conducted at Fuji-Zoki Pharmaceutical Research Division," Fujizoki Pharmaceutical Co., Ltd., Tokyo.
8. Shigeno, N.; T. Mitsuma; and K. Kojima, "Susceptibility of Staphylococcus aureus Clinical Isolates to Gratia Bacteriophage," Junior College of Medical Technology and Nursing affiliated with Niigata University.
9. Mitsuma, T.; N. Shigeno; K. Kojima; and M. Tanaka, "Influence of Staphage Lysate (SPL) on Immune Responses In Vitro," Junior College of Medical Technology and Nursing affiliated with Niigata University and Santo Hospital.
10. Azuma, C.; Y. Tokuda; and T. Shibata, "Immunopotiator Activity of Staphage Lysate (Mudd)," Department of Dermatology, Tokyo College of Medicine, Tokyo.
11. Tsuda, Shingo and Kikuo Minami, "Immunochemotherapy for Infections—With Particular Reference to Staphage Lysate," Department of Dermatology, Kurume University, School of Medicine, Kurume, Fukuoka Prefecture.
12. Salmon, G.G. and M. Symonds, "Staphage Lysate Therapy in Chronic Staphylococcal Infections," *Journal of*

*the Medical Society of New Jersey*, 60:180-193 (1963).

13. Rank, Dale, "Immune Stimulation Therapy for Inflammatory Disease of the Gut," and "Immune Stimulation for Aphthous (Herpetic) Stomatitis & Rhinitis," (Study Nov. 1975 to Dec. 1977).
14. Rank, Dale, "Immune Stimulation for Aphthous (Herpetic) Stomatitis & Rhinitis," (Jan. 1976 to Jan. 1978).

Dated: November 24, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-30441 Filed 12-3-10; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### National Advisory Council on Nurse Education and Practice; Notice for Request for Nominations

**SUMMARY:** The Health Resources and Services Administration (HRSA) is requesting nominations to fill eight vacancies on the National Advisory Council on Nurse Education and Practice (NACNEP).

**Authority:** 42 U.S.C. 297t, section 851 of the Public Health Service (PHS) Act, as amended by the Affordable Care Act. The NACNEP is governed by the Federal Advisory Committee Act, Public Law (Pub. L.) 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

**DATES:** The Agency must receive nominations on or before December 22, 2010. Addresses: All nominations are to be submitted either by mail to Lakisha Smith, MPH, Designated Federal Official, NACNEP, Division of Nursing, Bureau of Health Professions (BHPr), Health Resources and Services Administration (HRSA), Parklawn Building, Room 9B-45, 5600 Fishers Lane, Rockville, MD 20857 or e-mail at [Lsmith2@hrsa.gov](mailto:Lsmith2@hrsa.gov).

**FOR FURTHER INFORMATION CONTACT:** For additional information contact, Lakisha Smith, Executive Secretary, National Advisory Council on Nurse Education and Practice, by e-mail at [Lsmith2@hrsa.gov](mailto:Lsmith2@hrsa.gov) or telephone at (301) 443-5688. A copy of the current committee membership, charter and reports can be obtained by accessing the NACNEP Web site at <http://bhpr.hrsa.gov/nursing/nacnep.htm>.

**SUPPLEMENTARY INFORMATION:** Under the authorities that established the NACNEP and the Federal Advisory Committee Act, HRSA is requesting nominations

for eight committee members. The NACNEP advises and makes recommendations to the Secretary and Congress on policy matters arising in the administration of Title VIII, including the range of issues relating to the nurse workforce, nursing education and nursing practice improvement. The Advisory Council may make specific recommendations to the Secretary and Congress regarding programs administered by the Division of Nursing, Bureau of Health Professions, Health Resources and Services Administration. The Advisory Council provides advice to the Secretary and Congress in preparation of general regulations and with respect to policy matters in the administration of this Title including the range of issues relating to nurse supply, education, and practice improvement. The Advisory Council shall annually prepare and submit to the Secretary, the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report describing the activities of the Advisory Council including its findings and recommendations.

The Department of Health and Human Services is requesting a total of eight nominations for members of the NACNEP who represent any of the following groups: Full-time students representing various levels of education in schools of nursing; the general public; practicing professional nurses; leading authorities in the various fields of nursing, higher secondary education and associate degree schools of nursing; and representatives of advanced education nursing groups (such as nurse practitioners, nurse midwives, and nurse anesthetists), hospitals, and other institutions and organizations which provide nursing services. The majority of members of the fully constituted Council shall be nurses.

The Department is legally required to ensure that the membership of HHS Federal advisory committees is fairly balanced in terms of points of view represented and the functions to be performed by the advisory committee. Every effort is made to ensure that the views of women, all ethnic and racial groups, and people with disabilities are represented on all HHS Federal advisory committees and, therefore the Department encourages nominations of qualified candidates from these groups. The Department also encourages geographic diversity in Council composition. Appointment to this Council shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientations,

disability, culture, religion or socioeconomic status.

Interested persons may nominate one or more qualified persons for membership. Self-nominations are also accepted. Nominations must be typewritten. The following information should be included in the package of materials submitted for each individual being nominated: (1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.*, specific attributes that qualify the nominee for services in this capacity as described above), a statement that the nominee is willing to serve as a member of the NACNEP and appears to have no conflict of interest that would preclude this Council membership. Potential candidates will be asked to provide detailed information concerning such matters as financial holdings, consultancies, research grants, and/or contracts to permit an evaluation of possible sources of conflicts of interest; and (2) the nominator's name, address and daytime telephone number; the home/or work address, and telephone number; and finally, the e-mail address of the individual being nominated. HRSA requests inclusion of a current copy of the nominee's *curriculum vitae* and a statement of interest from the nominee which demonstrates experience working with or interest in Title VIII nursing programs; expertise in the field (if applying as a nursing candidate) or understanding of nursing issues (if applying as a general public candidate); and a personal desire to participate on a National Advisory Council. Members will receive a stipend for each day (including travel time) during which they are in attendance at official meetings of the Council, as well as per diem and travel expenses as authorized by section 5 U.S.C. 5703 for persons employed intermittently in government service. Qualified candidates will be invited to serve a four-year term.

Dated: November 30, 2010.

**Robert Hendricks,**

*Director, Division of Policy and Information Coordination.*

[FR Doc. 2010-30445 Filed 12-3-10; 8:45 am]

**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel Member Conflict: Cancer Immunotherapy.

*Date:* December 13, 2010.

*Time:* 12 p.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call).

*Contact Person:* Syed M. Quadri, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6210, MSC 7804, Bethesda, MD 20892. 301-435-1211. [quadris@csr.nih.gov](mailto:quadris@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 29, 2010.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-30458 Filed 12-3-10; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Cancer Institute Clinical Trials



and Translational Research Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

*Name of Committee:* National Cancer Institute Clinical Trials and Translational Research Advisory Committee.

*Date:* December 15, 2010.

*Time:* 9 a.m. to 4 p.m.

*Agenda:* Strategic Discussion of NCI's Clinical and Translational Research Programs.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, C-Wing, 6th Floor Conference Room, Bethesda, MD 20892.

*Contact Person:* Sheila A. Prindiville, MD, MPH, Director, Coordinating Center for Clinical Trials, Office of the Director, National Cancer Institute, National Institutes of Health, 6120 Executive Blvd., 3rd Floor Suite, Bethesda, MD 20892. 301-451-5048. [prindivs@mail.nih.gov](mailto:prindivs@mail.nih.gov).

This notice is being published less than 15 days prior to the meeting date due to scheduling conflicts.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: November 29, 2010.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-30456 Filed 12-3-10; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel Fellowship: Cell Biology Specials.

*Date:* December 10, 2010.

*Time:* 1:30 p.m. to 3:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call).

*Contact Person:* Alessandra M. Bini, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5142, MSC 7840, Bethesda, MD 20892. 301-435-1024. [binia@csr.nih.gov](mailto:binia@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel Member Conflict: Epidemiology and Genetics of Cancer.

*Date:* December 14, 2010.

*Time:* 11:30 a.m. to 1 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call).

*Contact Person:* Fungai Chanetsa, MPH, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3135, MSC 7770, Bethesda, MD 20892. 301-408-9436. [fungai.chanetsa@nih.hhs.gov](mailto:fungai.chanetsa@nih.hhs.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 29, 2010.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-30455 Filed 12-3-10; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

#### Notice of Cancellation of Customs Broker License

**AGENCY:** U.S. Customs and Border Protection, U.S. Department of Homeland Security.

**ACTION:** General notice.

**SUMMARY:** Pursuant to section 641 of the Tariff Act of 1930, as amended, (19 U.S.C. 1641) and the U.S. Customs and Border Protection regulations (19 CFR 111.45), the following Customs broker license and all associated permits are revoked with prejudice.

Name	License No.	Issuing port
Foreign Cargo Customs Brokers, Inc.	15965	New York

Dated: November 29, 2010.

**Daniel Baldwin,**

*Assistant Commissioner, Office of International Trade.*

[FR Doc. 2010-30427 Filed 12-3-10; 8:45 am]

**BILLING CODE 9111-14-P**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5376-N-113]

#### Notice of Submission of Proposed Information Collection to OMB; Notice of Proposed Information Collection for Public Comment; Mortgage Insurance for Cooperative and Condominium Housing

**AGENCY:** Office of the Chief Information Officer, HUD.

**ACTION:** Notice of proposed information collection.

**SUMMARY:** The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for emergency review and approval, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

Project information is analyzed to determine whether a cooperative or

condominium project is eligible for mortgage insurance.

**DATES:** *Comments Due Date:* January 5, 2011.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments must be received within thirty (30) days from the date of this Notice. Comments should refer to the proposal by name/or OMB approval number (2502–0141) and should be sent to: Ross A. Rutledge, HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; e-mail: *Ross.A.Rutledge@omb.eop.gov*; fax: 202–395–3086.

**FOR FURTHER INFORMATION CONTACT:** Colette Pollard, Departmental Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410; e-mail: *Colette*.

*Pollard@HUD.gov*; telephone: (202) 402–3400. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

**SUPPLEMENTARY INFORMATION:** This notice informs the public that the Department of Housing and Urban Development has submitted to OMB a request for approval of the Information collection described below. This notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (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 agency’s estimate of the burden of the proposed collection of information; (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 collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

*Title of Proposal:* Mortgage Insurance for Cooperative and Condominium Housing.

*Description of the Need for the Information and Its Proposed Use:* Project information is analyzed to determine whether a cooperative or condominium project is eligible for mortgage insurance.

*OMB Control Number:* 2502–0141.

*Form Numbers:* HUD–93201.

*Frequency of Submission:* On occasion.

	Number of respondents	Annual responses	×	Hours per response	=	Burden hours
Reporting Burden .....	20	0.25		4		20

*Total Estimated Burden Hours:* 20.

*Status:* Extension without change of a currently approved collection.

**Authority:** The Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35, as amended.

Dated: November 30, 2010.

**Colette Pollard,**

*Departmental Reports Management Officer, Office of the Chief Information Officer.*

[FR Doc. 2010–30494 Filed 12–3–10; 8:45 am]

**BILLING CODE 4210–67–P**

**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

[Docket No. FR–5380–N–48]

**Manufactured Home Construction and Safety Standards Act Reporting Requirements; Notice of Proposed Information Collection: Comment Request**

**AGENCY:** Office of the Assistant Secretary for Housing, HUD.

**ACTION:** Notice.

**SUMMARY:** The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

**DATES:** *Comments Due Date:* February 4, 2011.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Lillian Deitzer, Departmental Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410; e-mail *Colette.Pollard@HUD.gov* or telephone (202) 402–3400.

**FOR FURTHER INFORMATION CONTACT:** Teresa B. Payne, Associate Deputy Assistant Secretary for Regulatory Affairs and Manufactured Housing, Office of Risk Management and Regulatory Affairs, Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410, telephone (202) 708–6401 (this is not a toll free number) for copies of the proposed forms and other available information.

**SUPPLEMENTARY INFORMATION:** The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection 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 agency’s estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

*Title of Proposal:* Manufactured Home Construction and Safety Standards Reporting Requirements.

*OMB Control Number, if applicable:* 2502–0253.

*Description of the need for the information and proposed use:* Collection of this information will result in a better determination of reporting on placement of labels and notices in manufactured homes. It also will allow HUD and State Agencies to locate manufactured homes with defects.

*Agency form numbers, if applicable:*

*Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response:* The number of burden hours is 169,452. The number of respondents is 193, the number of responses is 116,833, the frequency of

response is on occasion, and the burden hour per response is 44.25.

*Status of the proposed information collection:* This is a new collection.

**Authority:** The Paperwork Reduction Act of 1995, 44 U.S.C., chapter 35, as amended.

Dated: November 30, 2010.

**Ronald Y. Spraker,**

*Associate General Deputy Assistant Secretary for Housing.*

[FR Doc. 2010-30496 Filed 12-3-10; 8:45 am]

**BILLING CODE 4210-67-P**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5380-N-47]

### Rehabilitation Mortgage Insurance Underwriting Program Section 203(k); Notice of Proposed Information Collection: Comment Request

**AGENCY:** Office of the Assistant Secretary for Housing, HUD.

**ACTION:** Notice.

**SUMMARY:** The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

**DATES:** *Comments Due Date: February 4, 2011.*

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Reports Liaison Officer, Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410, Room 9120 or the number for the Federal Information Relay Service (1-800-877-8339).

**FOR FURTHER INFORMATION CONTACT:**

Arlene Nunes, Deputy Director, Home Mortgage Insurance Division, Office of Single Family Program Development, Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410, telephone (202) 708-2121 (this is not a toll free number) for copies of the proposed forms and other available information.

**SUPPLEMENTARY INFORMATION:** The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed

collection of information to: (1) Evaluate whether the proposed collection 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 agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

*Title of Proposal:* Rehabilitation Mortgage Insurance Underwriting Program Section 203(k).

*OMB Control Number, if applicable:* 2502-0527.

*Description of the need for the information and proposed use:* The National Housing Act (12 U.S.C. 1703) authorizes the Secretary of Housing and Urban Development to insure financial institutions against losses as a result of borrower defaults on single-family mortgages. Specifically, under Section 203(k) of the Act, the Secretary is authorized to insure mortgages that fund the rehabilitation of single family homes. The information collection focuses on the loan origination process and issued for underwriting purposes and to document expenditures from repair escrow accounts.

*Agency form numbers, if applicable:* HUD-92700, HUD 92700-A, HUD-9746-A, HUD 92577.

*Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response:* The number of burden hours is 121,891. The number of respondents is 8225, the number of responses is 144,455, the frequency of response is on occasion, and the burden hour per response is an average 1.4 hours.

*Status of the proposed information collection:* This is an extension of a currently approved collection, OMB Control No. 2502-0527.

**Authority:** The Paperwork Reduction Act of 1995, 44 U.S.C., chapter 35, as amended.

Dated: November 30, 2010.

**Ronald Y. Spraker,**

*Associate General Deputy Assistant Secretary for Housing.*

[FR Doc. 2010-30497 Filed 12-3-10; 8:45 am]

**BILLING CODE 4210-67-P**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5448-N-01]

### Tax Credit Assistance Program—Reallocation of Funds

**AGENCY:** Office of the Assistant Secretary for Community Planning and Development, HUD.

**ACTION:** Notice.

**SUMMARY:** Through this notice, HUD announces the availability on its Web site of the application information, submission deadlines, funding criteria, and other requirements for the Reallocation of Tax Credit Assistance Program (TCAP) funds. This funding opportunity makes approximately \$16 million available to assist housing projects that received Low Income Housing Tax Credit (LIHTC) awards between October 1, 2006, and September 30, 2009. These TCAP funds may be used for capital investment in eligible LIHTC projects in accordance with CPD Notice 09-03. The information regarding the application process, funding criteria and eligibility requirements can be found at the HUD Web site at <http://portal.hud.gov/portal/page/portal/HUD/recovery/programs/tax>.

**FOR FURTHER INFORMATION CONTACT:**

Marcia Sigal, Director, Program Policy Division, Office of Affordable Housing Programs, Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410, telephone (202) 708-2684 (this is not a toll free number). Persons with speech or hearing impairments may access this telephone number via TTY by calling the toll-free Federal Information Relay Service during working hours at 800-877-8339.

Dated: November 16, 2010.

**Clifford Taffet,**

*General Deputy Assistant Secretary for Community Planning and Development (Acting).*

[FR Doc. 2010-30498 Filed 12-3-10; 8:45 am]

**BILLING CODE 4210-67-P**

## DEPARTMENT OF THE INTERIOR

### Geological Survey

#### National Cooperative Geologic Mapping Program (NCGMP) Advisory Committee

**AGENCY:** U.S. Geological Survey, Interior.

**ACTION:** Notice of audio conference.

**SUMMARY:** Pursuant to Public Law 106–148, the NCGMP Advisory Committee will hold an audio conference call on Wednesday, January 26, 2011, from 1 p.m.–3 p.m. Eastern Standard Time. The Committee will hear updates on progress of the NCGMP toward fulfilling the purposes of the National Geological Mapping Act of 1992; the Federal, State, and education components of the NCGMP; and the National Geological and Geophysical Data Preservation Program.

**DATES:** January 26, 2011, from 1 p.m.–3 p.m. Eastern Standard Time.

**FOR FURTHER INFORMATION CONTACT:** For the phone number and access code, please contact Stephanie Brown, U.S. Geological Survey, Mail Stop 908, National Center, Reston, Virginia 20192, (703) 648–6948.

**SUPPLEMENTARY INFORMATION:** Meetings of the National Cooperative Geologic Mapping Program Advisory Committee are open to the Public.

Dated: November 19, 2010.

**Kevin T. Gallagher,**

*Acting Associate Director for Core Science Systems.*

[FR Doc. 2010–30397 Filed 12–3–10; 8:45 am]

**BILLING CODE 4311–AM–P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Indian Affairs

#### Klamath Tribes Liquor Control Ordinance Correction

**AGENCY:** Bureau of Indian Affairs, Interior.

**ACTION:** Notice; correction.

**SUMMARY:** The Bureau of Indian Affairs published a notice in the **Federal Register** of October 22, 2010, concerning the Liquor Control Ordinance of the Klamath Tribes. This correction removes incorrect references to an amended ordinance and corrects the effective date of the ordinance.

**DATES:** *Effective Date:* This ordinance is effective as of October 22, 2010.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Colliflower, Office of Tribal Services, 1849 C Street, NW., Mail Stop 4513–MIB, Washington, DC 20240; Telephone (202) 513–7640; Fax (202) 208–5113.

#### Corrections

In the notice FR Doc. 2010–26695, beginning on page 65373 in the issue of October 22, 2010, make the following corrections:

(1) On page 65373, in the third column, in the **SUMMARY** section, remove

the words “the amendment to” from the first sentence. Also, remove the word “amendment” from the second and third sentences and add in its place “Ordinance.”

(2) On page 65373, in the third column, in the **DATES** section, change the effective date of the Ordinance from November 22, 2010 to October 22, 2010.

(3) On page 65374, in the first column, in the **SUPPLEMENTARY INFORMATION** section, remove the word “amended” in the third sentence of the first paragraph.

The corrected **SUMMARY** reads as follows:

**SUMMARY:** This notice publishes the Secretary’s certification of the Klamath Tribes Liquor Control Ordinance. The first Ordinance was published in the **Federal Register** on November 11, 1953 (18 FR 7178 (1953)). This Ordinance further regulates and controls the sale, possession and distribution of liquor within the tribal lands. The tribal lands are located in Indian country, and this Ordinance allows for possession of alcoholic beverages within their boundaries. This Ordinance will increase the ability of the tribal government to control liquor possession, sale, and use in the community.

The corrected first paragraph of the **SUPPLEMENTARY INFORMATION** section reads as follows:

**SUPPLEMENTARY INFORMATION:** Pursuant to the Act of August 15, 1953, Public Law 83–277, 67 Stat. 586, 18 U.S.C. 1161, as interpreted by the Supreme Court in *Rice v. Rehner*, 463 U.S. 713 (1983), the Secretary of the Interior shall certify and publish in the **Federal Register** notice of adopted liquor ordinances for the purpose of regulating liquor transactions in Indian country. The Klamath Tribes enacted this Liquor Control Ordinance by General Council Resolution #2010–004 on May 22, 2010. The purpose of this Ordinance is to govern the possession, sale, and distribution of alcohol within tribal lands of the Klamath Tribes.

Dated: November 22, 2010.

**Larry Echo Hawk,**

*Assistant Secretary—Indian Affairs.*

[FR Doc. 2010–30437 Filed 12–3–10; 8:45 am]

**BILLING CODE 4310–4J–P**

## INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–648]

### Certain Semiconductor Integration Circuits Using Tungsten Metallization and Products Containing Same; Notice of Commission Decision To Dismiss the Investigation as Moot

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has determined to issue an order dismissing the above-captioned investigation as moot.

#### FOR FURTHER INFORMATION CONTACT:

Clint Gerdine, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 708–2310. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at <http://www.usitc.gov>. The public record for this investigation may be viewed on the Commission’s electronic docket (EDIS) at <http://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205–1810.

**SUPPLEMENTARY INFORMATION:** The Commission instituted this investigation on May 21, 2008, based on a complaint filed on April 18, 2008, by LSI Corporation of Milpitas, California and Agere Systems Inc. of Allentown, Pennsylvania. The complaint, as amended, alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain semiconductor integrated circuits using tungsten metallization and products containing the same by reason of infringement of one or more of claims 1, 3, and 4 of U.S. Patent No. 5,227,335 (“the ‘335 patent”). The amended complaint named numerous respondents. Several respondents were terminated from the investigation due to settlement or failure to name the proper party. The following six respondents

remained in the investigation: Tower Semiconductor, Ltd. of Israel; Jazz Semiconductor of Newport Beach, California; Powerchip Semiconductor Corporation of Taiwan; Grace Semiconductor Manufacturing Corporation of China; Integrated Device Technology, Inc. of San Jose, California; and Nanya Technology Corporation of Taiwan. The complaint further alleged that an industry in the United States exists as required by subsection (a)(2) of section 337.

On March 22, 2010, the Commission issued notice of its final determination finding no violation, by reason of invalidity of the asserted claims of the '335 patent, of section 337 by the remaining respondents. Complainants appealed the Commission's final determination to the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit").

While the appeal was pending, the '335 patent expired. The Commission moved to dismiss the appeal as moot and complainants responded. On November 15, 2010, the Federal Circuit issued an order vacating the Commission's final determination and remanding the investigation to the Commission with instructions to dismiss the investigation as moot. *LSI Corp v. United States Int'l Trade Commission*, Appeal No. 10-1352 (Fed. Cir. Nov. 15, 2010). Accordingly, the Commission has determined to issue an order dismissing Investigation No. 337-TA-648 as moot.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in section 210.41 of the Commission's Rules of Practice and Procedure (19 CFR 210.41).

By order of the Commission.

Issued: November 30, 2010.

**Marilyn R. Abbott,**

*Secretary to the Commission.*

[FR Doc. 2010-30421 Filed 12-3-10; 8:45 am]

**BILLING CODE 7020-02-P**

## INTERNATIONAL TRADE COMMISSION

[Investigation No. 1205-8 (Addendum)]

### Certain Footwear: Recommendations for Modifying the Harmonized Tariff Schedule of the United States

**AGENCY:** United States International Trade Commission.

**ACTION:** Issuing an Addendum to an investigation for the purpose of making further recommendations.

**SUMMARY:** Following receipt of a request from the United States Trade Representative (USTR) on November 8, 2010, the Commission has decided to issue an Addendum to investigation No. 1205-8, *Certain Footwear:*

*Recommendations for Modifying the Harmonized Tariff Schedule of the United States*, for the purpose of making certain further recommendations to the President relating to the addition of new tariff lines applicable to the subject footwear.

**DATES:**

*December 22, 2010:* Deadline for filing submissions relating to entries liquidated prior to April 13, 2010, under heading 6405;

*December 29, 2010:* Date by which Commission will post proposed recommendations on its Web site;

*January 12, 2011:* Deadline for filing written views by other Federal agencies and interested parties;

*February 21, 2011:* Transmittal of (final) recommendations to the President.

**ADDRESSES:** All Commission offices are located in the United States International Trade Commission Building, 500 E Street SW., Washington, DC. All written submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street SW., Washington, DC 20436. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <http://edis.usitc.gov>.

**FOR FURTHER INFORMATION CONTACT:**

David Beck, Director, Office of Tariff Affairs and Trade Agreements (202-205-2603, fax 202-205-2616, [david.beck@usitc.gov](mailto:david.beck@usitc.gov)), or Janis L. Summers, Attorney Advisor, Office of Tariff Affairs and Trade Agreements (202-205-2605, [janis.summers@usitc.gov](mailto:janis.summers@usitc.gov)). The media should contact Margaret O'Laughlin, Office of External Affairs (202-205-1819, [margaret.olaughlin@usitc.gov](mailto:margaret.olaughlin@usitc.gov)). Hearing impaired individuals may obtain information on this matter by contacting the Commission's TDD terminal at 202-205-1810. General information concerning the Commission may also be obtained by accessing its Internet Web site at <http://www.usitc.gov>. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-205-2000.

*Background:* Section 1205(a) of the Omnibus Trade and Competitiveness Act of 1988 (the 1988 Act) (19 U.S.C. 3005(a)) provides that the Commission

shall keep the HTS under continuous review and periodically recommend to the President such modifications in the HTS as the Commission considers necessary or appropriate, *inter alia*, to promote the uniform application of the Harmonized System Convention. Subsections (b)-(d) of section 1205 set out procedures and requirements that the Commission must follow in making its recommendations.

On August 9, 2010, the Commission transmitted to the President a report containing its recommendations regarding modifications to the HTS for certain footwear that was the subject of its investigation No. 1205-8 (USITC Publication 4178, August 2010). A copy of that report is available on the Commission's Web site at [http://www.usitc.gov/tariff\\_affairs/hts\\_documents/1205-8FINALREPORTCOMBINED.pdf](http://www.usitc.gov/tariff_affairs/hts_documents/1205-8FINALREPORTCOMBINED.pdf). Pursuant to section 1206 of the 1988 Act, the President has submitted a report containing those recommendations to the House Committee on Ways and Means and Senate Committee on Finance for a 60-day layover period. The Commission noted in that report that it would keep the investigation open to allow it to make further recommendations.

On November 8, 2010, the Commission received a letter from the USTR requesting that the Commission make certain further recommendations concerning the footwear that was the subject of recommendations in the Commission's August 2010 report. More specifically, the USTR requested that the Commission, consistent with the provisions of section 1205(d)—

(1) Make further recommendations, based on new submissions to be filed by interested parties relating to entries liquidated prior to the Commission's initiation of this investigation on April 13, 2010, on the appropriateness of inserting new tariff lines under subheadings 6404.11 and 6404.19, in addition to those already recommended by the Commission in its August 2010 report; and

(2) Provide a further recommendation regarding whether the information previously provided to the Commission in investigation No. 1205-8 by the Footwear Distributors and Retailers of America (FDRA) and by Pro Line Manufacturing Company (Pro Line), covering entries liquidated prior to the initiation of the Commission's investigation on April 13, 2010, provides adequate support for their requests to add tariff lines under subheadings 6402.91.90, 6402.99.40, and 6401.99.

With respect to the first request, the USTR noted that the Commission in its August 2010 report correctly included descriptions specifying that footwear falling under the certain new tariff lines under current HTS subheadings 6404.11 and 6404.19 feature uppers of textile material other than vegetable fibers. The USTR further noted, however, that, because these descriptions appeared for the first time in the final report, interested parties may not have recognized the need to submit information on the tariff classification and rate of duty applied to imports in liquidated and undisputed entries of other footwear (e.g., having uppers of man-made fibers) falling into these new subheadings, so that the Commission could maintain tariff rate neutrality in making its recommendation.

With regard to the second request, the USTR noted that, shortly before the Commission issued its August 2010 report and recommendation, two interested parties, the FDRA and Pro Line, submitted copies of documents that, in their view, supported the need for the Commission to propose additional tariff lines under headings 6401 and 6402. The USTR noted that the Commission report indicated that the FDRA requested the addition of tariff lines under subheadings 6402.91.90 and 6402.99.40 for certain footwear, and that Pro Line requested an additional tariff line under subheading 6401.99 for other footwear. The USTR noted that the Commission did not recommend including these additional tariff lines and indicated that additional time could have been useful to the Commission in evaluating the information provided by the FDRA and Pro Line in that context.

For an up-to-date copy of the HTS, which incorporates the international Harmonized System in its structure, see the Commission's Web site at <http://www.usitc.gov/tata/hts/bychapter/index.htm>.

**Written Submissions:** Interested parties are invited to submit written copies of liquidated entries by December 22, 2010. The entry documentation solicited by the Commission in this notice should be for import entries liquidated before April 13, 2010, and covering footwear (1) having an outer sole with textile materials having the greatest surface area in contact with the ground; (2) currently classified under heading 6405; and (3) subject to reclassification under subheading 6404.11 or 6404.19 as a result of the Commission's recommendation set out in its August 2010 report. Recommendations in the Commission's addendum will be

limited to the possible new tariff subheadings specified in the USTR's request letter of November 8, 2010, and will not address any other facet of the Commission's August 2010 recommendation.

The Commission will post its proposed recommendations on this matter on its Web site at [http://www.usitc.gov/tariff\\_affairs/modifications\\_hts.htm](http://www.usitc.gov/tariff_affairs/modifications_hts.htm) by December 29, 2010. Interested Federal agencies and the public may file views on these proposed modifications by January 12, 2011.

All written submissions should be addressed to the Secretary and received no later than December 22, 2010 (for copies of the liquidated entries described above), and no later than January 12, 2011 (with regard to Commission's proposed recommendations). Submissions should be marked to refer to "Investigation No. 1205-8 (Addendum)". All written submissions must conform with the provisions of section 201.8 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.8). Section 201.8 requires that a signed original (or a copy so designated) and fourteen (14) copies of each document be filed. In the event that confidential treatment of a document is requested, at least four (4) additional copies must be filed, in which the confidential information must be deleted (see the following paragraph for further information regarding confidential business information). The Commission's rules authorize filing submissions with the Secretary by facsimile or electronic means only to the extent permitted by section 201.8 of the rules (see Handbook for Electronic Filing Procedures, [http://www.usitc.gov/docket\\_services/documents/handbook\\_on\\_electronic\\_filing.pdf](http://www.usitc.gov/docket_services/documents/handbook_on_electronic_filing.pdf)). Persons with questions regarding electronic filing should contact the Secretary (202-205-2000).

Any submissions that contain confidential business information must also conform with the requirements of section 201.6 of the *Commission's Rules of Practice and Procedure* (19 CFR 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the "confidential" or "non-confidential" version, and that the confidential business information be clearly identified by means of brackets. All written submissions, except for confidential business information, will be made available for inspection by the public. Any confidential business information received in the course of

the investigation may be included in the report that the Commission sends to the USTR and the President and may be made available to U.S. Customs and Border Protection and to the U.S. Census Bureau. The Commission will not otherwise publish or release any confidential business information received, nor release it to other government agencies or other persons.

Issued: November 30, 2010.

By order of the Commission.

**Marilyn R. Abbott,**

*Secretary to the Commission.*

[FR Doc. 2010-30422 Filed 12-3-10; 8:45 am]

**BILLING CODE 7020-02-P**

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## DEPARTMENT OF JUSTICE

[OMB Number 1123-0010]

### **Criminal Division; Agency Information Collection Activities: Proposed Collection; Comments Requested**

**ACTION:** 30-Day Notice of Information Collection Under Review: Request for Registration Under the Gambling Devices Act of 1962.

The Department of Justice (DOJ), Criminal Division will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 75, Number 187, page 59746 on September 28, 2010, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until January 5, 2011.

This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202) 395-5806. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agencies, estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

#### Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a currently approved collection.

(2) *Title of the Form/Collection:* Request for Registration Under the Gambling Devices Act of 1962.

(3) *Agency form number, if any, and the applicable component of the Department sponsoring the collection: Agency form number:* DOJ\CRM\OEO\GDR-1. *Sponsoring component:* Department of Justice, Criminal Division.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Business or other for-profit. *Other:* Not-for-profit institutions, individuals or households, and State, Local or Tribal Government. The form can be used by any entity required to register under the Gambling Devices Act of 1962 (15 U.S.C. 1171-1178).

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that 4,200 respondents will complete each form within approximately 5 minutes.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 350 total annual burden hours associated with this collection.

*If additional information is required contact:* Lynn Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street, NE., Suite 2E-502, Washington, DC 20530.

Dated: December 1, 2010.

**Lynn Murray,**  
Department Clearance Officer, PRA, U.S.  
Department of Justice.

[FR Doc. 2010-30517 Filed 12-3-10; 8:45 am]

**BILLING CODE 4410-14-P**

#### DEPARTMENT OF JUSTICE

[OMB Number 1103-0098]

#### Office of Community Oriented Policing Services; Agency Information Collection Activities: Revision of a Previously Approved Collection, With Change; Comments Requested

**ACTION:** 60-Day Notice of Information Collection Under Review: COPS Application Package.

The Department of Justice (DOJ) Office of Community Oriented Policing Services (COPS), has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The revision of a previously approved information collection is published to obtain comments from the public and affected agencies.

The purpose of this notice is to allow for 60 days for public comment until February 4, 2011. This process is conducted in accordance with 5 CFR 1320.10.

If you have comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Ashley Hoornstra, Department of Justice Office of Community Oriented Policing Services, 145 N Street, NE., Washington, DC 20530.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and

- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

#### Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a previously approved collection, with change; comments requested.

(2) *Title of the Form/Collection:* COPS Application Package.

(3) *Agency form number, if any, and the applicable component of the Department sponsoring the collection:* None. U.S. Department of Justice Office of Community Oriented Policing Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Law enforcement agencies and other public and private entities that apply for COPS Office grants or cooperative agreements will be asked to complete the COPS Application Package. The COPS Application Package includes all of the necessary forms and instructions that an applicant needs to review and complete to apply for COPS grant funding. The package is used as a standard template for all COPS programs.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that 14,100 respondents annually will complete the form within 11.3 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 159,330 total annual burden hours associated with this collection.

If additional information is required contact: Lynn Murray, Deputy Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street, NE., Suite 2E-502, Washington, DC 20530.

Dated: December 1, 2010.

**Lynn Murray,**  
Department Deputy Clearance Officer, PRA,  
U.S. Department of Justice.

[FR Doc. 2010-30514 Filed 12-3-10; 8:45 am]

**BILLING CODE 4410-AT-P**



**DEPARTMENT OF JUSTICE****Notice of Lodging of Consent Decree Under the Clean Air Act**

Notice is hereby given that on November 30, 2010, a proposed Consent Decree ("Decree") in *United States v. Interprint, Inc.*, Civil Action No. 3:10-cv-30223, was lodged with the United States District Court for the District of Massachusetts.

The Decree resolves claims of the United States against Interprint, Inc. under the Clean Air Act, 42 U.S.C. 7401-7671q, for injunctive relief and recovery of civil penalties in connection with Interprint Inc.'s construction and operation of a printing facility located in Pittsfield, Massachusetts. The Decree requires Interprint to pay \$80,000 in civil penalties, to institute injunctive relief in the form of production limits and restrictions while seeking plan approval under the Massachusetts State Implementation Plan, and to perform a supplemental environmental project valued at \$305,000.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the Decree. Comments should be addressed to the Assistant Attorney General, Environmental and Natural Resources Division, and either e-mailed to [pubcomment-ees.enrd@usdoj.gov](mailto:pubcomment-ees.enrd@usdoj.gov) or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044-7611, and should refer to *United States v. Interprint, Inc.*, 3:10-cv-30223 (D. Mass.), D.J. Ref. 90-5-2-1-09528.

The Decree may be examined at U.S. EPA Region I, 5 Post Office Square, Boston, MA 02109. During the public comment period, the Decree, may also be examined on the following Department of Justice Web site, [http://www.usdoj.gov/enrd/Consent\\_Decrees.html](http://www.usdoj.gov/enrd/Consent_Decrees.html). A copy of the Decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044-7611 or by faxing or e-mailing a request to Tonia Fleetwood ([tonia.fleetwood@usdoj.gov](mailto:tonia.fleetwood@usdoj.gov)), fax no. (202) 514-0097, phone confirmation number (202) 514-1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of \$23.25 (25 cents per page reproduction cost) payable to the U.S. Treasury or, if by e-mail or fax, forward a check in that amount to the

Consent Decree Library at the stated address.

**Maureen Katz,**

*Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.*

[FR Doc. 2010-30408 Filed 12-3-10; 8:45 am]

**BILLING CODE 4410-15-P**

**DEPARTMENT OF JUSTICE****Notice of Lodging of Modification To Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act**

Notice is hereby given that on November 30, 2010, a proposed modification ("Modification") to the Consent Decree in *United States v. City of Newburgh, et al.*, Civil Action No. 08 Civ. 7378 ("Consent Decree") was lodged with the United States District Court for the Southern District of New York.

The Modification resolves the claims of the United States, on behalf of the Environmental Protection Agency ("EPA"), under Sections 107 and 113 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended, 42 U.S.C. 9607 and 9613, against 27 potentially responsible parties ("Additional Settling Parties") who arranged for scrap metal containing hazardous substances to be transported to the Consolidated Iron and Metal Company Superfund Site (the "Site") for treatment or disposal.

The Site is a former junkyard and scrap metal processing facility located in the City of Newburgh, New York. Consolidated Iron and Metal Company, Inc. ("Consolidated") operated the facility from the 1950s until 1999. Consolidated, in the course of processing scrap metal materials, contaminated the Site with hazardous substances, including lead, polychlorinated biphenyls and volatile organic compounds. Consolidated is now a defunct company.

The original Consent Decree resolved the United States' claims against nine potentially responsible parties at the Site. The original Consent Decree was modified in October 2009 to add 58 additional settlers, and to resolve their potential liability at the Site.

The proposed Modification adds the 27 Additional Settling Parties to the Consent Decree and provides for them to pay \$276,655 to the United States to resolve their liability at the Site. The 27 Additional Settling Parties also are paying \$276,655 to five of the parties to the original Consent Decree. The Modification provides the 27 Additional

Settling Parties with covenants not to sue from the United States regarding the Site and contribution protection.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the Modification. Comments should be addressed to the Assistant Attorney General, Environmental and Natural Resources Division, and either e-mailed to [pubcomment-ees.enrd@usdoj.gov](mailto:pubcomment-ees.enrd@usdoj.gov) or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, D.C. 20044-7611, and should refer to *United States v. City of Newburgh, et al.*, D.J. Ref. 90-11-3-07979/2.

The Modification may be examined at the Office of the United States Attorney, 86 Chambers Street, 3rd Floor, New York, New York 10007, and at U.S. EPA Region 2, Office of Regional Counsel, 290 Broadway, New York, New York 10007-1866. During the public comment period, the Modification may also be examined on the following Department of Justice Web site, [http://www.usdoj.gov/enrd/Consent\\_Decrees.html](http://www.usdoj.gov/enrd/Consent_Decrees.html). A copy of the Modification may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044-7611 or by faxing or e-mailing a request to Tonia Fleetwood ([tonia.fleetwood@usdoj.gov](mailto:tonia.fleetwood@usdoj.gov)), fax no. (202) 514-0097, phone confirmation number (202) 514-1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of \$4.75 (25 cents per page reproduction cost) payable to the U.S. Treasury or, if by e-mail or fax, forward a check in that amount to the Consent Decree Library at the stated address.

**Maureen Katz,**

*Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.*

[FR Doc. 2010-30419 Filed 12-3-10; 8:45 am]

**BILLING CODE 4410-15-P**

**DEPARTMENT OF JUSTICE****Parole Commission****Sunshine Act Notice**

**Public Announcement; Pursuant to the Government in the Sunshine Act (Pub. L. 94-409) [5 U.S.C. Section 552b]**

**DATE AND TIME:** 12 a.m., Tuesday, December 7, 2010.

**PLACE:** U.S. Parole Commission, 5550 Friendship Boulevard, 4th Floor Chevy Chase, Maryland 20815.

**STATUS:** Closed.

**MATTERS CONSIDERED:** The following matter will be considered during the closed meeting: Consideration of two original jurisdiction cases pursuant to 28 CFR 2.27.

**AGENCY CONTACT:** Patricia W. Moore, Staff Assistant to the Chairman, United States Parole Commission, (301) 492-5933.

Dated: November 29, 2010.

**Rockne Chickinell,**

*General Counsel, U.S. Parole Commission.*

[FR Doc. 2010-30340 Filed 12-3-10; 8:45 am]

**BILLING CODE 4410-31-M**

## DEPARTMENT OF JUSTICE

### Parole Commission

#### Sunshine Act Notice

**Public Announcement; Pursuant to the Government in the Sunshine Act (Public Law 94-409) [5 U.S.C. Section 552b]**

**AGENCY HOLDING MEETING** Department of Justice, United States Parole Commission.

**TIME AND DATE** 10 a.m., December 7, 2010.

**PLACE** 5550 Friendship Blvd., Fourth Floor, Chevy Chase, MD 20815.

**STATUS** Open.

**MATTERS TO BE CONSIDERED** The following matters have been placed on the agenda for the open Parole Commission meeting:

1. Approval of Minutes September 9, 2010 Quarterly Business Meeting.
2. Reports from the Chairman, Commissioners and Section Administrators.
3. Revision of Original Jurisdiction Rule and Addition of a Rule on Tie Votes.

**AGENCY CONTACT** Patricia W. Moore, Staff Assistant to the Chairman, United States Parole Commission, (301) 492-5933.

Dated: November 29, 2010.

**Rockne J. Chickinell**

*General Counsel, U.S. Parole Commission.*

[FR Doc. 2010-30346 Filed 12-3-10; 8:45 am]

**BILLING CODE 4410-31-M**

## DEPARTMENT OF LABOR

### Employment and Training Administration

#### Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (19

U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers by (TA-W) number issued during the period of November 15, 2010 through November 19, 2010.

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Under Section 222(a)(2)(A), the following must be satisfied:

(1) A significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The sales or production, or both, of such firm have decreased absolutely; and

(3) One of the following must be satisfied:

(A) Imports of articles or services like or directly competitive with articles produced or services supplied by such firm have increased;

(B) Imports of articles like or directly competitive with articles into which one or more component parts produced by such firm are directly incorporated, have increased;

(C) Imports of articles directly incorporating one or more component parts produced outside the United States that are like or directly competitive with imports of articles incorporating one or more component parts produced by such firm have increased;

(D) Imports of articles like or directly competitive with articles which are produced directly using services supplied by such firm, have increased; and

(4) The increase in imports contributed importantly to such workers' separation or threat of separation and to the decline in the sales or production of such firm; or

II. Section 222(a)(2)(B) all of the following must be satisfied:

(1) A significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) One of the following must be satisfied:

(A) There has been a shift by the workers' firm to a foreign country in the production of articles or supply of services like or directly competitive with those produced/supplied by the workers' firm;

(B) There has been an acquisition from a foreign country by the workers' firm of articles/services that are like or directly competitive with those produced/supplied by the workers' firm; and

(3) the shift/acquisition contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected workers in public agencies and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) A significant number or proportion of the workers in the public agency have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The public agency has acquired from a foreign country services like or directly competitive with services which are supplied by such agency; and

(3) The acquisition of services contributed importantly to such workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected secondary workers of a firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(c) of the Act must be met.

(1) A significant number or proportion of the workers in the workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The workers' firm is a Supplier or Downstream Producer to a firm that employed a group of workers who received a certification of eligibility under Section 222(a) of the Act, and such supply or production is related to the article or service that was the basis for such certification; and

(3) Either—

(A) The workers' firm is a supplier and the component parts it supplied to the firm described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) A loss of business by the workers' firm with the firm described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected workers in firms identified by the International Trade Commission and a certification issued regarding eligibility to apply for worker

adjustment assistance, each of the group eligibility requirements of Section 222(f) of the Act must be met.

(1) The workers' firm is publicly identified by name by the International Trade Commission as a member of a domestic industry in an investigation resulting in—

(A) An affirmative determination of serious injury or threat thereof under section 202(b)(1);

(B) An affirmative determination of market disruption or threat thereof under section 421(b)(1); or

(C) An affirmative final determination of material injury or threat thereof under section 705(b)(1)(A) or 735(b)(1)(A) of the Tariff Act of 1930 (19 U.S.C. 1671d(b)(1)(A) and 1673d(b)(1)(A));

(2) The petition is filed during the 1-year period beginning on the date on which—

(A) A summary of the report submitted to the President by the International Trade Commission under section 202(f)(1) with respect to the affirmative determination described in paragraph (1)(A) is published in the **Federal Register** under section 202(f)(3); or

(B) Notice of an affirmative determination described in subparagraph (1) is published in the **Federal Register**; and

(3) The workers have become totally or partially separated from the workers' firm within—

(A) The 1-year period described in paragraph (2); or

(B) Notwithstanding section 223(b)(1), the 1-year period preceding the 1-year period described in paragraph (2).

**Affirmative Determinations for Worker Adjustment Assistance**

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) of the Trade Act have been met.

TA-W No.	Subject firm	Location	Impact date
73,462	Fantasy Activewear, Inc.	Vernon, CA	February 4, 2009.
74,572	Metal Powder Products	St. Marys, PA	August 26, 2009.
74,824	Electrolux International Company	Pittsburgh, PA	October 29, 2009.

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production or services) of the Trade Act have been met.

TA-W No.	Subject firm	Location	Impact date
73,696	Deloitte Financial Advisory Services LLP, Deloitte and Touche ...	Houston, TX	May 27, 2008.
73,928	Meyer Stamping & Manufacturing, Inc., Duffy Tool & Stamping, Brittany Stamping, Leased Wkrs Staffmark.	Fort Wayne, IN	April 5, 2009.
74,129	Vertafore, Leased Workers from Kelly Services	College Station, TX	May 19, 2009.
74,286	Pearson Education, Curriculum Group Division; Pearson, Inc.; Leased Workers from Corestaff.	Glenview, IL	June 8, 2009.
74,675	International Business Machines (IBM), The Hartford Insurance Company.	Hartford, CT	August 27, 2009.
74,675A	International Business Machines (IBM), The Hartford Insurance Company.	Simsbury, CT	August 27, 2009.
74,711	Silicon Valley Community Newspapers, Community Newspapers, LLC; Production.	San Jose, CA	September 14, 2009.
74,728	Dresser Incorporated, Flow Technologies Division	Avon, MA	October 8, 2009.
74,761	Miller Curtain Company, Inc.	San Antonio, TX	October 14, 2009.
74,770	Journal Register Company, Oakland Press Division; Leased Wkrs from Express Employment Professionals.	Pontiac, MI	October 20, 2009.
74,770A	Journal Register Company, Morning Star Division; Leased Workers from Express Employment Professionals.	Mt. Pleasant, MI	October 20, 2009.
74,782	American Bankers Insurance Co., dba Assurant Specialty Property, Leased Wkrs from Teksystems, Kforce, etc.	Miami, FL	October 25, 2009.
74,799	Brake Parts, Inc., a Division of Affinia Group, Inc	Litchfield, IL	November 19, 2010.
74,814	Elopak, Inc., Elopak A.S., Leased workers Lab Support, Venator, Lunch Specialist.	New Hudson, MI	October 18, 2009.
74,829	Chamberlain Access Solutions, Chamberlain Group, Inc.; Adecco Technical, Aerotek, etc.	Tucson, AZ	October 28, 2009.
74,830	Eaton Corporation, Industrial Controls Division; Leased Workers from Manpower Professional.	Clayton, NC	November 2, 2009.
74,855	Electrolux Homecare Products, Inc., Leased Wkrs from Spherion Recruiting and Staffing Excellence.	Bloomington, IL	November 8, 2009.
74,858	Benchmark Electronics, Leased Workers from Davis Companies	Nashua, NH	November 8, 2009.

The following certifications have been issued. The requirements of Section 222(c) (supplier to a firm whose workers are certified eligible to apply for TAA) of the Trade Act have been met.

TA-W No.	Subject firm	Location	Impact date
73,705	Lap Tech Industries	Dayton, OH	March 12, 2009.

TA-W No.	Subject firm	Location	Impact date
73,976 .....	Worthington Specialty Processing, A Joint Venture of Worthington Industries, Inc. and US Steel Corporation.	Canton, MI .....	April 18, 2009.
73,999 .....	Webb Furniture Enterprises, Inc., Leased Workers from Manpower.	Galax, VA .....	April 23, 2010.
74,525 .....	Emerson Transportation Division, A Division of Emerson Electric	Bridgeton, MO .....	August 10, 2009.
74,538 .....	Chris Stone, Inc. ....	Vernon, CA .....	August 12, 2009.
74,811 .....	Media Mail Packaging and Fulfillment Services, Inc .....	Algood, TN .....	November 1, 2009.

**Negative Determinations for Worker Adjustment Assistance**

In the following cases, the investigation revealed that the eligibility

criteria for worker adjustment assistance have not been met for the reasons specified.

The investigation revealed that the criterion under paragraph (a)(1), or

(b)(1), or (c)(1) (employment decline or threat of separation) of section 222 has not been met.

TA-W No.	Subject firm	Location	Impact date
74,380 .....	Wistron InfoComm (Texas) Corporation, Workers Operating from Home Offices Throughout the United States, etc.	Grapevine, TX.	
74,795 .....	Nevamar Company, LLC, Panolam Industries International, Inc.	Tarboro, NC.	

The investigation revealed that the criteria under paragraphs (a)(2)(A)

(increased imports) and (a)(2)(B) (shift in production or services to a foreign

country) of section 222 have not been met.

TA-W No.	Subject firm	Location	Impact date
73,747 .....	Synergy Solutions of Maine, LLC .....	Fort Kent, ME.	
74,366 .....	Ryder Truck Rental, Inc., Fleet Management Solutions Division.	Auburn Hills, MI.	
74,668 .....	Communication Cable Company .....	Malvern, PA.	
74,779 .....	Exel-Owens Corning, Chem/Industrial .....	Heath, OH.	

**Determinations Terminating Investigations of Petitions for Worker Adjustment Assistance**

After notice of the petitions was published in the **Federal Register** and

on the Department's Web site, as required by Section 221 of the Act (19 U.S.C. 2271), the Department initiated investigations of these petitions.

The following determinations terminating investigations were issued because the petitioner has requested that the petition be withdrawn.

TA-W No.	Subject firm	Location	Impact date
73,451 .....	Harley Davidson Motor Company .....	Milwaukee, WI.	
74,597 .....	International Game Technology .....	Corvallis, OR.	
74,683 .....	Los Angeles Daily News Publishing Company, Pre-Press Department.	San Bernardino, CA	
74,722 .....	Allied Marketing Group .....	Dallas, TX.	
74,739 .....	Chapman Data Services, Inc. ....	Dallas, TX.	
74,873 .....	HAVI Logistics North America .....	Lisle, IL.	

The following determinations terminating investigations were issued in cases where these petitions were not filed in accordance with the requirements of 29 CFR 90.11. Every petition filed by workers must be signed

by at least three individuals of the petitioning worker group. Petitioners separated more than one year prior to the date of the petition cannot be covered under a certification of a petition under Section 223(b), and

therefore, may not be part of a petitioning worker group. For one or more of these reasons, these petitions were deemed invalid.

TA-W No.	Subject firm	Location	Impact date
74,583 .....	David R. Webb Company .....	Williamsport, PA.	
74,822 .....	Bank of America .....	Los Angeles, CA.	

The following determinations terminating investigations were issued because the Department issued a

negative determination on petitions related to the relevant investigation period applicable to the same worker

group. The duplicative petitions did not present new information or a change in circumstances that would result in a

reversal of the Department's previous negative determination, and therefore,

further investigation would duplicate efforts and serve no purpose.

TA-W No.	Subject firm	Location	Impact date
74,697 .....	Bank of America, Card Customer Assistance Division .....	State College, PA.	

I hereby certify that the aforementioned determinations were issued during the period of November 15, 2010 through November 19, 2010. Copies of these determinations may be requested under the Freedom of Information Act. Requests may be submitted by fax, courier services, or mail to FOIA Disclosure Officer, Office of Trade Adjustment Assistance (ETA), U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 or [tofoiarequest@dol.gov](mailto:tofoiarequest@dol.gov). These determinations also are available on the Department's Web site at <http://www.doleta.gov/tradeact> under the searchable listing of determinations.

Dated: November 23, 2010.

**Michael W. Jaffe,**

*Certifying Officer, Office of Trade Adjustment Assistance.*

[FR Doc. 2010-30464 Filed 12-3-10; 8:45 am]

**BILLING CODE 4510-FN-P**

## NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[10-150]

### Notice of Information Collection

**AGENCY:** National Aeronautics and Space Administration (NASA).

**ACTION:** Notice of information collection.

**SUMMARY:** The National Aeronautics and Space Administration, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. 3506(c)(2)(A)).

**DATES:** All comments should be submitted within 60 calendar days from the date of this publication.

**ADDRESSES:** All comments should be addressed to Lori Parker, National Aeronautics and Space Administration, Washington, DC 20546-0001.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Lori Parker, NASA Clearance Officer, NASA Headquarters,

300 E Street, SW., JF0000, Washington, DC 20546, (202) 358-1351, [Lori.Parker@nasa.gov](mailto:Lori.Parker@nasa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Abstract

The NASA Office of the Chief Information Officer conducts an annual IT Summit, inviting government and private industry to join in collaboration about the latest trends in information technology. This collection covers the registration process for the conference as well as the post-conference survey.

##### II. Method of Collection

Electronic.

##### III. Data

*Title:* NASA IT Summit.

*OMB Number:* 2700-XXXX.

*Type of Review:* New Collection.

*Affected Public:* Federal Government and Individuals.

*Estimated Number of Respondents:* 2000.

*Estimated Number of Responses per Respondent:* 1.

*Estimated Time Per Response:* 5 minutes.

*Estimated Total Annual Burden Hours:* 167 hours.

*Estimated Total Annual Cost:* \$0.00.

##### IV. Request for Comments

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of NASA, including whether the information collected has practical utility; (2) the accuracy of NASA's estimate of the burden (including hours and cost) of the proposed collection of information; (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 automated collection techniques or the use of other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of this information collection. They will also become a matter of public record.

**Lori Parker,**

*NASA Clearance Officer.*

[FR Doc. 2010-30396 Filed 12-3-10; 8:45 am]

**BILLING CODE 7510-13-P**

## NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[10-152]

### Notice of Information Collection

**AGENCY:** National Aeronautics and Space Administration (NASA).

**ACTION:** Notice of information collection.

**SUMMARY:** The National Aeronautics and Space Administration, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. 3506(c)(2)(A)).

**DATES:** All comments should be submitted within 30 calendar days from the date of this publication.

**ADDRESSES:** All comments should be addressed to Lori Parker, National Aeronautics and Space Administration, Washington, DC 20546-0001.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Lori Parker, NASA PRA Officer, NASA Headquarters, 300 E Street, SW., JF0000, Washington, DC 20546, (202) 358-1351, [Lori.Parker@nasa.gov](mailto:Lori.Parker@nasa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Abstract

The KEEP is a job shadowing program intended to provide students with career exploration under the mentorship of a Kennedy Space Center (KSC) NASA of contractor employee. Participation in the program is limited to students who are U.S. citizens, 16 years or older, who have been recommended by a teacher, guidance counselor, or other school official. Students may shadow for 1 day or up to 1 week.

##### II. Method of Collection

The collection of information will be made by the use of a Web-based on-line application system, and a database of applicant information will be developed. We believe this is the most efficient and cost effective way to collect the information.

**III. Data**

*Title:* Kennedy Educational Experiences program (KEEP).

*OMB Number:* 2700-0135.

*Type of review:* Extension, without change, of a currently approved collection.

*Affected Public:* Individuals or households.

*Estimated Number of Respondents:* 20.

*Estimated Total Annual Burden Hours:* 20.

*Estimated Total Annual Cost to Government:* \$0.

**IV. Request for Comments**

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of NASA, including whether the information collected has practical utility; (2) the accuracy of NASA's estimate of the burden (including hours and cost) of the proposed collection of information; (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 automated collection techniques or the use of other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of this information collection. They will also become a matter of public record.

**Lori Parker,**

*NASA PRA Clearance Officer.*

[FR Doc. 2010-30523 Filed 12-3-10; 8:45 am]

**BILLING CODE 7510-13-P**

**NATIONAL AERONAUTICS AND SPACE ADMINISTRATION**

[10-151]

**Notice of Information Collection**

**AGENCY:** National Aeronautics and Space Administration (NASA).

**ACTION:** Notice of information collection.

**SUMMARY:** The National Aeronautics and Space Administration, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. 3506(c)(2)(A)).

**DATES:** All comments should be submitted within 30 calendar days from the date of this publication.

**ADDRESSES:** All comments should be addressed to Lori Parker, National Aeronautics and Space Administration, Washington, DC 20546-0001.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Lori Parker, NASA Clearance Officer, NASA Headquarters, 300 E Street, SW., JF0000, Washington, DC 20546, (202) 358-1351, *Lori.Parker@nasa.gov*.

**SUPPLEMENTARY INFORMATION:****I. Abstract**

This information collection helps to ensure that engineering changes to contracts are made quickly and in a cost effective manner. Proposals supporting such change orders contain detailed information to obtain best goods and services for the best prices.

**II. Method of Collection**

NASA does not prescribe a format for submission, though most contractors have cost collection systems which are used for proposal preparation. NASA encourages the use of computer technology for preparing proposals and submission.

**III. Data**

*Title:* JSC Cooperative Education Program—Housing Availability.

*OMB Number:* 2700-xxxx.

*Type of Review:* Existing Collection in use w/o an OMB number.

*Affected Public:* Individuals/ Households.

*Estimated Number of Respondents:* 101.

*Estimated Time per Response:* 5 minutes.

*Estimated Total Annual Burden Hours:* 8.4 hours.

*Estimated Total Annual Cost:* \$0.00.

**IV. Request for Comments**

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of NASA, including whether the information collected has practical utility; (2) the accuracy of NASA's estimate of the burden (including hours and cost) of the proposed collection of information; (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 automated collection techniques or the use of other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of this information collection. They will also become a matter of public record.

**Lori Parker,**

*NASA PRA Clearance Officer.*

[FR Doc. 2010-30522 Filed 12-3-10; 8:45 am]

**BILLING CODE 7510-13-P**

**NATIONAL LABOR RELATIONS BOARD****Sunshine Act Meetings****Time and Dates**

All meetings are held at 2:30 p.m.

Wednesday, December 1;

Thursday, December 2;

Tuesday, December 7;

Wednesday, December 8;

Thursday, December 9;

Tuesday, December 14;

Wednesday, December 15;

Thursday, December 16;

Tuesday, December 21;

Wednesday, December 22;

Thursday, December 23;

Tuesday, December 28;

Wednesday, December 29;

Thursday, December 30.

**PLACE:** Board Agenda Room, No. 11820, 1099 14th St., NW., Washington DC 20570.

**STATUS:** Closed.

**MATTERS TO BE CONSIDERED:** Pursuant to § 102.139(a) of the Board's Rules and Regulations, the Board or a panel thereof will consider "the issuance of a subpoena, the Board's participation in a civil action or proceeding or an arbitration, or the initiation, conduct, or disposition \* \* \* of particular representation or unfair labor practice proceedings under section 8, 9, or 10 of the [National Labor Relations] Act, or any court proceedings collateral or ancillary thereto." *See also* 5 U.S.C. 552b(c)(10).

Dated: December 2, 2010.

**Lester A. Heltzer,**

*Executive Secretary.*

[FR Doc. 2010-30681 Filed 12-2-10; 4:15 pm]

**BILLING CODE 7545-01-P**

## NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50-275-LR; 50-323-LR]

### Pacific Gas and Electric Company (Diablo Canyon Nuclear Power Plant, Units 1 And 2); Notice of Appointment of Adjudicatory Employee

*Commissioners:* Gregory B. Jaczko, Chairman; Kristine L. Svinicki; George Apostolakis; William D. Magwood, IV; William C. Ostendorff

Pursuant to 10 CFR 2.4, notice is hereby given that Dr. Tianqing Cao, Senior Seismologist, Office of Nuclear Material Safety and Safeguards, has been appointed as a Commission adjudicatory employee within the meaning of section 2.4, to advise the Commission regarding issues relating to pending appeals filed by the applicant and the Nuclear Regulatory Commission staff in this case, as well as a waiver request filed by the petitioner pursuant to 10 CFR 2.335(b). Dr. Cao has not previously performed any investigative or litigating function in connection with this proceeding. Until such time as a final decision is issued in this matter, interested persons outside the agency and agency employees performing investigative or litigating functions in this proceeding are required to observe the restrictions of 10 CFR 2.347 and 2.348 in their communications with Dr. Cao.

*It is so ordered.*

Dated at Rockville, Maryland, this 5th day of November, 2010.

**Annette L. Vietti-Cook,**  
*Secretary of the Commission.*

[FR Doc. 2010-30480 Filed 12-3-10; 8:45 am]

BILLING CODE 7590-01-P

## NUCLEAR REGULATORY COMMISSION

[Docket No. 30-36974; NRC-2010-0374]

### Notice of Availability of Draft Supplement to the Environmental Assessment for the Proposed Pa'ina Hawaii, LLC Irradiator in Honolulu, HI

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Notice of availability.

**SUMMARY:** Notice is hereby given that the U.S. Nuclear Regulatory Commission (NRC) is issuing and publishing for public comment a Draft Supplement to the Environmental Assessment (EA) for the irradiator proposed by Pa'ina Hawaii, LLC (Pa'ina). On June 23, 2005, Pa'ina submitted an application to NRC

requesting a license to possess and use byproduct material in connection with a proposed underwater irradiator. NRC completed the Final EA and Finding of No Significant Impact (FONSI) for this action on August 10, 2007, and subsequently issued a license to Pa'ina on August 17, 2007. The license authorizes Pa'ina to possess and use byproduct material (sealed sources) in a commercial underwater irradiator to be located adjacent to Honolulu International Airport on Palekona Street near Lagoon Drive. NRC is issuing this Draft Supplement to the EA in response to a decision of the Atomic Safety and Licensing Board (Board) from the NRC's Atomic Safety and Licensing Board Panel (ASLBP). As directed by the Board, this Draft Supplement addresses the following three areas: (1) Environmental impacts of accidents that might occur during the transport of cobalt-60 sources to and from Pa'ina's irradiator, (2) electron-beam technology as an alternative to cobalt-60 irradiation, and (3) alternative sites for Pa'ina's irradiator.

**DATES:** The public comment period on the Draft Supplement begins on the date of publication of this notice and ends on January 6, 2011. Written comments should be submitted as described in the **ADDRESSES** section of this notice.

Comments submitted by mail should be postmarked by January 6, 2011, to ensure consideration. Comments received or postmarked after January 6, 2011 will be considered to the extent practical, but the Commission is able to assure consideration only for comments received on or before this date.

**ADDRESSES:** You may submit comments by any one of the following methods. Please include the Docket ID NRC-2010-0374 in the subject line of your comments. 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.

*Electronic Mail:* Comments may be sent by electronic mail to the following address: [PainaEA@nrc.gov](mailto:PainaEA@nrc.gov).

*Federal Rulemaking Web site:* Go to <http://www.regulations.gov> and search for documents filed under Docket ID

NRC-2010-0374. Comments may be submitted electronically through this Web site. Address questions about NRC dockets to Carol Gallagher, 301-492-3668, e-mail [Carol.Gallagher@nrc.gov](mailto:Carol.Gallagher@nrc.gov).

*Mail comments to:* Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Division of Administrative Services, Office of Administration, Mail Stop: TWB5-B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by fax to RADB at 301-492-3446.

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>.

#### FOR FURTHER INFORMATION CONTACT:

Johari Moore, Project Manager, Environmental Review Branch A, Division of Waste Management and Environmental Protection, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Rockville, Maryland 20852. Telephone: 301-415-7694; fax number: 301-415-5369; e-mail: [Johari.Moore@nrc.gov](mailto:Johari.Moore@nrc.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Introduction

By letter dated August 17, 2007, the U.S. Nuclear Regulatory Commission (NRC) issued Materials License No. 53-29296-01 to Pa'ina authorizing possession and use of byproduct material (sealed sources) in a commercial underwater irradiator to be located immediately adjacent to Honolulu International Airport on Palekona Street near Lagoon Drive. Also on August 17, 2007, NRC published a Notice of Availability in the **Federal Register** for the EA and FONSI prepared in support of this licensing action (72 FRN 46249). On September 4, 2007, Concerned Citizens of Honolulu filed contentions challenging the NRC staff's analysis in the Final EA. In an August 27, 2009 decision, the Board found that the staff needed to supplement the Pa'ina EA in order to address (1) environmental impacts of accidents that might occur during the transport of cobalt-60 sources to and from Pa'ina's irradiator, (2) electron-beam technology as an alternative to cobalt-60 irradiation, and (3) alternative sites for Pa'ina's irradiator. The Board's findings on these issues were affirmed in a July 8, 2010 decision by the NRC's Commission. In the Draft Supplement issued today, the NRC staff addresses each of the issues identified by the Board.



## II. Summary of Draft Supplement to the EA

Pa'ina's license authorizes it to use byproduct material (sealed radioactive sources) in a pool irradiator to be located adjacent to Honolulu International Airport, Honolulu, Hawaii. The irradiator would be used for the production and research irradiation of food, cosmetic, and pharmaceutical products. Pa'ina's license request was previously noticed in the **Federal Register** on August 2, 2005 (70 FR 44396), with a notice of an opportunity to request a hearing.

The staff prepared an EA in support of its review of the license application. The staff considered impacts to areas such as public and occupational health, transportation, socioeconomic, ecology, water quality, and the effects of aircraft crashes and natural phenomena.

The staff has prepared a Draft Supplement to the EA as directed by the Board. In the first area identified by the Board, the staff found that accidents occurring during the transport of cobalt-60 to or from Pa'ina's proposed irradiator will not cause a significant impact to the environment. This is due primarily to the very low likelihood cobalt-60 will be released from a shipping package. The low likelihood of release is due to several factors, including the small number of cobalt-60 shipments to Pa'ina's irradiator and the stringent safety requirements for the design of cobalt-60 shipping packages. In the second area identified by the Board, the staff found that the environmental impacts of an electron-beam irradiator will be small for each resource area. The staff also found that the impacts will not be significantly different than those associated with construction and operation of a cobalt-60 irradiator. In the third area identified by the Board, the staff found that impacts associated with construction and operation of a cobalt-60 irradiator at alternative sites will be small and will not be significantly different than those at the proposed site. In particular, the staff found that aircraft crashes involving the alternative sites will have no significant impact on public health and safety. The staff also found that environmental impacts from earthquakes, tsunamis, and hurricanes at the alternative locations will be small.

## III. Further Information

Publicly available documents created or received at the NRC, including the Draft Supplement to the EA, the August 10, 2007, EA, and the Pa'ina license and supporting documentation, are available electronically at the NRC's Electronic

Reading Room at <http://www.nrc.gov/reading-rm/adams.html>. From this site, the public can access the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The ADAMS accession number for the Draft Supplement to the EA is ML103220072. The ADAMS accession numbers for the August 10, 2007, EA and the August 17, 2007, license are ML071150121 and ML072320269, respectively. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1-800-397-4209, 301-415-4737 or by e-mail to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov)

The public may examine and have copied for a fee publicly available documents at the NRC's PDR, Room O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. In addition, documents relating to the administrative litigation associated with Pa'ina's application may be found in the Electronic Hearing Docket maintained by the NRC's Office of the Secretary at <http://ehd1.nrc.gov/EHD/>.

Dated at Rockville, Maryland, this 29th day of November, 2010.

For the U.S. Nuclear Regulatory Commission.

### David Skeen,

*Acting Deputy Director, Environmental Protection and Performance Assessment Directorate, Division of Waste Management and Environmental Protection, Office of Federal and State Materials and Environmental Management Programs.*

[FR Doc. 2010-30488 Filed 12-3-10; 8:45 am]

**BILLING CODE 7590-01-P**

## NUCLEAR REGULATORY COMMISSION

[NRC-2010-0371]

### Notice of Availability of the Models for Plant-Specific Adoption of Technical Specifications Task Force (TSTF) Traveler TSTF-431, Revision 3, "Change in Technical Specifications End States (BAW-2441)"

**AGENCY:** Nuclear Regulatory Commission (NRC).

**ACTION:** Notice of availability.

**SUMMARY:** As part of the consolidated line item improvement process (CLIP), the NRC is announcing the availability of the model application (with model no significant hazards consideration (NSHC) determination) and model safety evaluation (SE) for the plant-specific adoption of Technical

Specifications Task Force (TSTF) Traveler TSTF-431, Revision 3, "Change in Technical Specifications End States (BAW-2441)." TSTF-431, Revision 3, is available in the Agencywide Documents Access and Management System (ADAMS) under Accession Number ML093570241. The proposed changes revise the Standard Technical Specifications (STS) to permit, for some systems, entry into a hot shutdown (Mode 4) end state rather than a cold shutdown (Mode 5) end state. These changes are associated with the implementation of Topical Report BAW-2441-A, Revision 2, "Risk-Informed Justification for LCO End-State Changes." The CLIIP model SE will facilitate expedited approval of plant-specific adoption of TSTF-431, Revision 3.

*Documents:* You can access publicly available documents related to this notice 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, Public File Area O1 F21, 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 the ADAMS, which provides text and image files of NRC's public documents. If you do not have access to the ADAMS or if there are problems in accessing the documents located in the ADAMS, contact the NRC's PDR reference staff at 1-800-397-4209, 301-415-4737, or by e-mail at [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov).

The model application (with model NSHC determination) and model SE for the plant-specific adoption of TSTF-431, Revision 3, are available electronically under ADAMS Accession Number ML102310365. The NRC staff disposition of comments received on the Notice of Opportunity for Comment announced in the **Federal Register** on November 21, 2007 (72 FR 65615-65629), is available electronically under ADAMS Accession Number ML102310364.

*Federal Rulemaking Web site:* The public comments received and supporting materials related to this notice can be found at <http://www.regulations.gov> by searching on Docket ID: NRC-2010-0371.

**FOR FURTHER INFORMATION CONTACT:** Mr. Ravi Grover, Reactor Systems Engineer,

Technical Specifications Branch, Mail Stop: O-7C2A, Division of Inspection and Regional Support, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC, 20555-0001; telephone 301-415-2166 or e-mail at [Ravinder.Grover@nrc.gov](mailto:Ravinder.Grover@nrc.gov) or Ms. Michelle C. Honcharik, Senior Project Manager, Licensing Processes Branch, Mail Stop: O-12 D1, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone 301-415-1774 or e-mail at [Michelle.Honcharik@nrc.gov](mailto:Michelle.Honcharik@nrc.gov).

**SUPPLEMENTARY INFORMATION:** TSTF-431, Revision 3, is applicable to Babcock & Wilcox reactor plants. Licensees opting to apply for this TS change are responsible for reviewing TSTF-431, Revision 3, and the NRC staff's SE, providing any necessary plant-specific information, and assessing the completeness and accuracy of their license amendment request (LAR). It is acceptable for licensees to use plant-specific system names, TS numbering and titles. The NRC will process each amendment application responding to this notice of availability according to applicable NRC rules and procedures.

The models do not prevent licensees from requesting an alternate approach or proposing changes other than those proposed in TSTF-431, Revision 3. However, significant deviations from the approach recommended in this notice or the inclusion of additional changes to the license require additional NRC staff review and would not be reviewed as a part of the CLIP. This may increase the time and resources needed for the review or result in NRC staff rejection of the LAR. Licensees desiring significant deviations or additional changes should instead submit an LAR that does not claim to adopt TSTF-431, Revision 3.

Dated at Rockville, Maryland, this 23rd day of November 2010.

For the Nuclear Regulatory Commission,

**John R. Jolicoeur,**

*Chief, Licensing Processes Branch, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation.*

[FR Doc. 2010-30490 Filed 12-3-10; 8:45 am]

**BILLING CODE 7590-01-P**

**NUCLEAR REGULATORY COMMISSION**

[Docket Nos. STN 50-237, STN 50-249, STN 50-254, and STN 50-265; NRC-2010-0373]

**Dresden Nuclear Power Station, Units 2 and 3 and Quad Cities Nuclear Power Station, Unit Nos. 1 and 2; Notice of Withdrawal of Application for Amendment to Facility Operating License**

The U.S. Nuclear Regulatory Commission (the Commission) has granted the request of Exelon Generation Company, LLC (the licensee) to withdraw its November 10, 2009; as supplemented by letters dated October 12, 2010 and November 16, 2010; application for proposed amendments to Renewed Facility Operating License Nos. DPR-19 and DPR-25 for Dresden Nuclear Power Station, Units 2 and 3, respectively, located in Grundy County, Illinois, and to Renewed Facility Operating License Nos. DPR-29 and DPR-30 for Quad Cities Nuclear Power Station, Unit Nos. 1 and 2, respectively, located in Rock Island, Illinois.

The proposed amendment would have revised Technical Specification 3.1.7, "Standby Liquid Control (SLC) System," to extend the completion time for Condition B (*i.e.*, "Two SLC subsystems inoperable") from 8 hours to 72 hours.

The Commission had previously issued a Notice of Consideration of Issuance of Amendment published in the **Federal Register** on February 9, 2010 (75 FR 6410). However, by letter dated November 16, 2010, the licensee withdrew the proposed change.

For further details with respect to this action, see the application for amendment dated November 10, 2009, as supplemented by letters dated October 12, 2010 and the licensee's letter dated November 16, 2010, which withdrew the application for license amendment. Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room (PDR), located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the Agencywide Documents Access and Management System (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, <http://www.nrc.gov/reading-rm/adams.html>. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC PDR Reference staff by telephone at 1-800-

397-4209, or 301-415-4737 or by e-mail to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov).

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

For the Nuclear Regulatory Commission.

**Eva A. Brown,**

*Senior Project Manager, Plant Licensing Branch III-2, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation,*

[FR Doc. 2010-30485 Filed 12-3-10; 8:45 am]

**BILLING CODE 7590-01-P**

**OFFICE OF PERSONNEL MANAGEMENT**

**Federal Prevailing Rate Advisory Committee; Open Committee Meetings**

According to the provisions of section 10 of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given that meetings of the Federal Prevailing Rate Advisory Committee will be held on—

Thursday, January 20, 2011.	Thursday, July 21, 2011.
Thursday, February 17, 2011.	Thursday, August 18, 2011.
Thursday, March 17, 2011.	Thursday, September 15, 2011.
Thursday, April 21, 2011.	Thursday, October 20, 2011.
Thursday, May 19, 2011.	Thursday, November 17, 2011.
Thursday, June 16, 2011.	Thursday, December 15, 2011.

The meetings will start at 10 a.m. and will be held in Room 5A06A, U.S. Office of Personnel Management Building, 1900 E Street, NW., Washington, DC.

The Federal Prevailing Rate Advisory Committee is composed of a Chair, five representatives from labor unions holding exclusive bargaining rights for Federal blue-collar employees, and five representatives from Federal agencies. Entitlement to membership on the Committee is provided for in 5 U.S.C. 5347.

The Committee's primary responsibility is to review the Prevailing Rate System and other matters pertinent to establishing prevailing rates under subchapter IV, chapter 53, 5 U.S.C., as amended, and from time to time advise the U.S. Office of Personnel Management.

These scheduled meetings are open to the public with both labor and management representatives attending. During the meetings either the labor members or the management members may caucus separately to devise strategy and formulate positions. Premature disclosure of the matters discussed in

these caucuses would unacceptably impair the ability of the Committee to reach a consensus on the matters being considered and would disrupt substantially the disposition of its business. Therefore, these caucuses will be closed to the public because of a determination made by the Director of the U.S. Office of Personnel Management under the provisions of section 10(d) of the Federal Advisory Committee Act (Pub. L. 92-463) and 5 U.S.C. 552b(c)(9)(B). These caucuses may, depending on the issues involved, constitute a substantial portion of a meeting.

Annually, the Chair compiles a report of pay issues discussed and concluded recommendations. These reports are available to the public, upon written request to the Committee.

The public is invited to submit material in writing to the Chair on Federal Wage System pay matters felt to be deserving of the Committee's attention. Additional information on these meetings may be obtained by contacting the Committee at U.S. Office of Personnel Management, Federal Prevailing Rate Advisory Committee, Room 5H27, 1900 E Street, NW., Washington, DC 20415, (202) 606-9400.

U.S. Office of Personnel Management.

**Sheldon Friedman,**

*Chairman, Federal Prevailing Rate Advisory Committee.*

[FR Doc. 2010-30503 Filed 12-3-10; 8:45 am]

**BILLING CODE 6325-49-P**

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## POSTAL SERVICE

### Board of Governors; Sunshine Act Meeting

**DATE AND TIME:** Tuesday, December 7, 2010, at 9 a.m.

**PLACE:** Washington, DC, at U.S. Postal Service Headquarters, 475 L'Enfant Plaza, SW.

**STATUS:** Closed.

**MATTERS TO BE CONSIDERED:** Tuesday, December 7, at 9 a.m. (Closed)

1. Financial Matters.
2. Pricing.
3. Strategic Issues.
4. Personnel Matters and Compensation Issues.
5. Governors' Executive Session—Discussion of prior agenda items and Board Governance.

**CONTACT PERSON FOR MORE INFORMATION:** Julie S. Moore, Secretary of the Board, U.S. Postal Service, 475 L'Enfant Plaza,

SW., Washington, DC 20260-1000. Telephone (202) 268-4800.

**Julie S. Moore,**

*Secretary.*

[FR Doc. 2010-30667 Filed 12-2-10; 4:15 pm]

**BILLING CODE 7710-12-P**

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## OFFICE OF SCIENCE AND TECHNOLOGY POLICY

### Request for Public Comment on the Draft National Nanotechnology Initiative Strategy for Nanotechnology-Related Environmental, Health, and Safety Research

**AGENCY:** White House Office of Science and Technology Policy.

**ACTION:** Notice: Request for Public Comment.

**SUMMARY:** With this notice, the White House Office of Science and Technology Policy and the Nanoscale Science, Engineering, and Technology Subcommittee of the National Science and Technology Council request comments from the public regarding the draft National Nanotechnology Initiative (NNI) Strategy for Nanotechnology-Related Environmental, Health, and Safety Research (hereafter referred to as "draft NNI EHS strategy"). The draft NNI EHS strategy is posted at <http://strategy.nano.gov>. Comments of approximately one page or less in length (4,000 characters) are requested. This request will be active from December 6, 2010, to January 6, 2011.

**DATES:** Comments are invited beginning December 6, 2010, and must be received by 11:59 p.m. EST on January 6, 2011.

**ADDRESSES:** Respondents are encouraged to register online at the NNI Strategy Portal at <http://strategy.nano.gov> to post their comments (4,000 characters or less) as a response to the request for public comment. Alternatively, comments of one page in length or less may be submitted via e-mail to: [nnistrategy@ostp.gov](mailto:nnistrategy@ostp.gov). Any information you provide to us may be posted online. Therefore, do *not* send any information that might be considered proprietary, personal, sensitive, or confidential.

**Overview:** The National Nanotechnology Initiative Strategy for Nanotechnology-Related Environmental, Health, and Safety Research or "NNI EHS Strategy" helps to facilitate achievement of the National Nanotechnology Initiative vision by laying out guidance for agency leaders, program managers, and the research community regarding planning and

implementation of nanotechnology EHS R&D investments and activities.

The NNI is a U.S. Government R&D program of 25 agencies working together toward the common challenging vision of a future in which the ability to understand and control matter at the nanoscale leads to a revolution in technology and industry that benefits society. The combined, coordinated efforts of these agencies have accelerated discovery, development, and deployment of nanotechnology towards agency missions and the broader national interest. Established in 2001, the NNI involves nanotechnology-related activities by the 25 member agencies, 15 of which have requested budgets for nanotechnology R&D for Fiscal Year (FY) 2011.

The NNI is managed within the framework of the National Science and Technology Council (NSTC), the Cabinet-level council that coordinates science and technology across the Federal government and interfaces with other sectors. The Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the NSTC coordinates planning, budgeting, program implementation, and review of the NNI. The NSET Subcommittee is composed of senior representatives from agencies participating in the NNI (<http://www.nano.gov>). The NSET Subcommittee and its Nanotechnology Environmental and Health Implications (NEHI) Working Group provide leadership in establishing the NNI environmental, health, and safety research agenda and in communicating data and information related to the environmental and health aspects of nanotechnology between NNI agencies and with the public. NNI activities support the development of the new tools and methods required for the research that will enable risk analysis and assist in regulatory decision-making.

The NSET Subcommittee has solicited multiple streams of input to inform the development of this latest NNI EHS Strategy. Independent reviews of the NNI by the President's Council of Advisors on Science and Technology and the National Research Council of the National Academies have made specific recommendations for improving the NNI EHS strategy. A series of four NNI workshops took place in 2009-2010 to solicit input for this strategy: 1. Human & Environmental Exposure Assessment of Nanomaterials (details at <http://www.nano.gov/html/meetings/exposure/>), 2. Nanomaterials and the Environment & Instrumentation, Metrology, and Analytical Methods (details at <http://www.nano.gov/html/>)

meetings/environment/), 3. Nanomaterials and Human Health & Instrumentation, Metrology, and Analytical Methods (details at <http://www.nano.gov/html/meetings/humanhealth/>), and 4. Capstone: Risk Management Methods & Ethical, Legal, and Societal Implications of Nanotechnology (details at <http://www.nano.gov/html/meetings/capstone/>). Additional input has come from the NNI Strategic Planning Stakeholders Workshop (details at <http://www.nano.gov/html/meetings/NNISPWorkshop/>) as well as in responses to a Request for Information published in the **Federal Register** on July 6, 2010, and comments posted online in response to challenge questions from July 13–August 15, 2010, at the NNI Strategy Portal (<http://strategy.nano.gov>).

The draft NNI EHS Strategy complements the 2010 NNI Strategic Plan by setting forth the NNI strategy for nanotechnology-related environmental, health, and safety (EHS) research. It describes the NNI vision and goals for Federal EHS research and presents the current NNI EHS research portfolio. The EHS strategy includes a description of the NNI EHS research investment by research need, the state of the science, and an analysis of the gaps and barriers to achieving that research as part of the NNI's adaptive management of this strategy. This strategy updates and replaces the NNI EHS Strategy of February 2008. The NNI EHS Strategy aims to ensure the responsible development of nanotechnology by providing guidance to the Federal agencies that produce the scientific information for risk management, regulatory decision-making, product use, research planning, and public outreach. The core research areas providing this critical information are measurement, human exposure assessment, human health, and the environment in order to inform risk assessment and risk management.

Your comments on this draft of the plan must be received by 11:59 p.m. EST on January 6, 2011. Please reference page and line numbers as appropriate, and keep your responses to 4,000 characters or less. You may also e-mail your responses, no more than one page in length, to [nnistrategy@ostp.gov](mailto:nnistrategy@ostp.gov). Responses to this notice are not offers and cannot be accepted by the Federal government to form a binding contract or issue a grant. Information obtained as a result of this notice may be used by the Federal government for program planning on a non-attribution basis. Any information you provide to us may be posted online. Therefore, do *not* send

any information that might be considered proprietary, personal, sensitive, or confidential.

**FOR FURTHER INFORMATION CONTACT:** Any questions about the content of this notice should be sent to [NNIStrategy@ostp.gov](mailto:NNIStrategy@ostp.gov). Questions and responses may also be sent by mail (please allow additional time for processing) to the address: Office of Science and Technology Policy, ATTN: NNI EHS Strategy Comments, Executive Office of the President, 725 17th Street Room 5228, Washington, DC, 20502. Phone: (202) 456–7116, Fax: (202) 456–6021.

**Ted Wackler,**

*Deputy Chief of Staff.*

[FR Doc. 2010–30414 Filed 12–3–10; 8:45 am]

**BILLING CODE 3170-W0-P**

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## SECURITIES AND EXCHANGE COMMISSION

[Release No. IC–29521; File No. 812–13780]

### American United Life Insurance Company, et al.; Notice of Application

November 30, 2010.

**AGENCY:** Securities and Exchange Commission (“Commission”).

**ACTION:** Notice of Application for an order pursuant to Section 26(c) of the Investment Company Act of 1940, as amended (“1940 Act”), the substitution of securities.

**APPLICANTS:** American United Life Insurance Company (“AUL”), AUL American Unit Trust (“AUL Account”). AUL and the AUL Account are together referred to herein as the “Applicants.”

**SUMMARY OF APPLICATION:** The AUL account is used to fund variable annuity contracts issued by AUL (“Contracts”). Applicants request an order to permit the substitution of units issued by the Vanguard Variable Insurance Fund Small Company Growth Portfolio (the “Substituted Portfolio” or “VVIF”), for units issued by the Vanguard Explorer Fund (the “Removed Portfolio” or “VEF”), a fund currently available as an investment option under certain Contracts.

**FILING DATE:** The application was filed on June 8, 2010 and amended and restated applications were filed on September 2, and October 15, 2010.

**HEARING OR NOTIFICATION OF HEARING:** An order granting the Application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving Applicants with a copy of the request,

personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on December 27, 2010 and should be accompanied by proof of service on Applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Secretary of the Commission.

**ADDRESSES:** Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–0609. Applicants: c/o Richard M. Ellery, Esq., American United Life Insurance Company, One American Square, Indianapolis, Indiana 46282. Copies to: Frederick H. Sherley, Esq., Dechert LLP, 100 North Tryon Street, Suite 4000, Charlotte, NC 28202.

**FOR FURTHER INFORMATION CONTACT:** Patrick Scott, Senior Counsel, Office of Insurance Products, Division of Investment Management, SEC, at (202) 551–6763, or Zandra Bailes, Branch Chief, at (202) 551–6975.

**SUPPLEMENTARY INFORMATION:** The following is a summary of the application; the complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at <http://www.sec.gov/search/search.htm>, or obtained for a fee from the Public Reference Branch of the Commission, 100 F Street, NE., Washington, DC 20549, or by calling: (202) 551–8090.

*Applicants' Representations:*

1. AUL is an Indiana stock insurance company. AUL is the depositor and sponsor of the AUL Account, a separate investment account established under Indiana law.

2. The AUL Account is used to fund variable annuity contracts issued by AUL (each, a “Contract”).<sup>1</sup> The income, gains or losses of the AUL Account are credited to or charged against the assets of the AUL Account without regard to other income, gains or losses of AUL. AUL owns the assets in the AUL Account and is required to maintain sufficient assets in the AUL Account to meet all AUL Account obligations under the Contracts. AUL may transfer to its general account assets that exceed anticipated obligations of the AUL Account. All obligations arising under the Contracts are general corporate

<sup>1</sup> The registration statement relating to these contracts is incorporated by reference into the application, to the extent necessary to support and supplement the descriptions and representations set forth in the application.

obligations of AUL. AUL serves as sponsor and depositor of the AUL Account.

3. The AUL Account is currently divided into 419 sub-accounts referred to as Investment Accounts. Each Investment Account invests exclusively in shares of one of the mutual fund portfolios offered by the fund companies with whom AUL has executed agreements so that the portfolios of those fund companies are eligible to be selected by a Contract Owner as an investment option under a Contract issued by AUL. Contributions may be allocated to one or more Investment Accounts available under a Contract. Not all of the Investment Accounts may be available under a particular Contract and some of the Investment Accounts are not available for certain types of Contracts. Each Contract permits allocations of value to available fixed and variable subaccounts; each variable subaccount invests in a specific investment portfolio of an underlying mutual fund. The group variable annuity Contracts may allow ongoing contributions that can vary in amount and frequency. All of the Contracts provide for the accumulation of values on a variable basis, a fixed basis or both. The Contracts also provide several options for fixed annuity payments to begin on a future date.

4. The AUL Account does not impose any limitations on the number of

transfers between Investment Accounts available under a Contract or between Investment Accounts and the Fixed Interest Account (an investment option under the Contracts to which contributions may be allocated for accumulation at rates guaranteed by AUL) or impose charges on transfers. Under certain circumstances, amounts transferred from the Fixed Interest Account to an Investment Account during any given year may not exceed 20% of the Fixed Interest Account's value as of the beginning of that year. AUL reserves the right, however, at a future date, to impose a different minimum or maximum transfer amount, to assess transfer charges, to change the limit on remaining balances, to limit the number and frequency of transfers, and to suspend the transfer privilege or the telephone authorization, interactive voice response, or Internet based transfers.

5. Each Contract reserves the right, upon notice to Contract Owners and in compliance with applicable law, to add, combine or remove subaccounts, or to withdraw assets from one subaccount and put them into another subaccount. Each Contract's prospectus provides that Applicants may add, remove or combine subaccounts or withdraw assets relating to a Contract from one subaccount and put them into another.

6. Applicants propose to substitute units of the VEF with units of the VVIF (the proposed "Substitution").

Applicants state that no material differences exist between VEF and VVIF from the perspective of the Contract Owners. As represented in the application, and as the table below indicates, the investment objectives and primary risks of the two portfolios are the same, and the investment strategies are substantially similar. Further, the expense ratio of the VVIF is lower than the expense ratio of VEF and the one, five and ten year performance of the VVIF for the period ended December 31, 2009 is better than that of the VEF over the same period. While VEF has seven investment advisers and VVIF has two, VVIF's advisers are both advisers of VEF.

7. Applicants submit that the foregoing demonstrates that no material difference exists between the Removed Portfolio and the Substituted Portfolio; both invest in small company stocks using a growth strategy and share the same primary risks. Accordingly, Applicants believe that the Contract Owners have a reasonable continuity in their investment expectation.

8. As of July 31, 2010, VEF had assets of approximately \$6,231,000,000. As of July 31, 2010, VVIF had assets of approximately \$601,000,000. Applicants believe that both VEF and VVIF hold sufficient assets such that the Substitution should be immaterial to portfolio management.

Removed portfolio <sup>2</sup>	Substituted portfolio <sup>3</sup>
<p>Vanguard Explorer Fund (cusip-921926101) .....</p> <p><i>Objective:</i> Long-term capital appreciation .....</p> <p><i>Principal Investment Strategies:</i> .....</p> <p>The Fund invests mainly in the stocks of small companies. These companies tend to be unseasoned but are considered by the Fund's advisors to have superior growth potential. Also, these companies often provide little or no dividend income. The Fund uses multiple investment advisors.</p> <p><i>Primary Risks:</i> An investment in the Fund could lose money over short or even long periods. You should expect the Fund's share price and total return to fluctuate within a wide range, like the fluctuations of the overall stock market. The Fund's performance could be hurt by:</p> <ul style="list-style-type: none"> <li>• <i>Stock market risk</i>, which is the chance that stock prices overall will decline. Stock markets tend to move in cycles, with periods of rising prices and periods of falling prices.</li> <li>• <i>Investment style risk</i>, which is the chance that returns from small-capitalization growth stocks will trail returns from the overall stock market. Historically, small-cap stocks have been more volatile in price than the large-cap stocks that dominate the overall market, and they often perform quite differently.</li> </ul>	<p>Vanguard Variable Insurance Fund Small Company Growth Portfolio (cusip-921925889).</p> <p><i>Objective:</i> Long-term capital appreciation.</p> <p><i>Principal Investment Strategies:</i> The portfolio invests at least 80% of its assets primarily in common stocks of smaller companies. These companies tend to be unseasoned but are considered by the Portfolio's advisors to have superior growth potential. Also, these companies often provide little or no dividend income. The Portfolio's 80% policy may be changed only upon 60 days' notice to shareholders. The Portfolio uses multiple investment advisors.</p> <p><i>Primary Risks:</i> An investment in the Portfolio could lose money over short or even long periods. You should expect the Portfolio's share price and total return to fluctuate within a wide range, like the fluctuations of the overall stock market. The Portfolio's performance could be hurt by:</p> <ul style="list-style-type: none"> <li>• <i>Stock market risk</i>, which is the chance that stock prices overall will decline. Stock markets tend to move in cycles, with periods of rising prices and periods of falling prices.</li> <li>• <i>Investment style risk</i>, which is the chance that returns from small-capitalization growth stocks will trail returns from the overall stock market. Historically, small-cap stocks have been more volatile in price than the large-cap stocks that dominate the overall market, and they often perform quite differently.</li> </ul>

<sup>2</sup> The application represents that the information in this table was transcribed as it appears in the registration statement dated February 24, 2010, File Nos. 811-01530, 002-27203. That registration statement was incorporated by reference into the application to the extent necessary to support and

supplement the descriptions and representations set forth in the application.

<sup>3</sup> The application represents that the information in this table was transcribed as it appears in the registration statement dated April 30, 2010, File

Nos. 811-05962, 033-32216. That registration statement was incorporated by reference into the application to the extent necessary to support and supplement the descriptions and representations set forth in the application.

Removed portfolio <sup>2</sup>			Substituted portfolio <sup>3</sup>		
<ul style="list-style-type: none"> <li>• <i>Manager risk</i>, which is the chance that poor security selection or focus on securities in a particular sector, category, or group of companies will cause the Fund to underperform relevant benchmarks or other funds with a similar investment objective.</li> </ul>			<ul style="list-style-type: none"> <li>• <i>Manager risk</i>, which is the chance that poor security selection or focus on securities in a particular sector, category, or group of companies will cause the Portfolio to underperform relevant benchmarks or other funds with a similar investment objective.</li> </ul>		
Total annual fund operating expenses: 0.54%			Total annual fund operating expenses: 0.40%		
Average annual total returns for periods ended December 31, 2009			Average annual total returns for periods ended December 31, 2009		
1 Year 36.21%	5 Years 0.44%	10 Years 3.35%	1 Year 39.38%	5 Years 0.50%	10 Years 4.47%

9. Among the reasons for the proposed Substitution, Applicants state that the proposed Substitution will strengthen the fund offerings within the Contracts' fund lineup. Applicants expect the proposed Substitution to provide benefits to the Contract Owners including a better performing, lower cost portfolio. The application states that Vanguard has been consulted about the proposed Substitution and has no objection to it.

10. Moreover, Applicants state that after the proposed Substitution,

Contract Owners will continue to be able to select among portfolios with a full range of investment objectives, investments strategies and risks.

11. In sum, the Applicants also have concluded that the Substituted Portfolio is better suited than the Removed Portfolio to serve as the underlying portfolio for the AUL Account as an operational and procedural matter; the Substituted Portfolio is designed to serve as an investment vehicle for insurance company separate accounts.

12. In comparing expense ratios, the application states that as set forth in the Prospectuses of the Substituted Portfolio and Removed Portfolio, the Substituted Portfolio has a lower total expense ratio (0.40%) than the Removed Portfolio (0.54%). Neither the Substituted Portfolio nor the Removed Portfolio pays fees pursuant to Rule 12b-1 of the Act.

13. The chart below, as included in the application, provides a comparison of expenses:

	Management expenses (in percent)	12b-1 distribution fee	Other expenses (in percent)	Total annual operating expenses (in percent)
Removed Portfolio, Investor Shares .....	0.50	None	0.04	0.54
Substituted Portfolio .....	0.35	None	0.05	0.40

14. In addition to expenses, Applicants state in the application that relative performance is a reason for the substitution. According to Vanguard, the Substituted Portfolio has outperformed the Removed Portfolio over the last one, five and ten year periods for the period ended December 31, 2009. In these time periods, respectively, the Substituted Portfolio has returned 39.38%, 0.50% and 4.47%, while the Removed Portfolio has returned 36.21%, 0.44% and 3.35%, each before taxes.

15. The proposed Substitution will take place at each Portfolio's relative net asset values determined on the date of the Substitution in accordance with Section 22 of the 1940 Act and Rule 22c-1 thereunder with no change in the amount of any Contract Owner's cash value of his or her investment in any of the subaccounts. Accordingly, there will be no financial impact on any Contract Owner. The Substitution will be effected by having the subaccount that invests in the Removed Portfolio redeem its shares at the net asset value calculated on the date of the Substitution and purchase shares of the

Substituted Portfolio at the net asset value calculated on the same date.

16. The application notes that the Substitution will be described in detail in a written notice mailed to Contract Owners. The notice will inform Contract Owners of Applicants' intent to implement the Substitution and describe the Substitution, the reasons for engaging in the proposed Substitution and how the Substitution will be implemented. The notice will be mailed to all Contract Owners at least 30 days prior to the Substitution and will inform affected Contract Owners that they may transfer assets from the subaccount investing in the Removed Portfolio at any time after receipt of the notice, and from the subaccount investing in the Substituted Portfolio for 30 days after the Substitution, to any subaccounts investing in other portfolios available under their respective Contracts without the imposition of any transfer charge or limitation and without diminishing the number of free transfers that may be made in a given contract year. A supplement will be filed with the Commission for the current prospectus

containing the information to be included in the notice.

17. Applicants state further that each Contract Owner will be provided a prospectus for the Substituted Portfolio. Within five business days after the Substitution, Applicants will send each affected Contract Owner written confirmation that the Substitution has occurred.

18. The application also indicates that:

- (a) Applicants will pay all expenses and transaction costs of the Substitution, including all legal, accounting and allocated brokerage expenses relating to the Substitution;
- (b) that no costs will be borne by the Contract Owners;

(c) that affected Contract Owners will not incur any fees or charges as a result of the Substitution, nor will their rights or the obligations of Applicants under the Contracts be altered in any way.

19. Applicants state that the proposed Substitution will not cause the fees and charges under the Contracts currently being paid by Contract Owners to be greater after the Substitution than before the Substitution. The Substitution will

have no adverse tax consequences to Contract Owners and will in no way alter the tax benefits to Contract Owners.

#### Applicants' Legal Analysis:

1. Section 26(c) of the 1940 Act provides that it shall be unlawful for any depositor or trustee of a registered unit investment trust holding the security of a single issuer to substitute another security for such security unless the Commission shall have approved such substitution; and the Commission shall issue an order approving such substitution if the evidence establishes that it is consistent with the protection of investors and the purposes fairly intended by the policies and provisions of the 1940 Act. Section 26(c) protects the expectation of investors that the unit investment trust will accumulate shares of a particular issuer and is intended to insure that unnecessary or burdensome sales loads, additional reinvestment costs or other charges will not be incurred due to unapproved substitutions of securities.

2. The proposed Substitution of shares held by the AUL Account, as described above, may be deemed to involve a substitution of securities within the meaning of Section 26(c) of the 1940 Act. The Applicants therefore request an order from the Commission pursuant to Section 26(c) approving the proposed Substitution.

3. The investment objective and primary risks of the Substituted Portfolio are the same as that of the Removed Portfolio and the investment strategies of the two are nearly identical; thus, Contract Owners will have reasonable continuity in investment expectations. Accordingly, the Substituted Portfolio is an appropriate investment vehicle for those Contract Owners who have Contract values allocated to the Removed Portfolio. Further, the Substituted Portfolio has lower expenses and better historical performance than that of the Removed Portfolio.

4. In connection with assets held under the Contracts affected by the Substitution, Applicants will not receive for three (3) years from the date of substitution any direct or indirect benefits from the Substituted Portfolio, its advisors or underwriters (or their affiliates) at a rate higher than that which they had received from the Removed Portfolio, its advisors or underwriters (or their affiliates) including but without limitation, 12b-1, shareholder service, administration or other service fees, revenue sharing or other arrangements.

5. Applicants represent and warrant that the Substitution and the selection of the Substituted Portfolio were not motivated by any financial consideration paid or to be paid to AUL or its affiliates by the Substituted Portfolio, its advisors or underwriters or their respective affiliates.

6. The Substitution will not result in the type of costly forced redemption that Section 26(c) was intended to guard against because the Contract Owner will continue to have the same type of investment choice, with better potential returns and lower expenses and will not otherwise have any incentive to redeem their shares or terminate their Contracts.

7. The purposes, terms and conditions of the proposed Substitution are consistent with the protection of investors, and the principles and purposes of Section 26(c), and do not entail any of the abuses that Section 26(c) is designed to prevent.

(a) The Substituted Portfolio has better historical performance than the Removed Portfolio.

(b) The current total annual operating expenses and management fee of the Substituted Portfolio are lower than those of the Removed Portfolio.

(c) The Substituted Portfolio is an appropriate portfolio to move Contract Owners' values currently allocated to the Removed Portfolio because the portfolios have the same objectives and risks and very similar strategies.

(d) All costs of the Substitution, including any allocated brokerage costs, will be borne by Applicants and will not be borne by Contract Owners. No charges will be assessed to effect the Substitution.

(e) The Substitution will be at the net asset value of the respective portfolio shares without the imposition of any transfer or similar charge and with no change in the amount of any Contract Owners' Contract values.

(f) The Substitution will not cause the fees and charges under the Contracts currently being paid by the Contract Owners to be greater after the Substitution than before the Substitution and will result in Contract Owners Contract values being moved to a portfolio with lower current total annual operating expenses.

(g) Notice of the proposed Substitution will be mailed to all Contract Owners at least 30 days prior to the Substitution. All Contract Owners will have an opportunity at any time after receipt of the notice of the Substitution and for 30 days after the Substitution to transfer Contract account value affected by the Substitution to other available subaccounts without the imposition of any transfer charge or

limitation and without being counted as one of the Contract Owner's free transfers in a contract year.

(h) Within five business days after the Substitution, Applicants will send to their affected Contract Owners a written confirmation that the Substitution has occurred.

(i) The Substitution will, in no way, alter the terms of the Contracts or the obligations of Applicants under them.

(j) The Substitution will have no adverse tax consequences to Contract Owners and will, in no way, alter the tax benefits to Contract Owners.

#### Conclusion

Applicants assert that, for the reasons summarized above, the Commission should grant the requested order approving the Proposed Substitution.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

**Florence E. Harmon,**

*Deputy Secretary.*

[FR Doc. 2010-30461 Filed 12-3-10; 8:45 am]

BILLING CODE 8011-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. SIPA-169; File No. SIPC-2010-01]

### Securities Investor Protection Corporation; Notice of Filing of a Proposed Bylaw Change Relating to SIPC Fund Assessments on SIPC Members

November 30, 2010.

Pursuant to Section 3(e)(1) of the Securities Investor Protection Act of 1970 ("SIPA"), 15 U.S.C. 78ccc(e)(1), notice is hereby given that on October 8, 2010, the Securities Investor Protection Corporation ("SIPC") filed with the Securities and Exchange Commission ("Commission") a proposed bylaw change. The Commission is publishing this notice to solicit comments on the proposed bylaw change from interested persons.

#### I. Description of Proposed Bylaw Change

Section 4(c)(2) of SIPA requires SIPC to impose assessments upon its member broker-dealers deemed necessary and appropriate to establish and maintain a broker-dealer liquidation fund administered by SIPC (the "SIPC Fund") and to repay any borrowings by SIPC used to liquidate a broker-dealer. Pursuant to this authority, SIPC collects an annual assessment from its members. The amount of the annual assessment is prescribed by SIPA and the SIPC



bylaws. For example, if SIPC has an outstanding loan from the Commission, SIPA provides that SIPC assess its member broker-dealers ½ of 1% of the gross revenues from their securities business.<sup>1</sup> In addition, if the SIPC Fund aggregates or is likely to aggregate less than \$2.5 billion for six months or more, SIPC must raise each member's assessment to ½ of 1% of net operating revenues.<sup>2</sup> When the SIPC Fund is at its targeted level, SIPC collects a minimum assessment as provided for in SIPA. The current target level for the SIPC Fund is \$2.5 billion.

The Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 ("Dodd-Frank Act") amended SIPA to change the minimum assessment from an amount not to exceed \$150 to an amount not to exceed 0.02 percent of the gross revenues from the securities business of the SIPC member.<sup>3</sup> Under Article 6 of the SIPC bylaws, SIPC must assess its members a minimum amount (\$150) unless certain conditions apply. Because in some cases an assessment of \$150 would exceed 0.02 percent of the gross revenues, the SIPC Assessment bylaw must be amended to be consistent with the Dodd-Frank Act. First, SIPC has proposed to amend Article 6, Section 1(a)(1)(B) of the SIPC bylaws by replacing "\$150" with the term "0.02 percent of the net operating revenues from the securities business." This amendment clarifies that the minimum assessment for members, once the SIPC Fund reaches its target, is 0.02 percent of a member's net operating revenues, not \$150. Second, SIPC has proposed deleting Section 1(a)(3) of Article 6, which stated that \$150 was the minimum assessment a SIPC member would be required to pay in any calendar year. These amendments were approved by SIPC's Board of Directors on September 16, 2010.

As indicated above, SIPC's bylaw changes refer to "net operating revenues" instead of "gross revenues." Since 1991, when assessing on a percentage basis (*i.e.*, not a flat \$150 minimum assessment), SIPC has based the assessment amount on a percentage of net operating revenues, not gross revenues, from the securities business. In 1991, a SIPC Task Force study found that securities firms no longer structured their business on a gross revenue basis but instead used a net operating revenue basis, which excludes interest expense and dividend expense in accounting for revenue. SIPC bases its assessment on the net revenues

associated with that business, which it believes is consistent with SIPA. Basing the assessment on net operating revenues as opposed to gross revenues will decrease the amount of the assessment in most situations. However, under SIPA, SIPC may adjust the basis for collecting assessments and the amount of assessments as long as the assessments are within the parameters prescribed in SIPA.<sup>4</sup> Using a minimum assessment of 0.02 percent of net operating revenues would not cause the amount of the assessment to exceed the maximum amount permitted for the minimum assessment under Section 4(d)(1)(C) of SIPA, as amended by the Dodd-Frank Act.

In 1991, when SIPC changed its assessment methodology from gross revenues to net operating revenues, the Commission published notice of the proposed change and requested comment.<sup>5</sup> The comments received were in support of the proposed change, which made the assessments more consistent with how industry revenues are calculated.<sup>6</sup>

## II. Need for Public Comment

Section 3(e)(1) of SIPA provides that SIPC must file with the Commission a copy of proposed bylaw changes. That section further provides that bylaw changes shall take effect 30 days after filing, unless the Commission either: (i) disapproves the change as contrary to the public interest or the purposes of SIPA, or (ii) finds that the change involves a matter of such significant public interest that public comment should be obtained. Thus, under Section 3(e)(1) of SIPA, a proposed bylaw change does not have to be noticed for public comment. However, under Section 3(e)(1)(B) of SIPA, the Commission can find that "such proposed change involves a matter of such significant public interest that public comment should be obtained," in which case, the Commission may, after notifying SIPC in writing of such finding, require that the proposed bylaw change be considered by the same procedures as a proposed rule change including, among other things, publication in the **Federal Register** and opportunity for public comment.

The SIPC Fund, which is built from assessments on its members and the

interest earned on the fund, is used for the protection of customers of members liquidated under SIPA to maintain investor confidence in the securities markets. In light of this fact and that the bylaw change provides for a new minimum assessment methodology, the Commission finds, pursuant to Section 3(e)(1)(B) of SIPA, that the proposed bylaw change involves a matter of such significant public interest that public comment should be obtained and that the procedures applicable to proposed SIPC rule changes in Section 3(e)(2) of SIPA should be followed. As required by Section 3(e)(1)(B) of SIPA, the Commission has notified SIPC of this finding in writing.

## III. Date of Effectiveness of the Proposed Bylaw Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register**, or within such longer period: (i) As the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which SIPC consents, the Commission will: (A) By order approve such proposed bylaw change, or (B) Institute proceedings to determine whether the proposed bylaw change should be disapproved.

## IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Comments may be submitted by any of the following methods:

### Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/other.shtml>); or
- Send an e-mail to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SIPC-2010-01 on the subject line.

### Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549-1090.

All submissions should refer to File Number SIPC-2010-01. 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/other.shtml>). Copies of the submission, all subsequent

<sup>1</sup> 15 U.S.C. 78ddd(d)(1)(A)(ii).

<sup>2</sup> SIPC Bylaws, Article 6, Section (a)(1)(C)(i).

<sup>3</sup> The Dodd-Frank Act, Section 929V.

<sup>4</sup> 15 U.S.C. 78ddd(c)(2) and 78lll(9).

<sup>5</sup> Securities Investor Protection Corporation; Notice of Proposed Bylaw Change Relating to SIPC Fund Assessments on SIPC Members, Rel. No. SIPA-156, 56 FR 51952 (Oct. 16, 1991).

<sup>6</sup> Securities Investor Protection Corporation; Order Approving Proposed Bylaw Change Relating to SIPC Fund Assessments on SIPC Members, Rel. No. SIPA-157, 56 FR 60145 (Nov. 27, 1991).

amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make publicly available. All submissions should refer to File Number SIPC-2010-01 and should be submitted on or before December 27, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>7</sup>

**Florence E. Harmon,**

*Deputy Secretary.*

[FR Doc. 2010-30434 Filed 12-3-10; 8:45 am]

**BILLING CODE 8011-01-P**

## SECURITIES AND EXCHANGE COMMISSION

### Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94-409, that the Securities and Exchange Commission will hold a Closed Meeting on Thursday, December 9, 2010 at 2 p.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the Closed Meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552(b)(3), (5), (7), 9(B) and (10) and 17 CFR 200.402(a)(3), (5), (7), 9(ii) and (10), permit consideration of the scheduled matters at the Closed Meeting.

Commissioner Aguilar, as duty officer, voted to consider the items listed for the Closed Meeting in a closed session.

The subject matter of the Closed Meeting scheduled for Thursday, December 9, 2010 will be:

institution and settlement of injunctive actions; institution and settlement of administrative proceedings; and other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact:

The Office of the Secretary at (202) 551-5400.

Dated: December 1, 2010.

**Elizabeth M. Murphy,**

*Secretary.*

[FR Doc. 2010-30530 Filed 12-1-10; 4:15 pm]

**BILLING CODE 8011-01-P**

## SECURITIES AND EXCHANGE COMMISSION

### Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94-409, that the Securities and Exchange Commission will hold a Closed Meeting on Wednesday, December 8, 2010 at 10 a.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the Closed Meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemption 5 U.S.C. 552(b)(3)(10) and 17 CFR 200.402(a)(10), permit consideration of the scheduled matter at the Closed Meeting.

Commissioner Aguilar, as duty officer, voted to consider the item listed for the Closed Meeting in a closed session.

The subject matter of the Closed Meeting scheduled for Wednesday, December 8, 2010 will be:

An adjudicatory matter

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact:

The Office of the Secretary at (202) 551-5400.

Dated: December 1, 2010.

**Elizabeth M. Murphy,**

*Secretary.*

[FR Doc. 2010-30628 Filed 12-2-10; 4:15 pm]

**BILLING CODE 8011-01-P**

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-63386; File No. SR-CBOE-2010-102]

### Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Related to the Penny Pilot Program

November 29, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on November 24, 2010, the Chicago Board Options Exchange, Incorporated ("Exchange" or "CBOE") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposal as a "non-controversial" proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act<sup>3</sup> and Rule 19b-4(f)(6) thereunder.<sup>4</sup> 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 is proposing to amend its rules relating to the Penny Pilot Program. The text of the proposed rule change is available on the Exchange's Web site (<http://www.cboe.org/Legal>), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

#### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange 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

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> 15 U.S.C. 78s(b)(3)(A)(iii).

<sup>4</sup> 17 CFR 240.19b-4(f)(6).

<sup>7</sup> 17 CFR 200.30-3(f)(2)(i).

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 Penny Pilot Program is scheduled to expire on December 31, 2010. CBOE proposes to extend the Penny Pilot Program until December 31, 2011. CBOE believes that extending the Pilot Program will allow for further analysis of the Pilot Program and a determination of how the Pilot Program should be structured in the future.

During this extension of the Pilot Program, CBOE may replace any option class which is currently included in the Pilot Program and which is delisted with the next most actively-traded, multiple-listed option class that is not yet participating in the Pilot Program ("replacement class"). Any replacement option would be determined based on national average daily volume in the preceding six months, and would be added on the second trading day following January 1, 2011 and July 1, 2011.<sup>5</sup> CBOE will employ the same parameters to prospective replacement issues as approved and applicable in determining the existing classes in the Penny Pilot Program, including excluding high-priced underlying securities.<sup>6</sup> CBOE will announce any replacement classes by circular.

CBOE is specifically authorized to act jointly with the other options exchanges participating in the Penny Pilot Program in identifying any replacement class. CBOE will submit to the SEC semi-annual reports that will analyze the impact of the Penny Pilot on market quality and systems capacity. This report will include, but is not limited to the following: (1) Data and analysis of the number of quotations generated for options included in the report; (2) an assessment of the quotation spreads for the options included in the report; (3) an assessment of the impact of the Pilot Program on CBOE's automated systems; (4) data reflecting the size and depth of markets; and (5) any capacity problems

<sup>5</sup> The month immediately preceding their addition to the Pilot Program, *i.e.*, December or June, would not be used for purposes of the six month analysis. For example, a replacement class to be added on the second trading day following January 1 would be identified based on OCC volume data from June 1 through November 30.

<sup>6</sup> See Securities Exchange Act Release No. 60864 (October 22, 2009), granting immediate effectiveness to SR-CBOE-2009-76.

or other problems that arose related to the operation of the Pilot Program and how the Exchange addressed them.

**2. Statutory Basis**

The Exchange believes the rule proposal is consistent with the Securities Exchange Act of 1934 (the "Act") and the rules and regulations under the Act applicable to a national securities exchange and, in particular, the requirements of Section 6(b) of the Act.<sup>7</sup> Specifically, the Exchange believes that the proposed rule change is consistent with the Section 6(b)(5) Act<sup>8</sup> requirements that the rules of an exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts and, in general, to protect investors and the public interest. In particular, the proposed rule change allows for an extension of the Penny Pilot Program for the benefit of market participants.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

CBOE does not believe that the proposed rule change will impose any burden on competition 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*

The Exchange neither solicited nor received comments on the proposal.

**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 prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act<sup>9</sup> and Rule 19b-4(f)(6)(iii) thereunder.<sup>10</sup>

<sup>7</sup> 15 U.S.C. 78f(b).

<sup>8</sup> 15 U.S.C. 78f(b)(5).

<sup>9</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>10</sup> 17 CFR 240.19b-4(f)(6)(iii). In addition, Rule 19b-4(f)(6)(iii) requires the self-regulatory organization to give the Commission notice of its intent to file the proposed rule change, along with a brief description and text of 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. CBOE has satisfied this requirement.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

**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](mailto:rule-comments@sec.gov). Please include File Number SR-CBOE-2010-102 on the subject line.

*Paper Comments*

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-CBOE-2010-102. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the self-regulatory organization. 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-CBOE-2010-102 and should be submitted on or before December 27, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>11</sup>

**Florence E. Harmon,**

*Deputy Secretary.*

[FR Doc. 2010-30428 Filed 12-3-10; 8:45 am]

BILLING CODE 8011-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-63393; File No. SR-NYSEAmex-2010-107]

### Self-Regulatory Organizations; NYSE Amex LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Option Trading Rules in Order To Extend the Penny Pilot in Options Classes in Certain Issues Through December 31, 2011

November 30, 2010.

Pursuant to Section 19(b)(1)<sup>1</sup> of the Securities Exchange Act of 1934 (the "Act")<sup>2</sup> and Rule 19b-4 thereunder,<sup>3</sup> notice is hereby given that on November 24, 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 substantially 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 its option trading rules in order to extend the Penny Pilot in options classes in certain issues ("Pilot Program") previously approved by the Securities and Exchange Commission ("Commission") through December 31, 2011. The text of the proposed rule change is available at the Exchange, <http://www.nyse.com>, the Commission's Public Reference Room, and on the Commission's Web site at <http://www.sec.gov>.

#### 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 hereby proposes to extend the time period of the Pilot Program<sup>4</sup> which is currently scheduled to expire on December 31, 2010, through December 31, 2011, and to provide revised dates for adding replacement issues to the Pilot. The Exchange proposes that the semi-annual dates to replace issues that have been delisted be revised to the second trading day following January 1, 2011 and July 1, 2011. The Exchange also wishes to clarify that the replacement issues will be selected based on trading activity for the six month period beginning June 1, 2010 and ending November 30, 2010 for the January 2011 replacement, and the six month period beginning December 1, 2010 and ending May 31, 2011 for the July 2011 replacements. This filing does not propose any substantive changes to the Pilot Program: all classes currently participating will remain the same and all minimum increments will remain unchanged. The Exchange believes the benefits to public customers and other market participants who will be able to express their true prices to buy and sell options have been demonstrated to outweigh the increase in quote traffic.

The Exchange agrees to [sic] reports that will analyze the impact of the Pilot Program on market quality and options systems capacity. The reports will analyze the impact of the Pilot Program on market quality and options systems capacity. These reports will include, but are not limited to: (1) Data and written analysis on the number of quotations generated for options selected for the Pilot Program; (2) an assessment of the

quotation spreads for the options selected for the Pilot Program; (3) an assessment of the impact of the Pilot Program on the capacity of the NYSE Amex's automated systems; (4) any capacity problems or other problems that arose related to the operation of the Pilot Program and how the Exchange addressed them; and (5) an assessment of trade through complaints that were sent by the Exchange during the operation of the Pilot Program and how they were addressed.

###### 2. Statutory Basis

The proposed rule change is consistent with Section 6(b)<sup>5</sup> of the Act, in general, and furthers the objectives of Section 6(b)(5)<sup>6</sup> in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanisms of a free and open market and a national market system. The Exchange believes that the Pilot Program promotes just and equitable principles of trade by enabling public customers and other market participants to express their true prices to buy and sell options.

##### B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

##### C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

#### III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act<sup>7</sup> and Rule 19b-4(f)(6) thereunder.<sup>8</sup> Because the 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 prior to 30 days from the date on which

<sup>11</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 15 U.S.C. 78a.

<sup>3</sup> 17 CFR 240.19b-4.

<sup>4</sup> See Securities Exchange Act Release No. 34-61106 (December 3, 2009), 74 FR 65193 (December 9, 2009); Securities Exchange Act Release No. 34-61479 (February 3, 2010), 75 FR 6772 (February 10, 2010).

<sup>5</sup> 15 U.S.C. 78f(b).

<sup>6</sup> 15 U.S.C. 78f(b)(5).

<sup>7</sup> 15 U.S.C. 78s(b)(3)(A)(iii).

<sup>8</sup> 17 CFR 240.19b-4(f)(6).

it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b-4(f)(6)(iii) thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

#### IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

##### *Electronic Comments*

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an e-mail to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-NYSEAmex-2010-107 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-2010-107. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public

Reference Room, 100 F Street, NE., Washington, DC 20549 on business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSEAmex-2010-107 and should be submitted on or before December 27, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>9</sup>

**Florence E. Harmon,**  
*Deputy Secretary.*

[FR Doc. 2010-30431 Filed 12-3-10; 8:45 am]

BILLING CODE 8011-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-63397; File No. SR-BX-2010-084]

### Self-Regulatory Organizations; NASDAQ OMX BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change as Modified by Amendment No. 1 To Extend, Through December 31, 2011, the Pilot Program That Permits Certain Classes To Be Quoted in Penny Increments on BOX

November 30, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on November 24, 2010, NASDAQ OMX BX, Inc. (the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. On November 30, 2010, the Exchange submitted Amendment No. 1 to the proposed rule change. The Commission is publishing this notice to solicit comments on the proposed rule from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Chapter V, Section 33 (Penny Pilot Program) of the Rules of the Boston Options Exchange Group, LLC ("BOX")

to extend, through December 31, 2011, the pilot program that permits certain classes to be quoted in penny increments on BOX ("Penny Pilot Program"). The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room, on the Commission's Web site at <http://www.sec.gov>, and also on the Exchange's Internet Web site at <http://nasdaqomxbx.cchwallstreet.com/NASDAQOMXBX/Filings/>.

#### 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 these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

##### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

###### 1. Purpose

The Exchange proposes to extend the effective time period of the Penny Pilot Program on BOX that is currently scheduled to expire on December 31, 2010, for an additional year, through December 31, 2011.<sup>3</sup> The Penny Pilot Program permits certain classes to be

<sup>3</sup> The Penny Pilot Program has been in effect on BOX since January 26, 2007. See Securities Exchange Act Release No. 55155 (Jan. 23, 2007), 72 FR 4741 (Feb. 1, 2007) (SR-BSE-2006-49). The Penny Pilot Program was later extended through September 27, 2007. See Securities Exchange Act Release No. 56149 (July 26, 2007), 72 FR 42450 (Aug. 2, 2007) (SR-BSE-2007-38). A subsequent rule filing by the Exchange on September 27, 2007 initiated a two-phased expansion of the Penny Pilot Program. See Securities Exchange Act Release No. 56566 (Sept. 27, 2007), 72 FR 56400 (Oct. 3, 2007) (S-ARBSE-2007-40). See also Securities Exchange Act Release No. 57566 (March 26, 2008), 73 FR 18013 (April 2, 2008) (SR-BSE-2008-20). The Penny Pilot Program was then extended and expanded a number of times and is set to expire on December 31, 2010. See Securities Exchange Act Release Nos. 59629 (March 26, 2009), 74 FR 15021 (April 2, 2009) (SR-BX-2009-017); 60213 (July 1, 2009), 74 FR 32998 (July 9, 2009) (SR-BX-2009-032); 60886 (Oct. 27, 2009), 74 FR 56897 (Nov. 3, 2009) (SR-BX-2009-067); 60950 (Nov. 6, 2009), 74 FR 58666 (Nov. 6, 2009) (SR-BX-2009-069); 61456 (Feb. 1, 2010), 75 FR 6235 (Feb. 8, 2010) (SR-BX-2010-011); 62039 (May 5, 2010), 75 FR 26313 (May 11, 2010) (SR-BX-2010-032) and 62615 (July 30, 2010), 75 FR 47875 (Aug. 9, 2010) (SR-BX-2010-052). The extension of the effective date is the only change to the Penny Pilot Program being proposed at this time.

<sup>9</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

quoted in penny increments on BOX. The minimum price variation for all classes included in the Penny Pilot Program, except for the QQQs, SPY and IWM, will continue to be \$0.01 for all quotations in option series that are quoted at less than \$3 per contract and \$0.05 for all quotations in option series that are quoted at \$3 per contract or greater. The QQQs, SPY and IWM, will continue to be quoted in \$0.01 increments for all options series. The Exchange is not currently proposing any changes to the classes included within the Penny Pilot Program.

Additionally, the Exchange proposes to amend Chapter V, Section 33(b) of the BOX Rules to continue to be able to replace, on a semi-annual basis, any Pilot Program classes that have been delisted. These delisted classes will be replaced by the next most actively traded multiply listed options classes that are not yet included in the Pilot Program, based on trading activity in the previous six months. The replacement classes may be added to the Pilot Program on the second trading day following January 1, 2011 and July 1, 2011.<sup>4</sup> The replacement issues will be selected based on trading activity for the six-month period beginning June 1, 2010 and ending November 30, 2010, for the January 2011 replacement, and the six month period beginning December 1, 2010 and ending May 31, 2011 for the July 2011 replacements. The Exchange will employ the same parameters to prospective replacement classes as approved and applicable under the Pilot Program, including excluding high-priced underlying securities.

Further, BOX agrees to submit to the Commission such reports regarding the Penny Pilot Program as the Commission may request. Such reports may include: (1) Data and analysis on the number of quotations generated for options included in the Pilot Program; (2) an assessment of the quotation spreads for the options included in the Pilot Program; (3) an assessment of the impact of the Pilot Program on the capacity of BOX's automated systems; (4) data reflecting the size and depth of markets; and (5) any capacity problems or other problems that arose related to the operation of the Pilot Program and how the Exchange addressed them.

## 2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Act,<sup>5</sup>

in general, and Section 6(b)(5) of the Act,<sup>6</sup> in particular, in that it is designed to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism for a free and open market and a national market system and, in general, to protect investors and the public interest. In particular, the proposed extension will allow the Penny Pilot Program to remain in effect on BOX without interruption.

### 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 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

The Exchange has neither solicited nor received comments on the proposed rule change.

## III. Basis for Summary Effectiveness Pursuant to Section 19(b)(3) or for Accelerated Effectiveness Pursuant to Section 19(b)(2)

This proposed rule change is filed pursuant to paragraph (A) of section 19(b)(3) of the Exchange Act<sup>7</sup> and Rule 19b-4(f)(6) thereunder.<sup>8</sup> This proposed rule change does not significantly affect the protection of investors or the public interest, does not impose any significant burden on competition, and, by its terms, does not 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.<sup>9</sup>

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

<sup>6</sup> 15 U.S.C. 78f(b)(5).

<sup>7</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>8</sup> 17 CFR 240.19b-4(f)(6).

<sup>9</sup> As required under Rule 19b-4(f)(6)(iii), BOX provided the Commission with written notice of its intent to file the proposed rule change along with a brief description and the text of 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.

## 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](mailto:rule-comments@sec.gov). Please include File Number SR-BX-2010-084 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-BX-2010-084. 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 business days between the hours of 10 a.m. and 3 p.m., located at 100 F Street, NE., Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-BX-2010-084 and should be submitted on or before December 27, 2010.

<sup>4</sup> The replacement classes will be announced to BOX Participants via Regulatory Circular and published by the Exchange on its Web site.

<sup>5</sup> 15 U.S.C. 78f(b).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>10</sup>

**Florence E. Harmon,**

*Deputy Secretary.*

[FR Doc. 2010-30432 Filed 12-3-10; 8:45 am]

BILLING CODE 8011-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-63391; File No. SR-FINRA-2010-063]

### Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend to July 16, 2011, the Pilot Period for FINRA Rule 4240 (Margin Requirements for Credit Default Swaps)

November 30, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) <sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on November 22, 2010, Financial Industry Regulatory Authority, Inc. (“FINRA”) filed with the Securities and Exchange Commission (“SEC” or “Commission”) the proposed rule change as described in Items I and II below, which Items have been substantially prepared by FINRA. FINRA has designated the proposed rule change as constituting a “non-controversial” rule change under paragraph (f)(6) of Rule 19b-4 under the Act,<sup>3</sup> which renders the proposal effective upon receipt of this filing by the Commission. 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

FINRA is proposing to extend to July 16, 2011, FINRA Rule 4240 (Margin Requirements for Credit Default Swaps) on an interim pilot program basis. FINRA Rule 4240, as approved by the SEC on May 22, 2009, will expire on November 30, 2010. The rule implements an interim pilot program with respect to margin requirements for transactions in credit default swaps executed by a member (regardless of the type of account in which the transaction is booked), including those in which the offsetting matching hedging transactions are effected by the member in credit

default swap contracts that are cleared through the central counterparty clearing services of the Chicago Mercantile Exchange.

The text of the proposed rule change is below. Proposed new language is underlined; proposed deletions are in brackets:

\* \* \* \* \*

#### 4000. FINANCIAL AND OPERATIONAL RULES

\* \* \* \* \*

#### 4200. MARGIN

\* \* \* \* \*

#### 4240. Margin Requirements for Credit Default Swaps

(a) Effective Period of Interim Pilot Program.

This Rule establishes an interim pilot program (“Interim Pilot Program”) with respect to margin requirements for any transactions in credit default swaps executed by a member (regardless of the type of account in which the transaction is booked), including those in which the offsetting matching hedging transactions (“matching transactions”) are effected by the member in contracts that are cleared through the central counterparty clearing services of the Chicago Mercantile Exchange (“CME”). The Interim Pilot Program shall automatically expire on [November 30, 2010] *July 16, 2011*. For purposes of this Rule, the term “credit default swap” (“CDS”) shall mean any “eligible credit default swap” as defined in Securities Act Rule 239T(d), as well as any other CDS that would otherwise meet such definition but for being subject to individual negotiation, and the term “transaction” shall include any ongoing CDS position.

(b) through (e) No Change.

\* \* \* Supplementary Material:

.01 No Change.

\* \* \* \* \*

#### II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

#### A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

##### 1. Purpose

On May 22, 2009, the Commission approved FINRA Rule 4240,<sup>4</sup> which implements an interim pilot program (the “Interim Pilot Program”) with respect to margin requirements for transactions in credit default swaps (“CDS”) executed by a member (regardless of the type of account in which the transaction is booked), including those in which the offsetting matching hedging transactions are effected by the member in credit default swap contracts that are cleared through the central counterparty clearing services of the Chicago Mercantile Exchange (“CME”). On September 21, 2009, FINRA extended the implementation of Rule 4240 to November 30, 2010.<sup>5</sup>

As explained in the Approval Order, FINRA Rule 4240 is intended to be coterminous with certain Commission actions intended to address concerns arising from systemic risk posed by CDS, including, among others, risks to the financial system arising from the lack of a central clearing counterparty to clear and settle CDS.<sup>6</sup> Recently, the Commission has determined to extend the period for which certain of these actions are in effect.<sup>7</sup> FINRA believes it

<sup>4</sup> See Securities Exchange Act Release No. 59955 (May 22, 2009), 74 FR 25586 (May 28, 2009) (Notice of Approval of Proposed Rule Change; File No. SR-FINRA-2009-012) (“Approval Order”).

<sup>5</sup> See Securities Exchange Act Release No. 60722 (September 25, 2009), 74 FR 50856 (October 1, 2010) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change; File No. SR-FINRA-2009-063).

<sup>6</sup> See 74 FR 25588 through 25589. In early 2009 the Commission enacted interim final temporary rules (the “interim final temporary rules”) providing enumerated exemptions under the Federal securities laws for certain CDS to facilitate the operation of one or more central clearing counterparties in such CDS. See Securities Act Release No. 8999 (January 14, 2009), 74 FR 3967 (January 22, 2009) (Temporary Exemptions for Eligible Credit Default Swaps To Facilitate Operation of Central Counterparties To Clear and Settle Credit Default Swaps); Securities Act Release No. 9063 (September 14, 2009) (Extension of Temporary Exemptions for Eligible Credit Default Swaps To Facilitate Operation of Central Counterparties To Clear and Settle Credit Default Swaps). See also Securities Exchange Act Release No. 59578 (March 13, 2009), 74 FR 11781 (March 19, 2009) (Order Granting Temporary Exemptions in Connection with Request of Chicago Mercantile Exchange Inc. and Citadel Investment Group, L.L.C. Related to Central Clearing of Credit Default Swaps); Securities Exchange Act Release No. 59165 (December 24, 2008), 74 FR 133 (January 2, 2009) (Order Granting Temporary Exemptions for Broker-Dealers and Exchanges Effecting Transactions in Credit Default Swaps).

<sup>7</sup> See Securities Act Release No. 9158 (November 19, 2010), 75 FR 72260 (November 26, 2009)

<sup>10</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> 17 CFR 240.19b-4(f)(6).



is appropriate to extend the implementation of the Interim Pilot Program accordingly, to July 16, 2011.<sup>8</sup>

FINRA has filed the proposed rule change for immediate effectiveness and has requested that the SEC waive the requirement that the proposed rule change not become operative for 30 days after the date of the filing, such that FINRA can implement the proposed rule change immediately. The proposed rule change will expire on July 16, 2011. FINRA is proposing to implement the proposed rule change on November 30, 2010.

## 2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,<sup>9</sup> which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. FINRA believes that the proposed rule change will further the purposes of the Act because, consistent with the goals set forth by the Commission when it adopted the interim final temporary rules with respect to the operation of central counterparties to clear and settle CDS, the margin requirements set forth by the proposed rule change will help to stabilize the financial markets.

### B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

### C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

## III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

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 from the date on which it was filed, or such shorter time

(Extension of Temporary Exemptions for Eligible Credit Default Swaps To Facilitate Operation of Central Counterparties To Clear and Settle Credit Default Swaps).

<sup>8</sup> See Exhibit 15.

<sup>9</sup> 15 U.S.C. 78o-3(b)(6).

as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act<sup>10</sup> and Rule 19b-4(f)(6) thereunder.<sup>11</sup>

FINRA requests that the Commission waive the five-day pre-filing notice requirement specified in Rule 19b-4(f)(6)(iii) under the Act.<sup>12</sup> FINRA proposes to make the proposed rule change operative on November 30, 2010.

FINRA has requested that the Commission waive the 30-day operative delay, so that the proposed rule change may become operative upon filing. The Commission hereby grants FINRA's request and believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest.<sup>13</sup> This will allow the existing pilot program to continue without interruption and extend the benefits of a pilot program that the Commission approved and previously extended. For these reasons, the Commission designates the proposed rule change as effective and operative on November 30, 2010.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

## 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](mailto:rule-comments@sec.gov). Please include File Number SR-FINRA-2010-063 on the subject line.

<sup>10</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>11</sup> 17 CFR 240.19b-4(f)(6).

<sup>12</sup> 17 CFR 240.19b-4(f)(6)(iii). In addition, Rule 19b-4(f)(6)(iii) requires a self-regulatory organization to submit to the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of 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 has waived the five-day pre-filing period in this case.

<sup>13</sup> For the purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

## 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-FINRA-2010-063. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. 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-FINRA-2010-063 and should be submitted on or before December 27, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>14</sup>

**Florence E. Harmon,**

*Deputy Secretary.*

[FR Doc. 2010-30429 Filed 12-3-10; 8:45 am]

BILLING CODE 8011-01-P

## SMALL BUSINESS ADMINISTRATION

### [Disaster Declaration #12398 and #12399]

### U.S. Virgin Islands Disaster # VI-00007

**AGENCY:** U.S. Small Business Administration.

**ACTION:** Notice.

**SUMMARY:** This is a Notice of the Presidential declaration of a major disaster for public assistance only for

<sup>14</sup> 17 CFR 200.30-3(a)(12).

the Territory of the U.S. Virgin Islands (FEMA-1949-DR), dated 11/24/2010.

*Incident:* Severe storms, flooding, rockslides, and mudslides associated with Tropical Storm Tomas.

*Incident Period:* 11/08/2010 through 11/12/2010.

*Effective Date:* 11/24/2010.

*Physical Loan Application Deadline Date:* 01/24/2011.

*Economic Injury (EIDL) Loan*

*Application Deadline Date:* 08/24/2011.

**ADDRESSES:** Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

**FOR FURTHER INFORMATION CONTACT:** A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that as a result of the President's major disaster declaration on 11/24/2010, private non-profit organizations that provide essential services of governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Area: The Island of Saint Croix.

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Non-Profit Organizations with Credit Available Elsewhere	3.250
Non-Profit Organizations without Credit Available Elsewhere .....	3.000
<i>For Economic Injury:</i>	
Non-Profit Organizations without Credit Available Elsewhere .....	3.000

The number assigned to this disaster for physical damage is 12398B and for economic injury is 12399B.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

**Roger B. Garland,**

*Acting Associate Administrator for Disaster Assistance.*

[FR Doc. 2010-30411 Filed 12-3-10; 8:45 am]

**BILLING CODE 8025-01-P**

**SMALL BUSINESS ADMINISTRATION**

[Disaster Declaration #12347 and #12348]

**Arizona Disaster #AZ-00012**

**AGENCY:** U.S. Small Business Administration.

**ACTION:** Amendment 1.

**SUMMARY:** This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Arizona (FEMA-1940-DR), dated 10/04/2010.

*Incident:* Severe Storms and Flooding. *Incident Period:* 07/20/2010 through 08/07/2010.

*DATES:* *Effective Date:* 10/04/2010.

*Physical Loan Application Deadline Date:* 12/03/2010.

*Economic Injury (EIDL) Loan*

*Application Deadline Date:* 07/05/2011.

**ADDRESSES:** Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

**FOR FURTHER INFORMATION CONTACT:** A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

**SUPPLEMENTARY INFORMATION:** The notice of the President's major disaster declaration for Private Non-Profit organizations in the State or Arizona, dated 10/04/2010, is hereby amended to include the following areas as adversely affected by the disaster.

*Primary Area:* The Hopi Tribe.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

**James E. Rivera,**

*Associate Administrator for Disaster Assistance.*

[FR Doc. 2010-30418 Filed 12-3-10; 8:45 am]

**BILLING CODE 8025-01-P**

**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

[Summary Notice No. PE-2010-54]

**Petition for Exemption; Summary of Petition Received**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of petition for exemption received.

**SUMMARY:** This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

**DATES:** Comments on this petition must identify the petition docket number involved and must be received on or before December 27, 2010.

**ADDRESSES:** You may send comments identified by Docket Number FAA-2010-1134 using any of the following methods:

- *Government-wide rulemaking Web site:* Go to <http://www.regulations.gov> and follow the instructions for sending your comments electronically.

- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12-140, Washington, DC 20590.

- *Fax:* Fax comments to the Docket Management Facility at 202-493-2251.

- *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

*Privacy:* We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477-78).

*Docket:* To read background documents or comments received, go to <http://www.regulations.gov> at any time or to the Docket Management Facility in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Mark Forseth, ANM-113, (425) 227-2796, Federal Aviation Administration, 1601 Lind Avenue SW., Renton, WA 98057-3356, or Frances Shaver, ARM-207, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue, SW.; Washington, DC 20591; e-mail, [Frances.m.shaver@faa.gov](mailto:Frances.m.shaver@faa.gov); (202) 267-4059; fax (202) 267-5075. This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on November 30, 2010.

**Pamela Hamilton-Powell,**  
*Director, Office of Rulemaking.*

### Petition for Exemption

*Docket No.:* FAA-2010-1134.

*Petitioner:* AerSale.

*Section of 14 CFR Affected:* Sections 25.561, 25.562, 25.853, and Appendix F of part 25.

*Description of Relief Sought:* AerSale seeks a limited-time exemption from the certification process described in §§ 25.561, 25.562, 25.853, and Appendix F of part 25, to allow installation of existing inventory of Koito seats, which are the subject of NPRM 2010-NM-156-AD.

[FR Doc. 2010-30425 Filed 12-3-10; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

#### Environmental Impact Statement: Billings County, North Dakota

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Revised Notice of Intent.

**SUMMARY:** The FHWA is issuing this notice to advise the public that an environmental impact statement will be prepared for a proposed roadway project and river crossing over the Little Missouri River within a study area bounded by the southern border of the North Unit of Theodore Roosevelt National Park (TRNP), the northern border of the South Unit of TRNP, the eastern border of U.S. Highway 85, and the western border of N.D. Highway 16.

**FOR FURTHER INFORMATION CONTACT:** Mark Schrader, Environment and Right-of-Way Engineer, Federal Highway Administration, 1471 Interstate Loop, Bismarck, North Dakota 58503, Telephone: (701) 250-4343 Extension 111. Bryon Fuchs, Local Government Division, North Dakota Department of Transportation, 608 East Boulevard Avenue, Bismarck, North Dakota 58505-0700, Telephone: (701) 328-2516.

**SUPPLEMENTARY INFORMATION:** On October 12, 2006, the FHWA, in cooperation with the NDDOT, published a Notice of Intent to develop an Environmental Impact Statement (EIS) for a proposed roadway project and river crossing over the Little Missouri River within a study area bounded by the northern border of the Billings County line, the southern border of the South Unit of Theodore Roosevelt National Park (TRNP), the eastern

border of U.S. Highway 85, and the western border of N.D. Highway 16. This project is ongoing and, since the initial Notice of Intent, the northern limits of the study area have been expanded to the southern border of the North Unit of TRNP. Additionally, the southern limits of the study area have been decreased to the northern border of the South Unit of TRNP. The Elkhorn Ranch Unit of TRNP is excluded from the project study area.

The purpose of the proposed project is to provide for the safe and efficient movement of people and commerce. Specifically, the purpose of the proposed project is to:

- Improve the transport of goods and services within the study area;
- Provide the public with a centrally accessible, safe, efficient, and reliable link between ND Highway 16 and US Highway 85 within the study area (system linkage);
- Connect the transportation network on the east side of the Little Missouri River to the transportation network on the west side of the Little Missouri River (internal linkage);
- Accommodate a variety of vehicles ranging from a two-wheel drive passenger vehicle to agricultural, commercial, and industrial vehicles and equipment.

The safe and efficient movement of people and commerce would be accomplished by improving connectivity through construction of a reliable crossing of the Little Missouri River, and upgrading existing roadways and/or creating new roadways to best meet roadway design standards. Alternatives under consideration include: (1) Take no action; (2) construction of a river crossing structure: bridge or low-water crossing; and (3) different roadway alignments to the river crossing, including upgrading and/or constructing roadways to meet NDDOT guidelines/standards.

Letters describing the proposed action and soliciting comments were distributed to appropriate Federal, State, and local agencies, as well as other interested parties, in February and May of 2007. Scoping meetings and alternatives public workshops were also held with agencies and the public in March and July of 2008. Due to the passage of time, Federal, State, and local agencies, as well as other interested parties, will be re-solicited for their views on the proposed action. Additional public workshops on the alternatives will be held. In addition, a public hearing will be held. Public notice will be given of the time and place of the meetings and hearing. The Draft EIS will be available for public

and agency review and comment prior to the public hearing.

To ensure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the EIS should be directed to the FHWA at the address provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Issued on: November 29, 2010.

**Wendall Meyer,**

*Division Administrator, Federal Highway Administration.*

[FR Doc. 2010-30424 Filed 12-3-10; 8:45 am]

**BILLING CODE 4910-22-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

#### Notice of Final Federal Agency Actions on Proposed Highway in Wisconsin

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Notice of limitation on claims for judicial review of actions by FHWA, Army Corps of Engineers (USACE), and Other Federal Agencies.

**SUMMARY:** This notice announces actions taken by FHWA that are final within the meaning of 23 U.S.C. 139(1)(1). The actions relate to a proposed highway project, the WIS 23 Corridor Expansion Project, in the State of Wisconsin. Those actions grant approval for the project. The project will widen the existing two-lane roadway to four travel lanes with a median for an 18.6-mile segment of WIS 23 between US 151 and County P in Fond du Lac and Sheboygan Counties, Wisconsin. Specific actions include acquiring additional right-of-way, constructing two interchanges and one jug-handle interchange, constructing new travel lanes, constructing a median with a median treatment, constructing a multi-use path, installing new bridges and box culverts, removing and placing fill, removing vegetation, and providing storm water management measures. The project also includes mitigation and restoration actions which are compatible with land use plans.

**DATES:** By this notice, FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(1)(1). A claim

seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed within 180 days of publication of this **Federal Register** notice. If the Federal law that authorizes judicial review of a claim provides a time period of less than 180 days for filing such claim, then that shorter time period still applies.

**FOR FURTHER INFORMATION CONTACT:**

Tracey McKenney, Major Projects Manager, Federal Highway Administration, 525 Junction Road, Suite 8000 Madison, Wisconsin 53717; telephone: 608-829-7510; and e-mail: [tracey.mckenney@dot.gov](mailto:tracey.mckenney@dot.gov).

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that FHWA has taken final agency actions by issuing approval for the following highway project: WIS 23 Corridor Expansion Project. The purpose of the project is to improve safety and mobility along the WIS 23 corridor between Fond du Lac and Plymouth, Wisconsin. The actions by FHWA on this project, and the laws under which such actions were taken, are described in the Final Environmental Impact Statement (FEIS) approved on June 3, 2010 [FHWA-WI-EIS-04-03-F], in the FHWA Record of Decision (ROD) issued September 27, 2010, and in other documents in the FHWA administrative record for the project. The EIS, ROD, and other documents in the FHWA administrative record are available by contacting FHWA or the Wisconsin Department of Transportation, Northeast Region, Green Bay office at the addresses provided. The FEIS can be viewed and downloaded from the project Web site <http://www.dot.wisconsin.gov/projects/d3/wis23/environ.htm>. Copies are also available for review at the following locations:

FHWA, Wisconsin Division Office,  
525 Junction Road, Suite 8000,  
Madison, Wisconsin 53717.

Bureau of Equity and Environmental Services, Wisconsin Department of Transportation, 4802 Sheboygan Ave, Room 451, PO Box 7965, Madison, WI 53707-7965.

Wisconsin Department of Transportation-NE Region, 944 Vanderperren Way, Green Bay, WI 54324-0080.

This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. General: National Environmental Policy Act (NEPA) [42 U.S.C. 4321-4335]; Federal-Aid Highway Act [23 U.S.C. 109].

2. Air: Clean Air Act, as amended [42 U.S.C. 7401-7671(g)].

3. Land: Section 4(f) of the Department of Transportation Act of 1966 [23 U.S.C. 138, 49 U.S.C. 303]; Farmland Protection Policy Act of 1980 [7 U.S.C. 4201-4209], National Trails System Act [16 U.S.C. 1241-1249].

4. Wildlife: Endangered Species Act of 1973 [16 U.S.C. 1531-1543 and Section 1536]; Fish and Wildlife Coordination Act [16 U.S.C. 661-666(c)]; Migratory Bird Treaty Act [16 U.S.C. 760c-760g].

5. Historic and Cultural Resources: Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) *et. seq.*]; Archeological Resources Protection Act of 1977 [16 U.S.C. 470(aa)-470(ll)]; Archeological and Historic Preservation Act [16 U.S.C. 469-469(c)]; Native American Grave Protection and Repatriation Act [25 U.S.C. 3001 *et. seq.*].

6. Social and Economic: Civil Rights Act of 1964 [42 U.S.C. 2000(d) *et. seq.*]; American Indian Religious Freedom Act [42 U.S.C. 1996]; Americans with Disabilities Act [42 U.S.C. 12101]; Uniform Relocation Assistance and Real Property Acquisition Act of 1970 [42 U.S.C. 4601 *et seq.* as amended by the Uniform Relocation Act Amendments of 1987 [Pub. L. 100-17].

7. Wetlands and Water Resources: Clean Water Act (Section 404, Section 401, Section 319) [33 U.S.C. 1251-1376]; Land and Water Conservation Fund [16 U.S.C. 460l-4 to 460l-11]; Safe Drinking Water Act [42 U.S.C. 300(f)-300(j)(6)]; TEA-21 Wetlands Mitigation [23 U.S.C. 103(b)(6)(m), 133(b)(11)]; Flood Disaster Protection Act, [42 U.S.C. 4001-4128]; Emergency Wetlands Resources Act, [16 U.S.C. 3921, 3931].

8. Hazardous Materials: Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) as amended [42 U.S.C. 9601-9657]; Superfund Amendments and Reauthorization Act of 1986 [Pub. L. 99-499]; Resource Conservation and Recovery Act [42 U.S.C. 6901 *et. seq.*].

9. Executive Orders: E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management as amended by E.O. 12148; E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13112 Invasive Species.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

**Authority:** 23 U.S.C. 139(1)(1).

Issued on: November 29, 2010.

**Tracey McKenney,**

*Major Projects Manager (Team Lead),  
Madison Wisconsin.*

[FR Doc. 2010-30511 Filed 12-3-10; 8:45 am]

**BILLING CODE 4910-RY-P**

## DEPARTMENT OF THE TREASURY

### Order Extending Temporary Exemptions From Certain Government Securities Act Provisions and Regulations in Connection With a Request From ICE Trust U.S. LLC Related to Central Clearing of Credit Default Swaps

**AGENCY:** Office of the Assistant Secretary for Financial Markets, Department of the Treasury.

**ACTION:** Notice of extension of temporary exemptions.

**SUMMARY:** The Department of the Treasury (Treasury) is extending its temporary exemptions from certain Government Securities Act provisions and regulations regarding the central clearing of credit default swaps that reference government securities. The extension of these temporary exemptions was requested by ICE Trust U.S. LLC.

**DATES:** *Effective Date:* Effective November 30, 2010.

**FOR FURTHER INFORMATION CONTACT:** Lori Santamarena, Lee Grandy, or Kevin Hawkins, Bureau of the Public Debt, Department of the Treasury, at 202-504-3632.

**SUPPLEMENTARY INFORMATION:** The following is Treasury's order extending the temporary exemptions:

#### I. Introduction

Treasury regulations govern transactions in government securities<sup>1</sup> by government securities brokers<sup>2</sup> and government securities dealers<sup>3</sup> under

<sup>1</sup> The term *government securities* is defined at 15 U.S.C. 78c(a)(42).

<sup>2</sup> A *government securities broker* generally is "any person regularly engaged in the business of effecting transactions in government securities for the account of others," with certain exclusions. 15 U.S.C. 78c(a)(43).

<sup>3</sup> A *government securities dealer* generally is "any person engaged in the business of buying and selling government securities for his own account, through a broker or otherwise," with certain exclusions. 15 U.S.C. 78c(a)(44).

Section 15C of the Securities Exchange Act of 1934 (Exchange Act), as amended by the Government Securities Act of 1986 (GSA). These regulations impose obligations concerning financial responsibility, protection of customer securities and balances, and recordkeeping and reporting.

Treasury has previously issued orders providing temporary exemptions to permit ICE Trust U.S. LLC (ICE Trust) to clear and settle transactions in credit default swaps (CDS)<sup>4</sup> that reference government securities.

Specifically, on March 6, 2009, Treasury granted a temporary exemption<sup>5</sup> from certain GSA provisions and regulations to ICE Trust, certain ICE Trust participants, and certain eligible contract participants (ECPs).<sup>6</sup> In the same order Treasury also granted a limited temporary exemption from certain GSA regulatory requirements to government securities brokers and government securities dealers that are not financial institutions. On December 7, 2009, Treasury extended the expiration date of these temporary exemptions until March 7, 2010.<sup>7</sup> On January 28, 2010, Treasury granted a temporary, conditional exemption until March 7, 2010, to certain ICE Trust clearing members and certain ECPs to accommodate using ICE Trust to clear customer CDS transactions.<sup>8</sup> On March

7, 2010, Treasury granted a conditional, temporary exemption from certain GSA provisions and regulations to certain ICE Trust participants, and certain ECPs (the March 2010 order).<sup>9</sup> In the same order Treasury also granted a temporary exemption from certain Treasury regulatory requirements for registered or noticed government securities brokers and government securities dealers that are not financial institutions. The temporary exemptions expire on November 30, 2010. Treasury has received no comments on its previous orders.

Subsequent to the March 2010 order, the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) was enacted on July 21, 2010.<sup>10</sup> Title VII of the Dodd-Frank Act establishes a comprehensive new regulatory framework for swaps and security-based swaps, and provides the Securities and Exchange Commission (SEC) and the Commodity Futures Trading Commission (CFTC) with the authority to regulate over-the-counter (OTC) derivatives. The SEC and CFTC are working together to address the regulation of CDS, in consultation with Treasury and other regulators.

## II. Discussion

On November 26, 2010, Treasury received a letter (the request)<sup>11</sup> from ICE Trust asking that Treasury extend the temporary exemptions in the March 2010 order. ICE Trust has stated in its request that the existing order has allowed the financial industry to advance the goal of central clearing of CDS, pending regulatory action to require such clearing. It also states that the order should be extended because allowing it to expire may jeopardize the ability of ICE Trust to continue its operations and that any regulatory uncertainty to the use of ICE Trust as a central counterparty (CCP) could create a significant barrier to Treasury's goal of encouraging the use of CCPs in the clearing of CDS. ICE Trust also notes

that the order provides regulatory agencies with adequate authority to monitor its activities, and that it is also comprehensively monitored and regulated by State and Federal banking supervisors. ICE Trust believes the extension is warranted to avoid creating regulatory uncertainty with respect to the significant amounts of current open interest.

The request states that, to date, the products eligible for clearing at ICE Trust include CDS transactions involving certain indices and CDS contracts based on individual reference entities or securities (single-name CDS contracts) that meet ICE Trust's risk management and other criteria. The request also states that since the date of the March 2009 order, ICE Trust has cleared approximately \$7.3 trillion in notional amount of index-based CDS contracts and approximately \$461.5 billion in notional amount of single-name CDS contracts. We understand that, to date, ICE Trust has not cleared any CDS contracts that reference U.S. government securities.

In its request for an extension of the temporary exemptions, ICE Trust represents that there have been no material changes to its operations or the representations made in its previous letters requesting the exemptive relief.<sup>12</sup>

Treasury believes that continuing to facilitate the central clearing of CDS transactions—including customer CDS transactions—through an extension of the temporary exemptions in this order will continue to provide important risk management and systemic benefits by avoiding an interruption in those CCP clearance and settlement services pending the effective date of Title VII of the Dodd-Frank Act. Any interruption in CCP clearance and settlement services for CDS transactions could eliminate the benefits ICE Trust provides. Treasury also believes that facilitating the central clearing of CDS transactions will continue to improve transparency, enhance counterparty risk management, and contribute generally to the goal of mitigating systemic risk.

Treasury finds that the circumstances upon which it issued the previous order

<sup>4</sup> A CDS is a bilateral contract between two parties, known as counterparties. The value of this financial contract is based on underlying obligations of a single entity (reference entity) or on a particular security or other debt obligation, or an index of several such entities, securities, or obligations. The obligation of a seller to make payments under a CDS contract is triggered by a default or other credit event as to such entity or entities or such security or securities.

<sup>5</sup> 74 FR 10647, March 11, 2009 Order Granting Temporary Exemptions from Certain Provisions of the Government Securities Act and Treasury's Government Securities Act Regulations in Connection with a Request on Behalf of ICE Trust LLC Related to Central Clearing of Credit Default Swaps, and Request for Comments, available at: [http://www.treasurydirect.gov/instit/statreg/gsaareq/gsaareq\\_treasexemptiveorder309.pdf](http://www.treasurydirect.gov/instit/statreg/gsaareq/gsaareq_treasexemptiveorder309.pdf).

<sup>6</sup> ECPs are defined in Section 1a(12) of the Commodity Exchange Act, 7 U.S.C. 1 *et seq.* The use of the term ECPs in this order refers to the definition of ECPs in effect on the date of this order, and excludes persons that are ECPs under Section 1a(12)(C). The temporary exemption provided to ECPs in this order also applies to interdealer brokers that are ECPs.

<sup>7</sup> 74 FR 64127, December 7, 2009 Order Extending Temporary Exemptions from Certain Government Securities Act Provisions and Regulations in Connection with a Request from ICE Trust U.S. LLC Related to Central Clearing of Credit Default Swaps, available at: [http://www.treasurydirect.gov/instit/statreg/gsaareq/FR\\_Treasury\\_Order\\_ICE\\_Extension\\_\(12-7-09\).pdf](http://www.treasurydirect.gov/instit/statreg/gsaareq/FR_Treasury_Order_ICE_Extension_(12-7-09).pdf).

<sup>8</sup> 75 FR 4626, January 28, 2010 Order Granting a Temporary Exemption from Certain Government Securities Act Provisions and Regulations in Connection with a Request from ICE Trust U.S. LLC

Related to Central Clearing of Credit Default Swaps, and Request for Comments, available at: <http://www.treasurydirect.gov/instit/statreg/gsaareq/TreasuryICEOrderFedRegisterJan282010.pdf>.

<sup>9</sup> 75 FR 11627, March 11, 2010 Order Granting Temporary Exemptions from Certain Government Securities Act Provisions and Regulations in Connection with a Request From ICE Trust U.S. LLC Related to Central Clearing of Credit Default Swaps, and Request for Comments, available at: <http://www.treasurydirect.gov/instit/statreg/gsaareq/TreasuryExemptiveOrderMarch112010FedRegister.pdf>.

<sup>10</sup> Public Law 111–203, 124 Stat. 1376.

<sup>11</sup> Letter from Kevin R. McClear, General Counsel, ICE Trust to the Commissioner of the Public Debt, Van Zeck, November 26, 2010, available at: <http://www.treasurydirect.gov/instit/statreg/gsaareq/gsaareq.htm>.

<sup>12</sup> ICE Trust indicated that on November 12, 2010, it applied to the CFTC for registration as a derivatives clearing organization (DCO) in advance of the date Title VII of the Dodd-Frank Act goes into effect in order to facilitate implementation of the Dodd-Frank Act requirements. As part of the transition to DCO status, ICE Trust expects to admit futures commission merchants registered with the CFTC (which may be registered as government securities brokers or government securities dealers) as clearing members for customer clearing and may introduce related changes to its rules. Treasury has not determined whether these developments would be material for purposes of this order.

to ICE Trust still exist and, therefore, Treasury believes that extending the temporary exemptions is warranted and appropriate. Accordingly, consistent with our findings in the March 2010 order, and, in particular, in light of the risk management and systemic benefits in continuing to accommodate clearing CDS that reference government securities by ICE Trust, the Secretary of the Treasury (Secretary) finds that it is consistent with the public interest, the protection of investors, and the purposes of the Exchange Act to extend the exemptive relief granted in the March 2010 order. The extension of the temporary exemptions will expire on July 16, 2011, unless revoked or modified by Treasury. In extending these temporary exemptions, Treasury has consulted with and considered the views of the staffs of the SEC, the CFTC, and the appropriate regulatory agencies for financial institutions.<sup>13</sup> The extension of these temporary exemptions is consistent with temporary exemptions the SEC has granted to ICE Trust related to the central clearing of CDS.<sup>14</sup>

In providing the extension of these temporary exemptions from certain provisions of Section 15C of the Exchange Act, Treasury is not determining whether particular CDS are "government securities" under 15 U.S.C. 78c(a)(42).

### III. Conclusion

*It is hereby ordered*, pursuant to Section 15C(a)(5) of the Exchange Act, that the order Treasury issued effective March 7, 2010 (75 FR 11627, March 11, 2010) is amended by replacing the expiration date of November 30, 2010, with a new expiration date of July 16, 2011, and in all other respects that order remains in effect.

The temporary exemptions contained in this order are based on the facts and circumstances about ICE Trust's current operations presented in the request. These temporary exemptions could become unavailable if the facts or circumstances change such that the representations in the request are no longer materially accurate. If the SEC

<sup>13</sup> The definition of *appropriate regulatory agency* with respect to a government securities broker or a government securities dealer is set out at 15 U.S.C. 78c(a)(34)(G). The definition includes the Board of Governors of the Federal Reserve System, the Comptroller of the Currency, the Federal Deposit Insurance Corporation, the Director of Thrift Supervision, and in limited circumstances the SEC.

<sup>14</sup> See the SEC's Web site at <http://www.sec.gov> for the recent Order Extending and Modifying Temporary Exemptions Under the Securities Exchange Act of 1934 in Connection with Request of ICE Trust U.S. LLC Related to Central Clearing of Credit Default Swaps and Request for Comment.

were to withdraw its order or modify the terms of its order, Treasury may revoke or modify this order accordingly. The status of cleared CDS submitted to ICE Trust prior to such change would be unaffected.

### IV. Paperwork Reduction Act

This order extends the March 2010 order that included two requests that fall within the definition of "information" under the regulations implementing the Paperwork Reduction Act (PRA). 5 CFR 1320.3(h). One is the certification that ICE Trust clearing members must provide to ICE Trust under paragraph (a)(3)(ii) of the March 2010 order concerning their reliance on Treasury's temporary exemption. The second is the disclosures that certain ICE Trust clearing members must make if they receive or hold funds or securities for the purpose of purchasing, selling, clearing, settling, or holding cleared CDS positions for U.S. persons, under paragraph (a)(4)(ii) of that same order.

However, Treasury continues to estimate that there will not be 10 or more ICE Trust clearing members that will be relying on this order to clear CDS that reference a government security. As a result, these requests do not constitute "collections of information" subject to the PRA. 5 CFR 1320.3(c). Therefore, the PRA does not apply.

Mary J. Miller,

*Assistant Secretary for Financial Markets.*

[FR Doc. 2010-30430 Filed 12-3-10; 8:45 am]

**BILLING CODE 4810-39-P**

## DEPARTMENT OF THE TREASURY

### Office of the Comptroller of the Currency

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** Office of the Comptroller of the Currency (OCC), Treasury.

**ACTION:** Notice and request for comment.

**SUMMARY:** The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. An agency may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is

soliciting comment concerning its information collection titled "Assessment of Fees—12 CFR 8." The OCC also gives notice that it has sent the collection to OMB for review.

**DATES:** You should submit written comments by January 5, 2011.

**ADDRESSES:** Communications Division, Office of the Comptroller of the Currency, Mail Stop 2-3, Attention 1557-0223, 250 E Street, SW., Washington, DC 20219. In addition, comments may be sent by fax to (202) 874-5274, or by electronic mail to [regs.comments@occ.treas.gov](mailto:regs.comments@occ.treas.gov). You may personally inspect and photocopy comments at the OCC, 250 E Street, SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 874-4700. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

Additionally, please send a copy of your comments to OCC Desk Officer, 1557-0223, by mail to U.S. Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, or by fax to (202) 395-6974.

**FOR FURTHER INFORMATION CONTACT:** You can request additional information or a copy of the collection from Mary H. Gottlieb, OCC Clearance Officer, (202) 874-5090, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 250 E Street, NW., Washington, DC 20219.

**SUPPLEMENTARY INFORMATION:** The OCC is proposing to extend OMB approval of the following information collection:

*Title:* Assessment of Fees—12 CFR 8.  
*OMB Control No.:* 1557-0223.

*Affected Public:* Business or other for-profit.

*Type of Review:* Regular review.

*Abstract:* The OCC is requesting comment on its proposed extension, without change, of the information collection titled, "Assessment of Fees—12 CFR 8." The National Bank Act authorizes the OCC to collect assessments, fees, and other charges as necessary or appropriate to carry out the responsibilities of the OCC. The OCC requires independent credit card banks to pay an additional assessment based on receivables attributable to accounts owned by the bank. Independent credit card banks are national banks that primarily engage in credit card operations and are not affiliated with a full service national bank. The OCC will require independent credit card banks to provide the OCC with "receivables

attributable" data. "Receivables attributable" refers to the total amount of outstanding balances due on credit card accounts owned by an independent credit card bank (the receivables attributable to those accounts) on the last day of an assessment period, minus receivables retained on the bank's balance sheet as of that day. The OCC will use the information to verify the accuracy of each bank's assessment computation and to adjust the assessment rate for independent credit card banks over time.

*Estimated Number of Respondents:* 9.

*Estimated Number of Responses:* 18.

*Frequency of Response:*

Semiannually.

*Estimated Time per Response:* 1 hour.

*Estimated Total Annual Burden:* 18

hours.

The information collection was issued for 60 days of comment on September 22, 2010. 75 FR 57832. No comments were received. Comments continue to be invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the information collection burden;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: November 30, 2010.

**Michele Meyer,**

*Assistant Director, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency.*

[FR Doc. 2010-30499 Filed 12-3-10; 8:45 am]

**BILLING CODE 4810-33-P**

## DEPARTMENT OF THE TREASURY

### Fiscal Service

#### **Financial Management Service; Proposed Collection of Information: Tax Time Card Account Pilot, Screening, Focus Groups, and Study**

**AGENCY:** Financial Management Service, Fiscal Service, Treasury.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Financial Management Service, 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 continuing information collection. By this notice, the Financial Management Service solicits comments concerning the "Tax Time Card Account Pilot Screening, Focus Groups, and Study."

**DATES:** Written comments should be received on or before February 4, 2011.

**ADDRESSES:** Direct all written comments to Financial Management Service, Records and Information Management Branch, Room 135, 3700 East West Highway, Hyattsville, Maryland, 20782.

#### **FOR FURTHER INFORMATION CONTACT:**

Request for additional information should be directed to Walt Henderson, EFT Strategy Division, 401 14th Street, SW., Room 303, Washington, DC 20227, 202-874-6624.

**SUPPLEMENTARY INFORMATION:** Pursuant to the Paperwork Reduction Act of 1995, (44 U.S.C. 3506(c)(2)(A)), the Financial Management Service solicits comments on the collection of information described below:

*Title:* Tax Time Card Account Piloting Screening Focus Group and Study.

*OMB Number:* 1510-0075.

*Form Number:* None.

*Abstract:* Study of Income Tax Refund recipients to identify barriers to significant increases in use of EFT for refund payments using a card account and use the account as an ongoing financial tool.

*Current Action:* Emergency approval of collection.

*Type of Review:* Emergency.

*Affected Public:* Individuals or households, Federal Government.

*Estimated Number of Respondents:* 208.

*Estimated Time per Respondent:* 2 hours 10 minutes.

*Estimated Total Annual Burden Hours:* 245.

*Comments:* Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the

collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up cost and cost of operation, maintenance and purchase of services to provide information.

Dated: November 24, 2010.

**Sheryl Morrow,**

*Assistant Commissioner, Payment Management & Chief Disbursing Officer.*

[FR Doc. 2010-30412 Filed 12-3-10; 8:45 am]

**BILLING CODE 4810-35-M**

## DEPARTMENT OF THE TREASURY

### Office of Thrift Supervision

#### **Survey of Information Sharing Practices With Affiliates**

**AGENCY:** Office of Thrift Supervision (OTS), Treasury.

**ACTION:** Amended Notice and request for comment.

**SUMMARY:** The OTS is amending the **Federal Register** notice published on November 26, 2010, 75 FR 72871. The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on proposed and continuing information collections, as required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3507. The Office of Thrift Supervision within the Department of the Treasury will submit the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. Today, OTS is soliciting public comments on its proposal to extend this information collection.

**DATES:** Submit written comments on or before January 25, 2011.

**ADDRESSES:** Send comments, referring to the collection by title of the proposal or by OMB approval number, to Information Collection Comments, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552; send a facsimile transmission to (202) 906-6518; or send an e-mail to [infocollection.comments@ots.treas.gov](mailto:infocollection.comments@ots.treas.gov). OTS will post comments and the related index on the OTS Internet Site at <http://www.ots.treas.gov>. In addition, interested persons may inspect comments at the Public Reading Room, 1700 G Street, NW., by appointment. To make an appointment, call (202) 906-5922, send an e-mail to



*public.info@ots.treas.gov*, or send a facsimile transmission to (202) 906-7755.

**FOR FURTHER INFORMATION CONTACT:** You can request additional information about this proposed information collection from Suzanne McQueen at (202) 906-6459, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

**SUPPLEMENTARY INFORMATION:** OTS may not conduct or sponsor an information collection, and respondents are not required to respond to an information collection, unless the information collection displays a currently valid OMB control number. As part of the approval process, we invite comments on the following information collection.

Comments should address one or more of the following points:

- a. Whether the proposed collection of information is necessary for the proper performance of the functions of OTS;
- b. The accuracy of OTS's estimate of the burden of the proposed information collection;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of the information collection on respondents, including through the use of information technology.

We will summarize the comments that we receive and include them in the OTS request for OMB approval. All comments will become a matter of public record. In this notice, OTS is soliciting comments concerning the following information collection.

*Title of Proposal:* Survey of Information Sharing Practices With Affiliates.

*OMB Number:* 1550-0121.

*Form Number:* N/A.

*Description:* The OTS is required to submit a report to the Congress with any recommendations for legislative or regulatory action, pursuant to Section 214(e) of the Fair and Accurate Transactions Act of 2003 ("FACT Act" or the "Act") Public Law 108-159, 117 Stat. 1952. The OTS will gather

information by means of a Survey to be completed by financial institutions and other persons that are creditors or users of consumer reports. The OTS will use the Survey responses to prepare a report to Congress on the information sharing practices by financial institutions, creditors, or users of consumer reports with their affiliates.

*Type of Review:* Extension of a currently approved collection.

*Affected Public:* Businesses or other for-profit.

*Estimated Number of Respondents:* 22.

*Estimated Frequency of Response:* On occasion.

*Estimated Total Burden:* 220 hours.

Dated: November 30, 2010.

**Ira L. Mills,**

*Paperwork Clearance Officer, Office of Chief Counsel, Office of Thrift Supervision.*

[FR Doc. 2010-30423 Filed 12-3-10; 8:45 am]

**BILLING CODE 6720-01-P**



# Federal Register

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**Monday,  
December 6, 2010**

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## **Part II**

# **Commodity Futures Trading Corporation**

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**17 CFR Part 165**

**Implementing the Whistleblower  
Provisions of Section 23 of the  
Commodity Exchange Act; Proposed Rule**

## COMMODITY FUTURES TRADING COMMISSION

### 17 CFR Part 165

RIN 3038-AD04

#### Implementing the Whistleblower Provisions of Section 23 of the Commodity Exchange Act

**AGENCY:** Commodity Futures Trading Commission.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Commodity Futures Trading Commission (“Commission” or “CFTC”) is proposing rules to implement new statutory provisions enacted by Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act. These proposed rules apply to the whistleblowers incentives and protection of section 748. The proposed rules establish a whistleblower program that enables the Commission to pay an award, under regulations prescribed by the Commission and subject to certain limitations, to eligible whistleblowers who voluntarily provide the Commission with original information about a violation of the Commodity Exchange Act that leads to the successful enforcement of a covered judicial or administrative action, or a related action. The proposed rules also provide public notice of section 748’s prohibition on retaliation by employers against individuals that provide the Commission with information about potential violations.

**DATES:** Comments must be received on or before February 4, 2011.

**ADDRESSES:** You may submit comments, identified by RIN number 3038-AD04, by any of the following methods:

- *Agency Web site, via its Comments Online process:* <http://comments.cftc.gov>. Follow the instructions for submitting comments through the Web site.

- *Mail:* David A. Stawick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

- *Hand Delivery/Courier:* Same as mail above.

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Please submit your comments using only one method.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to <http://www.cftc.gov>. You should submit only

information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in the procedures in CFTC Regulation 145.9, 17 CFR 145.9.

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from <http://www.cftc.gov> that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the rulemaking will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

**FOR FURTHER INFORMATION CONTACT:** Edward Riccobene, Chief, Policy and Review, Division of Enforcement, 202-418-5327, [ericcobene@cftc.gov](mailto:ericcobene@cftc.gov), Commodity Futures Trading Commission, Three Lafayette Centre, 1151 21st Street, NW., Washington, DC 20581.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On July 21, 2010, President Obama signed the Dodd-Frank Wall Street Reform and Consumer Protection Act (“Dodd-Frank Act”).<sup>1</sup> Title VII of the Dodd-Frank Act<sup>2</sup> amended the Commodity Exchange Act (“CEA”) to establish a comprehensive new regulatory framework for swaps and security-based swaps. The legislation was enacted to reduce risk, increase transparency, and promote market integrity within the financial system by, among other things: (1) Providing for the registration and comprehensive regulation of swap dealers and major swap participants; (2) imposing clearing and trade execution requirements on standardized derivative products; (3) creating robust recordkeeping and real-time reporting regimes; and (4) enhancing the Commission’s rulemaking and enforcement authorities with respect to, among others, all

<sup>1</sup> See Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111-203, 124 Stat. 1376 (2010). The text of the Dodd-Frank Act may be accessed at <http://www.cftc.gov/LawRegulation/OTCDERIVATIVES/index.htm>.

<sup>2</sup> Pursuant to Section 701 of the Dodd-Frank Act, Title VII may be cited as the “Wall Street Transparency and Accountability Act of 2010.”

<sup>3</sup> 7 U.S.C. 1 *et seq.* (2006).

registered entities and intermediaries subject to the Commission’s oversight.

In addition, Title VII of the Dodd-Frank Act contains provisions to provide incentives and protections for whistleblowers.

Section 748 of the Dodd-Frank Act amends the CEA by adding Section 23, entitled “Commodity Whistleblower Incentives and Protection.”<sup>4</sup> Section 23 directs that the Commission must pay awards, subject to certain limitations and conditions, to whistleblowers who voluntarily provide the Commission with original information about a violation of the CEA that leads to successful enforcement of an action brought by the Commission that results in monetary sanctions exceeding \$1,000,000, and of certain related actions.

The Commission is proposing Regulation 165 to implement Section 23 of the CEA. As described in detail below, the rules contained in proposed Regulation 165 define certain terms critical to the operation of the whistleblower program, outline the procedures for applying for awards and the Commission’s procedures for making decisions on claims, and generally explain the scope of the whistleblower program to the public and to potential whistleblowers. Further, Proposed Regulation 165 includes an appendix informing whistleblowers of their protections from employer retaliation under Section 23 of the CEA.

Section 23 of the CEA also requires the Commission to fund customer education initiatives designed to help customers protect themselves against fraud or other violations of the CEA, or rules or regulations thereunder. The Commission will, in a future rulemaking, address related internal procedural and organizational issues, including establishment of, and delegation of authority to, an office or offices to administer the Commission’s whistleblower and customer education programs.

Accordingly, the Commission is proposing rules to implement Section 748 and establish a whistleblower program. The Commission requests comment on all aspects of the proposed rules, as well as comment on the specific provisions and issues highlighted in the discussion below.

## II. Description of the Proposed Rules

### A. Proposed Rule 165.1—General

Proposed Rule 165.1 provides a general, plain English description of

<sup>4</sup> Section 922(a), Public Law 111-203, 124 Stat. 1841 (2010).

Section 23 of the CEA. It sets forth the purposes of the rules and states that the Commission administers the whistleblower program. In addition, the proposed rule states that, unless expressly provided for in the rules, no person is authorized to make any offer or promise, or otherwise to bind the Commission with respect to the payment of an award or the amount thereof.

### B. Proposed Rule 165.2—Definitions

#### 1. Proposed Rule 165.2(a) Action

Proposed Rule 165.2(a) defines the term “action” to mean a single captioned civil or administrative proceeding. This defined term is relevant for purposes of calculating whether monetary sanctions in a Commission action exceed the \$1,000,000 threshold required for an award payment pursuant to Section 23 of the CEA, as well as determining the monetary sanctions on which awards are based.<sup>5</sup> The Commission proposes to interpret the “action” to include all defendants or respondents, and all claims, that are brought within that proceeding without regard to which specific defendants or respondents, or which specific claims, were included in the action as a result of the information that the whistleblower provided. This approach to determining the scope of an “action” appears consistent with the most common meaning of the term,<sup>6</sup> will effectuate the purposes of Section 23 by enhancing the incentives for individuals to come forward and report potential violations to the Commission,<sup>7</sup> and will avoid the challenges associated with attempting to allocate monetary sanctions involving multiple individuals and claims based upon the select individuals and claims reported by whistleblowers.

The Commission requests comment on the proposed definition of the word “action.” Is it appropriate to pay

whistleblower awards based on all monetary sanctions obtained in a single proceeding, even when the whistleblower’s information did not concern all defendants or claims in that proceeding?

#### 2. Proposed Rule 165.2(b) Aggregate Amount

Proposed Rule 165.2(b) defines the phrase “aggregate amount” to mean the total amount of an award granted to one or more whistleblowers pursuant to Proposed Rule 165.7. The term is relevant for purposes of determining the amount of an award pursuant to Proposed Rule 165.8.

#### 3. Proposed Rule 165.2(c) Analysis

Under Section 23(a)(4) of the CEA, the original information provided by a whistleblower can include information that is derived from independent knowledge and also from independent “analysis” of a whistleblower. Proposed Rule 165.2(c) defines the term “analysis” to mean the whistleblower’s examination and evaluation of information that may be generally available, but which reveals information that is not generally known or available to the public. This definition recognizes that there are circumstances where individuals can review publicly available information, and, through their additional evaluation and analysis, provide vital assistance to the Commission staff in understanding complex schemes and identifying potential violations of the CEA.

The Commission requests comment on the definition of “analysis.” Is there a different or more specific definition of “analysis” that would better effectuate the purposes of Section 23 of the CEA?

#### 4. Proposed Rule 165.2(d) Collected by the Commission

Proposed Rule 165.2(d) defines the phrase “collected by the Commission,” when used in the context of deposits and credits into the Fund, to refer to a monetary sanction that is both collected by the Commission and is recorded as a payment receivable on the Commission’s books and records. While the amount of a whistleblower award is based upon “what has been collected of the monetary sanctions imposed in an action or related action,” see Section 23(b), Congress used different language to describe the source of funding for whistleblower awards. Specifically, Congress states that the Fund will be financed through monetary sanctions “collected by the Commission,” meaning that deposits into the Fund are based only upon what the Commission actually collects. See Section 23(g)(3).

The Commission generally collects civil monetary sanctions and disgorgement amounts in civil actions, or fines in administrative actions. A federal court or the Commission generally awards restitution to victims in civil and administrative actions, respectively, but the Commission does not “collect” restitution, *i.e.*, restitution is not recorded as a payment receivable on the Commission’s books and records. Consequently, restitution amounts collected in a covered action or related action will not be deposited into the Fund.

#### 5. Proposed Rule 165.2(e) Covered Judicial or Administrative Action

Proposed Rule 165.2(e) defines the phrase “covered judicial or administrative action” to mean any judicial or administrative action brought by the Commission under the CEA whose successful resolution results in monetary sanctions exceeding \$1,000,000.

#### 6. Proposed Rule 165.2(f) Fund

Proposed Rule 165.2(f) defines the term “Fund” to mean the “Commodity Futures Trading Commission Customer Protection Fund” established by Section 23(g) of the CEA. The Commission will use the Fund to pay whistleblower awards as provided in Proposed Rule 165.12 and to finance customer education initiatives designed to help customers protect themselves against fraud and other violations of the CEA or the Commission’s regulations.

#### 7. Proposed Rule 165.2(g) Independent Knowledge

Proposed Rule 165.2(g) defines “independent knowledge” as factual information in the whistleblower’s possession that is not obtained from publicly available sources, which would include such sources as corporate filings, media, and the Internet. Importantly, the proposed definition of “independent knowledge” does not require that a whistleblower have direct, first-hand knowledge of potential violations. Instead, independent knowledge may be obtained from any of the whistleblower’s experiences, observations, or communications (subject to the exclusion for knowledge obtained from public sources). Thus, for example, under Proposed Rule 165.2(g), a whistleblower would have “independent knowledge” of information even if that knowledge derives from facts or other information that has been conveyed to the whistleblower by third parties.

The Commission preliminarily believes that defining “independent

<sup>5</sup> See Proposed Rule 165.8.

<sup>6</sup> See Black’s Law Dictionary 31 (8th ed. 2004) (defining an “action” as “a civil or criminal judicial proceeding”). Section 23 of the CEA does not appear to contemplate the aggregation of separate judicial or administrative actions for purposes of determining whether the \$1,000,000 threshold is satisfied, even if the actions arise out of a single investigation.

<sup>7</sup> This approach offers enhanced potential incentives for whistleblowers when compared to other similar programs because those programs have typically limited awards to successful claims that the whistleblower actually identified. See *Rockwell International Corp. v. United States*, 549 U.S. 457 (2007) (False Claims Act); *John Doe v. United States*, 65 Fed. Cl. 184 (2005) (Customs moiety statute, 19 U.S.C. 1619); Internal Revenue Manual 25.2.2.2.8.A (under IRS whistleblower program, collected proceeds only include proceeds from the single issue identified by the whistleblower, or substantially similar improper activity).

knowledge” in this manner best effectuates the purposes of Section 23 of the CEA. An individual may learn about potential violations of the CEA without being personally involved in the conduct. If an individual voluntarily comes forward with such information, and the information leads the Commission to a successful enforcement action (as defined in Proposed Rule 165.2(i)), that individual should be eligible to receive a whistleblower award.<sup>8</sup>

Proposed Rule 165.2(g) further provides that an individual will not be considered to have “independent knowledge” in four other circumstances. The effect of these provisions would be to exclude individuals who obtain information under these circumstances from being eligible for whistleblower awards.

The first exclusion contemplated is for information that was obtained through a communication that is subject to the attorney-client privilege. (Proposed Rule 165.2(g)(2) and (3).) Compliance with the CEA is promoted when individuals, corporate officers, Commission registrants and others consult with counsel about potential violations, and the attorney-client privilege furthers such consultation. This important benefit could be undermined if the whistleblower award program vitiated the public’s perception of the scope of the attorney-client privilege or created monetary incentives for counsel to disclose information about potential CEA violations that they learned of through privileged communications.

The exception for knowledge obtained through privileged attorney-client

communications would not apply in circumstances where the disclosure of the information is otherwise permitted. This could include, for example, circumstances where the privilege has been waived, and where the privilege is not applicable because of a recognized exception such as the crime-fraud exception to the attorney-client privilege.

The second exclusion to “independent knowledge” in the proposed rule applies when a person with legal, compliance, audit, supervisory, or governance responsibilities for an entity receives information about potential violations, and the information was communicated to the person with the reasonable expectation that the person would take appropriate steps to cause the entity to remedy the violation.<sup>9</sup> (Proposed Rule 165.2(g)(4).)

The third exclusion is closely related to the second, and applies any other time that information is obtained from or through an entity’s legal, compliance, audit, or similar functions or processes for identifying, reporting, and addressing potential non-compliance with applicable law. (Proposed Rule 165.2(g)(5).) However, each of these two exclusions ceases to be applicable, with the result that an individual may be deemed to have “independent knowledge,” and therefore may become a whistleblower, if the entity fails to disclose the information to the Commission within sixty (60) days or otherwise proceeds in bad faith.

Compliance with the CEA is promoted when companies implement effective legal, audit, compliance, and similar functions. The rationale for these proposed exclusions is the concern that Section 23 not be implemented in a way that would create incentives for persons involved in such functions, as well as other responsible persons who are informed of wrongdoing, to circumvent or undermine the proper operation of the entity’s internal processes for investigating and responding to violations of law. Accordingly, under the proposed rule, officers, directors, employees, and others who learn of potential violations as part of their official duties in the expectation that they will take steps to address the violations, or otherwise from or through the various processes that companies

employ to identify problems and advance compliance with legal standards, would not be permitted to use that knowledge to obtain a personal benefit by becoming whistleblowers.

Nevertheless, if the entity failed to disclose the information to the Commission within sixty (60) days or otherwise proceeds in bad faith, the exclusion would no longer apply, thereby making an individual who knows this undisclosed information eligible to become a whistleblower. The rationale for this provision is that if the entity fails to report information concerning the violation to the Commission, it would be inconsistent with the purposes of Section 23 to continue to disable individuals with knowledge of the potential violations from coming forward and providing the information to the Commission. Furthermore, this provision provides a reasonable period of time for entities to report potential violations, thereby minimizing the potential of circumventing or undermining existing compliance programs.

The fourth and final exclusion to “independent knowledge” in the proposed rule applies if the whistleblower obtains the information by means or in a manner that violates applicable federal or state criminal law. This exclusion is necessary to avoid the unintended effect of incentivizing criminal misconduct.

The Commission requests comment on the definition of “independent knowledge.” Is it appropriate to include within the scope of the phrase “independent knowledge” knowledge that is not direct, first-hand knowledge, but is instead learned from others, subject only to an exclusion for knowledge learned from publicly-available sources? Is it appropriate to exclude from the definition of “independent knowledge” information that is obtained through a communication that is protected by the attorney-client privilege? Are there other ways these rules should address privileged communications?

The Commission also requests comment on the proposed exclusions for information obtained by a person with legal, compliance, audit, supervisory, or governance responsibilities for an entity under an expectation that the person would cause the entity to take steps to remedy the violation, and for information otherwise obtained from or through an entity’s legal, compliance, audit, or similar functions. Does this exclusion strike the proper balance? Will the carve-out for situations where the entity fails to disclose the information within sixty

<sup>8</sup>In addition, the distinction between “independent knowledge” (as knowledge not dependent upon publicly available sources) and direct, first-hand knowledge, is consistent with the approach courts have typically taken in interpreting similar terminology in the False Claims Act. Until this year, the “public disclosure bar” provisions of the False Claims Act defined an “original source” of information, in part, as “an individual who [had] direct and independent knowledge of the allegations of the information on which the allegations [were] based \* \* \*.” 31 U.S.C. 3130(e)(4) (prior to 2010 amendments). Courts interpreting these terms generally defined “independent knowledge” to mean knowledge that was not dependent on public disclosures, and “direct knowledge” to mean first-hand knowledge from the relator’s own work and experience, with no intervening agency. *E.g.*, *United States ex rel. Fried v. West Independent School District*, 527 F.3d 439 (5th Cir. 2008); *United States ex rel. Paranich v. Sorgnard*, 396 F.3d 326 (3d Cir. 2005). See generally John T. Boese, *Civil False Claims and Qui Tam Actions* § 4.02[D][2] (Aspen Publishers) (2006) (citing cases). Earlier this year, Congress amended the “public disclosure bar” to, among other things, remove the requirement that a relator have “direct knowledge” of information. Sec. 10104(h)(2), Public Law 111–148, 124 Stat. 901 (Mar. 23, 2010).

<sup>9</sup>This exclusion has been adapted from case law holding that a disclosure to a supervisor who is in a position to remedy the wrongdoing is a protected disclosure for purposes of the federal Whistleblower Protection Act, 5 U.S.C. 2302(b)(8). *E.g.*, *Reid v. Merit Systems Protection Board*, 508 F.3d 674 (Fed. Cir. 2007); *Hooven-Lewis v. Caldera*, 249 F.3d 259 (4th Cir. 2001).

(60) days promote effective self-policing functions and compliance with the law without undermining the operation of Section 23? Is sixty (60) days a “reasonable time” for the entity to disclose the information and, if not, what period should be specified (*e.g.*, three months, six months, one year)? Are there alternative provisions the Commission should consider that would promote effective self-policing and self-reporting while still being consistent with the goals and text of Section 23?

Finally, the Commission seeks comment on whether there are other sources of knowledge that should or should not be deemed “independent” for purposes of Section 23 and that should be specifically addressed by rule?

#### 8. Proposed Rule 165.2(h) Independent Analysis

Proposed Rule 165.2(h) defines the phrase “independent analysis” to mean the whistleblower’s own analysis, whether done alone or in combination with others. The proposed rule thus recognizes that analysis—in particular academic or professional studies—is often the product of collaboration among two or more individuals. The phrase is relevant to the definition of “original information” in Proposed Rule 165.2(k).

#### 9. Proposed Rule 165.2(i) Information That Led to Successful Enforcement

Under Section 23, a whistleblower’s eligibility for an award depends in part on whether the whistleblower’s original information “led to the successful enforcement” of the Commission’s covered judicial or administrative action or a related action. Proposed Rule 165.2(i) defines when original information “led to successful enforcement.”

The Commission’s enforcement practice generally proceeds in several stages. First, the staff opens an investigation based upon some indication of potential violations of the CEA and/or Commission regulations. Second, the staff conducts its investigation to gather additional facts in order to determine whether there is sufficient basis to recommend enforcement action. If so, the staff may recommend, and the Commission may authorize, the filing of an action. The definition in Proposed Rule 165.2(i) addresses the significance of the whistleblower’s information to both the decision to open an investigation and the success of the resulting enforcement action. The proposed rule would distinguish between situations where the whistleblower’s information causes the staff to begin an investigation or

inquire about new or different conduct as part of a current investigation, and situations where the whistleblower provides information about conduct that is already under investigation. In the latter case, awards would be limited to the rare circumstances where the whistleblower provided essential information that the staff would not have otherwise obtained in the normal course of the investigation. Subparagraphs (1) and (2) of Proposed Rule 165.2(i) reflect these considerations.

Subparagraph (1) of Proposed Rule 165.2(i) applies to situations where the staff is not already reviewing the conduct in question, and establishes a two-part test for determining whether “original information” voluntarily provided by a whistleblower led to successful enforcement of a Commission action. First, the information must have caused the staff to open an investigation, reopen an investigation that had been closed, or to inquire concerning new and different conduct as part of an open investigation. This does not necessarily contemplate that the whistleblower’s information will be the only information that the staff obtains before deciding to proceed. However, the proposed rule would apply when the whistleblower gave the staff information about conduct that the staff is not already investigating or examining, and that information was the principal motivating factor behind the staff’s decision to begin looking into the whistleblower’s allegations.

Second, if the whistleblower’s information caused the Commission staff to start looking at the conduct for the first time, the proposed rule would require that the information “significantly contributed” to the success of an enforcement action filed by the Commission. The proposed rule includes this requirement because the Commission believes that it is not the intent of Section 23 to authorize whistleblower awards for any and all tips about conduct that led to the opening of an investigation if the resulting investigation concludes in a successful covered judicial or administrative action. Rather, implicit in the requirement in Section 23(b) that a whistleblower’s information “led to \* \* \* successful enforcement” is the further expectation that the information, because of its high quality, reliability, and specificity, had a meaningful connection to the Commission’s ability to successfully complete its investigation and to either obtain a settlement or prevail in a litigated proceeding.

At bottom, successful enforcement of a judicial or administrative action depends on the staff’s ability to establish unlawful conduct by a preponderance of evidence. Thus, in order to have “led to successful enforcement,” the “original information” provided by a whistleblower should be connected to evidence that plays a significant role in successfully establishing the Commission’s claim. For example, the “led to” standard of Proposed Rule 165.2(i)(1) would be met if a whistleblower were to provide the Commission staff with strong, direct evidence of violations that supported one or more claims in a successful enforcement action. To give another example, a whistleblower whose information did not provide this degree of evidence in itself, but who played a critical role in advancing the investigation by leading the staff directly to evidence that provided important support for one or more of the Commission’s claims could also receive an award, in particular if the evidence the whistleblower pointed to might have otherwise been difficult to obtain. A whistleblower who only provided vague information, or an unsupported tip, or evidence that was tangential and did not significantly help the Commission successfully establish its claims, would ordinarily not meet the standard of this proposed rule.

If information that a whistleblower provides to the Commission consists of “independent analysis” (Proposed Rule 165.2(h)) rather than “independent knowledge” (Proposed Rule 165.2(g)), the evaluation of whether this analysis “led to successful enforcement” similarly would turn on whether it significantly contributed to the success of the action. This would involve, for example, considering the degree to which the analysis, by itself and without further investigation, indicated a high likelihood of unlawful conduct that was the basis, or was substantially the basis, for one or more claims in the Commission’s enforcement action. The purpose of this provision is to ensure that the analysis provided to the Commission results in the efficiency and effectiveness benefits to the enforcement program that were intended by Congress. Thus, if a person provided analysis based upon readily available public information and the staff opened an inquiry based upon this analysis but was required to conduct significant additional analysis and investigation to conclude a successful enforcement action, the person would not be deemed to have provided “independent analysis.”

Subparagraph (2) of Proposed Rule 165.2(i) sets forth a separate, and higher, standard for cases in which a whistleblower provides original information to the Commission about conduct that is already under investigation by the Commission, Congress, any other federal, state, or local authority, any self-regulatory organization, or the Public Company Accounting Oversight Board. In this situation, the information will be considered to have led to the successful enforcement of a judicial or administrative action if the information would not have otherwise been obtained and was essential to the success of the action.<sup>10</sup> Although the Commission believes that awards under Section 23 generally should be limited to cases where whistleblowers provide original information about violations that are not already under investigation,<sup>11</sup> there may be rare circumstances where information received from a whistleblower in relation to an ongoing investigation is so significant for the success of a Commission action that a whistleblower award should be considered. For example, a whistleblower who is not within the scope of the staff's investigation, but who nonetheless has access to, and comes forward with a document that had been concealed from the staff, and that establishes proof of wrongdoing that is critical to the Commission's ability to sustain its burden of proof, provides the type of assistance that should be considered for an award without regard to whether the staff was already investigating the conduct at the time the document was provided. The Commission anticipates applying Proposed Rule 165.2(i) in a strict fashion, however, such that awards under the proposed rule would be exceedingly rare.

In considering the relationship between information obtained from a whistleblower and the success of a covered judicial or administrative action, the Commission will take into account the difference between settled and litigated actions. Specifically, in a litigated action the whistleblower's information must significantly

contribute, or, in the case of conduct that is already under investigation, be essential, to the success of a claim on which the Commission prevails in litigation. For example, if a court finds in favor of the Commission on a number of claims in an enforcement action, but rejects the claims that are based upon the information the whistleblower provided, the whistleblower would not be considered eligible to receive an award.<sup>12</sup> By contrast, in a settled action the Commission would consider whether the whistleblower's information significantly contributed, or was essential, to allegations included in the Commission's federal court complaint, or to factual findings in the Commission's administrative order.

The Commission requests comment on the proposed standard for when original information voluntarily provided by a whistleblower "led to" successful enforcement action. Is the proposed standard appropriate?

The Commission also requests comment on cases where the original information provided by the whistleblower caused the staff to begin looking at conduct for the first time. Should the standard also require that the whistleblower's information "significantly contributed" to a successful enforcement action? If not, what standards should be used in the evaluation? If yes, should the proposed rule define with greater specificity when information "significantly contributed" to enforcement action? In what way should the phrase be defined?

Finally, the Commission requests comment on the proposal in Subparagraph (i)(2), which would consider that a whistleblower's information "led to" successful enforcement even in cases where the whistleblower gave the Commission original information about conduct that was already under investigation. Is this proposal appropriate? Should the Commission's evaluation turn on whether the whistleblower's information would not otherwise have been obtained and was essential to the success of the action? If not, what other standard(s) should apply?

#### 10. Proposed Rule 165.2(j) Monetary Sanctions

Proposed Rule 165.2(j) defines the phrase "monetary sanctions," when used with respect to any judicial or

<sup>12</sup> As discussed below, however, if the Commission prevails on a claim that is based upon the information the whistleblower provided, and if all the conditions for an award are otherwise satisfied, the award to the whistleblower would be based upon all of the monetary sanctions obtained as a result of the action. See Proposed Rule 165.8.

administrative action, to mean (1) any monies, including penalties, disgorgement, restitution, and interest ordered to be paid; and (2) any monies deposited into a disgorgement fund or other fund pursuant to Section 308(b) of the Sarbanes-Oxley Act of 2002 (15 U.S.C. 7246(b)), as a result of such action or any settlement of such action. This phrase is relevant to the definition of "covered judicial or administrative action" in Proposed Rule 165.2(d) and to the amount of a whistleblower award under Proposed Rule 165.8.

#### 11. Proposed Rule 165.2(k) Original Information and Proposed Rule 165.2(l) Original Source

Proposed Rule 165.2(k) tracks the definition of "original information" set forth in Section 23(a)(4) of the CEA.<sup>13</sup> "Original information" means information that is derived from the whistleblower's independent knowledge or analysis; is not already known to the Commission from any other source, unless the whistleblower is the original source of the information; and is not exclusively derived from an allegation made in a judicial or administrative hearing, in a governmental report, hearing, audit, or investigation, or from the news media, unless the whistleblower is a source of the information. Consistent with Section 23(l) of the CEA, the Dodd-Frank Act authorizes the Commission to pay whistleblower awards on the basis of original information that is submitted prior to the effective date of final rules implementing Section 23 (assuming that all of the other requirements for an award are met); the Dodd-Frank Act does not authorize the Commission to apply Section 23 retroactively to pay awards based upon information submitted prior to the enactment date of the statute.<sup>14</sup> Consistent with Congress's intent, Proposed Rule 165.2(k)(4) also requires that "original information" be provided to the Commission for the first time after July 21, 2010 (the date of enactment of the Dodd-Frank Act).

Under the statutory definition of "original information," a whistleblower who provides information that the Commission already knows from another source has not provided original information, unless the whistleblower is

<sup>13</sup> 7 U.S.C. 26(a)(4).

<sup>14</sup> Section 23(k) of the CEA directs that: "Information submitted to the Commission by a whistleblower in accordance with rules or regulations implementing this section shall not lose its status as original information solely because the whistleblower submitted such information prior to the effective date of such rules or regulations, provided that such information was submitted after the date of enactment of the Wall Street Transparency and Accountability Act of 2010."

<sup>10</sup> The proposed rule also makes clear that subparagraph (2) of Proposed Rule 165.2(i) does not apply when a whistleblower provides information to the Commission about a matter that is already under investigation by another authority if the whistleblower is the "original source" for that investigation under Proposed Rule 165.2(l). In those circumstances, subparagraph (1) of Proposed Rule 165.2(i) would govern the Commission's analysis.

<sup>11</sup> See *Lacy v. United States*, 221 Ct. Cl. 526 (1979); cf. *United States ex rel. Merena v. Smith-Kline Beecham Corp.*, 205 F.3d 97 (3d Cir. 2000).



the “original source” of that information. Proposed Rule 165.2(l) defines the term “original source,” which will be used in the definition of “original information.” Under the proposed rule, a whistleblower is an “original source” of the same information that the Commission obtains from another source if the other source obtained the information from the whistleblower or his representative. The whistleblower bears the burden of establishing that he is the original source of information.

In Commission investigations, this situation may arise if the staff receives a referral from another authority such as the Department of Justice, a self-regulatory organization, or another organization that is identified in the proposed rule. On occasion, the situation may also arise that the “original source” of information shares his information with another person, and such other person files a whistleblower claim with the Commission prior to the original source filing a claim for whistleblower status. In these circumstances, the proposed rule would credit a whistleblower as being the “original source” of information on which the referral was based as long as the whistleblower “voluntarily” provided the information to the other authority within the meaning of these rules; *i.e.*, the whistleblower or his representative must have come forward and given the other authority the information before receiving any request, inquiry, or demand to which the information was relevant, or was the individual who originally possessed either the independent knowledge or conducted the independent analysis.

As is described elsewhere in these proposed rules, a whistleblower will need to submit two forms, a Form TCR (“Tip, Complaint or Referral”) and Form WB-DEC (“Declaration Concerning Original Information Provided Pursuant to Section 23 of the Commodity Exchange Act”) in order to start the process and establish the whistleblower’s eligibility for award consideration.<sup>15</sup> A whistleblower who either provides information to another authority first, or who shared his independent knowledge or analysis with another who is also claiming to be a whistleblower, will need to follow these same procedures and submit the necessary forms to the Commission in order to perfect his status as a whistleblower under the Commission’s whistleblower program. However, under Proposed Rule 165.2(l)(2), as long as the whistleblower submits the necessary

forms to the Commission within 90 days after he provided the information to the other authority, or 90 days after the other person claiming to be a whistleblower submits his claim to the Commission, the Commission will consider the whistleblower’s submission to be effective.

As noted above, the whistleblower must establish that he is the original source of the information provided to the other authority as well as the date of his submission, but the Commission may seek confirmation from the other authority, or any other source, in making this determination. The objective of this procedure is to provide further incentive for persons with knowledge of CEA violations to come forward (consistent with the purposes of Section 23) by assuring potential whistleblowers that they can provide information to appropriate Government or regulatory authorities, and their “place in line” will be protected in the event that other whistleblowers later provide the same information directly to the Commission.

For similar reasons, the proposed rule extends the same protection to whistleblowers who provide information about potential violations to the persons specified in Proposed Rule 165.2(g)(3) and (4) (*i.e.*, personnel involved in compliance or similar functions, or who are informed about potential violations with the expectation that they will take steps to address them), and who, within 90 days, submit the necessary whistleblower forms to the Commission. Compliance with the CEA is promoted when companies have effective programs for identifying, correcting, and self-reporting unlawful conduct by company officers or employees. The objective of this provision is to support, not undermine, the effective functioning of company compliance and related systems by allowing employees to take their concerns about potential violations to appropriate company officials while still preserving their rights under the Commission’s whistleblower program.

Proposed Rule 165.2(l)(3) addresses circumstances where the Commission already possesses some information about a matter at the time that a whistleblower provides additional information about the same matter. The whistleblower will be considered the “original source” of any information that is derived from his independent knowledge or independent analysis and that materially adds to the information that the Commission already possesses. The standard is modeled after the definition of “original source” that Congress included in the False Claims

Act through amendments earlier this year.<sup>16</sup>

The Commission requests comment on all aspects of the definitions of “original information” and “original source” set forth in Proposed Rules 165.2(k) and (l). Is the provision that would credit individuals with providing original information to the Commission, as of the date of their submission to another Governmental or regulatory authority, or to company legal, compliance, or audit personnel, appropriate? In particular, does the provision regarding the providing of information to a company’s legal, compliance, or audit personnel appropriately accommodate the internal compliance process?

The Commission also requests comment on whether the ninety (90) day deadline for submitting Forms TCR and WB-DEC to the Commission (about initially providing information about violations or potential violations to another authority or the employer’s legal, compliance, or audit personnel) is the appropriate time frame? Should there be different time frames for disclosures to other authorities and disclosures to an employer’s legal, compliance or audit personnel?

#### 12. Proposed Rule 165.2(m) Related Action

The phrase “related action,” when used with respect to any judicial or administrative action brought by the Commission under the CEA, means any judicial or administrative action brought by an entity listed in Proposed Rule 165.11(a) that is based upon the original information voluntarily submitted by a whistleblower to the Commission pursuant to Proposed Rule 165.3 that led to the successful resolution of the Commission action. This phrase is relevant to the Commission’s determination of the amount of a whistleblower award under Proposed Rules 165.8 and 165.11.

#### 13. Proposed Rule 165.2(n) Successful Resolution or Successful Enforcement

Proposed Rule 165.2(n) defines the phrase “successful resolution,” when used with respect to any judicial or administrative action brought by the Commission under the Commodity Exchange Act, to include any settlement of such action or final judgment in favor of the Commission. It shall also have the same meaning as “successful enforcement.” This phrase is relevant to the definition of the phrase “covered

<sup>15</sup> See Proposed Rule 165.3.

<sup>16</sup> 31 U.S.C. 3730(e)(4)(B), Public Law 111-148 § 10104(h)(2), 124 Stat. 901 (Mar. 23, 2010).

judicial or administrative action” as set forth in Proposed Rule 165.2(e).

#### 14. Proposed Rule 165.2(o) Voluntary Submission or Voluntarily Submitted

Under Section 23(b)(1) of the CEA,<sup>17</sup> whistleblowers are eligible for awards only when they provide original information to the Commission “voluntarily.” Proposed Rule 165.2(o) would define “voluntary submission” or “voluntarily submitted” in the context of submission to the Commission of original information as a whistleblower’s provision of information to the Commission before receipt by the whistleblower (or anyone representing the whistleblower, including counsel) of any request, inquiry, or demand from the Commission, Congress, any other federal, state or local authority, or any self-regulatory organization about a matter to which the information in the whistleblower’s submission is relevant. The fact that such request, inquiry or demand is not compelled by subpoena or other applicable law, does not render a subsequent submission voluntary.

Proposed Rule 165.2(o) would make clear that, in order to have acted “voluntarily” under the statute, a whistleblower must do more than merely provide the Commission with information that is not compelled by subpoena (or by a court order following a Commission action to enforce a subpoena) or by other applicable law.<sup>18</sup> Rather, the whistleblower or his representative (such as an attorney) must come forward with the information before receiving any request, inquiry, or demand from the Commission staff or from any other investigating authority described in the proposed rule about a matter to which the whistleblower’s information is relevant. A request, inquiry, or demand that is directed to an employer is also considered to be directed to employees who possess the documents or other information that is necessary for the employer to respond. Accordingly, a subsequent whistleblower submission from any such employee will not be considered “voluntary” for purposes of the rule, and the employee will not be eligible for award consideration, unless the employer fails to provide the employee’s documents or information to the requesting authority within sixty (60) days.

This approach is consistent with the statutory purpose of creating a strong incentive for whistleblowers to come forward early with information about possible violations of the CEA rather than wait until Government or other official investigators “come knocking on the door.”<sup>19</sup> This approach is also consistent with the approach federal courts have taken in determining whether a private plaintiff, suing on behalf of the Government under the qui tam provisions of the False Claims Act, “voluntarily” provided information about the false or fraudulent claims to the Government before filing suit.<sup>20</sup>

Disclosure to the Government should also not be considered voluntary if the individual has a pre-existing legal or contractual duty to report violations of the type at issue to the Commission, Congress, any other federal or state authority, or any self-regulatory organization.<sup>21</sup> Thus, for example, Section 23(c)(2) of the CEA<sup>22</sup> prohibits awards to members, officers, or

<sup>19</sup> See S. Rep. No. 111–176 at 110 (2010) (discussing Section 922 of the Dodd-Frank Act, which establishes “Securities Whistleblower Incentives and Protection” similar to the “Commodity Whistleblower Incentives and Protection” in Section 748; “The Whistleblower Program aims to motivate those with inside knowledge to come forward and assist the Government to identify and prosecute persons who have violated securities laws \* \* \*”).

<sup>20</sup> See *United States ex rel. Barth v. Ridgedale Electric, Inc.*, 44 F.3d 699 (8th Cir. 1994); *United States ex rel. Paranych v. Sorgnard*, 396 F.3d 326 (3d Cir. 2005); *United States ex rel. Fine v. Chevron, USA, Inc.*, 72 F.3d 740 (9th Cir. 1995), cert. denied, 517 U.S.1233 (1996) (rejecting argument that provision of information to the Government is always voluntary unless compelled by subpoena). The qui tam provisions of the False Claims Act include a “public disclosure bar,” which, as recently amended, requires a court to dismiss a private action or claim if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed in certain fora, unless the Government opposes dismissal or the plaintiff is an “original source” of the information. 31 U.S.C. 3730(e)(4). An “original source” is further defined, in part, with reference to whether the plaintiff “voluntarily” disclosed the information to the Government before filing suit. *Id.* Because the qui tam provisions of the False Claims Act have played a significant role in the development of whistleblower law generally, and because some of the terminology used by Congress in Section 23 has antecedents in the False Claims Act, the Commission believes that precedent under the False Claims Act can provide helpful guidance in the interpretation of Section 23 of the CEA. At the same time, because the False Claims Act and Section 23 serve different purposes, are structured differently, and the two statutes may use the same words in different contexts, the Commission does not view False Claims Act precedent as necessarily controlling or authoritative in all circumstances for purposes of Section 23 of the CEA.

<sup>21</sup> See *United States ex rel. Biddle v. Board of Trustees of The Leland Stanford, Jr. University*, 161 F.3d 533 (9th Cir. 1998), cert. denied, 526 U.S. 1066 (1999); *United States ex rel. Schwedt v. Planning Research Corp.*, 39 F. Supp. 2d 28 (D.D.C. 1999).

<sup>22</sup> 15 U.S.C. 78u-6(c)(2).

employees of an appropriate regulatory agency, the Department of Justice, a registered entity, a registered futures association, or a self-regulatory organization. The Commission anticipates that other similarly-situated persons should not be eligible for award consideration if they are under a pre-existing legal duty to report the information to the Commission or to any of the other authorities described above. Proposed Rule 165.2(o) accomplishes this goal by providing that submissions from such individuals will not be considered voluntary for purposes of Section 23 of the CEA. Proposed Rule 165.2(o) also includes a similar exclusion for information that the whistleblower is contractually obligated to provide. This exclusion is intended to preclude awards to persons who provide information pursuant to preexisting agreements that obligate them to assist Commission staff or other investigative authorities.

The Commission requests comment on the definition of “voluntarily.” Does Proposed Rule 165.2(o) appropriately define the circumstances when a whistleblower should be considered to have acted “voluntarily” in providing information about CEA or Commission regulation violations to the Commission? Are there other circumstances not clearly included that should be in the rule? Is it appropriate for the proposed rule to consider a request or inquiry directed to an employer to be directed at individual employees who possess the documents or other information needed for the employer’s response? Should the persons who are considered to be within the scope of an inquiry be narrowed or expanded? Will the carve-out that permits such an employee to become a whistleblower if the employer fails to disclose the information the employee provided within sixty (60) days promote compliance with the law and the effective operation of Section 23? Is sixty (60) days a “reasonable time” for employers to disclose the information the employee provided, or should a different period be specified (*e.g.*, three months, six months, one year)?

The Commission also requests comment on the standard described in Proposed Rule 165.2(o) that would credit an individual with acting “voluntarily” in circumstances where the individual was aware of fraudulent conduct for an extended period of time, but chose not to come forward as a whistleblower until after he became aware of a governmental investigation (such as by observing document requests being served on his employer or colleagues, but before he received an

<sup>17</sup> 7 U.S.C. 26(b)(1).

<sup>18</sup> Various books and records provisions of the CEA and Commission regulations generally require registrants to furnish records to the Commission upon request. See *e.g.*, Section 4(g) of the CEA, 7 U.S.C. 6(g).

inquiry, request, or demand himself, assuming that he was not within the scope of an inquiry directed to his employer). Is this an appropriate result, and, if not, how should the proposed rule be modified to account for it?

Finally, the Commission seeks Comment on the exclusion set forth in Proposed Rule 165.2(o) for information provided pursuant to a pre-existing legal or contractual duty to report violations. Is the exclusion appropriate? Should the exclusion be expanded to other forms of duties such as ethical duties or duties imposed by codes of conduct?

#### 15. Proposed Rule 165.2(p) Whistleblower(s)

The term “whistleblower” is defined in Section 23(a)(7) of the CEA.<sup>23</sup> Consistent with this language, Proposed Rule 165.2(p) would define a whistleblower as an individual who, alone or jointly with others, provides information to the Commission relating to a potential violation of the CEA. A company or another entity is not eligible to receive a whistleblower award. This definition tracks the statutory definition of a “whistleblower,” except that the proposed rule uses the term “potential violation” in order to make clear that the whistleblower anti-retaliation protections set forth in Section 23(h) of the CEA do not depend on an ultimate adjudication, finding or conclusion that conduct identified by the whistleblower constituted a violation of the CEA.

Proposed Rule 165.2(p) (and Proposed Rule 165.6(b)) would further make clear that the anti-retaliation protections set forth in Section 23(h) of the CEA apply irrespective of whether a whistleblower satisfies all the procedures and conditions to qualify for an award under the Commission’s whistleblower program. Section 23(h)(1)(A) of the CEA prohibits employment retaliation against a whistleblower who provides information to the Commission (i) “in accordance with this section,” or (ii) “in assisting in any investigation or judicial or administrative action of the Commission based upon or related to such information.” The Commission interprets the statute as designed to extend the protections against employment retaliation that are provided for in Section 23(h)(1) to any individual who provides information to the Commission about potential violations of the CEA regardless of whether the person satisfies procedures and conditions necessary to qualify for an award under the Commission’s whistleblower program.

The Commission requests comment on whether the anti-retaliation protections set forth in Section 23(h)(1) of the CEA should be applied broadly to any person who provides information to the Commission concerning a potential violation of the CEA, or should they be limited by the various procedural or substantive prerequisites to consideration for a whistleblower award? Should the application of the anti-retaliation provisions be limited or broadened in any other ways?

#### C. Proposed Rule 165.3—Procedures for Submitting Original Information

The Commission proposes a two-step process for the submission of original information under the whistleblower award program. In general, the first step would require the submission of the standard form on which the information concerning potential violations of the CEA are reported. The second step would require the whistleblower to complete a unique form, signed under penalties of perjury (consistent with Section 23(m) of the CEA), in which the whistleblower would be required to make certain representations concerning the veracity of the information provided and the whistleblower’s eligibility for a potential award. The use of standardized forms will greatly assist the Commission in managing and tracking the thousands of tips that it receives annually. This will also better enable the Commission to connect tips to each other so as to make better use of the information provided, and to connect tips to requests for payment under the whistleblower provisions. The purpose of requiring a sworn declaration is to help deter the submission of false and misleading tips and the resulting inefficient use of the Commission’s resources. The requirement should also mitigate the potential harm to companies and individuals that may be caused by false or spurious allegations of wrongdoing.

As set forth in Proposed Rule 165.5, Commission staff may also request testimony and additional information from a whistleblower relating to the whistleblower’s eligibility for an award.

#### 1. Form TCR and Instructions

Subparagraph (a) of Proposed Rule 165.3 requires the submission of information to the Commission on proposed Form TCR. The Form TCR, “Tip, Complaint or Referral,” and the instructions thereto, are designed to capture basic identifying information about a complainant and to elicit sufficient information to determine whether the conduct alleged suggests a violation of the CEA.

#### 2. Form WB–DEC and Instructions

In addition to Form TCR, the Commission proposes in subparagraph (b) of Proposed Rule 165.3 to require that whistleblowers who wish to be considered for an award in connection with the information they provide to the Commission also complete and provide the Commission with proposed Form WB–DEC, “Declaration Concerning Original Information Provided Pursuant to Section 23 of the Commodity Exchange Act.” Proposed Form WB–DEC would require a whistleblower to answer certain threshold questions concerning the whistleblower’s eligibility to receive an award. The form also would contain a statement from the whistleblower acknowledging that the information contained in the Form WB–DEC, as well as all information contained in the whistleblower’s Form TCR, is true, correct and complete to the best of the whistleblower’s knowledge, information and belief. Moreover, the statement would acknowledge the whistleblower’s understanding that the whistleblower may be subject to prosecution and ineligible for an award if, in the whistleblower’s submission of information, other dealings with the Commission, or dealings with another authority in connection with a related action, the whistleblower knowingly and willfully makes any false, fictitious, or fraudulent statements or representations, or uses any false writing or document knowing that the writing or document contains any false, fictitious, or fraudulent statement or entry.

In instances where information is provided by an anonymous whistleblower, proposed subparagraph (c) of Proposed Rule 165.3 would require that the whistleblower’s identity must be disclosed to the Commission and verified in a form and manner acceptable to the Commission consistent with the procedure set forth in Proposed Rule 165.7(c) prior to Commission’s payment of any award.

The Commission proposes to allow two alternative methods of submission of Form TCRs and WB–DEC. A whistleblower would have the option of submitting a Form TCR electronically through the Commission’s website, or by mailing or faxing the form to the Commission. Similarly, a Form WB–DEC could be submitted electronically, in accordance with instructions set forth on the Commission’s website or, alternatively, by mailing or faxing the form to the Commission.

<sup>23</sup> 7 U.S.C. 26(a)(7).

### 3. Perfecting Whistleblower Status for Submissions Made Before Effectiveness of the Rules

As previously discussed, Section 748(k) of Dodd-Frank Act states that information submitted to the Commission by a whistleblower after the date of enactment, but before the effective date of these proposed rules, retains the status of original information. The Commission has already received tips from potential whistleblowers after the date of enactment of the Dodd-Frank Act. Proposed Rule 165.3(d) would provide a mechanism by which potential whistleblowers who provide tips between enactment of the Dodd-Frank Act and the effective date of the final rules could perfect their status as whistleblowers under the Commission's award program once final rules are adopted. Subparagraph (d)(1) requires a whistleblower who provided original information to the Commission in a format or manner other than a Form TCR to submit a completed Form TCR within one hundred twenty (120) days of the effective date of the proposed rules and to otherwise follow the procedures set forth in subparagraphs (a) and (b) of Proposed Rule 165.3. If the whistleblower provided the original information to the Commission in a Form TCR, subparagraph (d)(2) would require the whistleblower to submit Form WB-DEC within one hundred twenty (120) days of the effective date of the proposed rules in the manner set forth in subparagraph (b) of Proposed Rule 165.3.

Although the Commission is proposing alternative methods of submission of the Form TCR and WB-DEC, it expects that electronic submissions would dramatically reduce the administrative costs, enhance ability to evaluate tips (generally and using automated tools), and improve efficiency in processing whistleblower submissions. Accordingly, the Commission solicits comment on whether it would be appropriate to eliminate the fax and mail option and require that all submissions of proposed Form TCRs and WB-DEC be made electronically. Would the elimination of submissions by fax and mail create an undue burden for some potential whistleblowers who may not have easy access to a computer or who may prefer to submit their information in that manner? Is there other information that the Commission should elicit from whistleblowers on Form TCRs and WB-DEC? Are there categories of information included on these forms

that are unnecessary, or should be modified?

The Commission also requests comment on whether the requirement that an attorney for an anonymous whistleblower certify that the attorney has verified the whistleblower's identity and eligibility for an award is appropriate? Is there an alternative process the Commission should consider that would accomplish its goal of ensuring that it is communicating with a legitimate whistleblower?

Finally, the Commission seeks comment on whether the Commission's proposed process for allowing whistleblowers 120 days to perfect their status in cases where the whistleblower provided original information to the Commission in writing after the date of enactment of the Dodd-Frank Act but before adoption of the proposed rules is reasonable? Should the period be made shorter (*e.g.*, 30 or 60 days) or longer (*e.g.*, 180 days)?

#### *D. Proposed Rule 165.4—Confidentiality*

Proposed Rule 165.4 summarizes the confidentiality requirements set forth in Section 23(h)(2) of the CEA<sup>24</sup> with respect to information that could reasonably be expected to reveal the identity of a whistleblower. As a general matter, it is the Commission's policy and practice to treat all information obtained during its investigations as confidential and nonpublic. Disclosures of enforcement-related information to any person outside the Commission may only be made as authorized by the Commission and in accordance with applicable laws and regulations. Consistent with Section 23(h)(2), the proposed rule explains that the Commission will not reveal the identity of a whistleblower or disclose other information that could reasonably be expected to reveal the identity of a whistleblower, except under circumstances described in the statute and the rule.<sup>25</sup> As is further explained below, there may be circumstances in which disclosure of information that identifies a whistleblower will be legally required or will be necessary for the protection of investors.

Subparagraph (a)(1) of the proposed rule would authorize disclosure of

information that could reasonably be expected to reveal the identity of a whistleblower when disclosure is required to a defendant or respondent in a public proceeding that the Commission files or in another public action or a public proceeding filed by an authority to which the Commission is authorized to provide the information. For example, in a related action brought as a criminal prosecution by the Department of Justice, disclosure of a whistleblower's identity may be required, in light of the requirement of the Sixth Amendment of the Constitution that a criminal defendant have the right to be confronted with witnesses against him.<sup>26</sup> Subparagraph (a)(2) would authorize disclosure to: The Department of Justice; an appropriate department or agency of the Federal Government, acting within the scope of its jurisdiction; a registered entity, registered futures association, a self-regulatory organization; a state attorney general in connection with a criminal investigation; any appropriate state department or agency, acting within the scope of its jurisdiction; or a foreign futures authority.

Because many whistleblowers may wish to provide information anonymously, subparagraph (b) of the proposed rule, consistent with Section 23(d) of the CEA, states that anonymous submissions are permitted with certain specified conditions. Subparagraph (b) would require that anonymous whistleblowers who submit information to the Commission must follow the procedure in Proposed Rule 165.3(c) for submitting original information anonymously. Further, anonymous whistleblowers would be required to follow the procedures set forth in Proposed Rule 165.7(c) requiring that the whistleblower's identity be disclosed to the Commission and verified in a form and manner acceptable to the Commission prior to Commission's payment of any award.

The purpose of this requirement is to prevent fraudulent submissions and to facilitate communication and assistance between the whistleblower and the Commission's staff. Any whistleblower may be represented by counsel—whether submitting information anonymously or not.<sup>27</sup> The Commission emphasizes that anonymous whistleblowers have the same rights and responsibilities as other whistleblowers under Section 23 of the CEA and these

<sup>24</sup> 7 U.S.C. 26(h)(2).

<sup>25</sup> Section 23(h)(2)(A) provides that the Commission shall not disclose any information, including that provided to the whistleblower to the Commission, which could reasonably be expected to reveal the identity of the whistleblower, except in accordance with the provisions of Section 552a of title 5, United States Code, unless and until required to be disclosed to a defendant or respondent in connection with a public proceeding instituted by the Commission or governmental organizations described subparagraph (C).

<sup>26</sup> See U.S. Const. Amend. VI.

<sup>27</sup> See Section 23(d)(1), 7 U.S.C. 26(d)(1). Under the statute, however, an anonymous whistleblower seeking an award is required to be represented by counsel. Section 23(d)(2), 7 U.S.C. 26(d)(2).

proposed rules, unless expressly exempted.

*E. Proposed Rule 165.5—Prerequisites to the Consideration of an Award*

Proposed Rule 165.5 summarizes the general prerequisites for whistleblowers to be considered for the payment of awards set forth in Section 23(b)(1) of the CEA. As set forth in the statute, subparagraph (a) states that, subject to the eligibility requirements in the Regulations, the Commission will pay an award or awards to one or more whistleblowers who voluntarily provide the Commission with original information that led to the successful resolution of a covered Commission judicial or administrative action or the successful enforcement of a related action by: the Department of Justice; an appropriate department or agency of the Federal Government, acting within the scope of its jurisdiction; a registered entity, registered futures association, a self regulatory organization; a state attorney general in connection with a criminal investigation; any appropriate state department or agency, acting within the scope of its jurisdiction; or a foreign futures authority.

Subparagraph (b) of Proposed Rule 165.5 emphasizes that, in order to be eligible, the whistleblower must have submitted to the Commission original information in the form and manner required by Proposed Rule 165.3. The whistleblower must also provide the Commission, upon its staff's request, certain additional information, including: explanations and other assistance, in the manner and form that staff may request, in order that the staff may evaluate the use of the information submitted; all additional information in the whistleblower's possession that is related to the subject matter of the whistleblower's submission; and testimony or other evidence acceptable to the staff relating to the whistleblower's eligibility for an award. Subparagraph (b) of Proposed Rule 165.5 further requires that, to be eligible for an award, a whistleblower must, if requested by Commission staff, enter into a confidentiality agreement in a form acceptable to the Commission, including a provision that a violation of the confidentiality agreement may lead to the whistleblower's ineligibility to receive an award.

The terms "whistleblower," "voluntarily," "original information," "led to successful enforcement," "action," and "monetary sanctions" are defined in Proposed Rule 165.2.

*F. Proposed Rule 165.6—Whistleblowers Ineligible for an Award*

Subparagraph (a) of Proposed Rule 165.6 recites the categories of individuals who are statutorily ineligible for an award under Section 23 of the CEA. These include persons who are, or were at the time they acquired the original information a member, officer, or employee of: the Commission; the Board of Governors of the Federal Reserve System; the Office of the Comptroller of the Currency; the Board of Directors of the Federal Deposit Insurance Corporation; the Director of the Office of Thrift Supervision; the National Credit Union Administration Board; the Securities and Exchange Commission; the Department of Justice; a registered entity; a registered futures association; a self-regulatory organization; or a law enforcement organization. Further Proposed Rule 165.6(a)(2) makes clear that no award will be made to any whistleblower who is convicted of a criminal violation related to the judicial or administrative action for which the whistleblower otherwise could receive an award under Proposed Rule 165.7.

In order to prevent evasion of these exclusions, subparagraph (a)(3) of the proposed rule also provides that persons who acquire information from ineligible individuals are ineligible for an award. Consistent with Section 23(m) of the CEA, also ineligible for an award is any whistleblower that, in his submission of information or an application for an award, other dealings with the Commission, or his dealings with another authority in connection with a related action: knowingly and willfully makes any false, fictitious, or fraudulent statement or representation, or uses any false writing or document, knowing that it contains any false, fictitious, or fraudulent statement or entry; or omits any material fact whose absence would make any other statement or representation made to the Commission or any other authority misleading.

Subparagraph (b) of Proposed Rule 165.6 reiterates that a determination that a whistleblower is ineligible to receive an award for any reason does not deprive the individual of the anti-retaliation protections set forth in Section 23(h)(1) of the CEA.

The Commission requests comment on the ineligibility criteria set forth in Proposed Rule 165.6(a). Are there other statuses or activities that should render an individual ineligible for a whistleblower award?

*G. Proposed Rule 165.7—Procedures for Award Applications and Commission Award Determinations*

Proposed Rule 165.7 describes the steps a whistleblower would be required to follow in order to make an application for an award in relation to a Commission covered judicial or administrative action or related action. In addition, the rule describes the Commission's proposed claims review process.

In regard to covered actions, the proposed process would begin with the publication of a "Notice of a Covered Action" ("Notice") on the Commission's Web site. Whenever a covered judicial or administrative action brought by the Commission results in the imposition of monetary sanctions exceeding \$1,000,000, the Commission will cause this Notice of a covered judicial or administrative action to be published on the Commission's Web site subsequent to the entry of a final judgment or order in the action that by itself, or collectively with other judgments or orders previously entered in the action, exceeds the \$1,000,000 threshold. If the monetary sanctions are obtained without a judgment or order, the Notice would be published within thirty (30) days of the issuance of the settlement order that causes total monetary sanctions in the action to exceed \$1,000,000. The Commission's proposed rule requires claimants to file their claim for an award within sixty (60) days of the date of the Notice.

In regard to related actions, a claimant will be responsible for tracking the resolution of the related action. The Commission's proposed rule requires claimants to file their claim for an award in regard to a related action within sixty (60) days of the date of the monetary sanctions being imposed in the related action.

A claimant's failure to file timely a request for a whistleblower award would bar that individual later seeking a recovery.<sup>28</sup>

Subparagraph (b) of Proposed Rule 165.7 describes the procedure for making a claim for an award. Specifically, a claimant would be required to submit a claim for an award on proposed Form WB-APP ("Application for Award for Original Information Provided Pursuant to Section 23 of the Commodity Exchange Act"). Proposed Form WB-APP, and the instructions thereto, will elicit information concerning a whistleblower's eligibility to receive an

<sup>28</sup> See, e.g., *Yuen v. U.S.*, 825 F.2d 244 (9th Cir. 1987) (taxpayer barred from recovery due to failure to timely file a written request for refund).

award at the time the whistleblower files his claim. The form will also provide an opportunity for the whistleblower to “make his case” for why he is entitled to an award by describing the information and assistance he has provided and its significance to the Commission’s successful action.<sup>29</sup>

Subparagraph (b) of Proposed Rule 165.7 provides that a claim on Form WB-APP, including any attachments, must be received by the Commission within sixty (60) calendar days of the date of the Notice or sixty (60) calendar days of the date of the imposition of the monetary sanctions in the related action, depending upon which action the claimant is seeking an award, in order to be considered for an award.

Subparagraph (c) includes award application procedures for a whistleblower who submitted original information to the Commission anonymously. Whistleblowers who submitted original information anonymously, but who are making a claim for a whistleblower award on a disclosed basis, are required to disclose their identity on the Form WB-APP and include with the Form WB-APP a signed and completed Form WB-DEC. Whistleblowers who submitted information anonymously, and are making a claim for a whistleblower award on an anonymous basis, must be represented by counsel and must provide their counsel with a completed and signed Form WB-DEC by no later than the date upon which the counsel submits to the Commission the whistleblower’s Form WB-APP. In addition, whistleblower’s counsel must submit with the Form WB-APP a separate Form WB-DEC certifying that the counsel has verified your identity, has reviewed the whistleblower’s Form WB-DEC form for completeness and accuracy, will retain the signed original of your Form WB-DEC in counsel’s records, and will produce the whistleblower’s Form WB-DEC upon request of the Commission’s staff. Proposed Rule 165.7(c) makes explicit that regardless of whether they make an award application on a disclosed or anonymous basis, the whistleblower’s identity must be verified in a form and manner that is acceptable to the Commission prior to the payment of any award.

Subparagraph (d) of Proposed Rule 165.7 describes the Commission’s claims review process. The claims

review process would begin upon the later of once the time for filing any appeals of the Commission’s judicial or administrative action and the related action(s) has expired, or where an appeal has been filed, after all appeals in the action or related action(s) have been concluded.

Under the proposed process, the Commission would evaluate all timely whistleblower award claims submitted on Form WB-APP. In connection with this process, the Commission could require that claimants provide additional information relating to their eligibility for an award or satisfaction of any of the conditions for an award, as set forth in Proposed Rule 165.5(b). Following that evaluation, the Commission would send any claimant a Determination setting forth whether the claim is allowed or denied and, if allowed, setting forth the proposed award percentage amount.

#### *H. Proposed Rule 165.8—Amount of Award*

If all conditions are met, Proposed Rule 165.8 provides that the whistleblower awards shall be in an aggregate amount equal to between 10 and 30 percent, in total, of what has been collected of the monetary sanctions imposed in the Commission’s action or related actions. This range is specified in Section 23(b)(1) of the CEA. Where multiple whistleblowers are entitled to an award, subparagraph (b) states that the Commission will independently determine the appropriate award percentage for each whistleblower, but total award payments, in the aggregate, will equal between 10 and 30 percent of the monetary sanctions collected either in the Commission’s action or the related action (but not both the Commission’s action and the related action).

The Commission requests comment on whether the provision stating that the percentage amount of an award in a Commission covered judicial or administrative action may differ from the percentage awarded in a related action is appropriate?

#### *I. Proposed Rule 165.9—Criteria for Determining Amount of Award*

Assuming that all of the conditions for making an award to a whistleblower have been satisfied, Proposed Rule 165.9 sets forth the criteria that the Commission would take into consideration in determining the amount of the award. Subparagraphs (a)(1) through (3) of the proposed rule recite three criteria that Section 23(c)(1)(B) of the CEA requires the Commission to consider, and

subparagraph (a)(4) adds a fourth criterion based upon the discretion given to the Commission to consider “additional relevant factors” in determining the amount of an award.

Subparagraph (a)(1) requires the Commission to consider the significance of the information provided by a whistleblower to the success of the Commission action or related action. Subparagraph (a)(2) requires the Commission to consider the degree of assistance provided by the whistleblower and any legal representative of the whistleblower in the Commission action or related action. Subparagraph (a)(3) requires the Commission to consider the programmatic interest of the Commission in deterring violations of the CEA by making awards to whistleblowers that provide information that led to successful enforcement of covered judicial or administrative actions or related actions. Subparagraph (a)(4) would permit the Commission to consider whether an award otherwise enhances the Commission’s ability to enforce the CEA, protect customers, and encourage the submission of high quality information from whistleblowers.

The Commission anticipates that the determination of award amounts pursuant to subparagraphs (a)(1)–(4) will involve highly individualized review of the circumstances surrounding each award. To allow for this, the Commission preliminarily believes that the four criteria afford the Commission broad discretion to weigh a multitude of considerations in determining the amount of any particular award. Depending upon the facts and circumstances of each case, some of the considerations may not be applicable or may deserve greater weight than others.

The permissible considerations include, but are not limited to:

- The character of the enforcement action including whether its subject matter is a Commission priority, whether the reported misconduct involves regulated entities or fiduciaries, the type of CEA violations, the age and duration of misconduct, the number of violations, and the isolated, repetitive, or ongoing nature of the violations;
- The dangers to customers or others presented by the underlying violations involved in the enforcement action including the amount of harm or potential harm caused by the underlying violations, the type of harm resulting from or threatened by the underlying violations, and the number of individuals or entities harmed;

<sup>29</sup> See discussion of Proposed 165.9 for a non-exhaustive list of factors the Commission preliminarily believes it will consider in determining award amounts.

- The timeliness, degree, reliability, and effectiveness of the whistleblower's assistance;

- The time and resources conserved as a result of the whistleblower's assistance;

- Whether the whistleblower encouraged or authorized others to assist the staff who might not have otherwise participated in the investigation or related action;

- Any unique hardships experienced by the whistleblower as a result of his or her reporting and assisting in the enforcement action;

- The degree to which the whistleblower took steps to prevent the violations from occurring or continuing;

- The efforts undertaken by the whistleblower to remediate the harm caused by the violations including assisting the authorities in the recovery of the fruits and instrumentalities of the violations;

- Whether the information provided by the whistleblower related to only a portion of the successful claims brought in the covered judicial or administrative action or related action;<sup>30</sup> and

- The culpability of the whistleblower including whether the whistleblower acted with scienter, both generally and in relation to others who participated in the misconduct.

These considerations are not listed in order of importance nor are they intended to be all-inclusive or to require a specific determination in any particular case.

Finally, subparagraph (b) to Proposed Rule 165.9 reiterates the statutory prohibition in Section 23(c)(2) of the CEA from taking into consideration the balance of the Fund when making an award determination.

#### *J. Proposed Rule 165.10—Contents of Record for Award Determinations*

In order to promote transparency and consistency, and also to preserve a clear record for appellate review (under

<sup>30</sup> As described elsewhere in these rules, if the information provided by a whistleblower relates to only a portion of a successful covered judicial or administrative action or related action, the Commission proposes to look to the entirety of the action (including all defendants or respondents, all claims, and all monetary sanctions obtained) in determining whether the whistleblower is eligible for an award and the total dollar amount of sanctions on which the whistleblower's award will be based. However, under subparagraph (a) of Proposed Rule 165.9, the fact that the whistleblower's information related to only a portion of the overall action would be a factor in determining the amount of the whistleblower's award. Thus, if the whistleblower's information supported only a small part of a larger case, that would be a reason for making an award based upon a smaller percentage amount than otherwise would have been awarded.

Proposed Rule 165.13) of Commission award determinations (under Proposed Rule 165.7), Proposed Rule 165.10 sets forth the contents of record for award determinations relating to covered judicial or administrative actions or related actions. The record shall consist of: Required forms the whistleblower submits to the Commission, including related attachments; other documentation provided by the whistleblower to the Commission; the complaint, notice of hearing, answers and any amendments thereto; the final judgment, consent order, or administrative speaking order; the transcript of the related administrative hearing or civil injunctive proceeding, including any exhibits entered at the hearing or proceeding; any other documents that appear on the docket of the proceeding. The record shall also include any statements by litigation staff to the Commission regarding: The significance of the information provided by the whistleblower to the success of the covered judicial or administrative action or related action; the degree of assistance provided by the whistleblower and any legal representative of the whistleblower in a covered judicial or administrative action or related action; and any facts relating to a determination of whether the whistleblower provided original information, conducted an independent analysis, or possessed independent knowledge.

However, Proposed Rule 165.10(b) explicitly states that the record upon which the award determination under Proposed Rule 165.7 shall be made shall not include any Commission pre-decisional or internal deliberative process materials related to the Commission or its staff's determination: To file or settle the covered judicial or administrative action; and/or whether, to whom and in what amount to make a whistleblower award. Further, the record upon which the award determination under Proposed Rule 165.7 shall be made shall not include any other entity's pre-decisional or internal deliberative process materials related to its or its staff's determination to file or settle a related action.

The Commission requests comment on what other relevant items the Commission should consider as part of the record for its award determinations?

#### *K. Proposed Rule 165.11—Awards Based Upon Related Actions*

Proposed Rule 165.11 explains that the Commission, or its delegate, may grant an award based on amounts collected in certain related actions rather than the amount collected in a

covered judicial or administrative action. Proposed Rule 165.11 sets forth the requirements for a related action or related actions to serve as the basis of a whistleblower award. Regardless of whether the Commission's award determination will be based upon the Commission's covered judicial or administrative action or a related action or actions, Proposed Rule 165.7 sets forth the procedures for whistleblower award applications and Commission award determinations.

#### *L. Proposed Rule 165.12—Payment of Awards From the Fund, Financing Customer Education Initiatives, and Deposits and Credits to the Fund; and Proposed Rule 165.15—Delegations of Authority*

Proposed Rules 165.12 and 165.15 set forth certain internal Commission procedures. Specifically, paragraph (a) of Proposed Rule 165.12, consistent with Section 23(g)(2) of the CEA, requires the Commission to pay whistleblower awards from the Fund. Importantly, Proposed Rule 165.12(b)(2) makes clear that if there is an insufficient amount in the Fund to satisfy a whistleblower award made pursuant to Proposed Rule 165.7, the Commission shall deposit into the Fund monetary sanctions that are actually collected by the Commission in an amount equal to the unsatisfied portion of the award from *any* judicial or administrative action based on the information provided by *any* whistleblower.

Proposed Rule 165.15 includes the Commission's delegations to the Executive Director to take certain actions to carry out this Part 165 of the Rules and the requirements of Section 23(h) of CEA. Among the delegations to the Executive Director in Proposed Rule 165.15(a) is the authority to make deposits into the Fund.

Proposed Rule 165.12 also includes the Commission's financing of customer education initiatives. Proposed Rule 165.12(c) provides that the Commission shall undertake and maintain customer education initiatives. The initiatives shall be designed to help customers protect themselves against fraud or other violations of the CEA, or rules or regulations thereunder. The Commission shall fund the customer education initiatives, and may utilize funds deposited into the Fund during any fiscal year in which the beginning (October 1) balance of the Fund is greater than \$10,000,000. The Commission shall budget on an annual basis the amount used to finance customer education initiatives, taking



into consideration the balance of the Fund.

The Commission limited its discretion to finance customer education initiatives to fiscal years in which the beginning (October 1) balance of the Fund is greater than \$10,000,000 in order to limit the possibility that spending on customer education initiatives may inadvertently result in the Commission operating the Fund in a deficit and thereby delay award payments to whistleblowers.

The Commission requests comment on whether this limitation is appropriate, or would other limitations better effectuate this purpose? Is the \$10 million Fund balance trigger too high or too low, and, if so, what would be a better trigger amount?

#### *M. Proposed Rule 165.13—Appeals*

Section 23(f) of the CEA provides for rights of appeal of Final Orders of the Commission with respect to whistleblower award determinations.<sup>31</sup> Subparagraph (a) of Proposed Rule 165.13 tracks this provision and describes claimants' rights to appeal. Claimants may appeal any Commission final award determination, including whether, to whom, or in what amount to make whistleblower awards, to an appropriate court of appeals within thirty (30) days after the Commission's Final Order of determination.

Subparagraph (b) of Proposed Rule 165.13 designates the materials that shall be included in the record on any appeal. They include: The Contents of Record for Award Determination, as set forth in Proposed Rule 165.9; any Final Order of the Commission, as set forth in Rule 165.7(e).

#### *N. Proposed Rule 165.14—Procedures Applicable to the Payment of Awards*

Proposed Rule 165.14 addresses the timing for payment of an award to a whistleblower. Any award made pursuant to the rules would be paid from the Fund established by Section 23(g) of the CEA.<sup>32</sup> Subparagraph (a) provides that a recipient of a whistleblower award will be entitled to payment on the award only to the extent that a monetary sanction is collected in the covered judicial or administrative action or in a related action upon which the award is based. This requirement is derived from Section 23(b)(1) of the CEA,<sup>33</sup> which provides that an award is based upon the monetary sanctions

collected in the covered judicial or administrative action or related action.

Subparagraph (b) states that any payment of an award for a monetary sanction collected in a covered judicial or administrative action shall be made within a reasonable period of time following the later of either the completion of the appeals process for all whistleblower award claims arising from the covered judicial or administrative action, or the date on which the monetary sanction is collected. Likewise, the payment of an award for a monetary sanction collected in a related action shall be made within a reasonable period of time following the later of either the completion of the appeals process for all whistleblower award claims arising from the related action, or the date on which the monetary sanction is collected. This provision is intended to cover situations where a single action results in multiple whistleblowers claims. Under this scenario, if one whistleblower appeals a Final Order of the Commission relating to a whistleblower award determination, the Commission would not pay any awards in the action until that whistleblower's appeal has been concluded, because the disposition of that appeal could require the Commission to reconsider its determination and thereby affect all payments for that covered judicial or administrative action or related action.

Subparagraph (c) of Proposed Rule 165.14 describes how the Commission will address situations where there are insufficient amounts available in the Fund to pay an award to a whistleblower or whistleblowers within a reasonable period of time of when payment should otherwise be made. In this situation, the whistleblower or whistleblowers will be paid when amounts become available in the Fund, subject to the terms set forth in proposed subparagraph (c). Under proposed subparagraph (c), where multiple whistleblowers are owed payments from the Fund based on awards that do not arise from the same Notice or resolution of a related action, priority in making payment on these awards would be determined based upon the date that the Final Order of the Commission is made. If two or more of these Final Orders of the Commission are entered on the same date, those whistleblowers owed payments will be paid on a pro rata basis until sufficient amounts become available in the Fund to pay their entire payments. Under proposed subparagraph (c)(2), where multiple whistleblowers are owed payments from the Fund based on awards that arise from the same Notice

or resolution of a related action, they would share the same payment priority and would be paid on a pro rata basis until sufficient amounts become available in the Fund to pay their entire payments.

#### *O. Proposed Rule 165.16—No Immunity and Proposed Rule 165.17—Awards to Whistleblowers Who Engage in Culpable Conduct*

Proposed Rule 165.16 provides notice that the provisions of Section 23 of the CEA do not provide immunity to individuals who provide information to the Commission relating to a violation of the CEA. Whistleblowers who have not participated in misconduct will of course not need immunity. However, some whistleblowers who provide original information that significantly aids in detecting and prosecuting sophisticated manipulation or fraud schemes may themselves be participants in the scheme who would be subject to Commission enforcement actions. While these individuals, if they provide valuable assistance to a successful action, will remain eligible for a whistleblower award, they will not be immune from prosecution. Rather, the Commission will analyze the unique facts and circumstances of each case in accordance with its Enforcement Advisory, "Cooperation Factors in Enforcement Division Sanction Recommendations" to determine whether, how much, and in what manner to credit cooperation by whistleblowers who have participated in misconduct.

The options available to the Commission and its staff for facilitating and rewarding cooperation ranges from taking no enforcement action to pursuing charges and sanctions in connection with enforcement actions.

Whistleblowers with *potential* civil liability or criminal liability for CEA violations that they report to the Commission remain eligible for an award. However, pursuant to Section 23(c)(2)(B) of the CEA,<sup>34</sup> if a whistleblower is convicted of a criminal violation related to the judicial or administrative action, they are not eligible for an award. Furthermore, if a defendant or respondent in a Commission or related action is ordered to pay monetary sanctions in a civil enforcement action, this proposed rule states that the Commission will not count the amount of such monetary sanctions toward the \$1,000,000 threshold in considering an award payment to such a defendant or respondent in relation to a covered

<sup>31</sup> 7 U.S.C. 26(f).

<sup>32</sup> 7 U.S.C. 26(g).

<sup>33</sup> 7 U.S.C. 26(b)(1).

<sup>34</sup> 7 U.S.C. 26(c)(2)(B).

judicial or administrative action, and will not add that amount to the total monetary sanctions collected in the action for purposes of calculating any payment to the culpable individual. The rationale for this limitation is to prevent wrongdoers from financially benefiting from their own misconduct, and ensures equitable treatment of culpable and non-culpable whistleblowers. For example, without such a prohibition, a whistleblower that was the leader or organizer of a fraudulent scheme involving multiple defendants that resulted in total monetary sanctions of \$1,250,000 would exceed the \$1,000,000 minimum threshold required for making an award, even though he personally was ordered to pay \$750,000 of those monetary sanctions and, under similar circumstances, a non-culpable whistleblower would be deemed ineligible for an award if they reported a CEA or Commission regulation violation that resulted in monetary sanctions of less than \$1,000,000. The proposed rule would prevent such inequitable treatment.

*P. Proposed Rule 165.18—Staff Communications With Whistleblowers From Represented Entities*

Proposed Rule 165.18 clarifies the staff's authority to communicate directly with whistleblowers who are directors, officers, members, agents, or employees of an entity that has counsel, and who have initiated communication with the Commission relating to a potential CEA violation. The proposed rule makes clear that the staff is authorized to communicate directly with these individuals without first seeking the consent of the entity's counsel.

Section 23 of the CEA evinces a strong Congressional policy to facilitate the disclosure of information to the Commission relating to potential CEA violations and to preserve the confidentiality of those who do so.<sup>35</sup> This Congressional policy would be significantly impaired were the Commission required to seek the consent of an entity's counsel before speaking with a whistleblower who contacts us and who is a director, officer, member, agent, or employee of the entity. For this reason, Section 23 of the CEA authorizes the Commission to communicate directly with these individuals without first obtaining the consent of the entity's counsel.

The Commission believes that expressly clarifying this authority in the proposed rule would promote whistleblowers' willingness to disclose

potential CEA violations to the Commission by reducing or eliminating any concerns that whistleblowers might have that the Commission is required to request consent of the entity's counsel and, in doing so, might disclose their identity. The Commission also believes that this proposed rule is appropriate to clarify that, in accordance with American Bar Association Model Rule 4.2, the staff is authorized by law to make these communications.<sup>36</sup> Under this provision, for example, the Commission could meet or otherwise communicate with the whistleblower privately, without the knowledge or presence of counsel or other representative of the entity.

*Q. Proposed Rule 165.19—Nonenforceability of Certain Provisions Waiving Rights and Remedies or Requiring Arbitration of Disputes*

Consistent with Congressional intent to protect whistleblowers from retaliation as reflected in Section 23(h) of the CEA, Proposed Rule 165.19 provides that the rights and remedies provided for in this Part 165 of the Commission's regulations may not be waived by any agreement, policy, form, or condition of employment including by a predispute arbitration agreement. No predispute arbitration agreement shall be valid or enforceable, if the agreement requires arbitration of a dispute arising under this Part.

*R. Proposed Appendix A—Guidance With Respect to the Protection of Whistleblowers Against Retaliation*

The Commission has included a Proposed Appendix A ("Guidance With Respect To The Protection of Whistleblowers Against Retaliation") to better inform the public regarding the protections against retaliation from employers provided for whistleblowers in Section 23 of the CEA. Specifically, the Proposed Appendix A informs the public that Section 23(h)(1) of CEA provides whistleblowers with certain protections against retaliation, including: A Federal cause of action against the employer, which must be filed in the appropriate United States district court within two (2) years of the employer's retaliatory act; and potential relief for prevailing whistleblowers, including reinstatement, back pay, and compensation for other expenses,

<sup>36</sup> American Bar Association Model Rule 4.2 provides as follows: "In representing a client, a lawyer shall not communicate about the subject of the representation with a person the lawyer knows to be represented by another lawyer in the matter, unless the lawyer has the consent of the other lawyer or is authorized to do so by law or a court order." Model Rules of Prof'l Conduct R. 4.2 (emphasis added).

including reasonable attorney's fees. For ease of reference, the Proposed Appendix also includes a verbatim copy of the full Section 23(h)(1) of the CEA.

**III. Request for Comment**

The Commission requests comment on all aspects of the proposed rules.

**IV. Administrative Compliance**

*A. Cost-Benefit Analysis*

Section 15(a) of the CEA<sup>37</sup> requires the Commission to consider the costs and benefits of its actions before promulgating a regulation under the CEA. By its terms, section 15(a) does not require the Commission to quantify the costs and benefits of a rule or to determine whether the benefits of the regulation outweigh its costs; rather, it requires that the Commission "consider" the costs and benefits of its actions. Section 15(a) further specifies that the costs and benefits shall be evaluated in light of five broad areas of market and public concern: (1) Protection of market participants and the public; (2) efficiency, competitiveness and financial integrity of futures markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations. The Commission may in its discretion give greater weight to any one of the five enumerated areas and could in its discretion determine that, notwithstanding its costs, a particular rule is necessary or appropriate to protect the public interest or to effectuate any of the provisions or accomplish any of the purposes of the CEA.

With respect to benefits, the proposed rules would enhance the Commission's capacity to ensure fair and equitable markets. The Commission has determined that market participants and the public will benefit substantially from prevention and deterrence of violations of the CEA and Commission regulations, which will be buttressed by the whistleblower incentives and protections under Section 23 of the CEA and Proposed Part 165 of the regulations.

With respect to costs, the procedures set forth in the Proposed Rules may impose certain costs on prospective whistleblowers. As an initial matter, the procedures require potential whistleblowers to complete certain forms to establish eligibility for an award under the whistleblower program. As noted above, the Commission recognizes that it will take time and effort on the part of

<sup>35</sup> See Section 23 (b)–(d) & (h) of the CEA, 7 U.S.C. 26(b)–(d) & (h).

<sup>37</sup> 7 U.S.C. 19(a).

whistleblowers to complete and submit the required forms. In addition, any whistleblower wishing to submit one of the required forms in hard copy will need to arrange for delivery and pay the postage or other delivery costs. In these Proposed Rules, the Commission has attempted to mitigate the potential for burden or confusion in the procedures, but such costs cannot be eliminated.

The Commission invites public comment on its cost-benefit considerations. Commenters are also invited to submit any data or other information that they may have quantifying or qualifying the costs and benefits of the proposed rules with their comment letters.

#### B. Anti-Trust Considerations

Section 15(b) of the CEA, 7 U.S.C. 19(b), requires the Commission to consider the public interests protected by the antitrust laws and to take actions involving the least anti-competitive means of achieving the objectives of the CEA. The Commission believes that the proposed rules will have a positive effect on competition by improving the fairness and efficiency of the markets through improving detection and remediation of potential violations of the CEA and Commission regulations.

#### C. Paperwork Reduction Act

This regulation requires that a whistleblower seeking an award submit whistleblower information and file claims for an award determination. 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 control number. The Office of Management and Budget ("OMB") has not yet assigned a control number to the new collection. Proposed Commission Regulation 165 would result in new collection of information requirements within the meaning of the Paperwork Reduction Act ("PRA").<sup>38</sup> The Commission therefore is submitting this proposal to OMB for review in accordance with 44 U.S.C. 3507(d) and 5 CFR 1320.11. The title for this collection of information is "Regulation 165—Proposed Rules for Implementing Whistleblower Provisions of Section 23 of the Commodity Exchange Act." OMB control number 3038—NEW. If adopted, responses to this new collection of information would be mandatory.

The Commission will protect proprietary information according to the Freedom of Information Act and 17 CFR part 145, "Commission Records and Information." In addition, section 8(a)(1)

of the Act strictly prohibits the Commission, unless specifically authorized by the Act, from making public "data and information that would separately disclose the business transactions or market positions of any person and trade secrets or names of customers." The Commission is also required to protect certain information contained in a government system of records according to the Privacy Act of 1974, 5 U.S.C. 552a.

#### 1. Information Provided by Reporting Persons

The Proposed Rules 165.3 (Procedures for Submitting Original Information), 165.4 (Confidentiality), and 165.7 (Procedures for Award Applications and Commission Award Determinations) require that all individuals wishing to be eligible for an award under the Commission's whistleblower program must complete the following standard forms: Forms TCR ("Tip, Complaint or Referral"), WB-DEC ("Declaration Concerning Original Information Provided Pursuant to Section 23 of the Commodity Exchange Act," signed under penalty of perjury), and WB-APP ("Application for Award for Original Information Provided Pursuant to Section 23 of the Commodity Exchange Act"). The Commission estimates that there will be numerous individuals, approximately 160 per fiscal year, who may wish to file such forms. The Commission estimated the number of individuals based upon the current number of tips, complaints and referrals received by the Commission's Division of Enforcement and news articles regarding the whistleblower protections that indicate the SEC and Commission should expect to receive a high volume of claims. The proposed collection is estimated to involve approximately: 2 burden hours per Form TCR; 0.5 burden hours per Form WB-DEC; and 10 burden hours per Form WB-APP. The Commission expects that this will result in a total cost of 12.5 burden hours per individual seeking to be considered for an award under the Commission's whistleblower program, for an annual aggregate 2,000 burden hours per fiscal year. The Commission invites public comment on the accuracy of its estimate regarding the collection requirements that would result from the proposed regulations.

#### 2. Information Collection Comments

The Commission invites the public and other federal agencies to comment on any aspect of the reporting and recordkeeping burdens discussed above. Pursuant to 44 U.S.C. 3506(c)(2)(B), the Commission solicits comments in order

to: (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (ii) evaluate the accuracy of the Commission's estimate of the burden of the proposed collection of information; (iii) determine whether there are ways to enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

Comments may be submitted directly to the Office of Information and Regulatory Affairs, by fax at (202) 395-6566 or by e-mail at [OIRASubmissions@omb.eop.gov](mailto:OIRASubmissions@omb.eop.gov). Please provide the Commission with a copy of submitted comments so that they can be summarized and addressed in the final rule. Refer to the "Addresses" section of this notice of proposed rulemaking for comment submission instructions to the Commission. A copy of the supporting statements for the collections of information discussed above may be obtained by visiting [RegInfo.gov](http://RegInfo.gov). OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this release. Consequently, a comment to OMB is most assured of being fully effective if received by OMB (and the Commission) within 30 days after publication of this notice of proposed rulemaking.

#### D. Regulatory Flexibility Act

The Regulatory Flexibility Act ("RFA")<sup>39</sup> requires that agencies consider whether the rules they propose will have a significant economic impact on a substantial number of small entities and, if so, provide a regulatory flexibility analysis respecting the impact.<sup>40</sup> The rules proposed by the Commission will not have a significant economic impact on a substantial number of small entities. As explained above, because only individuals are eligible for participation in the Commission's whistleblower program under Section 23 of the CEA and Proposed Part 165 of the regulations, the proposed rules will not have a significant impact on small entities. Accordingly, the Chairman, on behalf of the Commission, hereby certifies, pursuant to 5 U.S.C. 605(b), that the proposed rules will not have a

<sup>39</sup> 5 U.S.C. 601.

<sup>40</sup> *Id.*

<sup>38</sup> 44 U.S.C. 3501 *et seq.*

significant impact on a substantial number of small entities.

Section 603(a) of the Regulatory Flexibility Act<sup>41</sup> requires the Commission to undertake an initial regulatory flexibility analysis of the proposed rule on small entities unless the Chairman certifies that the rule, if adopted, would not have a significant economic impact on a substantial number of small entities.<sup>42</sup> The Proposed Rules apply only to an individual, or individuals acting jointly, who provide information to the Commission relating to the violation of the CEA or Commission regulations. Companies and other entities are not eligible to participate in the Program as whistleblowers. Consequently, the persons that would be subject to the proposed rule are not “small entities” for purposes of the Regulatory Flexibility Act. Accordingly, the Chairman, on behalf of the Commission, hereby certifies pursuant to 5 U.S.C. 605(b) that the proposed rules will not have a significant economic impact on a substantial number of small entities. A copy of the certification is attached as an appendix to this document.

#### List of Subjects in 17 CFR Part 165

Whistleblower rules.

In consideration of the foregoing and pursuant to the authority contained in the Commodity Exchange Act, in particular, Sections 2, 3, 8a(5) and 26 thereof, the Commodity Futures Trading Commission proposes to add a new 17 CFR part 165 to read as follows:

### PART 165—WHISTLEBLOWER RULES

Sec.

- 165.1 General.
- 165.2 Definitions.
- 165.3 Procedures for submitting original information.
- 165.4 Confidentiality.
- 165.5 Prerequisites to the consideration of an award.
- 165.6 Whistleblowers ineligible for an award.
- 165.7 Procedures for award applications and commission award determinations.
- 165.8 Amount of award.
- 165.9 Criteria for determining amount of award.
- 165.10 Contents of record for award determination.
- 165.11 Awards based upon related actions.
- 165.12 Payment of awards from the fund, financing of customer education initiatives, and deposits and credits to the fund.
- 165.13 Appeals.
- 165.14 Procedures applicable to the payment of awards.
- 165.15 Delegations of authority.

- 165.16 No immunity.
  - 165.17 Awards to whistleblowers who engage in culpable conduct.
  - 165.18 Staff communications with whistleblowers from represented entities.
  - 165.19 Nonenforceability of certain provisions waiving rights and remedies or requiring arbitration of disputes.
- Appendix A to Part 165—Guidance With Respect to the Protection of Whistleblowers Against Retaliation

**Authority:** 7 U.S.C. 2, 3, 12a(5) and 26, as amended by Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. 111–203, 124 Stat. 1376 (June 16, 2010).

#### § 165.1 General.

Section 23 of the Commodity Exchange Act, entitled “Commodity Whistleblower Incentives and Protection,” requires the Commission to pay awards, subject to certain limitations and conditions, to whistleblowers who voluntarily provide the Commission with original information about violations of the Commodity Exchange Act. This part 165 describes the whistleblower program that the Commission intends to establish to implement the provisions of Section 23, and explain the procedures you will need to follow in order to be eligible for an award. Whistleblowers should read these procedures carefully, because the failure to take certain required steps within the time frames described in this part may serve as disqualification from receiving an award. Unless expressly provided for in this part, no person is authorized to make any offer or promise, or otherwise to bind the Commission with respect to the payment of any award or the amount thereof.

#### § 165.2 Definitions.

(a) *Action*. The term “action” means a single captioned judicial or administrative proceeding.

(b) *Aggregate Amount*. The phrase “aggregate amount” means the total amount of an award granted to one or more whistleblowers pursuant to § 165.8.

(c) *Analysis*. The term “analysis” means your examination and evaluation of information that may be generally available, but which reveals information that is not generally known or available to the public.

(d) *Collected by the Commission*. The phrase “collected by the Commission” refers to any funds received, and confirmed by the Treasury, in satisfaction of part or all of a civil monetary penalty, disgorgement obligation, or fine owed to the Commission.

(e) *Covered Judicial or Administrative action*. The phrase “covered judicial or administrative action” means any judicial or administrative action brought by the Commission under the Commodity Exchange Act whose successful resolution results in monetary sanctions exceeding \$1,000,000.

(f) *Fund*. The term “Fund” means the Commodity Futures Trading Commission Customer Protection Fund.

(g) *Independent Knowledge*. The phrase “independent knowledge” means factual information in your possession that is not generally known or available to the public. You may gain independent knowledge from your experiences, communications and observations in your personal business or social interactions. The Commission will not consider your information to be derived from your independent knowledge if you obtained the information:

(1) From sources generally available to the public such as corporate filings and the media, including the Internet;

(2) Through a communication that was subject to the attorney-client privilege, unless the disclosure is otherwise permitted by the applicable federal or state attorney conduct rules;

(3) As a result of the legal representation of a client on whose behalf your services, or the services of your employer or firm, have been retained, and you seek to use the information to make a whistleblower submission for your own benefit, unless disclosure is authorized by the applicable federal or state attorney conduct rules;

(4) Because you were a person with legal, compliance, audit, supervisory, or governance responsibilities for an entity, and the information was communicated to you with the reasonable expectation that you would take appropriate steps to cause the entity to remedy the violation, unless the entity subsequently failed to disclose the information to the Commission within sixty (60) days or otherwise proceeded in bad faith;

(5) Otherwise from or through an entity’s legal, compliance, audit or other similar functions or processes for identifying, reporting and addressing potential non-compliance with law, unless the entity failed to disclose the information to the Commission within sixty (60) days or otherwise proceeded in bad faith; or

(6) By a means or in a manner that violates applicable federal or state criminal law.

(h) *Independent Analysis*. The phrase “independent analysis” means your own

<sup>41</sup> 5 U.S.C. 603(a).

<sup>42</sup> 5 U.S.C. 605(b).

analysis, whether done alone or in combination with others.

(i) *Information That Led to Successful Enforcement.* The Commission will consider that you provided original information that led to the successful enforcement of a judicial or administrative action, or related action, in the following circumstances:

(1) If you gave the Commission original information that caused the staff to open an investigation, reopen an investigation that the Commission had closed, or to inquire concerning new or different conduct as part of a current investigation, and your information significantly contributed to the success of the action; or

(2) If you gave the Commission original information about conduct that was already under investigation by the Commission, Congress, any other federal, state, or local authority, any self-regulatory organization, or the Public Company Accounting Oversight Board (except in cases where you were an original source of this information as defined in paragraph (i)(1) of this section), and your information would not otherwise have been obtained and was essential to the success of the action.

(j) *Monetary Sanctions.* The phrase “monetary sanctions,” when used with respect to any judicial or administrative, or related action, action means—

(1) Any monies, including penalties, disgorgement, restitution, and interest ordered to be paid; and

(2) Any monies deposited into a disgorgement fund or other fund pursuant to section 308(b) of the Sarbanes-Oxley Act of 2002 (15 U.S.C. 7246(b)), as a result of such action or any settlement of such action.

(k) *Original Information.* (1) The phrase “original information” means information that—

(i) Is derived from the independent knowledge or independent analysis of a whistleblower;

(ii) Is not already known to the Commission from any other source, unless the whistleblower is the original source of the information;

(iii) Is not exclusively derived from an allegation made in a judicial or administrative hearing, in a governmental report, hearing, audit, or investigation, or from the news media, unless the whistleblower is a source of the information; and

(iv) Is submitted to the Commission for the first time after July 21, 2010 (the date of enactment of the Wall Street Transparency and Accountability Act of 2010).

(2) Original information shall not lose its status as original information solely

because the whistleblower submitted such information prior to the [EFFECTIVE DATE OF THE FINAL RULE], provided such information was submitted after July 21, 2010, the date of enactment of the Wall Street Transparency and Accountability Act of 2010. In order to be eligible for an award, a whistleblower who submits original information to the Commission after July 21, 2010, but prior to [EFFECTIVE DATE OF THE FINAL RULE], must comply with the procedure set forth in § 165.3(d).

(l) *Original Source.* You must satisfy your status as the original source of information to the Commission’s satisfaction.

(1) Information obtained from another source. The Commission will consider you to be an “original source” of the same information that the Commission obtains from another source if the information you provide satisfies the definition of original information and the other source obtained the information from you or your representative.

(i) In order to be considered an original source of information that the Commission receives from Congress, any other federal state or local authority, or any self-regulatory organization, you must have voluntarily given such authorities the information within the meaning of this part. In determining whether you are the original source of information, the Commission may seek assistance and confirmation from one of the other entities or authorities described above.

(ii) In the event that you claim to be the original source of information that an authority or another entity, other than as set forth in paragraph (l)(1)(i) of this section, provided to the Commission, the Commission may seek assistance and confirmation from such authority or other entity.

(2) Information first provided to another authority or person. If you provide information to Congress, any other federal, state, or local authority, any self-regulatory organization, the Public Company Accounting Oversight Board, or to any of any of the persons described in paragraphs (g)(3) and (4) of this section, and you, within 90 days, make a submission to the Commission pursuant to § 165.3, as you must do in order for you to be eligible to be considered for an award, then, for purposes of evaluating your claim to an award under § 165.7, the Commission will consider that you provided information as of the date of your original disclosure, report, or submission to one of these other authorities or persons. You must

establish your status as the original source of such information, as well as the effective date of any prior disclosure, report, or submission, to the Commission’s satisfaction. The Commission may seek assistance and confirmation from the other authority or person in making this determination.

(3) Information already known by the Commission. If the Commission already knows some information about a matter from other sources at the time you make your submission, and you are not an original source of that information, as described above, the Commission will consider you an “original source” of any information you separately provide that otherwise satisfies the definition of original information and materially adds to the information that the Commission already possesses.

(m) *Related Action.* The phrase “related action,” when used with respect to any judicial or administrative action brought by the Commission under the Commodity Exchange Act, means any judicial or administrative action brought by an entity listed in § 165.11(a) that is based upon the original information voluntarily submitted by a whistleblower to the Commission pursuant to § 165.3 that led to the successful resolution of the Commission action.

(n) *Successful Resolution.* The phrase “successful resolution,” when used with respect to any judicial or administrative action brought by the Commission under the Commodity Exchange Act, includes any settlement of such action or final judgment in favor of the Commission. It shall also have the same meaning as “successful enforcement.”

(o) *Voluntary Submission or Voluntarily Submitted.* The phrase “voluntary submission” or “voluntarily submitted” within the context of submission of original information to the Commission under this part, shall mean the provision of information made prior to any request from the Commission, Congress, any other federal or state authority, the Department of Justice, a registered entity, a registered futures association, or a self-regulatory organization to you or anyone representing you (such as an attorney) about a matter to which the information in the whistleblower’s submission is relevant. If the Commission or any of these other authorities make a request, inquiry, or demand to you or your representative first, your submission will not be considered voluntary, and you will not be eligible for an award, even if your response is not compelled by subpoena or other applicable law. For purposes of this paragraph, you will be considered

to have received a request, inquiry or demand if documents or information from you are within the scope of a request, inquiry, or demand that your employer receives, unless, after receiving the documents or information from you, your employer fails to provide your documents or information to the requesting authority in a timely manner.

In addition, your submission will not be considered voluntary if you are under a pre-existing legal or contractual duty to report the violations that are the subject of your original information to the Commission, Congress, any other federal or state authority, the Department of Justice, a registered entity, a registered futures association, or a self-regulatory organization.

(p) *Whistleblower(s)*. (1) The term “whistleblower” or “whistleblowers” means any individual, or two (2) or more individuals acting jointly, who provides information relating to a potential violation of the Commodity Exchange Act to the Commission, in a manner established by § 165.3.

(2) The retaliation protections afforded to whistleblowers by the provisions of Section 23(h) of the Commodity Exchange Act apply irrespective of whether a whistleblower satisfies the procedures and conditions to qualify for an award under this Part 165. Moreover, for purposes of the anti-retaliation provision of paragraph (h)(1)(A)(i) of Section 23, the requirement that a whistleblower provide “information to the Commission in accordance” with Section 23 is satisfied if an individual provides information to the Commission that relates to a potential violation of the Commodity Exchange Act.

#### **§ 165.3 Procedures for submitting original information.**

A whistleblower’s submission of information to the Commission will be a two-step process.

(a) First, you will need to submit your information to the Commission. You may submit your information:

(1) By completing and submitting a Form TCR online and submitting it electronically through the Commission’s Web site at [insert link] or;

(2) By completing the Form TCR and mailing or faxing the form to the Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581, Fax (202) XXX-XXXX.

(b) In addition to submitting a Form TCR, you will also need to complete and provide to the Commission a Form WB-DEC, “Declaration Concerning Original Information Provided Pursuant to Section 23 of the Commodity Exchange Act,” signed under penalty of perjury.

Your Form WB-DEC must be submitted as follows:

(1) If you submit a Form TCR electronically, your Form WB-DEC must be submitted either:

(i) Electronically (in accordance with the instructions set forth on the Commission’s Web site); or

(ii) By mailing or faxing the signed form to the Commission. Your Form WB-DEC must be received by the Commission within thirty (30) days of the Commission’s receipt of your Form TCR.

(2) If you submit a Form TCR either by mail or fax, your Form WB-DEC must be submitted by mail or fax at the same time as the Form TCR.

(c) Notwithstanding paragraph (b), if you submitted your original information to the Commission anonymously, then your identity must be disclosed to the Commission and verified in a form and manner acceptable to the Commission consistent with the procedure set forth in § 165.7(c) prior to the Commission’s payment of any award.

(d) If you submitted original information in writing to the Commission after July 21, 2010 (the date of enactment of the Wall Street Transparency and Accountability Act of 2010) but before the effective date of these rules, you will be eligible for an award only if:

(1) In the event that you provided the original information to the Commission in a format or manner other than that described in paragraph (a) of this section, you submit a completed Form TCR and Form WB-DEC within one hundred twenty (120) days of [EFFECTIVE DATE OF THE FINAL RULE] and otherwise follow the procedures set forth above in paragraphs (a) and (b) of this section; or

(2) In the event that you provided the original information to the Commission in a Form TCR in the manner described in paragraph (a) of this section, you submit a Form WB-DEC within one hundred twenty (120) days of the effective date of this section in the manner set forth above in paragraph (b) of this section.

#### **§ 165.4 Confidentiality.**

(a) *In General*. Section 23(h)(2) of the Commodity Exchange Act requires that the Commission not disclose information that could reasonably be expected to reveal the identity of a whistleblower, except that the Commission may disclose such information in the following circumstances:

(1) When disclosure is required to a defendant or respondent in connection with a public proceeding that the

Commission institutes or in another public proceeding that is filed by an authority to which the Commission provides the information, as described below;

(2) When the Commission determines that it is necessary to accomplish the purposes of the Commodity Exchange Act and to protect customers, it may provide whistleblower information to: The Department of Justice; an appropriate department or agency of the Federal Government, acting within the scope of its jurisdiction; a registered entity, registered futures association, a self regulatory organization; a state attorney general in connection with a criminal investigation; any appropriate state department or agency, acting within the scope of its jurisdiction; or a foreign futures authority.

(3) The Commission may make disclosures in accordance with the Privacy Act of 1974 (5 U.S.C. 552a).

(b) *Anonymous Whistleblowers*. A whistleblower may anonymously submit information to the Commission, however, the whistleblower must follow the procedures in § 165.3(c) for submitting original information anonymously. Such whistleblower who anonymously submits information to the Commission must also follow the procedures in § 165.7(c) in submitting to the Commission an application for a whistleblower award.

#### **§ 165.5 Prerequisites to the consideration of an award.**

(a) Subject to the eligibility requirements described in this part 165, the Commission will pay an award to one or more whistleblowers who:

(1) Provide a voluntary submission to the Commission;

(2) That contains original information; and

(3) That leads to the successful resolution of a covered Commission judicial or administrative action or successful enforcement of a related action; and

(b) In order to be eligible, the whistleblower must:

(1) Have given the Commission original information in the form and manner that the Commission requires in § 165.3 and be the original source of information;

(2) Provide the Commission, upon its staff’s request, certain additional information, including: Explanations and other assistance, in the manner and form that staff may request, in order that the staff may evaluate the use of the information submitted; all additional information in the whistleblower’s possession that is related to the subject matter of the whistleblower’s

submission; and testimony or other evidence acceptable to the staff relating to the whistleblower's eligibility for an award; and

(3) If requested by Commission staff, enter into a confidentiality agreement in a form acceptable to the Commission, including a provision that a violation of the confidentiality agreement may lead to the whistleblower's ineligibility to receive an award.

**§ 165.6 Whistleblowers ineligible for an award.**

(a) No award under § 165.7 shall be made:

(1) To any whistleblower who is, or was at the time, the whistleblower who acquired the original information submitted to the Commission, a member, officer, or employee of: The Commission; the Board of Governors of the Federal Reserve System; the Office of the Comptroller of the Currency; the Board of Directors of the Federal Deposit Insurance Corporation; the Director of the Office of Thrift Supervision; the National Credit Union Administration Board; the Securities and Exchange Commission; the Department of Justice; a registered entity; a registered futures association; a self-regulatory organization; or a law enforcement organization;

(2) To any whistleblower who is convicted of a criminal violation related to the judicial or administrative action for which the whistleblower otherwise could receive an award under this section;

(3) To any whistleblower who submits information to the Commission that is based on the facts underlying the covered judicial or administrative action submitted previously by another whistleblower;

(4) To any whistleblower who acquired the information you gave the Commission from any of the individuals described in paragraphs (a)(1), (2), or (3) of this section; or

(5) To any whistleblower who, in the whistleblower's submission, the whistleblower's other dealings with the Commission, or the whistleblower's dealings with another authority in connection with a related action, knowingly and willfully makes any false, fictitious, or fraudulent statement or representation, or use any false writing or document, knowing that it contains any false, fictitious, or fraudulent statement or entry, or omitted any material fact, where in the absence of such fact, other statements or representations made by the whistleblower would be misleading.

(b) Notwithstanding a whistleblower's ineligibility for an award for any reason

set forth in paragraph (a) of this section, the whistleblower will remain eligible for the anti-retaliation protections set forth in Section 23(h) of the Commodity Exchange Act.

**§ 165.7 Procedures for award applications and commission award determinations.**

(a) Whenever a Commission judicial or administrative action results in monetary sanctions totaling more than \$1,000,000 (i.e., a covered judicial or administrative action) the Commission will cause to be published on the Commission's Web site a "Notice of Covered Action." Such Notice of Covered Action will be published subsequent to the entry of a final judgment or order that alone, or collectively with other judgments or orders previously entered in the Commission covered administrative or judicial action, exceeds \$1,000,000 in monetary sanctions. A whistleblower claimant will have sixty (60) calendar days from the date of the Notice of Covered Action to file a claim for an award based on that action, or the claim will be barred.

(b) To file a claim for a whistleblower award, you must file Form WB-APP, "Application for Award for Original Information Provided Pursuant to Section 23 of the Commodity Exchange Act." You must sign this form as the claimant and submit it to the Commission by mail or fax to Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581, Fax (202) XXX-XXXX.

The Form WB-APP, including any attachments, must be received by the Commission within sixty (60) calendar days of the date of the Notice of Covered Action or sixty (60) calendar days following the date of a final judgment in a related action in order to be considered for an award.

(c) If you provided your original information to the Commission anonymously pursuant to §§ 165.3 and 165.4 and:

(1) You are making your claim for a whistleblower award on a disclosed basis, you must disclose your identity on the Form WB-APP and include with your Form WB-APP a signed and completed Form WB-DEC. Your identity must be verified in a form and manner that is acceptable to the Commission prior to the payment of any award; or

(2) You are making your claim for a whistleblower award on an anonymous basis, you must be represented by counsel. You must provide your counsel with a completed and signed Form WB-DEC by no later than the date upon

which your counsel submits to the Commission the Form WB-APP. In addition, your counsel must submit with the Form WB-APP a separate Form WB-DEC completed and signed by counsel certifying that counsel has verified your identity, has reviewed the whistleblower's Form WB-DEC for completeness and accuracy, and will retain the signed original of whistleblower's Form WB-DEC in counsel's records. Upon request of the Commission staff, whistleblower's counsel must produce to the Commission the whistleblower's WB-DEC and the whistleblower's identity must be verified in a form and manner that is acceptable to the Commission prior to the payment of any award.

(d) Once the time for filing any appeals of the Commission's judicial or administrative action and all related actions has expired, or where an appeal has been filed, after all appeals in the judicial, administrative and related actions have been concluded, the Commission will evaluate all timely whistleblower award claims submitted on Form WB-APP in accordance with the criteria set forth in this part 165. In connection with this process, the Commission may require that you provide additional information relating to your eligibility for an award or satisfaction of any of the conditions for an award, as set forth in § 165.5(b). Following that evaluation, the Commission will send you a Determination setting forth whether the claim is allowed or denied and, if allowed, setting forth the award percentage amount.

(e) The Commission's Office of the Secretariat will provide you with the Final Order of the Commission.

**§ 165.8 Amount of award.**

If all of the conditions are met for a whistleblower award in connection with a covered judicial or administrative action or a related action, the Commission will then decide the amount of the award pursuant to the procedure set forth in § 165.7.

(a) Whistleblower awards shall be in an aggregate amount equal to—

(1) Not less than 10 percent, in total, of what has been collected of the monetary sanctions imposed in the covered judicial or administrative action or related actions; and

(2) Not more than 30 percent, in total, of what has been collected of the monetary sanctions imposed in the covered judicial or administrative action or related actions.

(b) If the Commission makes awards to more than one whistleblower in connection with the same action or



related action, the Commission will determine an individual percentage award for each whistleblower, but in no event will the total amount awarded to all whistleblowers as a group be less than 10 percent or greater than 30 percent of the amount the Commission or the other authorities collect.

**§ 165.9 Criteria for determining amount of award.**

The determination of the amount of an award shall be in the discretion of the Commission. The Commission may exercise this discretion directly or through delegated authority pursuant to § 165.15.

(a) In determining the amount, the Commission shall take into consideration—

(1) The significance of the information provided by the whistleblower to the success of the covered judicial or administrative action or related action;

(2) The degree of assistance provided by the whistleblower and any legal representative of the whistleblower in a covered judicial or administrative action or related action;

(3) The programmatic interest of the Commission in deterring violations of the Commodity Exchange Act by making awards to whistleblowers who provide information that leads to the successful enforcement of such laws; and

(4) Whether the award otherwise enhances the Commission's ability to enforce the CEA, protect customers, and encourage the submission of high quality information from whistleblowers.

(b) The Commission shall not take into consideration the balance of the Fund in determining the amount of an award.

**§ 165.10 Contents of record for award determination.**

(a) The following items constitute the record upon which the award determination under § 165.7 shall be made:

(1) The whistleblower's Form TCR, "Tip, Complaint or Referral," and Form WB-DEC, "Declaration Concerning Original Information Provided Pursuant to Section 23 of the Commodity Exchange Act," including related attachments, and other documentation provided by the whistleblower to the Commission;

(2) The whistleblower's Form WB-APP, "Application for Award Pursuant to Section 23 of the Commodity Exchange Act," and related attachments

(3) The complaint, notice of hearing, answers and any amendments thereto;

(4) The final judgment, consent order, or administrative speaking order;

(5) The transcript of the related administrative hearing or civil injunctive proceeding, including any exhibits entered at the hearing or proceeding;

(6) Any other documents that appear on the docket of the proceeding; and

(7) Any statements by the Commission litigation staff, or the litigation staff involved in prosecuting the related action, to the Commission regarding: The significance of the information provided by the whistleblower to the success of the covered judicial or administrative action or related action; and/or the degree of assistance provided by the whistleblower and any legal representative of the whistleblower in a covered judicial or administrative action or related action.

(b) The record upon which the award determination under § 165.7 shall be made shall not include any Commission pre-decisional or internal deliberative process materials related to the Commission or its staff's determination: To file or settle the related covered judicial or administrative action; and/or whether, to whom and in what amount to make a whistleblower award. Further, the record upon which the award determination under § 165.7 shall be made shall not include any other entity's pre-decisional or internal deliberative process materials related to its or its staff's determination to file or settle a related action.

**§ 165.11 Awards based upon related actions.**

Provided that a whistleblower or whistleblowers comply with the requirements in §§ 165.3, 165.5 and 165.7, pursuant to § 165.8, the Commission or its delegate may grant an award based on the amount of monetary sanctions collected in a "related action" or "related actions," rather than the amount collected in a covered judicial or administrative action, where—

(a) A "related action" is a judicial or administrative action that is brought by:

(1) The Department of Justice;

(2) An appropriate department or agency of the Federal Government, acting within the scope of its jurisdiction;

(3) A registered entity, registered futures association, or self-regulatory organization; or

(4) A State criminal or appropriate civil agency; and

(b) The "related action" is based on the same original information that the whistleblower voluntarily submitted to the Commission and led to a successful

resolution of the Commission's judicial or administrative action.

**§ 165.12 Payment of awards from the fund, financing of customer education initiatives, and deposits and credits to the fund.**

(a) The Commission shall pay awards to whistleblowers from the Fund.

(b) The Commission shall deposit into or credit to the Fund:

(1) Any monetary sanctions collected by the Commission in any covered judicial or administrative action that is not otherwise distributed or ordered to be distributed, to victims of a violation of the Commodity Exchange Act underlying such action, unless the balance of the Fund at the time the monetary sanctions are collected exceeds \$100,000,000. In the event the Fund's value exceeds \$100,000,000, any monetary sanctions collected by the Commission in a covered judicial or administrative action that is not otherwise distributed or ordered to be distributed to victims of violations of the Commodity Exchange Act the Commission's rules and regulations thereunder underlying such action, shall be deposited into the general fund of the U.S. Treasury.

(2) In the event that the amounts deposited into or credited to the Fund under paragraph (b)(1) of this section are not sufficient to satisfy an award made pursuant to 165.7, then, pursuant to Section 23(g)(3)(B) of the Commodity Exchange Act;

(i) An amount equal to the unsatisfied portion of the award;

(ii) Shall be deposited into or credited to the Fund;

(iii) From any monetary sanction collected by the Commission, in any judicial or administrative action brought by the Commission under the Commodity Exchange Act, regardless of whether it qualifies as an "covered judicial or administrative action"; *provided*, such judicial or administrative action is based on information provided by a whistleblower.

(c) The Commission shall undertake and maintain customer education initiatives. The initiatives shall be designed to help customers protect themselves against fraud or other violations of the Act, or the Commission's rules or regulations thereunder. The Commission shall fund the customer education initiatives, and may utilize funds deposited into the Fund during any fiscal year in which the beginning (October 1) balance of the Fund is greater than \$10,000,000. The Commission shall budget on an annual basis the amount used to finance customer education initiatives, taking

into consideration the balance of the Fund.

**§ 165.13 Appeals.**

(a) Any Final Order of the Commission relating to a whistleblower award determination, including whether, to whom, or in what amount to make whistleblower awards, may be appealed to the appropriate court of appeals of the United States not more than thirty (30) days after the Final Order of the Commission is issued.

(b) The record on appeal shall consist of:

(1) The Contents of Record for Award Determination, as set forth in § 165.9;

(2) The Final Order of the Commission, as set forth in § 165.7.

**§ 165.14 Procedures applicable to the payment of awards.**

(a) A recipient of a whistleblower award is entitled to payment on the award only to the extent that the monetary sanction upon which the award is based is collected in the Commission judicial or administrative action or in a related action;

(b) Payment of a whistleblower award for a monetary sanction collected in a Commission action or related action shall be made within a reasonable time following the later of:

(1) The date on which the monetary sanction is collected; or

(2) The completion of the appeals process for all whistleblower award claims arising from:

(i) The Notice of Covered Action, in the case of any payment of an award for a monetary sanction collected in a covered judicial or administrative action; or

(ii) The related action, in the case of any payment of an award for a monetary sanction collected in a related action.

(c) If there are insufficient amounts available in the Fund to pay the entire amount of an award payment within a reasonable period of time from the time for payment specified by paragraph (b) of this section, then subject to the following terms, the balance of the payment shall be paid when amounts become available in the Fund, as follows:

(1) Where multiple whistleblowers are owed payments from the Fund based on awards that do not arise from the same Notice of Covered Action (or related action), priority in making these payments will be determined based upon the date that the Final Order of the Commission is made. If two or more of these Final Orders of the Commission are entered on the same date, those whistleblowers owed payments will be paid on a pro rata basis until sufficient

amounts become available in the Fund to pay their entire payments.

(2) Where multiple whistleblowers are owed payments from the Fund based on awards that arise from the same Notice of Covered Action (or related action), they will share the same payment priority and will be paid on a pro rata basis until sufficient amounts become available in the Fund to pay their entire payments.

**§ 165.15 Delegations of authority.**

(a) *Delegation of Authority to the Executive Director.* The Commission hereby delegates, until such time as the Commission orders otherwise, to the Executive Director or to any Commission employee under the Executive Director's supervision as he or she may designate, the authority to take the following actions to carry out this Part 165 and the requirements of Section 23(h) of Commodity Exchange Act.

(1) Delegated authority to deposit collected monetary sanctions into the Fund and the payment of awards therefrom shall be with the concurrence of the General Counsel and the Director of the Division of Enforcement or of their respective designees.

(2) [Reserved]

(b) [Reserved]

**§ 165.16 No immunity.**

The Commodity Whistleblower Incentives and Protections provisions set forth in Section 23(h) of Commodity Exchange Act and this Part 165 do not provide individuals who provide information to the Commission with immunity from prosecution. The fact that you may become a whistleblower and assist in Commission investigations and enforcement actions does not preclude the Commission from bringing an action against you based upon your own conduct in connection with violations of the Commodity Exchange Act and the Commission's regulations. If such an action is determined to be appropriate, however, the Commission's Division of Enforcement will take your cooperation into consideration in accordance with its sanction recommendations to the Commission.

**§ 165.17 Awards to whistleblowers who engage in culpable conduct.**

In determining whether the required \$1,000,000 threshold has been satisfied (this threshold is further explained in § 165.7) for purposes of making any award, the Commission will not take into account any monetary sanctions that the whistleblower is ordered to pay, or that are ordered against any entity whose liability is based primarily on

conduct that the whistleblower principally directed, planned, or initiated. Similarly, if the Commission determines that a whistleblower is eligible for an award, any amounts that the whistleblower or such an entity pay in sanctions as a result of the action or related actions will not be included within the calculation of the amounts collected for purposes of making payments pursuant to § 165.14.

**§ 165.18 Staff communications with whistleblowers from represented entities.**

If you are a whistleblower who is a director, officer, member, agent, or employee of an entity that has counsel, and you have initiated communication with the Commission relating to a potential violation of the Commodity Exchange Act, the Commission's staff is authorized to communicate directly with you regarding the subject of your communication without seeking the consent of the entity's counsel.

**§ 165.19 Nonenforceability of certain provisions waiving rights and remedies or requiring arbitration of disputes.**

The rights and remedies provided for in this Part 165 of the Commission's regulations may not be waived by any agreement, policy, form, or condition of employment including by a predispute arbitration agreement. No predispute arbitration agreement shall be valid or enforceable if the agreement requires arbitration of a dispute arising under this Part.

**Appendix A to Part 165—Guidance With Respect to the Protection of Whistleblowers Against Retaliation**

Section 23(h)(1) of the Commodity Exchange Act prohibits employers from engaging in retaliation against whistleblowers. This provision provides whistleblowers with certain protections against retaliation, including: A federal cause of action against the employer, which must be filed in the appropriate United States district court within two (2) years of the employer's retaliatory act; and potential relief for prevailing whistleblowers, including reinstatement, back pay, and compensation for other expenses, including reasonable attorney's fees. Specifically, Section 23(h)(1) of Commodity Exchange Act provides:

(A) *In General.*—No employer may discharge, demote, suspend, threaten, harass, directly or indirectly, or in any other manner discriminate against, a whistleblower in the terms and conditions of employment because of any lawful act done by the whistleblower—

(i) In providing information to the Commission in accordance with subsection (b); or

(ii) In assisting in any investigation or judicial or administrative action of the Commission based upon or related to such information.

(B) *Enforcement.* (i) *Cause of Action.*—An individual who alleges discharge or other discrimination in violation of subparagraph (A) may bring an action under this subsection in the appropriate district court of the United States for the relief provided in subparagraph (C), unless the individual who is alleging discharge or other discrimination in violation of subparagraph (A) is an employee of the Federal Government, in which case the individual shall only bring an action under section 1221 of title 5, United States Code.

(ii) *Subpoenas.*—A subpoena requiring the attendance of a witness at a trial or hearing conducted under this subsection may be served at any place in the United States.

(iii) *Statute of Limitations.*—An action under this subsection may not be brought more than 2 years after the date on which the violation reported in subparagraph (A) is committed.

(C) *Relief.*—Relief for an individual prevailing in an action brought under subparagraph (B) shall include—

(i) Reinstatement with the same seniority status that the individual would have had, but for the discrimination;

(ii) The amount of back pay otherwise owed to the individual, with interest; and

(iii) Compensation for any special damages sustained as a result of the discharge or discrimination, including litigation costs, expert witness fees, and reasonable attorney's fees.

**BILLING CODE 6351-01-P**

**UNITED STATES  
COMMODITY FUTURES TRADING COMMISSION  
Washington, D.C. 20581**

**FORM TCR  
TIP, COMPLAINT OR REFERRAL**

<b>A. INFORMATION ABOUT YOU</b>			
1. Last Name		First	M.I.
2. Street Address			Apartment/ Unit #
City	State/ Province	ZIP/ Postal Code	Country
3. Telephone	Alt. Phone	Email Address	Preferred method of communication
Your Occupation			
<b>B. ATTORNEY INFORMATION (If Applicable – See Instructions)</b>			
1. Attorney's Name			
2. Firm Name			
3. Street Address			
City	State/ Province	Zip/ Postal Code	Country
4. Telephone	Fax	Email Address	
<b>C. TELL US ABOUT THE INDIVIDUAL OR ENTITY YOU HAVE A COMPLAINT AGAINST.</b>			
Individual/Entity 1. Type: <input type="checkbox"/> Individual <input type="checkbox"/> Entity		If an individual, specify profession: If an entity, specify type:	
2. Name			
3. Street Address			Apartment/ Unit #
City	State/ Province	ZIP/ Postal Code	Country
4. Telephone	Email Address		Internet Address
<b>D. TELL US ABOUT YOUR COMPLAINT</b>			
1. Occurrence Date (mm/dd/yyyy): ____/____/____		2. Nature of Complaint:	
3. Are you complaining about an entity of which you are or were an officer, director, employee, consultant or contractor?			

4a. Have you taken any prior action regarding your complaint?
4b. If you answered "Yes" to question 41, please provide details. Use additional sheets if necessary.
4c. Date on which you took the action(s) described in question 4b (mm/dd/yyyy): ____/____/____
5. State in detail all facts pertinent to the activity that is the subject of your complaint. Use additional sheets if necessary.
6. Describe all materials in your possession supporting your complaint and the availability and location of any additional supporting materials not in your possession. Use additional sheets, if necessary.
7. Describe how you obtained the information that supports your complaint. If any information was obtained from a public source, identify the source with as much particularity as possible. Attach additional sheets if necessary.
8. Provide any additional information you think may be relevant.

**BILLING CODE 6351-01-C****Privacy Act of Statement**

The Privacy Act requires that the Commodity Futures Trading Commission (CFTC) inform individuals of the following when asking for information. This form may be used by anyone wishing to provide the CFTC with information concerning a violation of the Commodity Exchange Act or the Commission's regulations. If you are submitting this information for the Commission's whistleblower award program pursuant to Section 23 of the Commodity Exchange Act, the information provided will enable the Commission to determine your eligibility for payment of an award. This information may be disclosed to Federal, state, local, or foreign agencies responsible for investigating, prosecuting, enforcing, or

implementing laws, rules, or regulations implicated by the information consistent with the confidentiality requirements set forth therein. Furnishing the information is voluntary, but a decision not to do so may result in you not being eligible for award consideration.

Questions concerning this form may be directed to the Commodity Futures Trading Commission, Three Lafayette Centre, 1151 21st Street, NW., Washington, DC 20581.

**Submission Procedures**

- After completing this Form TCR, please send it to the Commission: electronically via the Commission's Web site; by mail to the Commodity Futures Trading Commission, Three Lafayette Centre, 1151 21st Street, NW., Washington, DC 20581; or by facsimile to (202) XXX-XXXX.

- You have the right to submit information anonymously.

- If you are submitting information for the Commission's whistleblower award program, you must submit your information using this Form TCR. In addition to submitting your information by this method, you must also submit a declaration on Form WB-DEC. The Form WB-DEC can be printed out from the Commission's Web site or obtained from the Commission, and it must be manually signed by you under penalty of perjury.

**Instructions for Completing Form TCR****Section A: Information About You**

Questions 1-3: Please provide the following information about yourself:

- Last name, first name, and middle initial;

○ Complete address, including city, state and zip code;

○ Telephone number and, if available, an alternative number where you can be reached;

○ Your e-mail address (to facilitate communications, the Commission strongly encourages you to provide your e-mail address); and

○ Your preferred method of communication.

Question 4: Describes your occupation, for example which of the following provides the best description:

○ Accountant, attorney, auditor, broker-dealer, compliance officer, financial representative, foreign officer, fund manager, investment advisor, commodity trading adviser, investor, customer, company officer or senior manager, trader, floor broker, government official (federal, state, or local), law enforcement personnel (federal, state, or local), or other (specific).

#### Section B: Information About Your Attorney.

Complete This Section Only If Your Are Represented By An Attorney In This Matter.

Questions 1–4: Provide the following information about the attorney representing you in this matter:

○ Attorney's name;

○ Firm name;

○ Complete address, including city, state and zip code;

○ Telephone number and fax number; and

○ E-mail address.

Section C: Tell Us About The Individual And/Or Entity You Have A Complaint Against. If your complaint relates to more than two individuals and/or entities, you may attach additional sheets.

Question 1: Choose the following that best describes the individual or entity to which your complaint relates:

○ For Individuals: accountant, analyst, associated person, attorney, auditor, broker, commodity trading advisor, commodity pool operator, compliance officer, employee, executing broker, executive officer or director, financial planner, floor broker, floor trader, trader, unknown, or other (specify).

○ For Entities: bank, commodity trading advisor, commodity pool operator, commodity pool, futures commission merchant, hedge fund, introducing broker, major swap participant, retail foreign

exchange dealer, swap dealer, unknown, or other (specify).

Questions 2–4: For each subject, provide the following information, if known:

○ Full name;

including city, state and zip code;

○ Telephone number;

○ E-mail address; and

○ Internet address, if applicable.

#### Section C: Tell Us About Your Complaint.

Question 1: State the date (mm/dd/yyyy) that the alleged conduct began.

Question 2: Choose the option that you believe best describes the nature of your complaint. If you are alleging more than one violation, please list all that you believe may apply. Use additional sheets, if necessary.

○ Theft/misappropriation;

○ Misrepresentation/omission (false/misleading marketing/sales literature; inaccurate, misleading or non-disclosure by commodity pool operator, commodity trading advisor, futures commission merchant, introducing broker, retail foreign currency dealer, swap dealer, or their associated person(s); false/material misstatements in any report or statement;

○ Ponzi/pyramid scheme;

○ Off-exchange foreign currency, commodity, or precious metal fraud;

○ Registration violations (including unregistered commodity pool operator, commodity trading advisor, futures commission merchant, introducing broker, retail foreign currency dealer, swap dealer, or their associated person(s));

○ Trading (after hours trading; algorithmic trading; disruptive trading; front running; insider trading; manipulation/attempted manipulation of commodity prices; market timing; inaccurate quotes/pricing information; program trading; trading suspensions; volatility);

○ Fees/mark-ups/commissions (excessive, unnecessary or unearned administrative, commission or sales fees; failure to disclose fees; insufficient notice of change in fees; excessive or otherwise improper spreads or fills);

○ Sales and advisory practices (background information on past violations/integrity; breach of fiduciary duty/responsibility; churning/excessive trading; cold calling; conflict of interest; a bout of authority in discretionary trading; failure to respond to client, customer or participant; guarantee against loss; promise to profit; high

pressure sales techniques; instructions by client, customer or participant not followed; investment objectives not followed; solicitation methods (non-cold calling, seminars);

○ Customer accounts (unauthorized trading); identity theft affecting account; inaccurate valuation of Net Asset Value; or

○ Other (analyst complaints; market maker activities; employer/employee disputes; specify other).

Question 3: Indicate whether you were in the past, or are currently, an officer, director, employee, consultant, or contractor of the entity to which your complaint relates.

Question 4a: Indicate whether you have taken any prior action regarding your complaint, including whether you reported the violation to the entity, including the compliance office, whistleblower hotline or ombudsman; complained to the Commission, another regulator, a law enforcement agency, or any other agency or organization; initiated legal action, mediation or arbitration, or initiated any other action.

Question 4b: If you answered "yes" to question 4a, provide details, including the date on which you took the action(s) described, the name of the person or entity to whom you directed any report or complaint and the contact information for the person or entity, if known, and the complete case name, case number, and forum of any legal action you have taken. Use additional sheets, if necessary.

Question 5: State in detail all the facts pertinent to your complaint. Attach additional sheets, if necessary.

Question 6: Describe all supporting materials in your possession, custody or control, and the availability and location of additional supporting materials not in your possession, custody or control. Attach additional sheets, if necessary.

Question 7: Describe how you obtained the information that supports your allegation. If any information was obtained from a public source, identify the source with as much particularity as possible. Attach additional sheets, if necessary.

Question 8: Please provide any additional information you think may be relevant.

**BILLING CODE 6351-01-P**

**UNITED STATES  
COMMODITY FUTURES TRADING COMMISSION  
Washington, D.C. 20581**

**FORM WB-DEC**

**DECLARATION CONCERNING ORIGINAL INFORMATION PROVIDED  
PURSUANT TO SECTION 23 OF THE COMMODITY EXCHANGE ACT**

<b>A. SUBMITTER'S INFORMATION</b>			
1. Last Name		First	M.I.
2. Street Address			Apartment/ Unit #
City	State/ Province	ZIP/ Postal Code	Country
3. Telephone	Alt. Phone	Email Address	Preferred method of communication
Your Occupation			
<b>B. ATTORNEY INFORMATION (If Applicable – See Instructions)</b>			
1. Attorney's Name			
2. Firm Name			
3. Street Address			
City	State/ Province	Zip/ Postal Code	Country
4. Telephone	Fax	Email Address	
<b>C. TIP/COMPLAINT DETAILS</b>			
1. Manner in which information was submitted to CFTC    CFTC website <input type="checkbox"/> Mail <input type="checkbox"/> Fax <input type="checkbox"/> Other _____			
2a. Date Tip, Complaint or Referral (TCR) was submitted to CFTC ___/___/___			
2b Individual or entity to which Tip, Complaint or Referral relates:			
3a. Has the submitter or counsel had any communication(s) with the CFTC concerning this matter?    YES <input type="checkbox"/> NO <input type="checkbox"/>			
3b. If the answer to 3a is "Yes," name of CFTC staff member with whom the submitter or counsel communicated:			
4a. Has the submitter or counsel provided the information to any other agency or organization? YES <input type="checkbox"/> NO <input type="checkbox"/>			
4b. If the answer to 4a is "Yes," please provide details. Use additional sheets if necessary.			
4c. Name and contact information for point of contact at agency or organization, if known			



<b>D. ELIGIBILITY REQUIREMENTS</b>	
1. Are you, or were you at the time you acquired the original information you submitted to us, a member, officer or employee of the Department of Justice, the Commodity Futures Trading Commission, the Comptroller of the Currency, the Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation, the Office Thrift Supervision, National Credit Union Administration Board, the Securities Exchange Commission, the Public Company Accounting Oversight Board, a registered entity, a registered futures association, a self-regulatory organization, or any law enforcement organization?	YES <input type="checkbox"/>
2. Did you provide the information identified in Section C above pursuant to a cooperation agreement with the CFTC or another agency or organization?	YES <input type="checkbox"/>
3. Are you a spouse, parent, child, or sibling of a member or employee of the Commission, or do you reside in the same household as a member or employee of the Commission?	YES <input type="checkbox"/>
4. Did you acquire the information you are providing to us from any person described in the questions D1 through D3?	YES <input type="checkbox"/>
5. If you answered "Yes" to any of the questions 1 through 4 above, please provide details. Use additional sheets if necessary.	
6a. Did you provide the information identified in Section C above before you (or anyone representing you) received any request, inquiry or demand from the CFTC, Congress, or any other federal, state or local authorities, or any self regulatory organization about a matter to which the information your submission was relevant?	YES <input type="checkbox"/>
6b. If you answered "no" to question 6a, please provide details. Use additional sheets if necessary.	
7a. Are you currently a subject or largest of a criminal investigation, or have you been convicted of a criminal violation, in connection with the information upon which your application for an award is based?	YES <input type="checkbox"/>
7b. If you answered "Yes" to question 7a, please provide details. Use additional sheets if necessary.	
<b>E. DECLARATION</b>	
I declare under penalty of perjury under the laws of the United States that the information contained herein, and all information submitted to the CFTC – either in the TCR referenced in Section C of this form or in the Form TCR accompanying this Form WB-DEC – is true, correct and complete to the best of my knowledge, information and belief. I fully understand that I may be subject to prosecution and ineligible for a whistleblower award if my submission of information, my other dealings with the CFTC, or my dealings with another authority in connection with a related action. I knowingly and willfully make any false, fictitious, or fraudulent statements or representations, or use any false writing or document knowing that the writing or document contains any false, fictitious, or fraudulent statement or entry.	
Signature	Date
<b>F. COUNSEL CERTIFICATION</b>	
I certify that I have verified the identity of the whistleblower who completed Form WB-DEC in connection with the information referenced in Section C of this form by viewing the whistleblower's valid, unexpired government issued identification (e.g. driver's license, passport, that I have reviewed the whistleblower's Form WB-DEC for completeness and accuracy, and that I will retain an original, signed copy of the Form WB-DEC completed by the whistleblower in the records.	
Signature	Date

BILLING CODE 6351-01-C

**Privacy Act Statement**

This notice is given under the Privacy Act of 1974. The Privacy Act requires that the Commodity Futures Trading Commission (CFTC) inform individuals of the following when asking for information. The information provided will enable the Commission to determine your eligibility for payment of an award pursuant to Section 23 of the Commodity Exchange Act. This information may be disclosed to Federal, state, local, or foreign agencies responsible for investigating, prosecuting, enforcing, or implementing rules, or regulations implicated by the information consistent with the confidentiality requirements set forth in Section 23 of the Commodity Exchange Act and part 165 of the Commissions regulations hereunder. Furnishing the information is voluntary, but a decision not to do so may result in you not being eligible for award consideration.

Questions concerning this form may be directed to the Commodity Futures Trading, Three Lafayette Centre, 1151 21st Street, NW., Washington, DC 20581.

**General Information**

Submitting information for the CFTC's whistleblower award program is a two-step process. First, you must provide us with your information by completing a Form TCR ("Tip, Complaint, or Referral"), instructions set forth on the form, and sending it to the Commission: electronically via the Commission's website; by mail to the Commodity Futures Trading Commission, Three Lafayette Centre, 1151 21st Street, NW., Washington, DC 20581; or by facsimile to (202) XXX-XXXX.

- Submitting your information to the Commission is the first step. If you want to be considered for a whistleblower award, you must also submit this Form WB-DEC and it must be manually signed under penalty of perjury.

- *If you submitted your information electronically through the Commission's website, the Commission must receive your completed Form WB-DEC within 30 days of your submission. If you did not submit your information electronically but instead are submitting your information on Form TCR, you must submit your declaration on Form WB-DEC at the same time that you submit your Form TCR.*

Follow the instructions set forth below for submitting this Form WB-DEC.

- If you follow these steps, and the information you submit leads to the successful enforcement of a CFTC judicial or administrative action, or a related action, you will have an opportunity at a later date to submit a claim for an award. That is a separate process and is described in our whistleblower rules, which are available on the Commission's Web site [insert link].

- You have the right to submit information anonymously. If you are doing so, please skip Part I of these instructions and proceed directly to Part II. Otherwise, please begin by following the instructions in Part I.

**Part I: Instructions for Filers who are Disclosing Their Identity**

You are required to complete Sections A, C, D, and E of this form. If you are represented by an attorney in this matter, you must also complete Section B. Specific instructions for answering these questions can be found in Part IV below.

If you previously submitted your complaint electronically through the Commission's website, you may submit this Form WB-DEC to us in any of the following ways:

- By mailing or delivering the signed form to the Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581-XXXX; or
- By faxing the signed form to (202) XXX-XXXX; or
- By scanning and emailing the form in PDF format to [insert e-mail address].

*Please note that the Commission must receive your Form WB-DEC within thirty (30) days of when you submitted your information to us through the Commission's website.*

If you did not previously submit your complaint electronically through the CFTC's website, but instead intend to send us a Form TCR, then you must submit your completed Form TCR and your declaration on this Form WB-DEC together. You may do so in one of two ways:

- By mailing or delivering the Form TCR and the signed Form WB-DEC to the Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581-XXXX; or
- By faxing the Form TCR and the signed Form WB-DEC form to (202) XXX-XXXX.

**Part II: Instructions for Anonymous Filers**

If you are submitting information anonymously, you may be represented by an attorney in this matter. If you are applying for a whistleblower award, you must be represented by an attorney in connection with such application.

In order for you to be eligible for a whistleblower award, your attorney must retain your signed original of Form WB-DEC in his or her records, and submit both your Form WB-APP (if you filled one out instead of submitting your complaint to us electronically) and a Form WB-DEC completed by the attorney declaration to the Commission. You are encouraged to confirm that your attorney followed these steps.

**Part III: Instructions for Attorneys Representing Anonymous Whistleblowers**

Obtain a completed and signed original of Form WB-DEC from your client. You must retain this signed original in your records because it may be required at a later date upon request of CFTC staff and prior to the payment a whistleblower award.

You must prepare your own Form WB-DEC, completing only Sections B, C and F. Specific instructions for answering these questions can be found in Part IV below.

You must submit your client's application on Form WB-APP and your attorney declaration on this Form WB-DEC together. You may do so in one of two ways:

- By mailing or delivering the Form WB-APP and the signed Form WB-DEC to the

Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581-XXXX; or

- By faxing the Form WB-APP and the signed Form WB-DEC to (202) XXX-XXXX.

**Part IV: Instructions for Completing Form WB-DEC***Section A: Submitter's Information*

Questions 1-3: Provide the following information about yourself:

- First and last name, and middle initial;
- Complete address, including city, state and zip code;
- Telephone number and, if available, an alternate number where you can be reached; and
- E-mail address.

*Section B: Information about Your Attorney. Complete this section only if you are represented by an attorney in this matter. You must be represented by an attorney, and this section must be completed, if you intend to apply for a whistleblower award anonymously.*

Questions 1-4: Provide the following information about the attorney representing you in this matter:

- Attorney's name;
- Firm name;
- Complete address, including city, state and zip code;
- Telephone number and fax number; and
- E-mail address.

*Section C: Tip/Complaint Details*

Question 1: Indicate the manner in which the information was submitted to the Commission.

Question 2a: Provide the date on which the TCR was submitted to the Commission.

Question 2b: Provide the name of the individual or entity to which your complaint relates.

Question 3a: Indicate whether the submitter or counsel have had any communication(s) with the Commission concerning this manner.

Question 3b: If you answered "yes" to question 3a, provide the name of the SEC staff member with whom the submitter or counsel communicated.

Question 4a: Indicate whether the submitted or counsel have provided the information being submitted to the CFTC to any other agency or organization.

Question 4b: If you answered "yes" to question 4a, provide details, including the name of the agency or organization, the date on which you provided your information to the agency or organization and any other relevant details.

Question 4c: Provide a name and contact information for your point of contact at the other agency or organization, if known.

*Section D: Eligibility Requirements*

Question 1: State whether you are currently, or were at the time you acquired the original information that you submitted to the CFTC a member, officer, or employee of the Department of Justice the Securities and Exchange Commission; the Comptroller of the

- Currency, the Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation, the Office of Thrift Supervision; National Credit Union Administration Board, registered entity, a registered futures association, a self-regulatory organization or; any law enforcement organization.
- Question 2: State whether you provided the information submitted to the CFTC pursuant to a cooperation agreement with the Commission or with any other agency or organization.
- Question 3: State whether you are a spouse, parent, child or sibling of a member or employee of the Commission, or whether you reside in the same household as a member or employee of the Commission.
- Question 4: State whether you acquired the information you are providing to the CFTC from any individual described in Question 1 through 3 of this Section.
- Question 5: If you answered “yes” to questions 1 through 4, please provide details.
- Question 5a: State whether you provided the information identified submitted to the CFTC before you (or anyone representing you) received any request, inquiry or demand from the CFTC, Congress, or any other federal, state or local authority, or any self regulatory organization about a matter to which the information your submission was relevant.
- Question 5b: If you answered “no” to questions 5a, please provide details. Use additional sheets if necessary.
- Question 6a: State whether you are the subject or target of a criminal investigation or have been convicted of a criminal violation in connection with the information upon which your application for award is based.
- Question 6b: If you answered “yes” to question 9a, please provide details, including the name of the agency or organization that conducted the investigation or initiated the action against you, the name and telephone number of your point of contact at the agency or organization, if available and the investigation/case name and number, if applicable. Use additional sheets, if necessary. If you previously provided this information on Form WB-DEC, you may leave this question blank, unless your response has changed since the time you submitted your Form WB-DEC.

*Section E: Declaration*

To be completed and signed by person submitting the information

*Section F: Counsel Certification*

To be completed and signed by attorney for an anonymous person submitting information

**UNITED STATES  
COMMODITY FUTURES TRADING COMMISSION  
Washington, D.C. 20581**

**FORM WB-APP**

**APPLICATION FOR AWARD CONCERNING ORIGINAL INFORMATION  
PROVIDED  
PURSUANT TO SECTION 23 OF THE COMMODITY EXCHANGE ACT**

<b>A. APPLICANT INFORMATION (Required for all Submissions)</b>			
1. Last Name	First	M.I.	Social Security No.
2. Street Address			Apartment/ Unit #
City	State/ Province	ZIP/ Postal Code	Country
3. Telephone	Alt. Phone	Email Address	Preferred method of communication
Your Occupation			
<b>B. ATTORNEY INFORMATION (If Applicable – See Instructions)</b>			
1. Attorney's Name			
2. Firm Name			
3. Street Address			
City	State/ Province	Zip/ Postal Code	Country
4. Telephone	Fax	Email Address	
<b>C. TIP/COMPLAINT DETAILS</b>			
1. Manner in which information was submitted to CFTC		CFTC website <input type="checkbox"/> Mail <input type="checkbox"/>	
<input type="checkbox"/> Fax <input type="checkbox"/> Other _____			
2a. Tip, Complaint or Referral (TCR) number		2b. Date TCR referenced in 2a submitted to CFTC ___/___/___	
2c Subject(s) of the Tip, Complaint or Referral:			
<b>D. NOTICE OF COVERED ACTION</b>			
1. Date of Notice of Covered Action to which claim relates ___/___/___		2. Notice Number:	
3a. Case Name		3b. Case number:	
<b>E. CLAIMS PERTAINING TO RELATED ACTIONS</b>			
1. Name and contact information for point of contact at agency or organization, if known.			

2. Name and contact information for point of contact at agency or organization, if known.	
3a. Date you provided your information ____/____/____	3b. Date action filed by agency/organization ____/____/____
4a. Case Name	4b. Case Number
<b>F. ELIGIBILITY REQUIREMENTS</b>	
1. Are you, or were you at the time you acquired the original information you submitted to us, a member, officer or employee of the Department of Justice, the Commodity Futures Trading Commission, the Comptroller of the Currency, the Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation, the Office Thrift Supervision, National Credit Union Administration, the Securities Exchange Commission, registered entity, registered futures association; a self-regulatory organization, , or any law enforcement organization? <span style="float: right;">YI</span>	
2. Did you provide the information identified in Section C above pursuant to a cooperation agreement with the CFTC or another agency or organization? <span style="float: right;">YI</span>	
3. Are you a spouse, parent, child, or sibling of a member or employee of the Commission, or do you reside in the same household as a member or employee of the Commission? <span style="float: right;">YI</span>	
4. If you answered "Yes" to any of the questions 1 through 3 above, please provide details. Use additional sheets if necessary.	
5a. Did you provide the information identified in Section C above before you (or anyone representing you) received any request, inquiry or demand from the CFTC, Congress, or any other federal, state or local authorities, or any self regulatory organization about a matter to which the information your submission was relevant? ? <span style="float: right;">YI</span>	
5b. If you answered "no" to question 5a, please provide details. Use additional sheets if necessary.	
6a. Are you currently a subject or largest of a criminal investigation, or have you been convicted of a criminal violation, in connection with the information upon which your application for an award is based? <span style="float: right;">YI</span>	
7b. If you answered "Yes" to question 9a, please provide details. Use additional sheets if necessary.	
<b>G. ENTITLEMENT TO AWARD</b>	

Explain the basis for your belief that you are entitled to an award in connection with your submission of information to us, or to another agency in a related action. Provide any additional information you think may be relevant in light of the criteria for determining the amount of an award set forth in Section 23 of the Commodities Exchange Act and part 165 of the Commissions regulations thereunder. Include any supporting documents in your possession or control, and attach additional sheets, if necessary.

## H. DECLARATION

I declare under penalty of perjury under the laws of the United States that the information contained herein, and all information submitted to the CFTC – either in the TCR referenced in Section C of this form or in the Form TCR accompanying this Form WB-DEC – is true, correct and complete to the best of my knowledge, information and belief. I fully understand that I may be subject to prosecution and ineligible for a whistleblower award if my submission of information, my other dealings with the CFTC, or my dealings with another authority in connection with a related action. I knowingly and willfully make an<sup>6</sup> false, fictitious, or fraudulent statements or representations, or use any false writing or document knowing that the writing or document contains any false, fictitious, or fraudulent statement or entry.

Signature

Date

### BILLING CODE 6351-01-P

#### Privacy Act Statement

This notice is given under the Privacy Act of 1974. The Privacy Act requires that the Commodity Futures Trading Commission (CFTC or Commission) inform individuals of the following when asking for information. The information provided will enable the Commission to determine your eligibility for payment of an award pursuant to Section 23 of the Commodity Exchange Act. This information may be disclosed to Federal, state, local, or foreign agencies responsible for investigating, prosecuting, enforcing, or implementing the laws, rules, or regulations implicated by the information consistent with the confidentiality requirements set forth in Section 23 of the Commodity Exchange Act and part 165 of the Commissions regulations thereunder. Furnishing the information is voluntary, but a decision not to do so may result in you not being eligible for award consideration.

Questions concerning this form may be directed to the Commodity Futures Trading Commission, Three Lafayette Centre, 1151 21st Street, NW., Washington, DC 20581.

#### General

This form should be used by persons making a claim for a whistleblower award in connection with information provided to the CFTC or to another agency in a related action. In order to be deemed eligible for an award, you must meet all the requirements set forth in Section 23 of the Commodities Exchange Act and the rules hereunder.

You must sign the Form WB-APP as the claimant. If you provided your information to

the CFTC anonymously, you must now disclose your identity on this form and your identity must be verified in a form and manner that is acceptable to the CFTC prior to the payment of any award.

- If you are filing your claim in connection with information that you provided to the CFTC, then Form WB-APP and any attachments thereto, must be received by the CFTC within sixty (60) days of the date of the Notice of Covered Action or the date of a final judgment in a related action to which the claim relates.

- If you are filing your claim in connection with information you provided to another agency in a related action, then your Form WB-APP, and any attachments there to, must be received by the CFTC within sixty (60) days of the date of a final judgment in the related action to which the claim relates.

You must submit your Form WB-APP to us in one of the following two ways:

- By mailing or delivering the signed form to the Commodity Futures Trading Commission, Three Lafayette Centre, 1151 21st Street, NW., Washington, DC 20581; or
- By faxing the signed form to (202) XXX-XXXX.

#### Instructions for Completing Form WB-APP

##### Section A: Applicant's Information

Questions 1–3: Provide the following information about yourself:

- First and last name, and middle initial;
- Complete address, including city, state and zip code;
- Telephone number and, if available, an alternate number where you can be reached; and

- E-mail address

*Section B: Attorney's Information. If you are represented by an attorney in this matter, provide the information requested. If you are not representing an attorney in this matter, leave this Section blank.*

Questions 1–4: Provide the following information about the attorney representing you in this matter:

- Attorney's name;
- Firm name;
- Complete address, including city, state and zip code;
- Telephone number and fax number; and
- E-mail address.

##### Section C: Tip/Complaint Details

Question 1: Indicate the manner in which your original information was submitted to the CFTC.

Question 2a: Provide the date on which you submitted your TCR (Tip, Complaint or Referral) information to the CFTC.

Question 2b: Provide the name of the individual(s) or entity(s) to which your complaint related.

##### Section D: Notice of Covered Action

The process for making a claim for a whistleblower award begins with the publication of a "Notice of a Covered Action" on the Commission's Web site. This notice is published whenever a judicial or administrative action brought by the Commission results in the imposition of monetary sanctions exceeding \$1,000,000. The Notice is published on the Commission's Web site subsequent to the entry of a final

judgment or order in the action that by itself, or collectively with other judgments or orders previously entered in the action, exceeds the \$1,000,000 threshold.

Question 1: Provide the date of the Notice of Covered Action to which this claim relates.

Question 2: Provide the notice number of the Notice of Covered Action.

Question 3a: Provide the case name referenced in Notice of Covered Action.

Question 3b: Provide the case number referenced in Notice of Covered Action.

#### *Section E: Claims Pertaining to Related Actions*

Question 1: Provide the name of the agency or organization to which you provided your information.

Question 2: Provide the name and contact information for your point of contact at the agency or organization, if known.

Question 3a: Provide the date on which that you provided your information to the agency or organization referenced in question E1.

Question 3b: Provide the date on which the agency or organization referenced in question E1 filed the related action that was based upon the information you provided.

Question 4a: Provide the case name of the related action.

Question 4b: Provide the case number of the related action.

#### *Section F: Eligibility Requirements*

Question 1: State whether you are currently, or were at the time you acquired the original information that you submitted to the CFTC a member, officer, or employee of the Department of Justice, the Securities and Exchange Commission, the Comptroller of the Currency, the Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation, the Office of Thrift Supervision, National Credit Union Administration Board, registered entity, a registered futures association, a self-regulatory organization or; any law enforcement organization.

Question 2: State whether you provided the information submitted to the CFTC pursuant to a cooperation agreement with the Commission or with any other agency or organization.

Question 3: State whether you are a spouse, parent, child or sibling of a member or employee of the Commission, or whether

you reside in the same household as a member or employee of the Commission.

Question 4: State whether you acquired the information you are providing to the CFTC from any individual described in Question 1 through 3 of this Section.

Question 5: If you answered "yes" to questions 1 through 4, please provide details.

Question 5a: State whether you provided the information identified submitted to the CFTC before you (or anyone representing you) received any request, inquiry or demand from the CFTC, Congress, or any other federal, state or local authority, or any self regulatory organization about a matter to which the information your submission was relevant.

Question 5b: If you answered "no" to questions 5a, please provide details. Use additional sheets if necessary.

Question 6a: State whether you are the subject or target of a criminal investigation or have been convicted of a criminal violation in connection with the information upon which your application for award is based.

Question 6b: If you answered "yes" to question 6a, please provide details, including the name of the agency or organization that conducted the investigation or initiated the action against you, the name and telephone number of your point of contact at the agency or organization, if available and the investigation/case name and number, if applicable. Use additional sheets, if necessary. If you previously provided this information on Form WB-DEC, you may leave this question blank, unless your response has changed since the time you submitted your Form WB-DEC.

#### *Section G: Entitlement to Award*

Use this section to explain the basis for your belief that you are entitled to an award in connection with your submission of information to us or to another agency in connection with a related action. Specifically address how you believe you voluntarily provided the Commission with original information that led to the successful enforcement of a judicial or administrative action filed by the Commission, or a related action. Refer to § 165.11 of this part for further information concerning the relevant award criteria. You may attach additional sheets, if necessary.

Section 23(c)(1)(B) of the CEA requires the Commission to consider, and subparagraph (a)(1) through (4) provides that in

determining the amount of an award, the Commission will evaluate the following factors: (a) The significance of the information provided by a whistleblower to the success of the Commission action or related action; (b) the degree of assistance provided by the whistleblower and any legal representative of the whistleblower in the Commission action or related action; (c) the programmatic interest of the Commission in deterring violations of the securities laws by making awards to whistleblowers who provide information that leads to the successful enforcement of such laws; and (d) whether the award otherwise enhances the Commission's ability to enforce the Commodity Exchange Act, protect customers, and encourage the submission of high quality information from whistleblowers. Address these factors in your response as well.

#### *Section G: Declaration*

This section must be signed by the claimant.

By the Commission.

Dated: November 10, 2010.

**David Stawick,**

*Secretary.*

#### **Statement of Chairman Gary Gensler**

##### *Proposed Rules for Implementing the Whistleblower Provisions of Section 23 of the Commodity Exchange Act*

I support the proposed rulemaking to establish a program for whistleblowers as mandated by the Dodd-Frank Act. Congress enacted these provisions to incentivize whistleblowers to come forward with new information about potential fraud in the financial markets. The proposed rulemaking authorizes the Commission to provide a monetary award to whistleblowers when their original information results in a successful enforcement action. The rule also provides that moneys recovered will fund new customer education initiatives to protect the public. The proposed rules encourage persons with knowledge to come forward and assist the Commission in identifying, investigating and prosecuting potential violations of the Commodity Exchange Act.

[FR Doc. 2010-29022 Filed 12-3-10; 8:45 am]

**BILLING CODE 6351-01-P**





# Federal Register

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**Monday,  
December 6, 2010**

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**Part III**

## **Environmental Protection Agency**

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**40 CFR Part 131**

**Water Quality Standards for the State of  
Florida's Lakes and Flowing Waters; Final  
Rule**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 131

[EPA-HQ-OW-2009-0596; FRL-9228-7]

RIN 2040-AF11

### Water Quality Standards for the State of Florida's Lakes and Flowing Waters

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA or Agency) is promulgating numeric water quality criteria for nitrogen/phosphorus pollution to protect aquatic life in lakes, flowing waters, and springs within the State of Florida. These criteria apply to Florida waters that are designated as Class I or Class III waters in order to implement the State's narrative nutrient provision at Subsection 62-302-530(47)(b), Florida Administrative Code (F.A.C.), which provides that "[i]n no case shall nutrient concentrations of a body of water be altered so as to cause an imbalance in natural populations of aquatic flora or fauna."

**DATES:** This final rule is effective March 6, 2012, except for 40 CFR 131.43(e), which is effective February 4, 2011.

**ADDRESSES:** An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.regulations.gov> to view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. For additional information about EPA's public docket, visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>. Although listed in the index, some information is not publicly available, *i.e.*, Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyright material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at the Docket Facility. The Office of Water (OW) Docket Center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The OW Docket Center telephone number is 202-566-1744 and the Docket address is OW Docket, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC 20004. The Public

Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744.

**FOR FURTHER INFORMATION CONTACT:** For information concerning this rulemaking, contact Danielle Salvaterra, U.S. EPA Headquarters, Office of Water, Mailcode: 4305T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone number: 202-564-1649; fax number: 202-566-9981; e-mail address: [salvaterra.danielle@epa.gov](mailto:salvaterra.danielle@epa.gov).

**SUPPLEMENTARY INFORMATION:** This supplementary information section is organized as follows:

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  - C. What entities may be affected by this rule?
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## I. General Information

### A. Executive Summary

Florida is known for its abundant and aesthetically beautiful natural resources, in particular its water resources. Florida's water resources are very important to its economy, for example, its \$6.5 billion fishing industry.<sup>1</sup> However, nitrogen/phosphorus pollution has contributed to severe water quality degradation in the State of Florida. Based upon waters assessed and reported by the Florida Department of Environmental Protection (FDEP) in its *2008 Integrated Water Quality Assessment for Florida*, approximately 1,049 miles of rivers and streams (about 5% of total assessed streams), 349,248 acres of lakes (about 23% of total assessed lakes), and 902 square miles of estuaries (about 24% of total assessed estuaries) are known to be impaired for nutrients by the State.<sup>2</sup>

The information presented in FDEP's latest water quality assessment report, the *2010 Integrated Water Quality Assessment for Florida*, documents increased identification of assessed waters that are impaired due to nutrients. In the FDEP *2010 Integrated Water Quality Assessment for Florida*, approximately 1,918 miles of rivers and streams (about 8% of assessed river and stream miles), 378,435 acres of lakes (about 26% of assessed lake acres), and 569 square miles of estuaries<sup>3</sup> (about 21% of assessed square miles of estuaries)<sup>4</sup> are identified as impaired by

<sup>1</sup> Florida Fish and Wildlife Conservation Commission. 2010. *The economic impact of freshwater fishing in Florida*. [http://www.myfwc.com/CONSERVATION/Conservation\\_ValueofConservation\\_EconFreshwaterImpact.htm](http://www.myfwc.com/CONSERVATION/Conservation_ValueofConservation_EconFreshwaterImpact.htm). Accessed August 2010.

<sup>2</sup> Florida Department of Environmental Protection (FDEP). 2008. *Integrated Water Quality Assessment for Florida: 2008 305(b) Report and 303(d) List Update*.

<sup>3</sup> The estimated miles for estuaries were recalculated in 2010. FDEP used revised GIS techniques to calculate mileages and corrected estuary waterbody descriptions by removing land drainage areas that had been included in some descriptions, which reduced the estimates of total estuarine water area for Florida waters generally, as well as for some of the estuary classifications in the 2010 report.

<sup>4</sup> For the Integrated Water Quality Assessment for Florida: 2010 305(b) Report and 303(d) List Update, Florida assessed about 3,637 additional miles of streams, about 24,833 fewer acres of lakes, and about 1,065 fewer square miles of estuaries than the 2008 Integrated Report. In addition, Florida reevaluated the WBID segment boundaries using "improved GIS techniques" for mapping. The most significant result of the major change in mapping was the reduction of assessed estuarine area from 3,726 to 2,661 square miles. The net result to the impaired waters for estuaries is that the percent of

nutrients.<sup>5</sup> The challenge of nitrogen/phosphorus pollution has been an ongoing focus for FDEP. Over the past decade or more, FDEP reports that it has spent over 20 million dollars collecting and analyzing data related to concentrations and impacts of nitrogen/phosphorus pollution in the State.<sup>6</sup> Despite FDEP's intensive efforts to diagnose and evaluate nitrogen/phosphorus pollution, substantial and widespread water quality degradation from nitrogen/phosphorus over-enrichment has continued and remains a significant problem.

On January 14, 2009, EPA determined under Clean Water Act (CWA) section 303(c)(4)(B) that new or revised water quality standards (WQS) in the form of numeric water quality criteria are necessary to protect the designated uses from nitrogen/phosphorus pollution that Florida has set for its Class I and Class III waters. The Agency considered (1) the State's documented unique and threatened ecosystems, (2) the large number of impaired waters due to existing nitrogen/phosphorus pollution, and (3) the challenge associated with growing nitrogen/phosphorus pollution associated with expanding urbanization, continued agricultural development, and a significantly increasing population that the U.S. Census estimates is expected to grow over 75% between 2000 and 2030.<sup>7</sup> EPA also reviewed the State's regulatory accountability system, which represents a synthesis of both technology-based standards and point source control authority, as well as authority to establish enforceable controls for nonpoint source activities.

A significant challenge faced by Florida's water quality program is its dependence and current reliance upon an approach involving resource-intensive and time-consuming site-by-site data collection and analysis to interpret non-numeric narrative criteria. This approach is used to make water quality impairment determinations under CWA section 303(d), to set appropriately protective numeric nitrogen and phosphorus pollution targets to guide restoration of impaired waters, and to establish numeric

nitrogen and phosphorus goals to ensure effective protection and maintenance of non-impaired waters. EPA determined that Florida's reliance on a case-by-case interpretation of its narrative criterion in implementing an otherwise comprehensive water quality framework of enforceable accountability mechanisms was insufficient to ensure protection of applicable designated uses under Subsection 62–302.530(47)(b), F.A.C., which, as noted above, provides “[i]n no case shall nutrient concentrations of a body of water be altered so as to cause an imbalance in natural populations of aquatic flora or fauna.”

In accordance with the terms of EPA's January 14, 2009 determination, an August 2009 Consent Decree, and June 7, 2010 and October 27, 2010 revisions to that Consent Decree, which are discussed in more detail in Section II.D, EPA is promulgating and establishing final numeric criteria for lakes and springs throughout Florida, and flowing waters (*e.g.*, rivers, streams, canals, *etc.*) located outside of the South Florida Region.<sup>8</sup>

Regarding numeric criteria for streams, the Agency conducted a detailed technical evaluation of the substantial amount of sampling, monitoring and associated water quality analytic data available on Florida streams together with a significant amount of related scientific analysis. EPA concluded that reliance on a reference-based methodology was a strong and scientifically sound approach for deriving numeric criteria, in the form of total nitrogen (TN) and total phosphorus (TP) concentration values for flowing waters including streams and rivers. This information is presented in more detail in Section III.B below.

For lakes, EPA is promulgating a classification approach using color and alkalinity based upon substantial data that show that lake color and alkalinity are important predictors of the degree to which TN and TP concentrations result in a biological response such as elevated chlorophyll *a* levels. EPA found that correlations between nitrogen/phosphorus and biological response parameters in the different types of

lakes in Florida were specific, significant, and documentable, and when considered in combination with additional lines of evidence, support a stressor-response approach to criteria development for Florida's lakes. EPA's results show a significant relationship between concentrations of nitrogen and phosphorus in lakes and algal growth. The Agency is also promulgating an accompanying supplementary analytical approach that the State can use to adjust TN and TP criteria within a certain range for individual lakes where sufficient data on long-term ambient chlorophyll *a*, TN, and TP levels are available to demonstrate that protective chlorophyll *a* criterion for a specific lake will still be maintained and attainment of the designated use will be assured. This information is presented in more detail in Section III.C below.

EPA also evaluated what downstream protection criteria for streams that flow into lakes is necessary for assuring the protection of downstream lake water quality pursuant to the provisions of 40 CFR 130.10(b), which requires that water quality standards (WQS) must provide for the attainment and maintenance of the WQS of downstream waters. EPA examined a variety of lake modeling techniques and data to ensure protection of aquatic life in downstream lakes that have streams flowing into them. Accordingly, this final rule includes a tiered approach to adjust instream TP and TN criteria for flowing waters to ensure protection of downstream lakes. This approach is detailed in Section III.C(2)(f) below.<sup>9</sup>

Regarding numeric criteria for springs, EPA is promulgating a nitrate+nitrite criterion for springs based on stressor-response relationships that are based on laboratory data and field evaluations that document the response of nuisance<sup>10</sup> algae and periphyton growth to nitrate+nitrite concentrations in springs. This criterion is explained in more detail in Section III.D below.

Finally, EPA is promulgating in this notice an approach to authorize and allow derivation of Federal site-specific alternative criteria (SSAC) based upon EPA review and approval of applicant submissions of scientifically defensible

assessed estuaries impaired remains about the same in 2008 (24%) as in 2010 (21%).

<sup>5</sup> FDEP. 2010. Integrated Water Quality Assessment for Florida: 2010 305(b) Report and 303(d) List Update.

<sup>6</sup> FDEP. 2009. Florida Numeric Nutrient Criteria History and Status. <http://www.dep.state.fl.us/water/wqssp/nutrients/docs/fl-nnc-summary-100109.pdf>. Accessed September 2010.

<sup>7</sup> U.S. Census Bureau, Population Division, Interim State Population Projections, 2005. <http://www.census.gov/population/projections/SummaryTabA1.pdf>.

<sup>8</sup> For purposes of this rule, EPA has distinguished South Florida as those areas south of Lake Okeechobee and the Caloosahatchee River watershed to the west of Lake Okeechobee and the St. Lucie watershed to the east of Lake Okeechobee, hereinafter referred to as the South Florida Region. Numeric criteria applicable to flowing waters in the South Florida Region will be addressed in the second phase of EPA's rulemaking regarding the establishment of estuarine and coastal numeric criteria. (Please refer to Section I.B for a discussion of the water bodies affected by this rule).

<sup>9</sup> As provided by the terms of the June 7, 2010 amended Consent Decree, downstream protection values for estuaries and coastal waters will be addressed in the context of the second phase of this rulemaking process.

<sup>10</sup> Nuisance algae is best characterized by Subsection 62–302.200(17), F.A.C.: “Nuisance Species” shall mean species of flora or fauna whose noxious characteristics or presence in sufficient number, biomass, or areal extent may reasonably be expected to prevent, or unreasonably interfere with, a designated use of those waters.

recalculations that meet the requirements of CWA section 303(c) and EPA's implementing regulations at 40 CFR part 131. Total maximum daily load (TMDL) targets submitted to EPA for consideration as new or revised WQS would be reviewed under this SSAC process. This approach is discussed in more detail in Section V.C below.

Throughout the development of this rulemaking, EPA has emphasized the importance of sound science and widespread input in developing numeric criteria. Stakeholders have reiterated that numeric criteria must be scientifically sound. As demonstrated by the extent and detail of scientific analysis explained below, EPA continues to strongly agree. Under the CWA and EPA's implementing regulations, numeric criteria must protect the designated use of a waterbody (as well as ensure protection of downstream uses) and must be based on sound scientific rationale. (See CWA section 303(c); 40 CFR 131.11). In Florida, EPA relied upon its published criteria development methodologies<sup>11</sup> and a substantial body of scientific analysis, documentation, and evaluation, much of it provided to EPA by FDEP. As discussed in more detail below, EPA believes that the final criteria in this rule meet requirements for designated use and downstream WQS protection under the CWA and that they are clearly based on sound and substantial data and analyses.

#### *B. Which water bodies are affected by this rule?*

The criteria in this final rulemaking apply to a group of inland waters of the United States within Florida. Specifically, as defined below, these criteria apply to lakes and springs throughout Florida, and flowing waters (e.g., rivers, streams, canals, etc.) located outside of the South Florida Region. For purposes of this rule, EPA has distinguished South Florida as those areas south of Lake Okeechobee and the Caloosahatchee River watershed to the west of Lake Okeechobee and the St. Lucie watershed to the east of Lake

Okeechobee, hereinafter referred to as the South Florida Region. In this section, EPA defines the water bodies affected by this rule with respect to the Clean Water Act, Florida Administrative Code, and geographic scope in Florida. Because this regulation applies to inland waters, EPA defines fresh water as it applies to the affected water bodies.

The CWA requires adoption of WQS for "navigable waters." CWA section 303(c)(2)(A). The CWA defines "navigable waters" to mean "the waters of the United States, including the territorial seas." CWA section 502(7). Whether a particular waterbody is a water of the United States is a waterbody-specific determination. Every waterbody that is a water of the United States requires WQS under the CWA. EPA is not aware of any waters of the United States in Florida that are currently exempted from the State's WQS. For any privately-owned water in Florida that is a water of the United States, the applicable numeric criteria for those types of waters would apply. This rule does not apply to waters for which the Miccosukee Tribe of Indians or Seminole Tribe of Indians has obtained Treatment in the Same Manner as a State status for Sections 303 and 401 of the CWA, pursuant to Section 518 of the CWA.

EPA's final rule defines "lakes and flowing waters" (a phrase that includes lakes, streams, and springs) to mean inland surface waters that have been classified as Class I (Potable Water Supplies) or Class III (Recreation, Propagation and Maintenance of a Healthy, Well-Balanced Population of Fish and Wildlife) water bodies pursuant to Section 62–302.400, F.A.C., which are predominantly fresh waters, excluding wetlands. Class I and Class III surface waters share water quality criteria established to "protect recreation and the propagation and maintenance of a healthy, well-balanced population of fish and wildlife" pursuant to Subsection 62–302.400(4), F.A.C.<sup>12</sup>

Geographically, the regulation applies to all lakes and springs throughout Florida. EPA is not finalizing numeric criteria for Florida's streams or canals in south Florida at this time. As noted

above, EPA has distinguished South Florida as those areas south of Lake Okeechobee and the Caloosahatchee River watershed to the west of Lake Okeechobee and the St. Lucie watershed to the east of Lake Okeechobee, hereinafter referred to as the South Florida Region. The Agency will propose criteria for south Florida flowing waters in conjunction with criteria for Florida's estuarine and coastal waters by November 14, 2011.

Consistent with Section 62–302.200, F.A.C., EPA's final rule defines "predominantly fresh waters" to mean surface waters in which the chloride concentration at the surface is less than 1,500 milligrams per liter (mg/L). Consistent with Section 62–302.200, F.A.C., EPA's final rule defines "surface water" to mean "water upon the surface of the earth, whether contained in bounds created naturally, artificially, or diffused. Water from natural springs shall be classified as surface water when it exits from the spring onto the earth's surface." In this rulemaking, EPA is promulgating numeric criteria for the following waterbody types: lakes, streams, and springs. EPA's final rule also includes definitions for each of these waters. "Lake" means a slow-moving or standing body of freshwater that occupies an inland basin that is not a stream, spring, or wetland. "Stream" means a free-flowing, predominantly fresh surface water in a defined channel, and includes rivers, creeks, branches, canals, freshwater sloughs, and other similar water bodies. "Spring" means a site at which ground water flows through a natural opening in the ground onto the land surface or into a body of surface water. Consistent with Section 62–312.020, F.A.C., "canal" means a trench, the bottom of which is normally covered by water with the upper edges of its two sides normally above water.

#### *C. What entities may be affected by this rule?*

Citizens concerned with water quality in Florida may be interested in this rulemaking. Entities discharging nitrogen or phosphorus to lakes and flowing waters of Florida could be indirectly affected by this rulemaking because WQS are used in determining National Pollutant Discharge Elimination System (NPDES) permit limits. Categories and entities that may ultimately be affected include:

<sup>11</sup> USEPA. 2000a. *Nutrient Criteria Technical Guidance Manual: Lakes and Reservoirs*. EPA-822-B-00-001. U.S. Environmental Protection Agency, Office of Water, Washington, DC. USEPA. 2000b. *Nutrient Criteria Technical Guidance Manual: Rivers and Streams*. EPA-822-B-00-002. U.S. Environmental Protection Agency, Office of Water, Washington, DC.

<sup>12</sup> Class I waters also include an applicable nitrate limit of 10 mg/L and nitrite limit of 1 mg/L for the protection of human health in drinking water supplies. The nitrate limit applies at the entry point to the distribution system (i.e., after any treatment); see Chapter 62–550, F.A.C., for additional details.

Category	Examples of potentially affected entities
Industry .....	Industries discharging pollutants to lakes and flowing waters in the State of Florida.
Municipalities .....	Publicly-owned treatment works discharging pollutants to lakes and flowing waters in the State of Florida.
Stormwater Management Districts ..	Entities responsible for managing stormwater runoff in Florida.

This table is not intended to be exhaustive, but rather provides a guide for entities that may be directly or indirectly affected by this action. This table lists the types of entities of which EPA is now aware that potentially could be affected by this action. Other types of entities not listed in the table, such as nonpoint source contributors to nitrogen/phosphorus pollution in Florida's waters may be affected through implementation of Florida's water quality standards program (*i.e.*, through Basin Management Action Plans (BMAPs)). Any parties or entities conducting activities within watersheds of the Florida waters covered by this rule, or who rely on, depend upon, influence, or contribute to the water quality of the lakes and flowing waters of Florida, may be affected by this rule. To determine whether your facility or activities may be affected by this action, you should carefully examine the language in 40 CFR 131.43, which is the final 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.

*D. How can I get copies of this document and other related information?*

1. *Docket.* EPA has established an official public docket for this action under Docket Id. No. EPA-HQ-OW-2009-0596. The official public docket consists of the document specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include CBI or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the OW Docket, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC 20004. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is 202-566-2426. A reasonable fee will be charged for copies.

2. *Electronic Access.* You may access this **Federal Register** document electronically through the EPA Internet under the "Federal Register" listings at <http://www.epa.gov/fedrgrstr/>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.regulations.gov> to view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. For additional information about EPA's public docket, visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the Docket Facility identified in Section I.C(1).

## II. Background

### A. Nitrogen/Phosphorus Pollution

#### 1. What is nitrogen/phosphorus pollution?

Excess loading of nitrogen and phosphorus compounds,<sup>13</sup> is one of the most prevalent causes of water quality impairment in the United States. Nitrogen/phosphorus pollution problems have been recognized for some time in the U.S., for example a 1969 report by the National Academy of Sciences<sup>14</sup> notes "[t]he pollution problem is critical because of increased population, industrial growth, intensification of agricultural production, river-basin development, recreational use of waters, and domestic and industrial exploitation of shore properties. Accelerated eutrophication causes changes in plant and animal life—changes that often interfere with use of water, detract from natural beauty, and reduce property values." Inputs of nitrogen and phosphorus lead to over-enrichment in many of the Nation's waters and constitute a

widespread, persistent, and growing problem. Nitrogen/phosphorus pollution in fresh water systems can significantly impact aquatic life and long-term ecosystem health, diversity, and balance. More specifically, high nitrogen and phosphorus loadings result in harmful algal blooms (HABs), reduced spawning grounds and nursery habitats, fish kills, and oxygen-starved hypoxic or "dead" zones. Public health concerns related to nitrogen/phosphorus pollution include impaired surface and groundwater drinking water sources from high levels of nitrates, possible formation of disinfection byproducts in drinking water, and increased exposure to toxic microbes such as cyanobacteria.<sup>15</sup> <sup>16</sup> Degradation of water bodies from nitrogen/phosphorus pollution can result in economic consequences. For example, given that fresh and salt water fishing in Florida are significant recreational and tourist attractions generating over six billion dollars annually,<sup>17</sup> changes in Florida's waters that degrade water quality to the point that sport fishing populations are affected, will also affect this important part of Florida's economy. Elevated nitrogen/phosphorus levels can occur locally in a stream or groundwater, or can accumulate much further downstream leading to degraded lakes, reservoirs, and estuaries where fish and aquatic life can no longer survive.

Excess nitrogen/phosphorus in water bodies comes from many sources, which can be grouped into five major categories: (1) Urban stormwater runoff—sources associated with urban land use and development, (2) municipal and industrial waste water discharges, (3) row crop agriculture, (4) livestock production, and (5) atmospheric deposition from the production of nitrogen oxides in electric

<sup>15</sup> Villanueva, C.M. *et al.*, 2006. Bladder Cancer and Exposure to Water Disinfection By-Products through Ingestion, Bathing, Showering, and Swimming in Pools. *American Journal of Epidemiology* 165(2):148–156.

<sup>16</sup> USEPA. 2009. *What is in Our Drinking Water?*. United States Environmental Protection Agency, Office of Research and Development. <http://www.epa.gov/extrmurl/research/process/drinkingwater.html>. Accessed December 2009.

<sup>17</sup> Florida Fish and Wildlife Conservation Commission. 2010. *The economic impact of freshwater fishing in Florida*. [http://www.myfwc.com/CONSERVATION/Conservation\\_Valueof\\_Conservation\\_EconFreshwaterImpactf.htm](http://www.myfwc.com/CONSERVATION/Conservation_Valueof_Conservation_EconFreshwaterImpactf.htm). Accessed August 2010.

<sup>13</sup> To be used by living organisms, nitrogen gas must be fixed into its reactive forms; for plants, either nitrate or ammonia (Boyd, C.E. 1979. *Water Quality in Warmwater Fish Ponds*. Auburn University: Alabama Agricultural Experiment Station, Auburn, AL). Eutrophication is defined as the natural or artificial addition of nitrogen/phosphorus to bodies of water and to the effects of added nitrogen/phosphorus (National Academy of Sciences (U.S.). 1969. *Eutrophication: Causes, Consequences, Correctives*. National Academy of Sciences, Washington, DC.)

<sup>14</sup> National Academy of Sciences (U.S.). 1969. *Eutrophication: Causes, Consequences, Correctives*. National Academy of Sciences, Washington, DC.

power generation and internal combustion engines. These sources contribute significant loadings of nitrogen and phosphorus to surface waters, causing major impacts to aquatic ecosystems and significant imbalances in the natural populations of flora and fauna.<sup>18 19</sup>

## 2. Adverse Impacts of Nitrogen/Phosphorus Pollution on Aquatic Life, Human Health, and the Economy

Fish, shellfish, and wildlife require clean water for survival. Changes in the environment resulting from elevated nitrogen/phosphorus levels (such as algal blooms, toxins from harmful algal blooms, and hypoxia/anoxia) can cause a variety of effects. The causal pathways that lead from human activities to excess nutrients to impacts on designated uses in lakes and streams are well established in the scientific literature (e.g., Streams: Stockner and Shortreed 1976, Stockner and Shortreed 1978, Elwood *et al.* 1981, Horner *et al.* 1983, Bothwell 1985, Peterson *et al.* 1985, Moss *et al.* 1989, Dodds and Gudder 1992, Rosemond *et al.* 1993, Bowling and Baker 1996, Bourassa and Cattaneo 1998, Francoeur 2001, Biggs 2000, Rosemond *et al.* 2001, Rosemond *et al.* 2002, Slavik *et al.* 2004, Cross *et al.* 2006, Mulholland and Webster 2010; Lakes: Vollenweider 1968, NAS 1969, Schindler *et al.* 1973, Schindler 1974, Vollenweider 1976, Carlson 1977, Paerl 1988, Elser *et al.* 1990, Smith *et al.* 1999, Downing *et al.* 2001, Smith *et al.* 2006, Elser *et al.* 2007).<sup>20</sup>

<sup>18</sup> National Research Council. 2000. *Clean coastal waters: Understanding and reducing the effects of nutrient pollution*. National Academies Press, Washington, DC; Howarth, R.W., A. Sharpley, and D. Walker. 2002. Sources of nutrient pollution to coastal waters in the United States: Implications for achieving coastal water quality goals. *Estuaries* 25(4b):656–676; Smith, V.H. 2003. Eutrophication of freshwater and coastal marine ecosystems. *Environmental Science and Pollution Research* 10(2):126–139; Dodds, W.K., W.W. Bouska, J.L. Eitzmann, T.J. Pilger, K.L. Pitts, A.J. Riley, J.T. Schloesser, and D.J. Thornbrugh. 2009. Eutrophication of U.S. freshwaters: Analysis of potential economic damages. *Environmental Science and Technology* 43(1):12–19.

<sup>19</sup> State-EPA Nutrient Innovations Task Group. 2009. *An Urgent Call to Action: Report of the State-EPA Nutrient Innovations Task Group*.

<sup>20</sup> For Streams:

Stockner, J.G., and K.R.S. Shortreed. 1976. Autotrophic production in Carnation Creek, a coastal rainforest stream on Vancouver Island, British Columbia. *Journal of the Fisheries Research Board of Canada* 33:1553–1563.

Stockner, J.G., and K.R.S. Shortreed. 1978. Enhancement of autotrophic production by nutrient addition in a coastal rainforest stream on Vancouver Island. *Journal of the Fisheries Research Board of Canada* 35:28–34.

Elwood, J.W., J.D. Newbold, A.F. Trimble, and R.W. Stark. 1981. The limiting role of phosphorus in a woodland stream ecosystem: effects of P

When excessive nitrogen/phosphorus loads change a waterbody's algae and plant species, the change in habitat and available food resources can induce changes affecting an entire food chain. Algal blooms block sunlight that submerged grasses need to grow, leading to a decline of submerged aquatic vegetation beds and decreased habitat for juvenile organisms. Algal blooms can also increase turbidity and impair the ability of fish and other aquatic life

enrichment on leaf decomposition and primary producers. *Ecology* 62:146–158.

Horner, R.R., E.B. Welch, and R.B. Veenstra. 1983. Development of nuisance periphytic algae in laboratory streams in relation to enrichment and velocity. Pages 121–134 in R.G. Wetzel (editor). *Periphyton of freshwater ecosystems*. Dr. W. Junk Publishers, The Hague, The Netherlands.

Bothwell, M.L. 1985. Phosphorus limitation of lotic periphyton growth rates: an intersite comparison using continuous-flow troughs (Thompson River system, British Columbia). *Limnology and Oceanography* 30:527–542.

Peterson, B.J., J.E. Hobbie, A.E. Hershey, M.A. Lock, T.E. Ford, J.R. Vestal, V.L. McKinley, M.A.J. Hullar, M.C. Miller, R.M. Ventullo, and G.S. Volk. 1985. Transformation of a tundra river from heterotrophy to autotrophy by addition of phosphorus. *Science* 229:1383–1386.

Moss, B., I. Hooker, H. Balls, and K. Manson. 1989. Phytoplankton distribution in a temperate floodplain lake and river system. I. Hydrology, nutrient sources and phytoplankton biomass. *Journal of Plankton Research* 11:813–835.

Dodds, W.K., and D.A. Gudder. 1992. The ecology of Cladophora. *Journal of Phycology* 28:415–427.

Rosemond, A. D., P. J. Mulholland, and J. W. Elwood. 1993. Top-down and bottom-up control of stream periphyton: Effects of nutrients and herbivores. *Ecology* 74:1264–1280.

Bowling, L.C., and P.D. Baker. 1996. Major cyanobacterial bloom in the Barwon-Darling River, Australia, in 1991, and underlying limnological conditions. *Marine and Freshwater Research* 47: 643–657.

Bourassa, N., and A. Cattaneo. 1998. Control of periphyton biomass in Laurentian streams (Quebec). *Journal of the North American Benthological Society* 17:420–429.

Francoeur, S.N. 2001. Meta-analysis of lotic nutrient amendment experiments: detecting and quantifying subtle responses. *Journal of the North American Benthological Society* 20:358–368.

Biggs, B.J.F. 2000. Eutrophication of streams and rivers: dissolved nutrient-chlorophyll relationships for Benthic algae. *Journal of the North American Benthological Society* 19:17–31.

Rosemond, A.D., C.M. Pringle, A. Ramirez, and M.J. Paul. 2001. A test of top-down and bottom-up control in a detritus-based food web. *Ecology* 82: 2279–2293.

Rosemond, A.D., C.M. Pringle, A. Ramirez, M.J. Paul, and J.L. Meyer. 2002. Landscape variation in phosphorus concentration and effects on detritus-based tropical streams. *Limnology and Oceanography* 47:278–289.

Slavik, K., B.J. Peterson, L.A. Deegan, W.B. Bowden, A.E. Hershey, and J.E. Hobbie. 2004. Long-term responses of the Kuparuk River ecosystem to phosphorus fertilization. *Ecology* 85:939–954.

Cross, W.F., J.B. Wallace, A.D. Rosemond, and S.L. Eggert. 2006. Whole-system nutrient enrichment increases secondary production in a detritus-based ecosystem. *Ecology* 87:1556–1565.

Mulholland, P.J. and J.R. Webster. 2010. Nutrient dynamics in streams and the role of J-NABS. *Journal of the North American Benthological Society* 29:100–117.

to find food.<sup>21</sup> Algae can also damage or clog the gills of fish and invertebrates.<sup>22</sup> Excessive algal blooms (those that use oxygen for respiration during periods without sunlight) can lead to diurnal shifts in a waterbody's production and consumption of dissolved oxygen (DO) resulting in reduced DO levels that are sufficiently low to harm or kill important recreational species such as largemouth bass.

Excessive algal growth also contributes to increased oxygen consumption associated with decomposition (e.g. decaying vegetative matter), in many instances reducing

For Lakes:

Vollenweider, R.A. 1968. *Scientific Fundamentals of the Eutrophication of Lakes and Flowing Waters, With Particular Reference to Nitrogen and Phosphorus as Factors in Eutrophication* (Tech Rep DAS/CS/68.27, OECD, Paris).

National Academy of Science. 1969. *Eutrophication: Causes, Consequences, Correctives*. National Academy of Science, Washington, DC.

Schindler D.W., H. Kling, R.V. Schmidt, J. Prokopowich, V.E. Frost, R.A. Reid, and M. Capel. 1973. Eutrophication of Lake 227 by addition of phosphate and nitrate: The second, third, and fourth years of enrichment 1970, 1971, and 1972. *Journal of the Fishery Research Board of Canada* 30:1415–1440.

Schindler D.W. 1974. Eutrophication and recovery in experimental lakes: Implications for lake management. *Science* 184:897–899.

Vollenweider, R.A. 1976. *Advances in Defining Critical Loading Levels for Phosphorus in Lake Eutrophication*. Memorie dell'Istituto Italiano di Idrobiologia 33:53–83.

Carlson R.E. 1977. A trophic State index for lakes. *Limnology and Oceanography* 22:361–369.

Paerl, H.W. 1988. Nuisance phytoplankton blooms in coastal, estuarine, and inland waters. *Limnology and Oceanography* 33:823–847.

Elser, J.J., E.R. Marzolf, and C.R. Goldman. 1990. Phosphorus and nitrogen limitation of phytoplankton growth in the freshwaters of North America: a review and critique of experimental enrichments. *Canadian Journal of Fisheries and Aquatic Science* 47:1468–1477.

Smith, V.H., G.D. Tilman, and J.C. Nekola. 1999. Eutrophication: impacts of excess nutrient inputs on freshwater, marine, and terrestrial ecosystems. *Environmental Pollution* 100:179–196.

Downing, J.A., S.B. Watson, and E. McCauley. 2001. Predicting cyanobacteria dominance in lakes. *Canadian Journal of Fisheries and Aquatic Sciences* 58:1905–1908.

Smith, V.H., S.B. Joye, and R.W. Howarth. 2006. Eutrophication of freshwater and marine ecosystems. *Limnology and Oceanography* 51:351–355.

Elser, J.J., M.E.S. Bracken, E.E. Cleland, D.S. Gruner, W.S. Harpole, H. Hillebrand, J.T. Ngai, E.W. Seabloom, J.B. Shurin, and J.E. Smith. 2007. Global analysis of nitrogen and phosphorus limitation of primary production in freshwater, marine, and terrestrial ecosystems. *Ecology Letters* 10:1135–1142.

<sup>21</sup> Hauxwell, J., C. Jacoby, T. Frazer, and J. Stevely. 2001. *Nutrients and Florida's Coastal Waters: Florida Sea Grant Report No. SGEB-55*. Florida Sea Grant College Program, University of Florida, Gainesville, FL.

<sup>22</sup> NOAA. 2009. Harmful Algal Blooms: Current Programs Overview. National Oceanic and Atmospheric Administration. <http://www.cop.noaa.gov/stressors/extremeevents/hab/default.aspx>. Accessed December 2009.

oxygen to levels below that needed for aquatic life to survive and flourish.<sup>23, 24</sup> Mobile species, such as adult fish, can sometimes survive by moving to areas with more oxygen. However, migration to avoid hypoxia depends on species mobility, availability of suitable habitat, and adequate environmental cues for migration. Less mobile or immobile species, such as mussels, cannot move to avoid low oxygen and are often killed during hypoxic events.<sup>25</sup> While certain mature aquatic animals can tolerate a range of dissolved oxygen levels that occur in the water, younger life stages of species like fish and shellfish often require higher levels of oxygen to survive.<sup>26</sup> Sustained low levels of dissolved oxygen cause a severe decrease in the amount of aquatic life in hypoxic zones and affect the ability of aquatic organisms to find necessary food and habitat.

In freshwater, HABs including, for example, blue-green algae from the phylum of bacteria called cyanobacteria,<sup>27</sup> can produce toxins that have been implicated as the cause of a number of fish and bird mortalities.<sup>28</sup> These toxins have also been tied to the death of pets and livestock that may be exposed through drinking contaminated water or grooming themselves after bodily exposure.<sup>29</sup> Many other States, and countries for that matter, are experiencing problems with algal

blooms.<sup>30</sup> Ohio on September 3, 2010,<sup>31</sup> for example, listed eight water bodies as “Bloom Advisory,”<sup>32</sup> six water bodies as “Toxin Advisory,”<sup>33</sup> and two waters as “No Contact Advisory.”<sup>34</sup> Species of cyanobacteria associated with freshwater algal blooms include: *Microcystis aeruginosa*, *Anabaena circinalis*, *Anabaena flos-aquae*, *Aphanizomenon flos-aquae*, and *Cylindrospermopsis raciborskii*. The toxins from cyanobacterial harmful algal blooms can produce neurotoxins (affect the nervous system), hepatotoxins (affect the liver), produce lipopolysaccharides that affect the gastrointestinal system, and some are tumor promoters.<sup>35</sup> A recent study showed that at least one type of cyanobacteria has been linked to cancer and tumor growth in animals.<sup>36</sup> Cyanobacteria toxins can also pass through normal drinking water treatment processes and pose an increased risk to humans or animals.<sup>37</sup>

Health and recreational use impacts to humans result directly from exposure to elevated nitrogen/phosphorus pollution levels and indirectly from the subsequent waterbody changes that occur from increased nitrogen/phosphorus pollution (such as algal blooms and toxins). Direct impacts include effects to human health through potentially contaminated drinking water. Indirect impacts include

restrictions on recreation (such as boating and swimming). Algal blooms can prevent opportunities to swim and engage in other types of recreation. In areas where recreation is determined to be unsafe because of algal blooms, warning signs are often posted to discourage human use of the waters.

Nitrate in drinking water can cause serious health problems for humans,<sup>38</sup> especially infants. EPA developed a Maximum Contaminant Level (MCL) of 10 mg/L for nitrate in drinking water.<sup>39</sup> In the 2010 USGS National Water-Quality Assessment Program report, nitrate was found to be the most frequently detected nutrient in streams at concentrations greater than 10 mg/L. The report also found that concentrations of nitrate greater than the MCL of 10 mg/L were more prevalent and widespread in groundwater used for drinking water than in streams.<sup>40</sup> Florida has adopted EPA's recommendations for the nitrate MCL in Florida's regulated drinking water systems and a 10 mg/L criteria for nitrate in Class I waters. FDEP shares EPA's concern regarding blue-baby syndrome as can be seen in information FDEP reports on its drinking water information for the public: “Nitrate is used in fertilizer and is found in sewage and wastes from human and/or farm animals and generally gets into drinking water from those activities. Excessive levels of nitrate in drinking water have caused serious illness and sometimes death in infants less than six months of age<sup>41</sup> \* \* \* EPA has set the drinking water standard at 10 parts per million (ppm) [or 10 mg/L] for nitrate to protect

<sup>23</sup> NOAA. 2009. Harmful Algal Blooms: Current Programs Overview. National Oceanic and Atmospheric Administration. <http://www.cop.noaa.gov/stressors/extremeevents/hab/default.aspx>. Accessed December 2009.

<sup>24</sup> USGS. 2009. Hypoxia. U.S. Geological Survey. <http://toxics.usgs.gov/definitions/hypoxia.html>. Accessed December 2009.

<sup>25</sup> ESA. 2009. Hypoxia. Ecological Society of America. [http://www.esa.org/education\\_diversity/pdfDocs/hypoxia.pdf](http://www.esa.org/education_diversity/pdfDocs/hypoxia.pdf). Accessed December 2009.

<sup>26</sup> USEPA. 1986. *Ambient Water Quality Criteria for Dissolved Oxygen Freshwater Aquatic Life*. EPA-800-R-80-906. Environmental Protection Agency, Office of Water, Washington DC.

<sup>27</sup> CDC. 2010. *Facts about cyanobacteria and cyanobacterial harmful algal blooms. Centers for Disease Control and Prevention*. <http://www.cdc.gov/hab/cyanobacteria/facts.htm>. Accessed August 2010.

<sup>28</sup> Ibelings, Bas W. and Karl E. Havens. 2008. *Chapter 32: Cyanobacterial toxins: a qualitative meta-analysis of concentrations, dosage and effects in freshwater, estuarine and marine biota. In Cyanobacterial Harmful Algal Blooms: State of the Science and Research Needs. From the Monograph of the September 6-10, 2005 International Symposium on Cyanobacterial Harmful Algal Blooms (ISOC-HAB) in Durham, NC*. [http://www.epa.gov/cyano\\_habs\\_symposium/monograph/Ch32.pdf](http://www.epa.gov/cyano_habs_symposium/monograph/Ch32.pdf). Accessed August 19, 2010.

<sup>29</sup> WHOI. 2008. *HAB Impacts on Wildlife*. Woods Hole Oceanographic Institution. <http://www.whoi.edu/redtide/page.do?pid=9682>. Accessed December 2009.

<sup>30</sup> FDEP. 2010. Blue Green Algae Frequently Asked Questions. <http://www.dep.state.fl.us/water/bgalgae/faq.htm>. Accessed August 2010.

<sup>31</sup> Ohio DNR. 2010. News Release September 3, 2010. <http://www.epa.state.oh.us/portals/47/nr/2010/september/9-3samplingresults.pdf>. Accessed September 2010.

<sup>32</sup> Defined as: Cautionary advisory to avoid contact with any algae. Ohio DNR. 2010. News Release September 3, 2010. <http://www.epa.state.oh.us/portals/47/nr/2010/september/9-3samplingresults.pdf>. Accessed September 2010.

<sup>33</sup> Defined as: Avoid contact with any algae and direct contact with water. Ohio DNR. 2010. News Release September 3, 2010. <http://www.epa.state.oh.us/portals/47/nr/2010/september/9-3samplingresults.pdf>. Accessed September 2010.

<sup>34</sup> Defined as: Avoid any and all contact with or ingestion of the lake water. This includes the launching of any watercraft on the lake. Ohio DNR. 2010. News Release September 3, 2010. <http://www.epa.state.oh.us/portals/47/nr/2010/september/9-3samplingresults.pdf>. Accessed September 2010.

<sup>35</sup> CDC. 2010. Facts about cyanobacteria and cyanobacterial harmful algal blooms, Centers for Disease Control and Prevention. <http://www.cdc.gov/hab/cyanobacteria/facts.htm>. Accessed August 2010.

<sup>36</sup> Falconer, I.R., and A.R. Humpage. 2005. Health Risk Assessment of Cyanobacterial (Blue-green Algal) Toxins in Drinking Water. *International Journal of Research and Public Health* 2(1): 43-50.

<sup>37</sup> Carmichael, W.W. 2000. *Assessment of Blue-Green Algal Toxins in Raw and Finished Drinking Water*. AWWA Research Foundation, Denver, CO.

<sup>38</sup> For more information, refer to Manassaram, Deana M., Lorraine C. Backer, and Deborah M. Moll. 2006. *A Review of Nitrates in Drinking Water: Maternal Exposure and Adverse Reproductive and Developmental Outcomes*. Environmental Health Perspect. 114(3): 320-327.

<sup>39</sup> USEPA. 2007. *Nitrates and Nitrites: TEACH Chemical Summary*. U.S. Environmental Protection Agency. [http://www.epa.gov/teach/chem\\_summ/Nitrates\\_summary.pdf](http://www.epa.gov/teach/chem_summ/Nitrates_summary.pdf). Accessed December 2009.

<sup>40</sup> Dubrovsky, N.M., Burow, K.R., Clark, G.M., Gronberg, J.M., Hamilton P.A., Hitt, K.J., Mueller, D.K., Munn, M.D., Nolan, B.T., Puckett, L.J., Rupert, M.G., Short, T.M., Spahr, N.E., Sprague, L.A., and Wilber, W.G. 2010. *The quality of our Nation's waters—Nutrients in the Nation's streams and groundwater, 1992-2004*: U.S. Geological Survey Circular 1350, 174p. Available electronically at: <http://water.usgs.gov/nawqa/nutrients/pubs/circ1350>.

<sup>41</sup> The serious illness in infants is caused because nitrate is converted to nitrite in the body. Nitrite interferes with the oxygen carrying capacity of the child's blood. This is an acute disease in that symptoms can develop rapidly in infants. In most cases, health deteriorates over a period of days. Symptoms include shortness of breath and blueness of the skin. (source: FDEP. 2010. Drinking Water: Inorganic Contaminants. Florida Department of Environmental Protection. [http://www.dep.state.fl.us/water/drinkingwater/inorg\\_con.htm](http://www.dep.state.fl.us/water/drinkingwater/inorg_con.htm). Accessed September 2010.)



against the risk of these adverse effects.<sup>42</sup> \* \* \* Drinking water that meets the EPA standard is associated with little to none of this risk and is considered safe with respect to nitrate.<sup>43</sup>

Human health can also be impacted by disinfection byproducts formed when disinfectants (such as chlorine) used to treat drinking water react with organic carbon (from the algae in source waters). Some disinfection byproducts have been linked to rectal, bladder, and colon cancers; reproductive health risks; and liver, kidney, and central nervous system problems.<sup>44 45</sup>

Economic losses from algal blooms and harmful algal blooms can include increased costs for drinking water treatment, reduced property values for streams and lakefront areas, commercial fishery losses, and lost revenue from recreational fishing, boating trips, and other tourism-related businesses.

In terms of increased costs for drinking water treatment, for example, in 1991, Des Moines (Iowa) Water Works constructed a \$4 million ion exchange facility to remove nitrate from its drinking water supply. This facility was designed to be used an average of 35–40 days per year to remove excess nitrate levels at a cost of nearly \$3000 per day.<sup>46</sup>

Fremont, Ohio (a city of approximately 20,000) has experienced high levels of nitrate from its source, the Sandusky River, resulting in numerous drinking water use advisories. An estimated \$15 million will be needed to build a reservoir (and associated piping) that will allow for selective withdrawal from the river to avoid elevated levels

of nitrate, as well as to provide storage.<sup>47</sup>

In regulating allowable levels of chlorophyll *a* in Oklahoma drinking water reservoirs, the Oklahoma Water Resources Board estimated that the long-term cost savings in drinking water treatment for 86 systems would range between \$106 million and \$615 million if such regulations were implemented.<sup>48</sup>

### 3. Nitrogen/Phosphorus Pollution in Florida

Florida's flat topography causes water to move slowly over the landscape, allowing ample opportunity for nitrogen and phosphorus to dissolve and eutrophication responses to develop. Florida's warm and wet, yet sunny, climate further contributes to increased run-off and ideal temperatures for subsequent eutrophication responses.<sup>49</sup>

As outlined in the EPA January 2009 determination and the January 2010 proposal, water quality degradation resulting from excess nitrogen and phosphorus loadings is a documented and significant environmental issue in Florida. FDEP notes in its *2008 Integrated Water Quality Assessment* that nutrient pollution poses several challenges in Florida. For example, the FDEP *2008 Integrated Water Quality Assessment* notes: "the close connection between surface and ground water, in combination with the pressures of continued population growth, accompanying development, and extensive agricultural operations, present Florida with a unique set of challenges for managing both water quality and quantity in the future. After trending downward for 20 years, beginning in 2000 phosphorus levels again began moving upward, likely due to the cumulative impacts of nonpoint source pollution associated with increased population and development. Increasing pollution from urban stormwater and agricultural activities is having other significant effects. In many springs across the State, for example, nitrate levels have increased dramatically (twofold to threefold) over the past 20 years, reflecting the close link between surface and ground water."<sup>50</sup> To clarify current nitrogen/

phosphorus pollution conditions in Florida, EPA analyzed recent STORET data pulled from Florida's Impaired Waters Rule (IWR),<sup>51</sup> (which are the data Florida uses to create its integrated reports) and found increasing levels of nitrogen and phosphorus compounds in Florida waters over the past 12 years (1996–2008). Florida's IWR STORET data indicates that levels of total nitrogen have increased from a State-wide average of 1.06 mg/L in 1996 to 1.27 mg/L in 2008 and total phosphorus levels have increased from an average of 0.108 mg/L in 1996 to 0.151 mg/L in 2008.

The combination of the factors reported by FDEP and listed above (including population increase, climate, stormwater runoff, agriculture, and topography) has contributed to significant nitrogen/phosphorus effects to Florida's waters.<sup>52</sup> For example, newspapers in Florida regularly report about impacts associated with nitrogen/phosphorus pollution; recent examples include reports of algal blooms and fish kills in the St Johns River<sup>53</sup> and reports of white foam associated with algal blooms lining parts of the St. Johns River.<sup>54</sup> Spring releases of water from Lake Okeechobee into the St Lucie Canal, necessitated by high lake levels due to rainfall, resulted in reports of floating mats of toxic *Microcystis aeruginosa* that prompted Martin and St Lucie county health departments to issue warnings to the public.<sup>55</sup>

The *2008 Integrated Water Quality Assessment* lists nutrients as the fourth major source of impairment for rivers and streams in Florida (after dissolved oxygen, mercury in fish, and fecal coliforms). For lakes and estuaries, nutrients are ranked first and second, respectively. These same rankings are also confirmed in FDEP's latest *2010 Integrated Water Quality Assessment*.

<sup>51</sup> IWR Run 40. Updated through February 2010.

<sup>52</sup> FDEP. 2008. *Integrated Water Quality Assessment for Florida: 2008 305(b) Report and 303(d) List Update*.

<sup>53</sup> Patterson, S. 2010, July 23. *St John's River Looks Sick*. Florida Times Union. <http://jacksonville.com/news/metro/2010-07-23/story/st-johns-looks-sick-nelson-says>. Accessed September 2010.

<sup>54</sup> Patterson, S. 2010, July 21. *Foam on St. John's River Churns Up Environmental Interest*. Florida Times Union. <http://jacksonville.com/news/metro/2010-07-21/story/foam-st-johns-churns-environmental-questions>. Accessed October 2010.

<sup>55</sup> Killer, E. 2010, June 10. *Blue-green Algae Found Floating Near Palm City as Lake Okeechobee Releases Continue*. Treasure Coast Times. <http://www.tcpalm.com/news/2010/jun/10/blue-green-algae-found-floating-near-palm-city-of>. Accessed October 2010.

<sup>42</sup> EPA has also set a drinking water standard for nitrate at 1 mg/L. To allow for the fact that the toxicity of nitrate and nitrite are additive, EPA has also established a standard for the sum of nitrate and nitrite at 10 mg/L. (source: FDEP. 2010. *Drinking Water: Inorganic Contaminants*. Florida Department of Environmental Protection. [http://www.dep.state.fl.us/water/drinkingwater/inorg\\_con.htm](http://www.dep.state.fl.us/water/drinkingwater/inorg_con.htm). Accessed September 2010.)

<sup>43</sup> FDEP. 2010. *Drinking Water: Inorganic Contaminants*. Florida Department of Environmental Protection. [http://www.dep.state.fl.us/water/drinkingwater/inorg\\_con.htm](http://www.dep.state.fl.us/water/drinkingwater/inorg_con.htm). Accessed September 2010.

<sup>44</sup> USEPA. 2009. *National Primary Drinking Water Regulations*. Contaminants. U.S. Environmental Protection Agency. Accessed <http://www.epa.gov/safewater/hfacts.html>. December 2009.

<sup>45</sup> National Primary Drinking Water Regulations: Stage 2 Disinfectants and Disinfection Byproducts Rule, 40 CFR parts 9, 141, and 142. U.S. Environmental Protection Agency, FR 71:2 (January 4, 2006), pp. 387–493. Available electronically at: <http://www.epa.gov/fedrgstr/EPA-WATER/2006/January/Day-04/w03.htm>. Accessed December 2009.

<sup>46</sup> Jones, C.S., D. Hill, and G. Brand. 2007. Use a multifaceted approach to manage high sourcewater nitrate. *Opflow* June pp. 20–22.

<sup>47</sup> Taft, Jim. Association of State Drinking Water Administrators (ASDWA). 2009. Personal Communication.

<sup>48</sup> Moershel, Philip, Oklahoma Water Resources Board (OWRB) and Mark Derischweiler, Oklahoma Department of Environmental Quality (ODEQ). 2009. Personal Communication.

<sup>49</sup> Perry, W. B. 2008. Everglades restoration and water quality challenges in south Florida. *Ecotoxicology* 17:569–578.

<sup>50</sup> FDEP. 2008. *Integrated Water Quality Assessment for Florida: 2008 305(b) Report and 303(d) List Update*.



According to FDEP's 2008 *Integrated Water Quality Assessment*,<sup>56</sup> approximately 1,049 miles of rivers and streams, 349,248 acres of lakes, and 902 square miles of estuaries are impaired by nutrients in the State. To put this in context and as noted above, approximately 5% of the total assessed river and stream miles, 23% of the total assessed lake acres, and 24% of the total assessed square miles of estuaries are impaired for nutrients according to the 2008 Integrated Report.<sup>57</sup> In recent published listings of impairments for 2010, Florida Department of Environmental Protection lists nutrient impairments in 1,918 stream miles (about 8% of the total assessed stream miles), 378,435 lake acres (about 26% of total assessed lake acres), and 569 square miles of estuaries (about 21% of total assessed estuarine square miles).<sup>58</sup>

Compared to FDEP's 2008 *Integrated Water Quality Assessment*, the 2010 *Integrated Water Quality Assessment* shows an increase in nutrient impairments for rivers and streams (from approximately 1000 miles to 1918 miles) and lakes (from approximately 350,000 lake acres to 378,435 lake acres). While the square miles of estuaries identified as impaired by nutrients decreased from 2008 to 2010 (from approximately 900 to 569 square miles), the 2010 *Integrated Water Quality Assessment* notes that all square miles of estuaries in the report were decreased based on improved GIS techniques and corrected waterbody descriptions.<sup>59</sup> Consequently, the decrease in estuarine square miles identified as impaired by nutrients in 2010 does not necessarily reflect a corresponding decrease in nitrogen/phosphorus pollution affecting Florida's estuarine water bodies.

FDEP has expressed concern about nitrogen/phosphorus pollution in Florida surface waters,<sup>60</sup> in addition to

concerns about freshwater harmful algal blooms and the potential for adverse human health impacts as noted in FDEP's 2008 *Integrated Water Quality Assessment*.<sup>61</sup> This concern is underscored by a toxic blue-green algae bloom that occurred north of the Franklin Lock on the Caloosahatchee River in mid-June 2008. The Olga Water Treatment Plant, which obtains its source water from the Caloosahatchee and provides drinking water for 30,000 people, was forced to temporarily shut down as a result of this bloom.<sup>62</sup>

There has also been an increase in the level of pollutants, especially nitrate, in groundwater over the past decades.<sup>63</sup> The Florida Geological Survey concluded that "The presence of nitrate and the other nitrogenous compounds in ground water, is not considered in Florida to be a result of interaction of aquifer system water with surrounding rock materials. Nitrate in ground water is a result of specific land uses."<sup>64</sup>

Historically, nitrate+nitrite concentrations in Florida's spring discharges were estimated to have been around 0.05 mg/L or less, which is sufficiently low to restrict growth of algae and vegetation under "natural" conditions.<sup>65</sup> Of 125 spring vents sampled by the Florida Geological Survey in 2001–2002, 42% had nitrate+nitrite concentrations exceeding 0.50 mg/L and 24% had concentrations greater than 1.0 mg/L.<sup>66</sup> In the same

Quality Assessment for Florida: 2010 305(b) Report and 303(d) List Update.

<sup>61</sup> "Freshwater harmful algal blooms (HABs) are increasing in frequency, duration, and magnitude and therefore may be a significant threat to surface drinking water resources and recreational areas. Abundant populations of blue-green algae, some of them potentially toxigenic, have been found statewide in numerous lakes and rivers. In addition, measured concentrations of cyanotoxins—a few of them of above the suggested guideline levels—have been reported in finished water from some drinking water facilities." FDEP. 2008. *Integrated Water Quality Assessment for Florida: 2008 305(b) Report and 303(d) List Update*.

<sup>62</sup> Peltier, M. 2008. *Group files suit to enforce EPA water standards*. Naples News. [http://news.caloosahatchee.org/docs/NaplesNews\\_080717.htm](http://news.caloosahatchee.org/docs/NaplesNews_080717.htm). Accessed August 2010.

<sup>63</sup> Scott, T.M., G.H. Means, R.P. Meegan, R.C. Means, S.B. Upchurch, R.E. Copeland, J. Jones, T. Roberts, and A. Willet. 2004. *Springs of Florida*. Bulletin No. 66. Florida Geological Survey, Tallahassee, FL. 677 pp.

<sup>64</sup> FL Geological Survey. 1992. *Special Publication No. 34. Florida's Ground Water Quality Monitoring Program*, (nitrate-pp 36–6).

<sup>65</sup> Maddox, G.L., J.M. Lloyd, T.M. Scott, S.B. Upchurch and R. Copeland. 1992. *Florida's Groundwater Quality Monitoring Program—Background Hydrochemistry*. Florida Geological Survey Special Publication No. 34, Tallahassee, FL.

<sup>66</sup> Scott, T.M., G.H. Means, R.P. Meegan, R.C. Means, S.B. Upchurch, R.E. Copeland, J. Jones, T. Roberts, and A. Willet. 2004. *Springs of Florida*. Bulletin No. 66. Florida Geological Survey, Tallahassee, FL. 677 pp.

study, mean nitrate+nitrite levels in 13 first-order springs were observed to have increased from 0.05 mg/L to 0.9 mg/L between 1970 and 2002. Overall, data suggest that nitrate+nitrite concentrations in many spring discharges have increased by an order of magnitude or a factor of 10 over the past 50 years, with the level of increase closely correlated with anthropogenic activity and land use changes within the karst regions of Florida where springs most often occur.<sup>67</sup>

Nitrates are found in ground water and wells in Florida, ranging from the detection limit of 0.02 mg/L to over 20 mg/L. Monitoring of Florida Public Water Supplies from 2004–2009 indicates that exceedances of nitrate maximum contaminant levels (MCL) (which are measured at the entry point of the distribution system and represent treated drinking water from a supplier) reported by drinking water plants in Florida ranged from 34–40 annually, during this period.<sup>68</sup>

About 10% of Florida residents receive their drinking water from a private well or small public source not inventoried under public supply.<sup>69</sup> A study in the late 1980s conducted by Florida Department of Agriculture and Consumer Services (FDACS) and FDEP, analyzed 3,949 shallow drinking water wells for nitrate.<sup>70 71</sup> Nitrate was detected in 2,483 (63%) wells, with 584 wells (15%) above the MCL of 10 mg/L. Of the 584 wells that exceeded the MCL, 519 were located in Lake, Polk,

<sup>67</sup> Katz, B.G., H.D. Hornsby, J.F. Bohlke and M.F. Mokray. 1999. *Sources and chronology of nitrate contamination in spring water, Suwannee River Basin, Florida*. Water-Resources Investigations Report 99–4252. U.S. Geological Survey, Tallahassee, FL. Available electronically at: [http://fl.water.usgs.gov/PDF\\_files/wri99\\_4252\\_katz.pdf](http://fl.water.usgs.gov/PDF_files/wri99_4252_katz.pdf).

Scott, T.M., G.H. Means, R.P. Meegan, R.C. Means, S.B. Upchurch, R.E. Copeland, J. Jones, T. Roberts, and A. Willet. 2004. *Springs of Florida*. Bulletin No. 66. Florida Geological Survey, Tallahassee, FL. 677 pp.

<sup>68</sup> FDEP. 2009. *Chemical Data for 2004, 2005, 2006, 2007 2008, and 2009*. Florida Department of Environmental Protection. <http://www.dep.state.fl.us/water/drinkingwater/chemdata.htm>. Accessed January 2010.

<sup>69</sup> Marella, R.L. 2009. *Water Withdrawals, Use, and Trends in Florida, 2005*. Scientific Investigations Report 2009–5125. U.S. Geological Survey, Reston, VA.

<sup>70</sup> Southern Regional Water Program. 2010. *Drinking Water and Human Health in Florida*. <http://srwqis.tamu.edu/florida/program-information/florida-target-themes/drinking-water-and-human-health.aspx>. Accessed January 2010.

<sup>71</sup> T.A. Obreza and K.T. Morgan. 2008. *Nutrition of Florida Citrus Trees* 15 months after publication of the final rule, except for the Federal site-specific alternative criteria (SSAC) procedure in section 131.43(e) of the rule which will go into effect 60 days after publication. 2nd ed. SL 253. University of Florida, IFAS Extension. <http://edis.ifas.ufl.edu/pdf/FILES/SS/SS47800.pdf>. Accessed September 2010.

<sup>56</sup> FDEP. 2008. *Integrated Water Quality Assessment for Florida: 2008 305(b) Report and 303(d) List Update*.

<sup>57</sup> FDEP. 2008. *Integrated Water Quality Assessment for Florida: 2008 305(b) Report and 303(d) List Update*.

<sup>58</sup> FDEP. 2010. *Integrated Water Quality Assessment for Florida: 2010 305(b) Report and 303(d) List Update*.

<sup>59</sup> FDEP. 2010. *Integrated Water Quality Assessment for Florida: 2010 305(b) Report and 303(d) List Update*.

<sup>60</sup> "While significant progress has been made in reducing nutrient loads from point sources and from new development, nutrient loading and the resulting harmful algal blooms continue to be an issue. The occurrence of blue-green algae is natural and has occurred throughout history; however, algal blooms caused by nutrient loading from fertilizer use, together with a growing population and the resulting increase in residential landscapes, are an ongoing concern." FDEP. 2010. *Integrated Water*

and Highland counties located in Central Florida. Results of monitoring conducted between 1999 and 2003 in a network of wells in that area indicated that of the 31 monitoring wells, 90% exceeded the nitrate drinking-water standard of 10 mg/L one or more times.<sup>72</sup> FDEP monitored this same area (the VISA monitoring network) in 1990, 1993, and 1996, analyzing samples from 15–17 wells each cycle and reported median concentrations ranging from 17 to 20 mg/L nitrate, depending on the year.<sup>74</sup> Some areas of Florida tend to be more susceptible to groundwater impacts from nitrogen pollution, especially those that have sandy soils, have high hydraulic conductivity, and have overlying land uses that are subject to applications of fertilizers and animal or human wastes.<sup>75</sup> For example, USGS reports that in Highland county, highly developed suburban and agricultural areas tend to have levels of nitrates in the surficial groundwater that approach and can exceed the State primary drinking water standard of 10 mg/L for public water systems. Other areas in Highland county that are less developed tend to have much lower levels of nitrates in the surficial groundwater, often below detection levels.

The Floridian aquifer system is one of the largest sources of ground water in the U.S., and serves as a primary source of drinking water in Northern Florida. The Upper Floridian aquifer is unconfined or semiconfined in areas in Northern Florida, but is also confined by the overlying surficial aquifer system which is used for water supply. Wells in unconfined areas of the Upper Floridian aquifer tested in northern Florida had nitrate levels higher than 1 mg/L in 40% of wells; 17% of samples from the semiconfined area had nitrate levels above 1 mg/L. In both aquifer systems this indicates the widespread impact of nitrate on groundwater quality

<sup>72</sup> T.A. Obreza and K.T. Morgan. 2008. *Nutrition of Florida Citrus Trees*. 2nd ed. SL 253. University of Florida, IFAS Extension. <http://edis.ifas.ufl.edu/pdf/SS/SS47800.pdf>. Accessed September 2010.

<sup>73</sup> USGS. 2009, November. *Overview of Agricultural Chemicals: Pesticides and Nitrate*. [http://fl.water.usgs.gov/Lake\\_Wales\\_Ridge/html/overview\\_of\\_agrichemicals.html](http://fl.water.usgs.gov/Lake_Wales_Ridge/html/overview_of_agrichemicals.html). Accessed September 2010.

<sup>74</sup> FDEP. 1998. *Ground Water Quality and Agricultural Land Use in the Polk County Very Intense Study Area (VISA)*. Florida Department of Environmental Protection, Division of Water Facilities. <http://www.dep.state.fl.us/water/monitoring/docs/facts/fs9802.pdf>. Accessed September 2010.

<sup>75</sup> USGS. 2010. *Hydrogeology and Groundwater Quality of Highlands County, FL*. Scientific Investigations Report 2010–5097. U.S. Geological Survey, Reston, VA.

in this area.<sup>76</sup> This baseline sampling indicates a pattern of widespread nitrate occurrence in the Upper Floridian aquifer from two decades ago. A portion of these early samples exceeded 10 mg/L nitrate (25 of the 726 samples taken from this unconfined or semi-confined aquifer; 50 of the 421 water samples from the surficial aquifer).

Growing population trends in Florida contribute to the significant challenge of addressing nitrogen/phosphorus pollution in Florida. Historically, the State has experienced a rapidly expanding population. Significantly growing demographics are considered to be a strong predictor of nitrogen/phosphorus loading and associated effects because of increases in stormwater runoff from increased impervious surfaces and increased wastewater treatment flows both of which typically contain some level of nitrogen/phosphorus.<sup>78</sup> Florida is currently the fourth most populous State in the nation, with an estimated 18 million people.<sup>79</sup> The U.S. Census bureau predicts the Florida population will exceed 28 million people by 2030, making Florida the third most populous State in the U.S.<sup>80</sup>

#### B. Statutory and Regulatory Background

Section 303(c) of the CWA (33 U.S.C. 1313(c)) directs States to adopt WQS for their navigable waters. Section 303(c)(2)(A) and EPA's implementing regulations at 40 CFR part 131 require, among other things, that State WQS include the designated use or uses to be made of the waters and criteria that protect those uses. EPA regulations at 40 CFR 131.11(a)(1) provide that States shall "adopt those water quality criteria that protect the designated use" and that such criteria "must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use." As noted

<sup>76</sup> Berndt, M.P., 1996. *Ground-water quality assessment of the Georgia-Florida Coastal Plain study unit—Analysis of available information on nutrients, 1972–92*. Water-Resources Investigations Report 95–4039. U.S. Geological Survey, Tallahassee, FL.

<sup>77</sup> Berndt, Marian P., 1993. *National Water-Quality Assessment Program—Preliminary assessment of nitrate distribution in ground water in the Georgia-Florida Coastal Plain Study Unit, 1972–90*. Open-File Report 93–478. U.S. Geological Survey.

<sup>78</sup> National Research Council, Committee on Reducing Stormwater Discharge Contributions to Water Pollution. 2008. *Urban Stormwater Management in the United States*. National Academies Press, Washington, DC.

<sup>79</sup> U.S. Census Bureau. 2009. 2008 Population Estimates Ranked by State. <http://factfinder.census.gov>. Accessed January 2010.

<sup>80</sup> U.S. Census Bureau. 2009. 2008 Population Estimates Ranked by State. <http://factfinder.census.gov>. Accessed January 2010.

above, 40 CFR 130.10(b) provides that "[i]n designating uses of a waterbody and the appropriate criteria for those uses, the State shall take into consideration the water quality standards of downstream waters and ensure that its water quality standards provide for the attainment and maintenance of the water quality standards of downstream waters."

States are also required to review their WQS at least once every three years and, if appropriate, revise or adopt new standards. (See CWA section 303(c)(1)). Any new or revised WQS must be submitted to EPA for review and approval or disapproval. (See CWA section 303(c)(2)(A)). Finally, CWA section 303(c)(4)(B) authorizes the Administrator to determine, even in the absence of a State submission, that a new or revised standard is needed to meet CWA requirements. The criteria finalized in this rulemaking translate Florida's narrative nutrient provision at Subsection 62–302–530(47)(b), F.A.C., into numeric values that apply to lakes and springs throughout Florida and flowing waters outside of the South Florida Region.<sup>81</sup>

#### C. Water Quality Criteria

Under CWA section 304(a), EPA periodically publishes criteria recommendations (guidance) for use by States in setting water quality criteria for particular parameters to protect recreational and aquatic life uses of waters. Where EPA has published recommended criteria, States have the option of adopting water quality criteria based on EPA's CWA section 304(a) criteria guidance, section 304(a) criteria guidance modified to reflect site-specific conditions, or other scientifically defensible methods. (See 40 CFR 131.11(b)(1)). For nitrogen/phosphorus pollution, EPA has published under CWA section 304(a) a series of peer-reviewed, national technical approaches and methods regarding the development of numeric criteria for lakes and reservoirs,<sup>82</sup> rivers and streams,<sup>83</sup> and estuaries and coastal marine waters.<sup>84</sup>

<sup>81</sup> The criteria finalized in this rulemaking do not address or translate Florida's narrative nutrient provision at Subsection 62–302.530(47)(a), F.A.C. Subsection 62–302.530(47)(a), F.A.C., remains in place as an applicable WQS for CWA purposes.

<sup>82</sup> USEPA. 2000a. *Nutrient Criteria Technical Guidance Manual: Lakes and Reservoirs*. EPA–822–B–00–001. U.S. Environmental Protection Agency, Office of Water, Washington, DC.

<sup>83</sup> USEPA. 2000b. *Nutrient Criteria Technical Guidance Manual: Rivers and Streams*. EPA–822–B–00–002. U.S. Environmental Protection Agency, Office of Water, Washington, DC.

<sup>84</sup> USEPA. 2001. *Nutrient Criteria Technical Manual: Estuarine and Coastal Marine Waters*.

EPA based the methodologies used to develop numeric criteria for Florida in this regulation on its published guidance on developing criteria that identifies three general approaches for criteria setting. The three types of empirical analyses provide distinctly different, independently and scientifically defensible, approaches for deriving nutrient criteria from field data: (1) Reference condition approach derives candidate criteria from observations collected in reference waterbodies, (2) mechanistic modeling approach represents ecological systems using equations that represent ecological processes and parameters for these equations that can be calibrated empirically from site-specific data, and (3) empirical nutrient stressor-response modeling is used when data are available to accurately estimate a relationship between nutrient concentrations and a response measure that is directly or indirectly related to a designated use of the waterbody (e.g., a biological index or recreational use measure). Then, nutrient concentrations that are protective of designated uses can be derived from the estimated relationship).<sup>85</sup> Each of these three analytical approaches is appropriate for deriving scientifically defensible numeric nutrient criteria when applied with consideration of method-specific data needs and available data. In addition to these empirical approaches, consideration of established (e.g., published) nutrient response thresholds is also an acceptable approach for deriving criteria.<sup>86</sup>

For lakes, EPA used a stressor-response approach to link nitrogen/phosphorus concentrations to predictions of corresponding chlorophyll *a* concentrations. EPA used a reference-based approach for streams, relying on a comprehensive screening methodology to identify least-disturbed

streams as reference streams. For springs, EPA used algal or nitrogen/phosphorus thresholds developed under laboratory conditions and stressor-response relationships from several field studies of algal growth in springs. For each type of waterbody, EPA carefully considered the available data and evaluated several lines of evidence to derive scientifically sound approaches (as noted above) for developing the final numeric criteria.

Based on comments received from the Scientific Advisory Board (SAB), EPA has modified a draft methodology guidance document on using stressor-response relationships for deriving numeric criteria, which is available as a final technical guidance document.<sup>87</sup> In addition, the reference-based and algal or nitrogen/phosphorus threshold approaches have been peer reviewed and have been available for many years.

As mentioned above, the criteria finalized in this rulemaking translate Florida's narrative nutrient provision at Subsection 62–302.530(47)(b), F.A.C., (“[i]n no case shall nutrient concentrations of a body of water be altered so as to cause an imbalance in natural populations of aquatic flora or fauna”) into numeric values that apply to lakes and springs throughout the State and flowing waters outside of the South Florida Region. EPA believes that numeric criteria will expedite and facilitate the effective implementation of Florida's existing point and non-point source water quality programs in terms of timely water quality assessments, TMDL development, NPDES permit issuance and, where needed, Basin Management Action Plans (BMAPs) to address nitrogen/phosphorus pollution. EPA notes that Subsection 62–302.530(47)(a), F.A.C. (“[t]he discharge of nutrients shall continue to be limited as needed to prevent violations of other standards contained in this chapter. Man-induced nutrient enrichment (total nitrogen or total phosphorus) shall be considered degradation in relation to the provisions of Sections 62–302.300, 62–302.700, and 62–4.242, F.A.C.”) could result in more stringent nitrogen/phosphorus limits, where necessary to protect other applicable WQS in Florida.

#### *D. EPA Determination Regarding Florida and EPA's Rulemaking*

On January 14, 2009, EPA determined under CWA section 303(c)(4)(B) that new or revised WQS in the form of

numeric water quality criteria for nitrogen/phosphorus pollution are necessary to meet the requirements of the CWA in the State of Florida. As noted above, the portion of Florida's currently applicable narrative criterion translated by this final rule provides, in part, that “in no case shall nutrient concentrations of a body of water be altered so as to cause an imbalance in natural populations of aquatic flora or fauna.” (See Subsection 62–302.530(47)(b), F.A.C.). EPA determined that Florida's narrative criterion alone was insufficient to ensure protection of applicable designated uses. The determination recognized that Florida has a comprehensive regulatory and non-regulatory administrative water quality program to address nitrogen/phosphorus pollution through a water quality strategy of assessments, non-attainment listing and determinations, TMDL development, and National Pollutant Discharge Elimination System (NPDES) permit regulations; individual watershed management plans through the State's BMAPs; advanced wastewater treatment technology-based requirements under the 1990 Grizzle-Figg Act; together with rules to limit nitrogen/phosphorus pollution in geographically specific areas like the Indian River Lagoon System, the Everglades Protection Area, and Wekiva Springs. However, the determination noted that despite Florida's existing regulatory and non-regulatory water quality framework and the State's intensive efforts to diagnose nitrogen/phosphorus pollution and address it on a time-consuming and resource-intensive case-by-case basis, substantial water quality degradation from nitrogen/phosphorus over-enrichment remains a significant challenge in the State and conditions are likely to worsen with continued population growth and land-use changes.

Overall, the combined impacts of urban and agricultural activities, along with Florida's physical features and important and unique aquatic ecosystems, made it clear that the current reliance on the narrative criterion alone and a resource-intensive, site-specific implementation approach, and the resulting delays that it entails, do not ensure protection of applicable designated uses for the many State waters that either have been listed as impaired and require loadings reductions or those that are high quality and require protection from future degradation. EPA concluded that numeric criteria for nitrogen/phosphorus pollution will enable the State to take necessary action to protect

EPA-822-B-01-003. U.S. Environmental Protection Agency, Office of Water, Washington, DC.

<sup>85</sup> USEPA. 2000a. *Nutrient Criteria Technical Guidance Manual: Lakes and Reservoirs*. EPA-822-B-00-001. U.S. Environmental Protection Agency, Office of Water, Washington, DC.

USEPA. 2000b. *Nutrient Criteria Technical Guidance Manual: Rivers and Streams*. EPA-822-B-00-002. U.S. Environmental Protection Agency, Office of Water, Washington, DC.

USEPA. 2001. *Nutrient Criteria Technical Guidance Manual: Estuarine and Coastal Marine Waters*. EPA-822-B-01-003. U.S. Environmental Protection Agency, Office of Water, Washington, DC.

USEPA. 2008. *Nutrient Criteria Technical Guidance Manual: Wetlands*. EPA-822-B-08-001. U.S. Environmental Protection Agency, Office of Water, Washington, DC.

<sup>86</sup> USEPA. 2000a. *Nutrient Criteria Technical Guidance Manual: Lakes and Reservoirs*. EPA-822-B-00-001. U.S. Environmental Protection Agency, Office of Water, Washington, DC.

<sup>87</sup> USEPA. 2010. *Using Stressor-Response Relationships to Derive Numeric Nutrient Criteria*. EPA-820-S-10-001. U.S. Environmental Protection Agency, Office of Water, Washington, DC.

the designated uses in a timely manner that will ensure protection of the designated use. The resource-intensive efforts to interpret the State's narrative criterion contribute to substantial delays in implementing the criterion and, therefore, undercut the State's ability to provide the needed protections for applicable designated uses. EPA, therefore, determined that numeric criteria for nitrogen/phosphorus pollution are necessary for the State of Florida to meet the CWA requirement to have criteria that protect applicable designated uses. EPA determined that numeric water quality criteria would strengthen the foundation for identifying impaired waters, establishing TMDLs, and deriving water quality-based effluent limits in NPDES permits, thus providing the necessary protection for the State's designated uses in its waters. In addition, numeric criteria will support the State's ability to effectively partner with point and nonpoint sources to control nitrogen/phosphorus pollution, thus further providing the necessary protection for the designated uses of the State's water bodies. EPA's determination is available at the following Web site: <http://www.epa.gov/waterscience/standards/rules/fl-determination.htm>.

While Florida continues to work to implement its watershed management program, the impairments for nutrient pollution are increasing as evidenced by the 2008 and 2010 *Integrated Water Quality Assessment for Florida* report results, and the tools to correct the impairments (TMDLs and BMAPs) are not being completed at a pace to keep up. Numeric criteria can be used as a definitive monitoring tool to identify impaired waters and as an endpoint for TMDLs to establish allowable loads necessary to correct impairments. When developing TMDLs, as it does when determining reasonable potential and deriving limits in the permitting context, Florida translates the narrative criterion into a numeric target that the State determines is necessary to meet its narrative criterion and protect applicable designated uses. This process involves a site-specific analysis to determine the nitrogen and phosphorus concentrations that would "cause an imbalance in natural populations of aquatic flora or fauna" in a particular water.

When deriving NPDES water quality-based permit limits, Florida initially conducts a site-specific analysis to determine whether a proposed discharge has the reasonable potential to cause or contribute to an exceedance of its narrative water quality criterion. The absence of numeric criteria make this

"reasonable potential" analysis more complex, data-intensive, and protracted. Following a reasonable potential analysis, the State then evaluates what levels of nitrogen and phosphorus would "cause an imbalance in natural populations of aquatic flora or fauna" and translates those levels into numeric "targets" for the receiving water and any other affected waters. Determining on a State-wide, water-by-water basis the levels of nitrogen and phosphorus that would "cause an imbalance in natural populations of aquatic flora or fauna" is a difficult, lengthy, and data-intensive undertaking. This work involves performing detailed location-specific analyses of the receiving water. If the State has not already completed this analysis for a particular waterbody, it can be very difficult to accurately determine in the context and timeframe of the NPDES permitting process. For example, in some cases, site-specific data may take several years to collect and, therefore, may not be available for a particular waterbody at the time of permitting issuance or re-issuance.

The January 14, 2009 determination stated EPA's intent to propose numeric criteria for lakes and flowing waters in Florida within 12 months of the January 14, 2009 determination, and for estuarine and coastal waters within 24 months of the determination. On August 19, 2009, EPA entered into a Consent Decree with Florida Wildlife Federation, Sierra Club, Conservancy of Southwest Florida, Environmental Confederation of Southwest Florida, and St. Johns Riverkeeper, committing to the schedule stated in EPA's January 14, 2009 determination to propose numeric criteria for lakes and flowing waters in Florida by January 14, 2010, and for Florida's estuarine and coastal waters by January 14, 2011. The Consent Decree also required that final rules be issued by October 15, 2010 for lakes and flowing waters, and by October 15, 2011 for estuarine and coastal waters. FDEP, independently from EPA, initiated its own State rulemaking process in the spring/summer of 2009 to adopt nutrient water quality standards protective of Florida's lakes and flowing waters. FDEP held several public workshops on its draft numeric criteria for lakes and flowing waters. In October 2009, however, FDEP decided not to bring the draft criteria before the Florida Environmental Regulation Commission, as had been previously scheduled.

Pursuant to the Consent Decree, EPA's Administrator signed the proposed numeric criteria for Florida's lakes and flowing waters on January 14, 2010, which was published in the **Federal Register** on January 26, 2010. EPA

conducted a 90-day public comment period for this rule that closed on April 28, 2010. During this period, EPA also conducted 13 public hearing sessions in 6 cities in Florida. EPA received over 22,000 public comments from a variety of sources, including environmental groups, municipal wastewater associations, industry, State agencies, local governments, agricultural groups, and private citizens. The comments addressed a wide range of issues, including technical analyses, policy issues, economic costs, and implementation concerns. In this notice, EPA explains the inland waters final rule and provides a summary of major comments and the Agency's response in the sections that describe each of the provisions of the final rule. EPA has prepared a detailed "Comment Response Document," which includes responses to the comments contributed during the public hearing sessions, as well as those submitted in writing on the proposed rule, and is located in the docket for this rule.

On June 7, 2010, EPA and Plaintiffs filed a joint notice with the Court extending the deadlines for promulgating numeric criteria for Florida's estuaries and coastal waters, flowing waters in south Florida (including canals), and the downstream protection values for flowing waters into estuaries and coastal waters. The new deadlines are November 14, 2011 for proposing this second phase of criteria, and August 15, 2012 for publishing a final rule for these three categories. This will allow EPA time to hold a public peer review by EPA's Scientific Advisory Board (SAB) of the scientific methodologies for estuarine and coastal criteria, flowing waters in south Florida, and downstream protection values for estuaries and coastal waters.

Based upon comments and new data and information received during the public comment phase of the January 2010 proposed rule, on August 3, 2010 EPA published a supplemental notice of data availability and request for comment related to the Agency's January 26, 2010 notice of proposed rulemaking. In its supplemental notice, EPA solicited comment on a revised regionalization approach for streams, additional information and analysis on least-disturbed sites as part of a modified benchmark distribution approach, and additional options for developing downstream protection values (DPVs) for lakes. EPA did not solicit additional comment on any other provisions of the January 2010 proposal. EPA received 71 public comments from a variety of sources, including local and State governments, industry, and

environmental groups. As mentioned above, EPA provides a summary of major comments and the Agency's response in the sections that describe each of the provisions of the final rule. Responses to comments submitted during the public comment period associated with the supplemental notice are also included in EPA's detailed "Comment Response Document," located in the docket for this rule.

On October 8, 2010, EPA filed an unopposed motion with the Court requesting that the deadline for signing the final rule be extended to November 14, 2010. The Court granted EPA's motion on October 27, 2010. EPA used this additional time to review and confirm that all comments were fully considered.

In accordance with the January 14, 2009 determination, the August 19, 2009 Consent Decree, and the June 7, 2010 and October 27, 2010 revisions to that Consent Decree, in this final notice EPA is promulgating final numeric criteria for streams, lakes, and springs in the State of Florida.<sup>88</sup>

### III. Numeric Criteria for Streams, Lakes, and Springs in the State of Florida

#### A. General Information

For this final rule, EPA derived numeric criteria for streams, lakes and springs to implement Florida Subsection 62–302.530(47)(b), F.A.C.<sup>89</sup> This final rule also includes downstream protection values (DPVs) to ensure the attainment and maintenance of the WQS for downstream lakes. Derivation of these criteria is based upon an extensive amount of Florida-specific data. EPA has carefully considered numerous comments from a range of stakeholders and has worked in close collaboration with FDEP technical and scientific experts to analyze, evaluate, and interpret these Florida-specific data in deriving scientifically sound numeric criteria for this final rulemaking.

To support derivation of the final streams criteria, EPA screened and evaluated water chemistry data from

more than 11,000 samples from over 6,000 sites statewide. EPA also evaluated biological data consisting of more than 2,000 samples from over 1,100 streams. To support derivation of the final lakes criteria, EPA screened and evaluated relevant lake data, which consisted of over 17,000 samples from more than 1,500 lakes statewide. Finally, for the final springs criterion, EPA evaluated and relied on scientific information and analyses from more than 40 studies including historical accounts, laboratory scale dosing studies and field surveys.

In deriving these final numeric values, the EPA met and consulted with FDEP expert scientific and technical staff on numerous occasions as part of an ongoing collaborative process. EPA carefully considered and evaluated the technical approaches and scientific analysis that FDEP presented as part of its July 2009 draft numeric criteria,<sup>90</sup> as well as its numerous comments on different aspects of this rule. The Agency also received and carefully considered substantial stakeholder input from 13 public hearings in 6 Florida cities. Finally, EPA reviewed and evaluated further analysis and information included in more than 22,000 comments on the January 2010 proposal and an additional 71 comments on the August 2010 supplemental notice.

EPA has created a technical support document that provides detailed information regarding the methodologies discussed herein and the derivation of the final criteria. This document is entitled "Technical Support Document for EPA's Final Rule for Numeric Criteria for Nitrogen/Phosphorus Pollution in Florida's Inland Surface Fresh Waters" ("EPA Final Rule TSD for Florida's Inland Waters" or "TSD") and is part of the record and supporting documentation for this final rule. As part of its review of additional technical and scientific information, EPA has documented its consideration of key comments and issues received from a wide range of interested parties during the rulemaking process. This analysis and consideration is included as part of a comment response document entitled "Response to Comments—EPA's Numeric Criteria for Nitrogen/Phosphorus Pollution in the State of Florida's Lakes and Flowing

Waters" that is also part of the record and supporting documentation for this final rule.

This section of the preamble describes EPA's final numeric criteria for Florida's streams (III.B), lakes (III.C), and springs (III.D), with the associated methodologies EPA employed to derive them. Each subsection includes the final numeric criteria (magnitude, duration, and frequency) and background information and supporting analyses. Section III.E discusses the applicability and implementation of these final criteria.

As discussed, the scientific basis for the derivation of the applicable criteria for streams, lakes and springs in this final rule is outlined below and explained in more detail in the Technical Support Document accompanying this rulemaking. The final criteria and related provisions in this rule reflect a detailed consideration and full utilization of the best available science, data, literature, and analysis related to the specific circumstances and contexts for deriving numeric criteria in the State of Florida. This includes, but is not limited to, the substantial quantity and quality of available data in Florida, Florida's regional hydrologic, biological, and land use characteristics, and the biological responses in Florida's surface water systems.

#### B. Numeric Criteria for the State of Florida's Streams

##### (1) Final Rule

EPA is promulgating numeric criteria for TN and TP in five geographically distinct watershed regions of Florida's streams classified as Class I or III waters under Florida law (Section 62–302.400, F.A.C.).

TABLE B–1—EPA'S NUMERIC CRITERIA FOR FLORIDA STREAMS

Nutrient watershed region	Instream protection value criteria	
	TN (mg/L)*	TP (mg/L)*
Panhandle West <sup>a</sup> .....	0.67	0.06
Panhandle East <sup>b</sup> .....	1.03	1.18
North Central <sup>c</sup> .....	1.87	0.30
West Central <sup>d</sup> .....	1.65	0.49
Peninsula <sup>e</sup> .....	1.54	0.12

Watersheds pertaining to each Nutrient Watershed Region (NWR) were based principally on the NOAA coastal, estuarine, and fluvial drainage areas with modifications to the NOAA drainage areas in the West Central and Peninsula Regions that account for unique watershed geologies. For more detailed information on regionalization and which WBIDs pertain to each NWR, see the Technical Support Document.

<sup>88</sup> For purposes of this rule, EPA has distinguished South Florida as those areas south of Lake Okeechobee and the Caloosahatchee River watershed to the west of Lake Okeechobee and the St. Lucie watershed to the east of Lake Okeechobee, hereinafter referred to as the South Florida Region. Numeric criteria applicable to flowing waters in the South Florida Region will be addressed in the second phase of EPA's rulemaking regarding the establishment of estuarine and coastal numeric criteria. (Please refer to Section I.B for a discussion of the water bodies affected by this rule).

<sup>89</sup> In no case shall nutrient concentrations of a body of water be altered so as to cause an imbalance in natural populations of aquatic flora or fauna.

<sup>90</sup> FDEP. 2009. *Draft Technical Support Document: Development of Numeric Nutrient Criteria for Florida's Lakes and Streams*. Florida Department of Environmental Protection, Standards and Assessment Section. Available electronically at: [http://www.dep.state.fl.us/water/wqssp/nutrients/docs/tsd\\_nutrient\\_crit.docx](http://www.dep.state.fl.us/water/wqssp/nutrients/docs/tsd_nutrient_crit.docx). Accessed October 2010.

<sup>a</sup>Panhandle West region includes: Perdido Bay Watershed, Pensacola Bay Watershed, Choctawhatchee Bay Watershed, St. Andrew Bay Watershed, Apalachicola Bay Watershed.

<sup>b</sup>Panhandle East region includes: Apalachee Bay Watershed, and Econfina/Steinhatchee Coastal Drainage Area.

<sup>c</sup>North Central region includes the Suwannee River Watershed.

<sup>d</sup>West Central region includes: Peace, Myakka, Hillsborough, Alafia, Manatee, Little Manatee River Watersheds, and small, direct Tampa Bay tributary watersheds south of the Hillsborough River Watershed.

<sup>e</sup>Peninsula region includes: Waccasassa Coastal Drainage Area, Withlacoochee Coastal Drainage Area, Crystal/Pithlachascotee Coastal Drainage Area, small, direct Tampa Bay tributary watersheds west of the Hillsborough River Watershed, Sarasota Bay Watershed, small, direct Charlotte Harbor tributary watersheds south of the Peace River Watershed, Caloosahatchee River Watershed, Estero Bay Watershed, Kissimmee River/Lake Okeechobee Drainage Area, Loxahatchee/St. Lucie Watershed, Indian River Watershed, Daytona/St. Augustine Coastal Drainage Area, St. John's River Watershed, Nassau Coastal Drainage Area, and St. Mary's River Watershed.

\*For a given waterbody, the annual geometric mean of TN or TP concentrations shall not exceed the applicable criterion concentration more than once in a three-year period.

## (2) Background and Analysis

### (a) Methodology for Stream Classification

In January 2010, EPA proposed to classify Florida's streams into four regions (referred to in the proposed rule as "Nutrient Watershed Regions") for application of TN and TP criteria. This proposal was based upon the premise that streams within each of these regions (Panhandle, Bone Valley, Peninsula and North Central) reflect similar geographical characteristics, including phosphorus-rich soils, nitrogen/phosphorus concentrations and nitrogen to phosphorus ratios. To classify these four regions, EPA began by considering the watershed boundaries of downstream estuaries and coastal waters in recognition of the hydrology of Florida's flowing waters and the importance of protecting downstream water quality. This is consistent with a watershed approach to water quality management, which EPA encourages to integrate and coordinate efforts within a watershed in order to most effectively and efficiently protect our nation's water resources.<sup>91</sup> EPA then classified Florida's streams based upon a consideration of the natural factors that contribute to variability in nutrient concentrations in streams (*e.g.*, geology, soil composition). In the State of Florida, these natural factors are mainly

associated with phosphorus. EPA's proposal reflected a conclusion that these natural factors could best be represented by separating the watersheds in the State into four regions and then using the least-disturbed sites within those regions to differentiate between the expected natural concentrations of TN and TP.

EPA received comments suggesting that the proposed stream regionalization be amended to more accurately account for naturally-high phosphorus soils in the northern Panhandle, west of the proposed North Central region. Specifically, EPA was asked to consider the westward extent of the Hawthorn Group, a phosphorus-rich geological formation that can influence stream phosphorus concentrations. At proposal, EPA had taken the Hawthorn Group into account when it proposed two distinct stream regions to the east and south of the panhandle region: the North Central and the West Central (formerly called the Bone Valley at proposal). Following proposal and in response to these comments, EPA revisited its review of underlying soils and geology in the Panhandle, itself, and the relationship of those geological characteristics to observed patterns in phosphorus concentrations in streams. EPA further considered how well such a revised regionalization explained observed variability in TP concentrations relative to the proposed regionalization. EPA concluded that a revised regional classification subdividing the proposed Panhandle region into a western and eastern section accurately reflected phosphate contributions from the underlying geologic formations that are reflected in the expected instream phosphorus concentrations. As discussed in the August 2010 supplemental notice, EPA has used the revised Panhandle regions for TN criteria to assure consistency and clarity in applicability decisions and implementation. This approach addresses the concerns of commenters that regionalization is an important consideration in developing stream criteria. EPA provided a supplemental notice and solicitation of comment in August 2010 on this potential change to the Panhandle region. In this final rule, EPA has thus taken into account the portion of the Hawthorn Group that lies in the eastern portion of the Panhandle region and has delineated the Panhandle region along watershed boundaries into East and West portions divided by the eastern edge of the Apalachicola River watershed (or alternatively, the western edge of the Suwannee River watershed). For more

information regarding the EPA's consideration of alternative approaches for classification, please see the TSD and response to comments.

EPA also received comment that the original West Central region (referred to as the Bone Valley in the proposed rule) was too broad and incorporated watersheds that were not influenced by underlying Hawthorn Group geology, especially small, direct coastal drainage watersheds along the western and southern boundaries. EPA reexamined the watershed delineations of the West Central and Peninsula regions based on information in these comments and concluded that the comments were technically correct. EPA also provided a supplemental notice and solicitation of comment on this potential change to the West Central and Peninsula regions. In this final rule, EPA has refined the boundary delineations accordingly. The result for the West Central region was a modified boundary that shifts small, direct Tampa Bay tributary watersheds west of the Hillsborough River Watershed; small, direct Charlotte Harbor tributary watersheds south of the Peace River Watershed; and the entire Sarasota Bay Watershed from the West Central (Bone Valley) to the Peninsula region. EPA believes these adjustments to the West Central and Peninsula stream region boundaries more accurately reflect the watershed boundaries and better reflect natural differences in underlying geological formations and expected stream chemistry.

In summary, EPA is finalizing numeric stream criteria for TN and TP for five separate Nutrient Watershed Regions (NWR): Panhandle West, Panhandle East, North Central, West Central and Peninsula (north of Lake Okeechobee, including the Caloosahatchee River Watershed to the west and the St. Lucie Watershed to the east). For a map of these regions, refer to "Technical Support Document for U.S. EPA's Final Rule for Numeric Criteria for Nitrogen/Phosphorus Pollution in Florida's Inland Surface Fresh Waters" (Chapter 1: Derivation of EPA's Numeric Criteria for Streams) included in the docket as part of the record for this final rule.

### (b) Methodology for Calculating Instream Protective TN and TP Values

In the January 2010 proposal, EPA used a reference condition approach to derive numeric criteria that relied on the identification of biologically healthy sites that were unimpaired by nitrogen or phosphorus. EPA identified these sites from FDEP's streams data set, selecting sites where Stream Condition

<sup>91</sup>U.S. EPA. 2008. *Handbook for Developing Watershed Plans to Restore and Protect Our Waters*. EPA 841-B-08-002. U.S. Environmental Protection Agency, Office of Water, Washington, DC.

Index (SCI) scores were 40 and higher. The SCI is a multi-metric index of benthic macroinvertebrate community composition and taxonomic data developed by FDEP to assess the biological health of Florida's streams.<sup>92</sup> An SCI score > 40 has been determined to be indicative of biologically healthy conditions based on an expert workshop and analyses performed by both FDEP and EPA. Please refer to the EPA's January 2010 proposal and the final TSD accompanying this final rule for more information on the SCI and the selection of the SCI value of 40 as an appropriate threshold to identify biologically healthy sites.

EPA further screened these sites by cross-referencing them with Florida's 2008 CWA section 303(d) list and excluded sites in waterbody identification numbers (WBIDs) with identified nutrient impairments or dissolved oxygen impairments. EPA grouped the remaining sites (hereinafter referred to as "SCI sites") according to the four proposed Nutrient Watershed Regions (Panhandle, North Central, West Central (referred to as Bone Valley at proposal), and Peninsula). For each NWR, EPA compiled data (TN and TP concentrations). EPA then calculated the average concentration at each site using all available samples. The resulting site average concentrations represent the distribution of nitrogen/phosphorus concentrations for each region. EPA found that while these sites were determined to be biologically healthy, the proposed SCI approach does not include information that can be directly related to an evaluation of least anthropogenically-impacted conditions (e.g., a measure of land use surrounding a reference site), which can be used as a factor in identifying a minimally-impacted reference population for criteria development. For these reasons, EPA concluded the 75th percentile of the distribution of site average values was an appropriate threshold to use in the SCI approach for criteria derivation.

EPA requested comment on basing the TN and TP criteria for the Nutrient Watershed Regions on the SCI approach. The Agency also requested comment on an alternative approach that utilizes benchmark sites identified by FDEP. EPA received comments supporting the benchmark reference condition approach and the selection of the 90th percentile (generally) for deriving the

TN and TP criteria. The criteria in this final rule are based on a further evaluation and more rigorous screening of the benchmark data set of reference sites using the population of least-disturbed benchmark sites developed by FDEP and further refined by EPA as discussed in the August 2010 supplemental notice. EPA concluded that the revised benchmark approach is an appropriate reference condition approach for deriving stream criteria because it utilizes a quantitative assessment of potential human disturbance through the use of surrounding land cover analysis of stream corridor and watershed land development indices that provide an added dimension to the benchmark approach not considered in EPA's proposed SCI site approach. EPA is finalizing stream criteria for most NWRs based on the benchmark approach with the addition of supplemental data screening steps to ensure that an evaluation of benchmark sites utilizes best available information representing reference conditions related to least-disturbed as well as and biologically healthy streams in the State. For this reason, EPA found the benchmark reference condition approach to be a compelling basis to support numeric criteria for Florida's streams more closely associated with least-disturbed sites. For the West Central region only, EPA is finalizing stream criteria based on SCI sites because the benchmark approach resulted in the identification of only one WBID as being least-disturbed. EPA found the SCI sites provide a more compelling basis to support numeric criteria in that region because more data are available at more sites that have been identified as biologically healthy, which provide a broader representation of nitrogen and phosphorus concentrations within this region.

For this final rule, EPA is using the large amount of high-quality scientific data available on TN and TP concentrations with corresponding information on land use and human disturbance for a wide variety of stream types as part of a reference condition approach to derive numeric criteria for Florida's streams. EPA used available data that are quantitative measures of land use, indicators of human disturbance, and site-specific evaluations of biological condition using a multi-metric biological index to identify a population of least-disturbed benchmark locations (benchmark sites). EPA used associated measurements of TN and TP concentrations from the benchmark sites and SCI sites (in the

case of the West Central region) as the basis for deriving the final numeric criteria for streams.

The reference condition approach used in this final rule for streams consist of three steps: (1) Defining the reference population, (2) calculating a distribution of values, and (3) determining appropriate thresholds. For the first step as discussed above, EPA used the least-disturbed benchmark reference condition approach initially developed by FDEP to define the reference condition population, this approach starts with a query of FDEP's data in the STORET<sup>93</sup> (STORage and RETrieval) and GWIS (Generalized Water Information System) databases and identified sites with data that met quality assurance standards.<sup>94</sup> Sites with data were then evaluated by FDEP to assess the level of human disturbance in the vicinity of the site using the Landscape Development Intensity Index (LDI)<sup>95</sup> to analyze a 100 meter distance of land on both sides of and 10 kilometers upstream of each stream site (i.e., corridor LDI). Sites with stream corridor LDI scores less than or equal to two<sup>96</sup> were considered sites with relatively low potential human disturbance. The group of sites with LDI scores less than or equal to two were further reviewed and inspected by FDEP based on site visits and aerial photography to assess the degree of potential human impact. Based on this review, sites that FDEP determined had potential human impact were removed. Sites with mean nitrate concentrations greater than 0.35 mg/L, a concentration identified by several lines of evidence to result in the growth of excessive algae in laboratory studies and extensive field evaluations of spring and clear stream sites in Florida<sup>97</sup> were also removed. Following proposal and in response to additional comments and information, EPA further evaluated the benchmark sites and screened out additional sites with identified nutrient impairments or dissolved oxygen impairments according to Florida's 2008 CWA section 303(d) list. EPA also removed sites that have available watershed LDI scores greater than three as this reflects a higher level of human disturbance on

<sup>93</sup> FL STORET can be found at: <http://www.dep.state.fl.us/WATER/STORET/INDEX.HTM>.

<sup>94</sup> Quality assurance review conducted by FDEP and detailed in EPA's accompanying Technical Support Document.

<sup>95</sup> Brown, M.T., and M.B. Vivas. 2005. Landscape Development Intensity Index. *Environmental Monitoring and Assessment* 101: 289-309.

<sup>96</sup> Brown, M.T., and M.B. Vivas. 2005. Landscape Development Intensity Index. *Environmental Monitoring and Assessment* 101: 289-309.

<sup>97</sup> See the springs criterion discussion below.

<sup>92</sup> The SCI method was developed and calibrated by FDEP. See Fore et al. 2007. *Development and Testing of Biomonitoring Tools for Macroinvertebrates in Florida Streams (Stream Condition Index and BioRecon)*. Final prepared for the Florida Department of Environmental Protection, Tallahassee, FL.



a watershed basis.<sup>98</sup> Finally, EPA removed benchmark sites that have available Stream Condition Index (SCI) scores less than 40. These additional screens provide greater confidence that the remaining sites are both least-disturbed and biologically healthy. The benchmark approach resulted in the identification of only one WBID as least-disturbed within the West Central region. For this reason, EPA is utilizing the SCI sites identified at proposal to define the reference population for the West Central region in this final rule. EPA grouped the remaining sites (hereinafter referred to as "reference sites") according to its Nutrient Watershed Regions (Panhandle West, Panhandle East, North Central, West Central, and Peninsula). For each NWR, EPA compiled data (TN and TP concentrations) from the reference sites.

The second step in deriving instream protection values was to calculate the distribution of nitrogen/phosphorus values of benchmark sites within each region. EPA calculated the geometric mean of the annual geometric mean of nitrogen/phosphorus concentrations for each WBID within which reference sites occurred. EPA provided notice and solicited comment on calculating streams criteria on the basis of WBIDs in the August 2010 supplemental notice. All samples from reference sites within those WBIDs were used to calculate the annual geometric mean. The geometric mean of this annual geometric mean for each WBID is utilized so that each WBID represents one average concentration in the distribution of concentrations for each NWR. Geometric means were used for all averages because concentrations were log-normally distributed.

The third step in deriving instream protection values was to determine appropriate thresholds from these distributions to support balanced natural populations of aquatic flora and fauna. The upper end of the distribution (the 90th percentile) is appropriate if there is confidence that the distribution reflects minimally-impacted reference conditions and can be shown to be supportive of designated uses (*i.e.*, balanced natural populations of aquatic flora and fauna).<sup>99</sup> EPA concluded that

<sup>98</sup> The threshold value for watershed LDI is higher than the threshold value for the corridor LDI because human disturbance in the watershed is known to more weakly influence in-stream nitrogen/phosphorus concentrations than human disturbance in the stream corridor (Peterjohn, W.T. and D. L. Correll. 1984. Nutrient dynamics in an agricultural watershed: Observations on the role of a riparian forest. *Ecology* 65: 1466–1475).

<sup>99</sup> USEPA. 2008. *Nutrient Criteria Technical Guidance Manual: Wetlands*. EPA-822-B-08-001.

the benchmark data set and the resulting benchmark distributions of TN and TP were based on substantial evidence of least-disturbed reference conditions after the additional quality assurance screens applied by EPA. This analysis provides EPA with the confidence that the benchmark sites are least-disturbed sites and with the additional screens applied by the Agency provide a basis for the use of the 90th percentile of values from this population to establish the final rule criteria. It is appropriate to use the 90th percentile for the benchmark distribution because the least-disturbed sites identified in Florida that are used to derive the criteria more closely approximate minimally-impacted conditions.<sup>100</sup> For the West Central region, where reference sites are identified using the SCI approach, there is less confidence that these sites are least-disturbed and represent minimally-impacted conditions. As mentioned above, this is because this approach does not rely on a quantitative assessment of potential human disturbance through the use of surrounding land cover analysis of stream corridor and watershed land development indices. Therefore, EPA is finalizing the stream criteria in the West Central region using the 75th percentile values of the distribution from the SCI sites.<sup>101</sup>

EPA's approach in this final rule results in numeric criteria that are protective of a balanced natural population of aquatic flora and fauna in Florida's streams. EPA has determined, however, that these instream values may not always ensure the attainment and maintenance of WQS in downstream lakes and that more stringent criteria may be necessary to assure compliance with 40 CFR 131.10(b). Therefore, EPA is finalizing an approach in this rule for deriving TN and TP values for streams to ensure the attainment and maintenance of WQS in downstream

U.S. Environmental Protection Agency, Office of Water, Washington, DC.

<sup>100</sup> The 90th percentile is selected so that nitrogen/phosphorus concentrations that are above the criterion value have a low probability (< 10%) of being observed in sites that are similar to benchmark sites.

<sup>101</sup> USEPA. 2000b. *Nutrient Criteria Technical Guidance Manual: Rivers and Streams*. EPA-822-B-00-002. U.S. Environmental Protection Agency, Office of Water, Washington, DC.

These percentages were initially proposed by FDEP. See FDEP. 2009. *Draft Technical Support Document: Development of Numeric Nutrient Criteria for Florida's Lakes and Streams*. Florida Department of Environmental Protection, Standards and Assessment Section. Available electronically at: [http://www.dep.state.fl.us/water/wqssp/nutrients/docs/tsd\\_nutrient\\_crit.docx](http://www.dep.state.fl.us/water/wqssp/nutrients/docs/tsd_nutrient_crit.docx). Accessed October 2010.

lakes.<sup>102</sup> This approach is discussed in Section III.C(2)(f).

### (c) Duration and Frequency

Aquatic life water quality criteria contain three components: Magnitude, duration, and frequency. For the numeric TN and TP criteria for streams, the derivation of the criterion-magnitude values is described above and these values are provided in the table in Section III.B(1). The duration component of these stream criteria is specified in *footnote a* of Table B-1 as an annual geometric mean. EPA is finalizing the proposed frequency component as a no-more-than-one-in-three-years excursion frequency for the annual geometric mean criteria for streams. These duration and frequency components of the criteria are consistent with the data set used to derive these criteria, which applied distributional statistics to measures of annual geometric mean values from multiple years of record. EPA has determined that this frequency of excursions will not result in unacceptable effects on aquatic life as it will allow the stream ecosystem enough time to recover from occasionally elevated levels of nitrogen/phosphorus in the stream.<sup>103 104 105</sup> These selected duration and frequency components recognize that hydrological variability (*e.g.*, high and low flows) will produce variability in nitrogen and phosphorus concentrations, and that individual measurements may at times be greater than the criteria magnitude concentrations without causing unacceptable effects to aquatic organisms and their uses. Furthermore, the frequency and duration components balance the representation of underlying data and analyses based on the central tendency of many years of data with the need to exercise some caution to ensure that streams have sufficient time to process individual years of elevated nitrogen and phosphorus levels and

<sup>102</sup> EPA will propose and request comment on the comparable issue for deriving TN and TP values for streams to ensure the attainment and maintenance of WQS in downstream estuaries as part of the coastal and estuarine waters rule on November 14, 2011.

<sup>103</sup> USEPA. 1985. *Guidelines for Deriving Numeric National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses*. EPA PB85-227049. U.S. Environmental Protection Agency, Office of Research and Development, Environmental Research Laboratories.

<sup>104</sup> Hutchens, J. J., K. Chung, and J. B. Wallace. 1998. Temporal variability of stream macroinvertebrate abundance and biomass following pesticide disturbance. *Journal of the North American Benthological Society* 17:518–534.

<sup>105</sup> Wallace, J.B. D. S.Vogel, and T.F. Cuffney. 1986. Recovery of a headwater stream from an insecticide induced community disturbance. *Journal of North American Benthological Society* 5: 115–126.



avoid the possibility of cumulative and chronic effects (*i.e.*, the no-more-than-one-in-three-year component). More information on this specific topic is provided in EPA's Final Rule TSD for Florida's Inland Waters, Chapter 1: Methodology for Deriving U.S. EPA's Criteria for Streams located in the record for this final rule.

#### d. Reference Condition Approach

In deriving the final criteria for streams, EPA has relied on a reference condition approach, which has been well documented, peer reviewed, and developed in a number of different contexts.<sup>106 107 108 109 110</sup> In the case of Florida, this approach is supported by a substantial Florida-specific database of high quality information, sound scientific analysis and extensive technical evaluation.

EPA received comments regarding the scientific defensibility of the reference condition approach, using either the benchmark sites or the SCI sites. Many commenters observed that such approaches do not mechanistically link biological effects to nitrogen/phosphorus levels and therefore assert that EPA cannot scientifically justify numeric criteria without an observed biological effect. EPA views the reference condition approach as scientifically appropriate to derive the necessary numeric criteria in Florida streams. Reference conditions provide the appropriate benchmark against which to determine the nitrogen and phosphorus concentrations present when the designated use is being met. When the natural background concentrations of specific parameters can be defined by identifying reference conditions at anthropogenically-undisturbed sites, then the concentrations at these sites can be considered as sufficient to support the aquatic life expected to occur naturally

at that site.<sup>111</sup> Also, setting criteria based on the conditions observed in reference condition sites reflects both the stated goal of the Clean Water Act and EPA's National Nutrient Strategy that calls for States, including Florida, to take protective and preventative steps in managing nitrogen/phosphorus pollution to maintain the chemical, physical and biological integrity of the Nation's waters before adverse biological and/or ecological effects are observed.<sup>112</sup>

The effects of TN and TP on an aquatic ecosystem are well understood and documented. There is a substantial and compelling scientific basis for the conclusion that excess TN and TP will have adverse effects on streams<sup>113 114 115 116 117 118 119 120 121 122 123 124 125 126 127,</sup>

<sup>111</sup> Davies, T.T., USEPA. 1997, November 5. Memorandum to Water Management Division Directors, Regions 1–10, and State and Tribal Water Quality Management Program Directors on Establishing Site Specific Aquatic Life Criteria Equal to Natural Background.

<sup>112</sup> USEPA. 1998. *National Strategy for the Development of Regional Nutrient Criteria*. EPA 822-R-98-002. U.S. Environmental Protection Agency, Office of Water, Washington, DC; Grubbs, G., USEPA. 2001, November 14. Memorandum to Directors of State Water Programs, Directors of Great Water Body Programs, Directors of Authorized Tribal Water Quality Standards Programs and State and Interstate Water Pollution Control Administrators on Development and Adoption of Nutrient Criteria into Water Quality Standards.; Grumbles, B.H., USEPA. 2007, May 25. Memorandum to Directors of State Water Programs, Directors of Great Water Body Programs, Directors of Authorized Tribal Water Quality Standards Programs and State and Interstate Water Pollution Control Administrators on Nutrient Pollution and Numeric Water Quality Standards.

<sup>113</sup> Biggs, B.J.F. 2000. Eutrophication of streams and rivers: dissolved nutrient–chlorophyll relationships for benthic algae. *Journal of the North American Benthological Society* 19:17–31

<sup>114</sup> Bothwell, M.L. 1985. Phosphorus limitation of lotic periphyton growth rates: an intersite comparison using continuous-flow troughs (Thompson River system, British Columbia). *Limnology and Oceanography* 30:527–542

<sup>115</sup> Bourassa, N., and A. Cattaneo. 1998. Control of periphyton biomass in Laurentian streams (Quebec). *Journal of the North American Benthological Society* 17:420–429

<sup>116</sup> Bowling, L.C., and P.D. Baker. 1996. Major cyanobacterial bloom in the Barwon-Darling River, Australia, in 1991, and underlying limnological conditions. *Marine and Freshwater Research* 47: 643–657

<sup>117</sup> Cross, W. F., J. B. Wallace, A. D. Rosemond, and S. L. Eggert. 2006. Whole-system nutrient enrichment increases secondary production in a detritus-based ecosystem. *Ecology* 87: 1556–1565

<sup>118</sup> Dodds, W.K., and D.A. Gudder. 1992. The ecology of Cladophora. *Journal of Phycology* 28:415–427

<sup>119</sup> Elwood, J.W., J.D. Newbold, A.F. Trimble, and R.W. Stark. 1981. The limiting role of phosphorus in a woodland stream ecosystem: effects of P enrichment on leaf decomposition and primary producers. *Ecology* 62:146–158

<sup>120</sup> Francoeur, S.N. 2001. Meta-analysis of lotic nutrient amendment experiments: detecting and quantifying subtle responses. *Journal of the North American Benthological Society* 20: 358–368

As discussed in Section II above, excess nitrogen/phosphorus in streams, like other aquatic ecosystems, increase vegetative growth (plants and algae), and change the assemblage of plant and algal species present in the system. These changes can affect the organisms that are consumers of algae and plants by altering the balance of food resources available to different trophic levels. For example, excess nitrogen/phosphorus promotes the growth of opportunistic and short-lived plant species that die quickly leaving more dead vegetative material available for consumption by lower trophic levels. Additionally, excess nitrogen/phosphorus can promote the growth of less palatable nuisance algae species that results in less food available for filter feeders. These changes can also alter the habitat structure by covering the stream or river bed with periphyton (attached algae) rather than submerged aquatic plants, or clogging the water column with phytoplankton (floating algae). In addition, excess nitrogen/phosphorus can lead to the production of algal toxins that can be toxic to fish, invertebrates, and humans. Chemical characteristics of the water, such as pH and concentrations of dissolved oxygen (DO), can also be affected by excess nitrogen/phosphorus leading to low DO conditions and hypoxia. Each of these changes can, in turn, lead to other changes in the stream community and, ultimately, to changes in the stream ecology that supports the overall function of the linked aquatic ecosystem.

<sup>121</sup> Moss, B., I. Hooker, H. Balls, and K. Manson. 1989. Phytoplankton distribution in a temperate floodplain lake and river system. I. Hydrology, nutrient sources and phytoplankton biomass. *Journal of Plankton Research* 11: 813–835

<sup>122</sup> Mulholland, P.J. and J.R. Webster. 2010. Nutrient dynamics in streams and the role of J-NABS. *Journal of the North American Benthological Society* 29: 100–117

<sup>123</sup> Peterson, B.J., J.E. Hobbie, A.E. Hershey, M.A. Lock, T.E. Ford, J.R. Vestal, V.L. McKinley, M.A.J. Hullar, M.C. Miller, R.M. Ventullo, and G. S. Volk. 1985. Transformation of a tundra river from heterotrophy to autotrophy by addition of phosphorus. *Science* 229:1383–1386

<sup>124</sup> Rosemond, A. D., P. J. Mulholland, and J. W. Elwood. 1993. Top-down and bottom-up control of stream periphyton: Effects of nutrients and herbivores. *Ecology* 74: 1264–1280

<sup>125</sup> Rosemond, A. D., C. M. Pringle, A. Ramirez, and M.J. Paul. 2001. A test of top-down and bottom-up control in a detritus-based food web. *Ecology* 82: 2279–2293

<sup>126</sup> Rosemond, A. D., C. M. Pringle, A. Ramirez, M.J. Paul, and J. L. Meyer. 2002. Landscape variation in phosphorus concentration and effects on detritus-based tropical streams. *Limnology and Oceanography* 47: 278–289.

<sup>127</sup> Slavik, K., B. J. Peterson, L. A. Deegan, W. B. Bowden, A. E. Hershey, J. E. Hobbie. 2004. Long-term responses of the Kuparuk River ecosystem to phosphorus fertilization. *Ecology* 85: 939–954.

<sup>106</sup> USEPA. 2000a. *Nutrient Criteria Technical Guidance Manual: Lakes and Reservoirs*. EPA-822-B-00-001. U.S. Environmental Protection Agency, Office of Water, Washington, DC.

<sup>107</sup> USEPA. 2000b. *Nutrient Criteria Technical Guidance Manual: Rivers and Streams*. EPA-822-B-00-002. U.S. Environmental Protection Agency, Office of Water, Washington, DC.

<sup>108</sup> Stoddard, J. L., D. P. Larsen, C. P. Hawkins, R. K. Johnson, and R. H. Norris. 2006. Setting expectations for the ecological condition of streams: the concept of reference condition. *Ecological Applications* 16:1267–1276.

<sup>109</sup> Herlihy, A. T., S. G. Paulsen, J. Van Sickle, J. L. Stoddard, C. P. Hawkins, L. L. Yuan. 2008. Striving for consistency in a national assessment: the challenges of applying a reference-condition approach at a continental scale. *Journal of the North American Benthological Society* 27:860–877.

<sup>110</sup> U.S. EPA. 2001. *Nutrient Criteria Technical Manual: Estuarine and Coastal Marine Waters*. Office of Water, Washington, DC. EPA-822-B-01-003.

*C. Numeric Criteria for the State of Florida's Lakes*

classes of Florida's lakes, classified as Class I or III waters under Florida law (Section 62-302.400, F.A.C.):

(1) Final Rule

EPA is promulgating numeric criteria for chlorophyll *a*, TN and TP in three

TABLE C-17—EPA'S NUMERIC CRITERIA FOR FLORIDA LAKES

Lake color <sup>a</sup> and alkalinity	Chl- <i>a</i> (mg/L) <sup>b *</sup>	TN (mg/L)	TP (mg/L)
Colored Lakes <sup>c</sup> .....	0.020	1.27 [1.27–2.23]	0.05 [0.05–0.16]
Clear Lakes, High Alkalinity <sup>d</sup> .....	0.020	1.05 [1.05–1.91]	0.03 [0.03–0.09]
Clear Lakes, Low Alkalinity <sup>e</sup> .....	0.006	0.51 [0.51–0.93]	0.01 [0.01–0.03]

<sup>a</sup>Platinum Cobalt Units (PCU) assessed as true color free from turbidity.  
<sup>b</sup>Chlorophyll *a* is defined as corrected chlorophyll, or the concentration of chlorophyll *a* remaining after the chlorophyll degradation product, phaeophytin *a*, has been subtracted from the uncorrected chlorophyll *a* measurement.  
<sup>c</sup>Long-term Color > 40 Platinum Cobalt Units (PCU).  
<sup>d</sup>Long-term Color ≤ 40 PCU and Alkalinity > 20 mg/L CaCO<sub>3</sub>.  
<sup>e</sup>Long-term Color ≤ 40 PCU and Alkalinity ≤ 20 mg/L CaCO<sub>3</sub>.  
<sup>\*</sup>For a given waterbody, the annual geometric mean of chlorophyll *a*, TN or TP concentrations shall not exceed the applicable criterion concentration more than once in a three-year period.

For each class of water defined by color and alkalinity, the applicable criteria are the values in **bold** for chlorophyll *a*, TN and TP. The criteria framework provides flexibility for FDEP to derive lake-specific, modified TN and TP criteria if the annual geometric mean chlorophyll *a* concentration is less than the criterion for an individual lake in each of the three immediately preceding years. In such a case, the corresponding criteria for TN and/or TP may be modified to reflect maintenance of ambient conditions within the range specified in the parenthetical below each baseline TN and TP criteria printed in bold in Table C-1 above. Modified criteria for TN and/or TP must be based on data from at least the immediately preceding three years<sup>128</sup> in a particular lake. Modified TN and/or TP criteria may not be greater than the higher value specified in the range. Modified TN and/or TP criteria for a lake also may not be above criteria applicable to streams to which a lake discharges in order to ensure the attainment and maintenance of downstream water quality standards.

Utilization of the range flexibility in the numeric lake criteria in this final rule requires that the ambient calculation for modified TN and TP criteria be based on: (1) The immediately preceding three-year

record of observation for each parameter,<sup>129</sup> (2) representative sampling during each year (at least one sample in May–September and at least one sample in October–April), and (3) a minimum of 4 samples from each year. Requiring at least three years of data accounts for year-to-year hydrological variability, ensures longer-term stable conditions, and appropriately accounts for anomalous conditions in any given year that could lead to erroneous conclusions regarding the true relationship between nitrogen/phosphorus and chlorophyll *a* levels in a lake. Representative samples from each year minimize the effects of seasonal variations in nitrogen/phosphorus and chlorophyll *a* concentrations. Finally, the minimum sample size of 4 samples per year allows estimates of reliable geometric means while still maintaining a representative sample of lakes. The State shall notify EPA Region 4 and provide the supporting record within 30 days of determination of modified lake criteria.

To ensure attainment of applicable downstream lake criteria, this final rule provides a tiered approach for adjusting instream criteria presented in section III.B.(1) above for those streams that flow into lakes.<sup>130</sup> Where site-specific data on lake characteristics are

available, the final rule provides a modeling approach for the calculation of downstream lake protection values that relies upon the use of the BATHTUB model.<sup>131</sup> In circumstances where sufficient site-specific lake data are readily available and either EPA or FDEP determine that another scientifically defensible model is more appropriate (e.g., the Water Quality Analysis Simulation Program, or WASP), the modeling approach accommodates use of a scientifically defensible alternative. In the absence of models, other approaches for ensuring protection of downstream lakes are provided and described further below.

(2) Background and Analysis

(a) Methodology for Lake Classification

In the January 2010 proposal, EPA used color and alkalinity to classify Florida's lakes based on substantial data demonstrating that these characteristics influence the response of lakes to increased nitrogen/phosphorus and the expected background chlorophyll *a* concentration. Many of Florida's lakes contain dissolved organic matter leached from surface vegetation that

<sup>128</sup>The previous three years of data are required as a basis for modifying TN and TP criteria and must meet FDEP's data quality assurance objectives. Additional historical data may be used to augment the three years of data characterizing the lake's annual and inter-annual variability. Only historical data containing data for all three parameters can be used and the data must meet FDEP's data quality assurance objectives.

<sup>129</sup>As noted above, if more than three years of data are available for each parameter, then more data can be used.

<sup>130</sup>Approximately 30% of Florida lakes are fed by streams to which this DPV analysis would apply (Schiffer, Donna M. 1998. *Hydrology of Central Florida Lakes—A Primer*. U.S. Geological Survey in cooperation with SJWMD and SFWMD: Circular 1137).

<sup>131</sup>Kennedy, R.H. 1995. *Application of the BATHTUB model to Selected Southeastern Reservoirs*. Technical Report EL-95-14. U.S. Army Engineer Waterways Experiment Station, Vicksburg, MS.; Walker, W.W., 1985. *Empirical Methods for Predicting Eutrophication in Impoundments; Report 3, Phase II: Model Refinements*. Technical Report E-81-9. U.S. Army Engineer Waterways Experiment Station, Vicksburg, MS.; Walker, W.W., 1987. *Empirical Methods for Predicting Eutrophication in Impoundments; Report 4, Phase III: Applications Manual*. Technical Report E-81-9. U.S. Army Engineer Waterways Experiment Station, Vicksburg, MS.

colors the water. More color in a lake limits light penetration within the water column, which in turn limits algal growth. Thus, in lakes with colored water, higher levels of nitrogen/phosphorus may occur without exceeding the chlorophyll *a* criteria concentrations. EPA evaluated relationships among TN, TP, and chlorophyll *a* concentration data, and found that lake color influenced these relationships. More specifically, EPA found the correlations between nitrogen/phosphorus and chlorophyll *a* concentrations to be stronger and less variable when lakes were categorized into two distinct groups based on a color threshold of 40 PCU, with clear lakes demonstrating more algal growth with increased nitrogen/phosphorus, as would be predicted by the increased light penetration. This threshold is consistent with the distinction between clear and colored lakes long observed in Florida.<sup>132</sup>

Within the clear lakes category, color is not the dominant controlling factor in algal growth. For these clear lakes, EPA proposed the use of alkalinity as an additional distinguishing characteristic. Alkalinity and pH increase when water is in contact with carbonate rocks, such as limestone, or limestone-derived soil in the State of Florida. Limestone is also a natural source of phosphorus, and thus, in Florida, lakes that are higher in alkalinity are often associated with naturally elevated TP levels. The alkalinity (measured as CaCO<sub>3</sub> concentration) of Florida clear lakes ranges from zero to over 200 mg/L. EPA proposed classifying clear Florida lakes into acidic and alkaline classes based on an alkalinity threshold of 50 mg/L CaCO<sub>3</sub>, and solicited comment on whether a 20 mg/L CaCO<sub>3</sub> threshold would be more appropriate. EPA received comments noting that the lower alkalinity classification threshold would be more representative of naturally oligotrophic conditions by creating a class of lakes with very low alkalinity and correspondingly low chlorophyll *a* concentrations. After reviewing available lake data, EPA found that clear lakes below 20 mg/L CaCO<sub>3</sub> were more similar to one another in terms of naturally expected chlorophyll *a*, TN, and TP concentrations than clear lakes below 50 mg/L CaCO<sub>3</sub>. Thus, EPA concluded that an alkalinity threshold of 20 mg/L CaCO<sub>3</sub> was an appropriate threshold for classifying clear lakes and EPA is

finalizing the lower alkalinity threshold in this rule. More information on this specific topic is provided in EPA's Finals TSD for Florida's Inland Waters, Chapter 2: Methodology for Deriving U.S. EPA's Criteria for Lakes located in the record for this final rule.

EPA also proposed the use of specific conductance as a surrogate for alkalinity. EPA received comments that conductivity was not an accurate surrogate measure for alkalinity. EPA evaluated the association between specific conductivity and alkalinity and concluded that alkalinity is a preferred parameter for lake classification because it is a more direct measure of the presence of carbonate rocks, such as limestone that are associated with natural elevated phosphorus levels. Changes in specific conductivity can be attributed to changes in alkalinity, but in many cases may be caused by increases in the concentrations of other compounds that originate from human activities. Thus, EPA has concluded that alkalinity is a more reliable indicator for characterizing natural background conditions for Florida lakes.

A number of comments suggested EPA consider a system that delineates 47 lake regions and a system that classifies lakes as a continuous function of both alkalinity and color. As discussed in more detail in the TSD supporting this final rule, EPA evaluated each of these alternative classification approaches, and found that they did not improve the predictive accuracy of biological responses to nitrogen/phosphorus over EPA's classification, nor result in a practical system that can be implemented by FDEP. For example, in the case of the 47 lake region approach, insufficient data are available to derive numeric criteria across all of the 47 regions and in the case of the continuous function approach there is a reliance on an assumption that TN and TP are always co-limiting that is not always true.<sup>133</sup>

A number of commenters suggested that lake-specific criteria would be more appropriate than the three broad classes that EPA proposed. The substantial data available in the record for this final rule supports the conclusion that many of Florida's lakes share similar physical, chemical, and geological characteristics, which in turn justifies, based on sound scientific evidence, broad classification of Florida lakes. EPA concluded, based on the substantial data and associated analysis explained above, that color and

alkalinity are primary distinguishing factors in Florida lakes with respect to nitrogen/phosphorus dynamics and the associated biological response. With respect to consideration of site-specific information that goes beyond the detailed site-specific sampling and monitoring analysis already discussed,<sup>134</sup> the numeric lake criteria in this final rule are established within a flexible regulatory framework that allows adjustment of TN, TP, and/or chlorophyll *a* criteria based on additional lake-specific data. This framework provides an opportunity to derive lake-specific criteria similar to the manner suggested in public comment, where lake-specific data and information are available, while ensuring that numeric criteria are in place to protect all of Florida's lakes. Further site-specific flexibility is provided in this final rule through the derivation of alternative criteria by a Federal Site Specific Adjusted Criteria (SSAC) process discussed in more detail below in Section V.C.

In this final rule, EPA is dividing Florida's lakes into three classes: (1) Colored Lakes >40 Platinum Cobalt Units (PCU), (2) Clear, High Alkalinity Lakes (≤40 PCU with alkalinity >20 mg/L calcium carbonate (CaCO<sub>3</sub>)), and (3) Clear, Low Alkalinity Lakes (≤40 PCU with alkalinity ≤20 mg/L CaCO<sub>3</sub>). These two parameters, color and alkalinity, both affect lake productivity and plant biomass, as measured by chlorophyll *a*. For more information regarding these classes, please refer to EPA's Final Rule TSD for Florida's Inland Waters, Chapter 2: Methodology for Deriving U.S. EPA's Criteria for Lakes.

#### (b) Methodology for Chlorophyll *a* Criteria

EPA proposed the use of chlorophyll *a* concentration as an indicator of a healthy biological condition, supportive of natural balanced populations of aquatic flora and fauna in each of the classes of Florida's lakes. Excess algal growth is associated with degradation in aquatic life, and chlorophyll *a* levels are a measure of algal growth. To derive the proposed chlorophyll *a* concentrations that would be protective of natural balanced populations of aquatic flora and fauna in Florida's lakes, EPA utilized the expected trophic status of the lake, based on internationally accepted lake use classifications.<sup>135</sup>

<sup>134</sup> Technical Support Document for EPA's Final Rule for Numeric Nutrient Criteria for Nitrogen/Phosphorus Pollution in Florida's Inland Surface Fresh Waters.

<sup>135</sup> OECD. 1982. *Eutrophication of Waters. Monitoring, Assessment and Control*. Organisation

<sup>132</sup> Shannon, E.E., and P.L. Brezonik. 1972. Limnological characteristics of north and central Florida lakes. *Limnology and Oceanography* 17(1): 97-110.

<sup>133</sup> Guildford, S. J. and R. E. Hecky. 2000. Total nitrogen, total phosphorus, and nutrient limitation in lakes and oceans: Is there a common relationship? *Limnology and Oceanography* 45: 1213-1223.

As discussed in more detail at proposal, lakes can be classified into one of three trophic State categories (*i.e.*, oligotrophic, mesotrophic, eutrophic).<sup>136</sup> EPA concluded at proposal that healthy colored lakes and clear, high alkalinity lakes should maintain a mesotrophic status, because they receive significant natural nitrogen/phosphorus input and still support a healthy diversity of aquatic life in warm, productive climates such as Florida. For these two categories of lakes, EPA proposed a chlorophyll *a* criterion of 0.020 mg/L to support balanced natural populations of aquatic life flora and fauna. At concentrations above 0.020 mg/L chlorophyll *a*, the trophic status of the lake is more likely to become eutrophic and the additional chlorophyll *a* will reduce water clarity, negatively affecting native submerged macrophytes, and the invertebrate and fish communities that depend on them. Commenters suggested that this threshold is overly protective of naturally eutrophic lakes in the State. For those lakes that may currently be naturally eutrophic, this final rule contains a formal SSAC process to revise these criteria for this unique type of lake. For more information on the SSAC process, please refer to Section V.C of this final rule.

In contrast, clear, low alkalinity lakes in Florida do not receive natural nitrogen/phosphorus input from underlying geological formations in the watershed and thus, they support less algal growth and have lower chlorophyll *a* levels than colored or clear, high alkalinity lakes. EPA concluded at proposal that these lakes should maintain an oligotrophic status to support balanced natural populations of aquatic flora and fauna. EPA proposed a chlorophyll *a* criterion of 0.006 mg/L in clear, low alkalinity lakes to support balanced natural populations of aquatic life flora and fauna. At concentrations above 0.006 mg/L chlorophyll *a*, the trophic status of the lake is more likely to become mesotrophic and the additional chlorophyll *a* will reduce water clarity, negatively affecting native submerged macrophytes, and the invertebrate and fish communities that depend on them. Commenters suggested that this chlorophyll *a* concentration may not be appropriate for clear lakes

with alkalinity less than 50 mg/L. As explained in more detail above, in this final rule EPA concluded that 20 mg/L is an appropriate threshold between low and high alkalinity lakes. Thus, lakes with alkalinity greater than 20 mg/L will have a chlorophyll *a* criterion that is applicable to clear, high alkalinity lakes. Based on the revision of the alkalinity threshold to 20 mg/L, EPA reviewed the available chlorophyll *a* data for clear, low alkalinity lakes and found that the majority of lakes have chlorophyll *a* concentrations less than 0.006 mg/L reflective of oligotrophic conditions which leads EPA to conclude that this chlorophyll *a* concentration will serve to maintain the trophic status of these lakes.

In this final rule, EPA is promulgating chlorophyll *a* criteria of 0.020 mg/L in colored lakes and clear, high alkalinity lakes and a chlorophyll *a* criterion of 0.006 mg/L in clear, low alkalinity lakes as an indicator of a healthy biological condition, supportive of natural balanced populations of aquatic flora and fauna in these classes of Florida's lakes. For more information regarding these chlorophyll *a* criteria, please refer to EPA's Final Rule TSD for Florida's Inland Waters, Chapter 2: Methodology for Deriving U.S. EPA's Criteria for Lakes.

#### (c) Methodology for Total Nitrogen (TN) and Total Phosphorus (TP) Criteria in Lakes

EPA proposed TN and TP criteria for each of the classes of lakes described in Section III.C(2)(a) based on the response of chlorophyll *a* to increases in TN and TP for clear and colored lakes in Florida. These responses were quantitatively estimated with linear regressions. Each data point used in estimating the statistical relationships was the geometric mean of samples taken over the course of a year in a particular Florida lake. Statistical analyses of these relationships showed that the chlorophyll *a* responses to changes in TN and TP differed for colored versus clear lakes, as would be expected, because color blocks light penetration in the water column and limits algal growth. These analyses also showed that chlorophyll *a* responds to changes in TN and TP in high and low alkalinity clear lakes similarly, as would be expected, because alkalinity does not affect light penetration. These relationships were used to derive TN and TP criteria that would maintain chlorophyll *a* concentrations at desired levels known to be supportive of balanced natural populations of aquatic flora and fauna as discussed above. These analyses are explained in more

detail in EPA's Final Rule TSD for Florida's Inland Waters, Chapter 2: Methodology for Deriving U.S. EPA's Criteria for Lakes included in the record for this final rule.

EPA proposed baseline TN and TP criteria based on the 75th percentile of the predicted distribution of chlorophyll *a* concentrations, given a TN or TP concentration. Commenters suggested alternative approaches for deriving TN and TP criteria, including using either the mean predicted chlorophyll *a* concentration, using the 25th percentile of the predicted distribution of chlorophyll *a* concentrations, and using an additional criterion based on a higher percentile that is associated with a different exceedance frequency. EPA considered these alternative approaches and concluded that calculating the TN and TP criteria as a baseline concentration with an associated concentration range was a more flexible approach than a single value approach manifested as the TN and TP concentration associated with a specific chlorophyll *a* concentration. Thus, the approach included in this final rule takes into account the natural variability observed in different classes of lakes (*i.e.*, colored or clear) in a way that a single value approach based on the regression line or the lower value of the 50th percentile prediction interval does not.

In this final rule, the TN and TP criteria are based on linear regressions (*i.e.*, best-fit lines) predicting the annual geometric mean chlorophyll *a* concentration as a function of the annual geometric mean TN or TP. Baseline TN and TP criteria are calculated as the point at which the 75th percentile of the predicted distribution of chlorophyll *a* concentrations from the regression relationship is equivalent to the chlorophyll *a* criterion for the appropriate lake class. The range of values in the predicted distribution of chlorophyll *a* concentrations arises from small differences in the nitrogen/phosphorus-chlorophyll *a* relationships across different lakes and variability in these relationships between years in the same lake. Hence, TN and TP criteria are based on the 75th percentile that will be protective at the majority of lakes and in the majority of years.

The predicted distribution of chlorophyll *a* concentrations for lakes differs inherently from the distribution of TN and TP concentrations calculated from reference sites for criteria for Florida streams (Section III.B(2)(b)). In the case of the criteria for Florida streams for most NWRs, benchmark sites represent a population of least-

for Economic Development and Co-Operation, Paris, France.

<sup>136</sup> Trophic state describes the nitrogen/phosphorus levels and algal state of an aquatic system: Oligotrophic (low nitrogen/phosphorus and algal productivity), mesotrophic (moderate nitrogen/phosphorus and algal productivity), and eutrophic (high nitrogen/phosphorus and algal productivity).

disturbed sites and the criteria based on the 90th percentile of nitrogen and phosphorus concentrations from these sites are selected to characterize the upper bound of nitrogen/phosphorus concentrations that one would expect from such sites. Criteria for Florida lakes rely on a predictive relationship between nitrogen/phosphorus and chlorophyll *a* concentrations, and the 75th percentile is selected from the distribution of chlorophyll *a* concentrations predicted for *specific* concentrations of TN and TP. As discussed above, basing criteria on this percentile provides a means of accounting for variability in chlorophyll *a* concentrations predicted for a given TN and TP concentration. In short, the percentile for the streams criteria is selected to ensure that nitrogen/phosphorus concentrations in all streams are at least as low as those observed in reference streams, whereas the percentile for the lakes criteria is selected such that concentrations appropriately account for variability in the relationships between nitrogen/phosphorus and chlorophyll *a* concentrations.

#### (d) Duration and Frequency

Aquatic life water quality criteria include magnitude, duration, and frequency components. For the chlorophyll *a*, TN, and TP criteria for lakes, the criterion-magnitude values, expressed as a concentration, are provided in Table C-1 in bold. The criterion-duration of this magnitude is specified in a footnote to this Table as an annual geometric mean. EPA is finalizing the criterion-frequency as a no-more-than-once-in-three-years excursion frequency of the annual geometric mean criteria for lakes. The duration component of the criteria is based on annual geometric means to be consistent with the data set used to derive these criteria, which applied stressor-response relationships based on annual geometric means for individual years at individual lakes. These selected duration and frequency components recognize that hydrological variability (e.g., high and low flows) will produce variability in nitrogen and phosphorus concentrations, and that individual measurements may at times be greater than the criterion-magnitude concentrations without causing unacceptable effects to aquatic organisms and their uses. Furthermore, they balance the representation of the central tendency of the predicted relationship between TN or TP and chlorophyll *a* based from many years of data with the need to exercise some caution to ensure that lakes have

sufficient time to process individual years of elevated nitrogen and phosphorus concentrations and avoid the possibility of cumulative and chronic effects (i.e., the no-more-than-one-in-three-year component). Additionally, because nitrogen/phosphorus pollution is best managed on a watershed basis, this is the same frequency and duration used in the final streams criteria. More information on this specific topic is provided in EPA's Final Rule TSD for Florida's Inland Waters, Chapter 2: Methodology for Deriving U.S. EPA's Criteria for Lakes located in the record for this final rule.

#### (e) Application of Lake-Specific, Ambient Condition-Based Modified TN and TP Criteria

EPA proposed an accompanying approach that the State could use to adjust TN and TP criteria for a particular lake within a certain range where sufficient data on long-term ambient chlorophyll *a*, TN and TP levels are available to demonstrate that protective chlorophyll *a* criterion for a specific lake will still be maintained and a balance of natural populations of aquatic flora and fauna will be supported. This approach allows for readily available site-specific data to be taken into account in the expression of TN and TP criteria, while still ensuring support of balanced natural populations of aquatic flora and fauna by maintaining the associated chlorophyll *a* level at or below the chlorophyll *a* criterion level. The scientific premise for the lake-specific ambient calculation provision for modified TN and/or TP criteria is that if ambient lake data show that a lake's chlorophyll *a* levels are at or below the established criteria (i.e., magnitude) for at least the last three years and its TN and/or TP levels are within the lower and upper bounds, then those ambient levels of TN and TP represent conditions that will continue to support the specified chlorophyll *a* response level. The lower bound of the range is based on the TN/TP values that correspond to the 75th percentile of the predicted chlorophyll *a* distribution and the upper bound of the range is based on the TN/TP values that correspond to the 25th percentile of the same predicted distribution. The use of the 25th and 75th percentiles accounts for the majority of variability that may occur around the central tendency of the predicted relationship between TN or TP and chlorophyll *a*.

This final rule provides that FDEP must establish and document these modified criteria in a manner that clearly recognizes their status as the applicable criteria for a particular lake.

To this end, FDEP must submit a letter to EPA Region 4 formally documenting the use of modified criteria as the applicable criteria for particular lakes. This final rule allows for a one-time adjustment without a requirement that FDEP go through a formal SSAC process. EPA believes that such modified TN and TP criteria do not need to go through the SSAC process because the conditions under which they are applicable are clearly stated in this final rule and data requirements are clearly laid out so that the outcome is clear, consistent, transparent, and reproducible. By providing a specific process for deriving modified criteria within the WQS rule itself, each individual outcome of this process is an effective WQS for CWA purposes and does not need separate adoption by FDEP or approval by EPA. For more information on the SSAC process, please refer to Section V.C of this final rule.

Application of the ambient calculation provision has implications for assessment and permitting because the outcome of applying this provision is to establish alternate numeric TN and/or TP values as the applicable lake criteria. For accountability and tracking purposes, the State must document the result of the ambient calculation for any given lake. Once modified criteria are established under this approach, they remain the applicable criteria for the long-term for purposes of implementing the State's water quality program until they are subsequently modified either through the Federal SSAC process or State revision to the applicable WQS, which has been approved by EPA pursuant to CWA section 303(c).

This site-specific lake criteria adjustment provision is subject to the downstream protection requirements more broadly discussed below. Thus in a comparable manner this final rule provides that calculated TN and/or TP values in a lake that discharges to a stream may not exceed criteria applicable to the stream to which a lake discharges.

#### (f) Downstream Protection of Lakes

In developing the proposed stream criteria, EPA also evaluated their effectiveness for assuring the protection of downstream lake water quality standards pursuant to the provisions of 40 CFR 130.10(b), which requires that WQS must provide for the attainment and maintenance of the WQS of downstream waters.<sup>137</sup> EPA's criteria for

<sup>137</sup> EPA will assess the effectiveness of final stream criteria for assuring the protection of

lakes are, in some cases, more stringent than the final criteria for streams that flow into the lakes, and thus the instream criteria may not be stringent enough to ensure protection of WQS in certain downstream lakes. As a result, EPA proposed application of the Vollenweider equation to ensure that the TP criteria in streams are protective of downstream lakes, and requested comment on alternative approaches such as the BATHTUB model and whether there should be an allowance for use of other models that are demonstrated to be protective and scientifically defensible.

The proposed use of the Vollenweider model equation to ensure the protection of downstream lakes requires input of two lake-specific characteristics: the fraction of inflow due to stream flow and the hydraulic retention time. EPA provided alternative preset values for percent contribution from stream flow and hydraulic retention time that could be used in those instances where lake-specific input values are not readily available. EPA's January 2010 proposed rule discussed the flexibility for the State to use site-specific inputs to the Vollenweider equation for these two parameters, as long as the State determines that such inputs are appropriate and documents the site-specific values. Some commenters stated that the Vollenweider equation is overly simplistic and does not include the necessary factors to account for physical, hydrologic, chemical, and biological processes necessary to determine protective criteria. Several commenters also suggested the need for TN values to protect downstream lakes that are nitrogen-limited (such as many of the lakes in the phosphorus-rich areas of the State). Comments included a recommendation to use models that can better represent site-specific conditions, such as BATHTUB.

EPA's August 2010 Supplemental Notice of Data Availability and Request for Comment requested additional comment on using the BATHTUB model in place of the Vollenweider equation for deriving both TP and TN criteria to protect downstream lakes, allowing the use of alternative models under certain circumstances, and providing for an alternative approach to protect downstream lakes when limited data are available that would use the lake criteria themselves as criteria for upstream waters flowing into the lake.

In the final rule, protection of downstream lakes is accomplished through establishment of a downstream protection value (DPV). The applicable criteria for streams that flow into downstream lakes include both the instream criteria for TN and TP and the DPV, which is a concentration or loading value at the point of entry into a lake that results in attainment of the lake criteria. EPA selected the point of entry into the lake, also referred to as the "pour point," as the location to measure water quality because the lake responds to the input from the pour point and all contributions from the stream network above this point in a watershed affect the water quality at the pour point. When a DPV is exceeded at the pour point, the waters that collectively comprise the network of streams in the watershed above that pour point are considered to not attain the DPV for purposes of section 303(d) of the Clean Water Act. The State may identify these impaired waters as a group rather than individually.

It is appropriate to express the DPV as either a load or concentration (load divided by flow) because both are expressions of the amount of TN and TP that are delivered to the downstream water. In an expression of load, the amount is expressed directly as mass per time (*e.g.*, pounds per year), whereas a concentration expresses the amount in terms of the mass contained in a particular volume of water (*e.g.*, milligrams per liter). Either expression may be used for assessment and source control allocation purposes. Calculating a DPV as a load will require modeling or other technical information, such as a TMDL, that accounts for both the volume of the receiving water and the flow contributed through the pour point. A DPV expressed as a concentration may be based on a model or TMDL or may reflect a TN or TP level that corresponds to a TN, TP, or chlorophyll *a* concentration that protects the lake.

Contributions of TN and/or TP from sources in stream tributaries upstream of the point of entry are accountable to the DPV because the water quality in the stream tributaries must result in attainment of the DPV at the pour point into the lake. The spatial allocation of load within the watershed is an important accounting step to ensure that the DPV is achieved at the point of entry into the lake. How the watershed load is allocated may differ based on watershed characteristics and existing sources (*e.g.*, areas that are more susceptible to physical loss of nitrogen; location of towns, farms, and dischargers), so long as the DPV is met

at the point of entry into the downstream lake. Where additional information is available, watershed modeling could be used to develop allocations that reflect hydrologic variability and other water quality considerations. For protection of the downstream lake, what is important is an accounting for nutrient loadings on a watershed scale that results in meeting the DPV at the point of entry into the downstream lake.

The final rule provides that additional DPVs may be established in upstream locations to represent sub-allocations of the total allowable loading or concentration. Such sub-allocations may be useful where there are differences in hydrological conditions and/or sources of TN and/or TP in different parts of the watershed. The rule specifies that DPVs apply to stream tributaries up to the point of reaching a waterbody that is not a stream as defined in the rule (*e.g.*, up to reaching another lake in a "nested" or chain of lakes situation). The rule also includes an option, however, to establish a DPV to account for a larger watershed area in a modeling context. Establishing DPVs that apply to a larger watershed may be useful to address a situation where the water that is furthest downstream in a watershed is also the water that is most sensitive to nitrogen/phosphorus pollution. That situation may require a more equitable distribution, across the larger watershed, of the load that protects the most sensitive waterbody.

Where multiple tributaries enter a lake, the total allowable loading to the lake may be distributed among the tributaries for purposes of DPV calculation in any manner that results in meeting the total allowable loading for the lake, remembering that those tributaries are also subject to the instream protection value established for the tributaries.

Where sufficient data and information are available, DPVs may be established through application of the BATHTUB model. BATHTUB applies empirical models to morphometrically complex lakes and reservoirs. The model performs steady-state water and nutrient balance calculations, uses spatially segmented hydraulic networks, and accounts for advective and diffusive transport of nutrients. When properly calibrated and applied, BATHTUB predicts nutrient-related water quality conditions such as TP, TN, and chlorophyll *a* concentrations, transparency, and hypolimnetic oxygen depletion rates. The model can apply to a variety of lake sizes, shapes and transport characteristics. A high degree of flexibility is available for specifying

downstream estuaries in a separate rulemaking that focuses on estuarine and coastal waters to be proposed by November 14, 2011 and finalized by August 15, 2012.

model segments as well as multiple influent streams. Because water quality conditions are calculated using relationships derived from data specific to each lake, BATHTUB accounts for differences between lakes, such as the rate of internal loading of phosphorus from bottom sediments. The above descriptive information is summarized from available technical references that also describe the model and its applications in greater detail.<sup>138 139 140</sup> EPA believes BATHTUB is appropriate for DPV calculations because BATHTUB can represent a number of site-specific variables that may influence nutrient responses and can estimate both TN and TP concentrations at the pour points to protect the receiving lake. BATHTUB has been previously used for lake water quality management purposes, such as the development of TMDLs in States, including Florida. This model was selected because it does not have extensive data requirements, yet it provides for the capability to be calibrated based on observed site-specific lake data and it provides for reliable estimates that will ensure the protection of downstream lakes.

EPA's final rule also specifically authorizes FDEP or EPA to use a model other than BATHTUB when either FDEP or EPA determines that it would be appropriate to use another scientifically defensible modeling approach that results in the protection of downstream lakes. While BATHTUB is a peer-reviewed and versatile model, there are other models that, when appropriately calibrated and applied, can offer additional capability to address complex situations with an even greater degree of site-specificity. Adopted and approved TMDLs may contain sufficient information to support derivation of a DPV when the TMDL is based on relevant data, defensible science, and accurate analysis.

As discussed in more detail in the Agency's August 2010 Supplemental Notice of Data Availability and Request for Comment on this issue, one example of an alternative model that FDEP or EPA might consider using for

particularly complex site-specific conditions is the Water Quality Analysis Simulation Program (WASP) model. This model allows users to conduct detailed simulations of water quality responses to natural and manmade pollutant inputs. WASP is a dynamic compartment-modeling program for aquatic systems, including both the water column and the underlying benthos. WASP allows the user to simulate systems in 1, 2, or 3 dimensions, and a variety of pollutant types. The model can represent time varying processes of advection, dispersion, point and diffuse mass loading, and boundary exchange. WASP also can be linked with hydrodynamic and sediment transport models that can provide flows, depths, velocities, temperature, salinity and sediment fluxes. The above summary information as well as additional technical information may be found at <http://www.epa.gov/athens/wwqts/html/wasp.html>. Like BATHTUB, WASP has also been previously used for lake water quality management purposes, such as TMDLs, nationally and in the State of Florida. This model is different from BATHTUB because it does have extensive data requirements that allow for the capability to be finely calibrated based on observed site-specific lake data, but is similar to BATHTUB in that it also provides for reliable estimates that will ensure the protection of downstream lakes.

EPA is finalizing a provision in this section of the rule for situations where data are not readily available to derive TN and/or TP DPVs using BATHTUB or another scientifically defensible model. In that situation, the rule describes how DPVs are determined where the downstream lake is attaining the lake criteria and where the downstream lake is either not assessed or is impaired.

Where sufficient information is not available to derive TN and/or TP DPVs using BATHTUB or another scientifically defensible technical model and the lake attains the applicable criteria, the DPVs would be the associated ambient instream levels of TN and/or TP at the point of entry into the lake. As long as the TN and TP concentrations necessary to support a balanced natural population of aquatic flora and fauna in the downstream lake are maintained in the inflow from streams, this approach will provide adequate protection of downstream lakes and would be used as the applicable DPVs in the absence of readily available data to support derivation of TN and TP DPVs using BATHTUB or another scientifically

defensible technical model such as WASP.

EPA's final rule provides that when the DPV is based on the ambient condition associated with attainment of criteria in the downstream lake, degradation in water quality from those established levels would be considered impairment, unless the State or EPA revises the DPV using a modeling approach or TMDL to show that higher levels of nutrient contribution from the tributaries would still result in attainment of applicable lake criteria. This provision is not intended to limit growth and/or development in the watershed, nor intended to maintain current conditions regardless of further analysis. Rather this provision is intended to ensure that WQS are not only restored when found to be impaired, but are in fact maintained when found to be attained, consistent with the goals of the Clean Water Act. Higher levels of TN and/or TP may be allowed in such watersheds where it is demonstrated that such higher levels will fully protect the lake's WQS.

Where sufficient information is not available to derive TN and/or TP DPVs using BATHTUB or another scientifically defensible technical model and the lake does not attain the applicable TN, TP, and/or chlorophyll *a* criteria or is un-assessed, lake criteria values for TN and/or TP are to be used as the DPVs. EPA believes that this approach is protective because the TN and TP concentrations entering the lake are unlikely to need to be lower than the criterion concentration necessary to be protective of the lake itself.

#### (g) Stressor-Response Approach

In deriving the final criteria for lakes, EPA has relied on a stressor-response approach which has been well documented and developed in a number of different contexts.<sup>141 142 143</sup> Stressor-response approaches estimate the relationship between nitrogen/phosphorus concentrations and a response measure that is either directly or indirectly related to the designated use (in this case, chlorophyll *a* as a measure of attaining a balanced natural population of aquatic flora and fauna). Then, concentrations that support the

<sup>138</sup> Walker, W.W., 1981. *Empirical Methods for Predicting Eutrophication in Impoundments; Report 1, Phase I: Data Base Development*. Technical Report E-81-9. U.S. Army Engineer Waterways Experiment Station, Vicksburg, MS.

<sup>139</sup> Walker, W.W., 1982. *Empirical Methods for Predicting Eutrophication in Impoundments; Report 2, Phase II: Model Testing*. Technical Report E-81-9. U.S. Army Engineer Waterways Experiment Station, Vicksburg, MS.

<sup>140</sup> Walker, W.W., 1999. *Simplified Procedures for Eutrophication Assessment and Prediction: User Manual*; Instruction Report W-96-2. U.S. Army Corps of Engineers Waterways Experiment Station, Vicksburg, MS.

<sup>141</sup> USEPA. 2000a. *Nutrient Criteria Technical Guidance Manual: Lakes and Reservoirs*. EPA-822-B-00-001. U.S. Environmental Protection Agency, Office of Water, Washington, DC.

<sup>142</sup> USEPA. 2000b. *Nutrient Criteria Technical Guidance Manual: Rivers and Streams*. EPA-822-B-00-002. U.S. Environmental Protection Agency, Office of Water, Washington, DC.

<sup>143</sup> USEPA. 2008. *Nutrient Criteria Technical Guidance Manual: Wetlands*. EPA-822-B-08-001. U.S. Environmental Protection Agency, Office of Water, Washington, DC.



designated use can be derived from the estimated relationship. In the case of Florida, the use of this approach is supported by a substantial Florida-specific database of high quality information, sound scientific analysis and technical evaluation.

The effects of nitrogen/phosphorus pollution are manifested in lakes in a variety of ways and are well-documented.<sup>144 145 146 147</sup> A common effect of nitrogen/phosphorus pollution in lakes is the over-stimulation of algal growth resulting in algal blooms, which can cause changes in algal and animal assemblages due to adverse changes in important water quality parameters necessary to support aquatic life. Algal blooms can decrease water clarity and aesthetics, which in turn can affect the suitability of a lake for primary (e.g., swimming) and secondary (e.g., boating) contact recreation. Algal blooms can adversely affect drinking water supplies by releasing toxins, interfering with disinfection processes, or requiring additional treatment. Algal blooms can adversely affect biological process by decreasing light availability to submerged aquatic vegetation (which serves as habitat for aquatic life), degrading food quality and quantity for other aquatic life, and increasing the rate of oxygen consumption.

#### D. Numeric Criterion for the State of Florida's Springs

##### (1) Final Rule

EPA defines "spring" as a site at which ground water flows through a natural opening in the ground onto the land surface or into a body of surface water. This definition is drawn from the U.S. Geological Survey, Circular 1137.<sup>148</sup> This definition is not intended to include streams that flow in a defined channel that have some groundwater baseflow component. EPA recognized that groundwater-surface water interactions in Florida are complex and that FDEP will need to make site-specific determinations about whether

<sup>144</sup> Lee, G.F., W. Rast, R.A. Jones. 1978. Eutrophication of water bodies: Insights for an age-old problem. *Environmental Science and Technology* 12: 900–908.

<sup>145</sup> Carlson R.E. 1977. A trophic state index for lakes. *Limnology and Oceanography* 22:361–369.

<sup>146</sup> Smith, V.H., G.D. Tilman, and J.C. Nekola. 1999. Eutrophication: impacts of excess nutrient inputs on freshwater, marine, and terrestrial ecosystems. *Environmental Pollution* 100: 179–196.

<sup>147</sup> Smith, V.H., S.B. Joye, and R.W. Howarth. 2006. Eutrophication of freshwater and marine ecosystems. *Limnology and Oceanography* 51:351–355.

<sup>148</sup> Schiffer, Donna M. 1998. *Hydrology of Central Florida Lakes—A Primer*. U.S. Geological Survey in cooperation with SJWMD and SFWMD: Circular 1137.

water is subject to the stream criteria or the springs criterion. EPA is promulgating the numeric criterion for nitrate+nitrite for Florida's springs classified as Class I or III waters under Florida law (Section 62–302.400, F.A.C.):

The applicable nitrate (NO<sub>3</sub><sup>-</sup>) + Nitrite (NO<sub>2</sub><sup>-</sup>) is 0.35 mg/L as an annual geometric mean, not to be exceeded more than once in a three-year period

##### (2) Background and Analysis

###### (a) Derivation of Nitrate + Nitrite Criterion

In its January proposal, EPA proposed a nitrate+nitrite criterion of 0.35 mg/L for springs and clear streams that would support balanced natural populations of aquatic flora and fauna in springs. EPA proposed criteria for nitrate+nitrite because one of most significant factors causing adverse changes in spring ecosystems is the pollution of groundwater, principally with nitrate+nitrite, resulting from human land use changes, cultural practices, and significant population growth.<sup>149 150</sup>

EPA based its proposed criterion on multiple lines of stressor-response evidence, which included controlled, laboratory-scale experimental data and analysis of field-based data. EPA's first line of evidence is stressor-response data from controlled laboratory experiments, which studied the growth response of algae in springs to different concentrations of nitrate+nitrite. EPA found in its review of comprehensive surveys<sup>151 152</sup> and a study<sup>153</sup> of 29

<sup>149</sup> Katz, B.G., H.D. Hornsby, J.F. Bohlke and M.F. Mokrav. 1999. *Sources and chronology of nitrate contamination in spring water, Suwannee River Basin, Florida*. Water-Resources Investigations Report 99–4252. U.S. Geological Survey, Tallahassee, FL. Available electronically at: [http://fl.water.usgs.gov/PDF\\_files/wri99\\_4252\\_katz.pdf](http://fl.water.usgs.gov/PDF_files/wri99_4252_katz.pdf).

<sup>150</sup> Brown M.T., K. Chinnners Reiss, M.J. Cohen, J.M. Evans, P.W. Inglett, K. Sharma Inglett, K. Ramesh Reddy, T.K. Frazee, C.A. Jacoby, E.J. Philips, R.L. Knight, S.K. Notestein, R.G. Hamann, and K.A. McKee. 2008. *Summary and Synthesis of the Available Literature on the Effects of Nutrients on Spring Organisms and Systems*. University of Florida, Gainesville, Florida. Available electronically at: [http://www.dep.state.fl.us/springs/reports/files/UF\\_SpringsNutrients\\_Report.pdf](http://www.dep.state.fl.us/springs/reports/files/UF_SpringsNutrients_Report.pdf). Accessed October 2010.

<sup>151</sup> Pinowska, A., R.J. Stevenson, J.O. Sickman, A. Albertin, and M. Anderson. 2007a. *Integrated interpretation of survey for determining nutrient thresholds for macroalgae in Florida Springs: Macroalgal relationships to water, sediment and macroalgal nutrients, diatom indicators and land use*. Florida Department of Environmental Protection, Tallahassee, FL.

<sup>152</sup> Stevenson, R.J., A. Pinowska, and Y.K. Wang. 2004. *Ecological Condition of Algae and Nutrients in Florida Springs*. Florida Department of Environmental Protection, Tallahassee, FL.

<sup>153</sup> Pinowska, A., R.J. Stevenson, J.O. Sickman, A. Albertin, and M. Anderson. 2007b. *Integrated interpretation of survey and experimental*

Florida springs at over 150 sampling sites, conducted on behalf of FDEP over three years, that two nuisance algal taxa, the cyanobacterium *Lyngbya wollei* and the macroalgae *Vaucheria sp.*, were the most commonly occurring taxa. The authors of the study conducted controlled laboratory experiments, which tested the growth response of *Lyngbya wollei* and *Vaucheria sp.* to different doses of nitrate+nitrite. They found that *Lyngbya wollei* and *Vaucheria sp.* growth rates increased in response to increased doses of nitrate+nitrite and that most of their highest growth rates were reached at and above 0.23 mg/L nitrate+nitrite. EPA interpreted the results from these studies as strong empirical evidence of a stressor-response relationship between nuisance algae and nitrate+nitrite and further indicated specific concentrations above which undesirable growth of nuisance algal may be likely to occur.

In addition to the laboratory-based experimental evidence, EPA reviewed information compiled by FDEP in its assessment of limits to restore springs and protect them from excess algal growth.<sup>154 155</sup> The second line of evidence was based on data collected from *in-situ* algal monitoring and long-term field surveys in rivers FDEP considered to exhibit similar aquatic conditions to springs (e.g., algal communities, water clarity, and proportion of flow coming from a spring). EPA found additional stressor-response evidence in an analysis<sup>156</sup> based on over 200 algal samples collected from 13 different algal monitoring stations along the Suwannee, Santa Fe, and Withlacoochee Rivers from 1990 to 1998. The analysis examined algal growth response over a range of nitrate+nitrite concentration. Results indicated a sharp increase in

*approaches for determining nutrient thresholds for macroalgae in Florida Springs: Laboratory experiments and disturbance study*. Florida Department of Environmental Protection, Tallahassee, FL.

<sup>154</sup> Gao, X. 2008. *Nutrient TMDLs for the Wekiva River (WBIDs 2956, 2956A, and 2956C) and Rock Springs Run (WBID 2967)*. Florida Department of Environmental Protection, Division of Water Resource Management, Tallahassee, FL.

<sup>155</sup> Hallas, J.F. and W. Magley. 2008. *Nutrient and Dissolved Oxygen TMDL for the Suwannee River, Santa Fe River, Manatee Springs (3422R), Fanning Springs (3422S), Branford Spring (3422J), Ruth Spring (3422L), Troy Spring (3422T), Royal Spring (3422U), and Falmouth Spring (3422Z)*. Florida Department of Environmental Protection, Bureau of Watershed Management, Tallahassee, FL.

<sup>156</sup> Niu, X.-F. 2007. Appendix B. Change Point Analysis of the Suwannee River Algal Data. In Gao, X. 2008. *Nutrient TMDLs for the Wekiva River (WBIDs 2956, 2956A, and 2956C) and Rock Springs Run (WBID 2967)*. Florida Department of Environmental Protection, Division of Water Resource Management, Tallahassee, FL.

algal abundance and biomass above 0.4 mg/L nitrate + nitrite.

EPA concluded the two different lines of stressor-response evidence point to a nitrate+nitrite concentration of 0.35 mg/L that would prevent excess algal growth and be supportive of balanced natural populations of aquatic flora and fauna in Florida springs. This concentration is higher than that observed in laboratory-scale experiments that may not be closely representative of reference spring sites in Florida, but lower than the concentration that was associated with changes in the balance of natural populations of aquatic flora and fauna observed in an analysis of field data. EPA believes a nitrate+nitrite criterion set at 0.35 mg/L represents an appropriate and reasonable balance of the scientific evidence.

EPA received a number of comments regarding EPA's proposed criterion for springs, including concerns that the biological responses observed in the field were not representative of all springs in Florida. EPA disagrees with these commenters who suggested that the observed effects in the field are not sufficient evidence to support numeric criteria derivation in springs. The algal taxa, *Lyngbya sp.* and *Vaucheria sp.*, are representative taxa found in Florida springs. In fact, *Lyngbya* and *Vaucheria* are the most commonly observed macroalgae in Florida springs.<sup>157</sup> Thus, the Agency considers the biological responses of these representative taxa observed in the field and in laboratory experiments to be ecologically meaningful and indicative of an adverse biological response to elevated nitrate+nitrite concentrations above 0.35 mg/L.

EPA also received comment that the proposed nitrate+nitrite criterion was inappropriately applied to all clear streams within the State. After considering these comments, EPA concluded that clear streams are more appropriately addressed as part of the regionalized reference approach that is supported by a broader range of stream monitoring data as discussed above. Therefore, EPA has decided not to finalize the springs nitrate+nitrite criterion in clear streams because EPA considers the numeric criteria it is finalizing in this rule for streams in the five NWRs, which includes clear streams, to be adequately protective and scientifically defensible. These systems will also be protected from excess

nitrogen from groundwater by the nitrate+nitrite criteria applicable in the springs that flow into them; thus, additional nitrate+nitrite criteria are not needed.

In this final rule, EPA is finalizing nitrate+nitrite criterion for springs with a magnitude of 0.35 mg/L. For more information regarding the springs criterion, please refer to EPA's Final Rule TSD for Florida's Inland Waters, Chapter 3: Methodology for Deriving U.S. EPA's Criteria for Springs located in the record for this final rule.

#### (b) Duration and Frequency

EPA proposed a nitrate+nitrite criterion duration as an annual geometric mean with a criterion frequency of not to be exceeded more than once in three years. EPA also took comment on alternative durations, such as a monthly geometric mean, and alternative frequencies, such as a not to be exceeded more than 10% of the time. EPA considered that the timescales of the algal responses in the laboratory experiments (*i.e.*, 21 to 28 days) might support a shorter duration over which biological response to nitrate+nitrite could occur. However, EPA found in its review of springs data and information that nitrate concentrations can be variable from month to month, and this intra-annual variability was not necessarily associated with impairment of the designated use. Therefore, to account for intra-annual variability, EPA chose to express the nitrate+nitrite criterion for springs on an annual basis. Comments included a suggestion to express the frequency component of the criterion as "not to be exceeded during a three year period as a three year average." However, EPA is concerned that cumulative effects of exposure may manifest themselves in shorter periods of time than three years. This is because springs tend to be clear which provides the opportunity for fast growing nuisance algal species to quickly utilize the excess nitrogen. When nuisance algae species grow prolifically, they outcompete and replace native submerged aquatic vegetation. Thus, more frequent exceedances of the criterion-magnitude will not support a balanced natural population of aquatic flora and fauna in springs because submerged aquatic vegetation can be lost quickly from the effects of nitrate+nitrite pollution, but can take many years, if not decades, to recover.<sup>158</sup> For these reasons, EPA is

finalizing the proposed duration and frequency of an annual geometric mean not to be exceeded more than once in three years.

#### E. Applicability of Criteria When Final

##### (1) Final Rule

This final rule is effective 15 months after publication in the **Federal Register**, except for the Federal site-specific alternative criteria (SSAC) provision of section 131.43(e), which is effective 60 days after publication in the **Federal Register**. This rule will apply in addition to any other existing CWA-effective criteria for Class I or Class III waters already adopted and submitted to EPA by the State (and for those adopted and submitted to EPA after May 30, 2000, approved by EPA). FDEP establishes its designated uses through a system of classes and Florida waters are designated into one of several different classes. Class III waters provide for healthy aquatic life and safe recreational use. Class I waters include all the protection of designated uses provided for Class III waters, and also include protection for designated uses related to drinking water supply. *See* Section 62–302.400, F.A.C. Class I and III waters, together with Class II waters that are designated for shellfish propagation or harvesting, comprise the set of Florida waters that are assigned designated uses that include the goals articulated in Section 101(a)(2) of the CWA (*i.e.* protection and propagation of fish, shellfish, and wildlife and recreation in and on the water).<sup>159</sup> Class II waters will be covered under EPA's forthcoming rulemaking efforts for estuarine and coastal waters. EPA is promulgating numeric criteria for lakes and flowing waters, consistent with the terms of the Agency's Consent Decree, that Florida has designated as Class I or Class III.

In terms of final rule language, EPA has removed regulatory provisions at 40 CFR 131.43(c)(2)(iii) and 131.43(c)(4)–(6) because these criteria (criteria for protection of downstream estuarine waters, flowing waters in the South Florida Region, and estuaries and coastal waters) will be included with the Agency's 2011 proposed rulemaking for estuarine and coastal waters. For water bodies designated as Class I and Class III predominately fresh waters, EPA's final numeric criteria will be applicable CWA water quality criteria for purposes of implementing CWA programs, including permitting under the NPDES program, as well as

<sup>157</sup> Stevenson, R.J., A. Pinowska, and Y.K. Wang. 2004. *Ecological Condition of Algae and Nutrients in Florida Springs*. Florida Department of Environmental Protection, Tallahassee, FL.

<sup>158</sup> Duarte, C.M. 1995. Submerged aquatic vegetation in relation to different nutrient regimes. *Ophelia: International Journal of Marine Biology* 41: 87–112.

<sup>159</sup> Because FL classifications are cumulative, Class I waters include protections for aquatic life and recreation, in addition to protecting drinking water supply use.

monitoring, assessments, and listing of impaired waters based on applicable CWA WQS and establishment of TMDLs.

In this final rule, the Agency has also deleted proposed regulatory provisions at 40 CFR 131.43(d)(2)(i)–(iii) on mixing zones, design flow, and listing impaired waters. EPA notes that the final criteria in this rule are subject to Florida's general rules of applicability in the same way and to the same extent as are other State-adopted and/or Federally-promulgated criteria for Florida waters. (See 40 CFR 131.43(d)(2)). States have discretion to adopt policies generally affecting the application and implementation of WQS. (See 40 CFR 131.13). There are many applications of criteria in Florida's water quality programs. Therefore, EPA believes that it is not necessary for purposes of this final rule to enumerate each of them, nor is it necessary to restate any otherwise applicable requirements. This broad reference to general rules of applicability provides sufficient coverage and has been used without further elaboration in EPA's most recent criteria promulgation applicable to State waters.<sup>160</sup> The Agency is also concerned that addressing some applications in this final regulations and not others may create unnecessary and unintended questions, confusion, and uncertainty about the overall application of Florida's general rules.

## (2) Summary of Major Comments

Regarding application of criteria, several commenters asked EPA to provide more detail on how waters would be monitored, whether EPA would use the rotating basin approach that FDEP uses, how EPA would enforce the criteria, and how specific entities would be affected. In response, EPA points out that WQS generally, and EPA's rule specifically, do not specify how to achieve those WQS. As discussed above, the State of Florida will determine how best to meet these Federal numeric criteria in a way that most effectively meets the needs of its citizens and environment. FDEP is the primary agency responsible for implementing CWA programs in the State of Florida. As such, EPA defers to FDEP in administering applicable CWA programs consistent with the CWA and EPA's implementing regulations. EPA has worked closely with the State to address nitrogen/phosphorus pollution problems in Florida. EPA will continue to collaborate with FDEP as the State implements EPA's Federally-promulgated numeric criteria.

Several commenters asserted that Florida would not be able to implement EPA's Federally-promulgated numeric criteria without first adopting the criteria into State law. EPA does not believe that, in order to implement EPA's Federally-promulgated numeric criteria, FDEP is required to adopt EPA's rule into State law. EPA's numeric criteria for Florida's lakes and flowing waters will be effective for CWA purposes 15 months after publication of the final criteria in the **Federal Register** and will apply in addition to any other existing CWA-effective criteria for Class I or Class III waters already adopted by the State and submitted to EPA (and for those adopted after May 30, 2000, adopted and submitted by FDEP and approved by EPA). FDEP retains the authority to move forward with its own rulemaking process at any time to establish State numeric criteria and to submit such criteria to EPA for review and approval under section 303(c) of the CWA. If FDEP does not adopt State numeric criteria, the Department retains its current authority to implement Federally promulgated criteria through the State's narrative or "free from" criteria. FDEP's General Counsel has confirmed, in a 2005 letter to EPA that the State's water quality criteria regulations for surface waters, set out at Section 62–302.500, F.A.C., provide authority for the Department to address and implement EPA promulgated criteria in CWA programs.<sup>161</sup>

Several commenters suggested that EPA incorporate water quality targets from adopted and approved TMDLs as site-specific criteria (SSAC) for specific waters in lieu of the more broadly applicable criteria promulgated by EPA. These commenters asserted that the TMDL values better reflect site-specific needs and were already serving as the basis for many pollutant reduction actions, including Basin Management Action Plans (BMAPs). Commenters expressed concern that actions to implement the TMDLs would be curtailed or delayed because of the uncertainty whether additional reductions might be required, and that both the Federal SSAC process (described in Section V.C of this notice) and use attainability analysis (UAA)/variance process would be too burdensome and time-consuming to be effective alternatives. Similarly, some commenters requested that specific restoration projects be exempted from EPA's criteria or that EPA employ a

process for delaying application of the criteria where a water is under study.

EPA's position is that EPA-established or approved TMDLs may provide sufficient information to support a site-specific alternative criterion, but that such a demonstration should be made after considering and taking into account any new relevant information available, including but not limited to the substantial analysis and data considered and made a part of the record for this final rule. For this reason, EPA considers the Federal SSAC procedure to be the appropriate mechanism for determining whether any specific TMDL target should be adopted as a SSAC. For restoration projects or waters under study, a State-issued variance may also be an appropriate vehicle for regulatory flexibility.

Several commenters requested clarification regarding the effect of EPA's Federally-promulgated numeric criteria on existing TMDLs. A TMDL is established at levels necessary to attain and maintain "applicable narrative and numerical water quality standards." (See 40 CFR 130.7(c)(1)). A TMDL addressing a narrative WQS requires translating the narrative WQC into a numeric water quality target (*e.g.*, a concentration). TMDLs are not implemented directly but through other programs such as NPDES permitting and non-point source programs. For example, a NPDES permitting authority must ensure at the time of permit issuance that WQBELs are consistent with the assumptions and requirements of any available wasteload allocation (WLA) for that discharge contained in a TMDL, as well as derive from and comply with all applicable WQS. (See 40 CFR 122.44(d)(1)(vii)(A) and (B)).

Some existing TMDLs translate the same portion of Florida's narrative criterion, Subsection 62–302.530(47)(b), F.A.C., as EPA has translated to derive its numeric criteria, *e.g.* no imbalance in natural populations of aquatic flora and fauna. The permitting authority must ensure that any permit issuance or re-issuance include WQBELs that are as stringent as necessary to meet the promulgated numeric criteria, pursuant to CWA section 301(b)(1)(C) and 40 CFR 122.44(d)(1). These existing TMDLs will likely include information that is relevant and helpful in evaluating necessary discharge limitations, such as consideration of other sources of the pollutant and hydrodynamics of the waterbody. EPA recommends that existing TMDLs that are based on translation of Subsection 62–302.520(47)(b), F.A.C. ("no imbalance in natural population of aquatic flora and

<sup>161</sup> FDEP, 2005, January 5, "Petition to Withdraw Florida's NPDES Authority of March 19, 2004 Response to EPA Letter of December 8, 2004." Letter from George Munson, General Counsel.

<sup>160</sup> See 40 CFR 131.41(d)(2).

fauna”), undergo a two-part evaluation. The first step is to assess whether the waterbody is still, in fact, water quality-limited (impaired) using the new numeric WQC. If the waterbody is still water quality-limited, then a second evaluation should be conducted to determine whether the existing TMDL based on the narrative is sufficient to meet the new numeric criterion, and in turn, whether or not it may be appropriate to revise the TMDL. The State may also wish to pursue submitting the TMDL water quality target derived by translating the narrative for determination as a Federal SSAC.

Other existing TMDLs translate another part of Florida’s narrative nutrient criterion, Subsection 62–302.530(47)(a) F.A.C. This provision provides that nitrogen/phosphorus pollution shall be limited so as to prevent violation of another Florida WQS. Where a TMDL water quality target was developed as a translation of this part of Florida’s narrative nutrient criterion (for example, that amount of nitrogen/phosphorus that would not cause excursions of Florida’s dissolved oxygen WQS), the appropriate WQBEL is the more stringent result of applying the TMDL WLA or the promulgated numeric criteria.

It is important to keep in mind that no TMDL will be rescinded or invalidated as a result of this final rule, nor does this final rule have the effect of withdrawing any prior EPA approval of a TMDL in Florida. Neither the CWA nor EPA regulations require TMDLs to be completed or revised within any specific time period after a change in water quality standards occurs. TMDLs are typically reviewed as part of States’ ongoing water quality assessment programs. Florida may review TMDLs at its discretion based on the State’s priorities, resources, and most recent assessments. NPDES permits are subject to five-year permit cycles, and in certain circumstances are administratively continued beyond five years. In practice, States often prioritize their administrative workload in permits. This prioritization could be coordinated with TMDL review.

EPA-established or approved TMDLs may provide sufficient information to support a site-specific alternative criterion (SSAC). The SSAC path is one that local governments or businesses may want to pursue where they desire assurance that the TMDL will become the applicable numeric criteria in advance of the State’s review of the TMDL or where substantial investments in pollution controls are predicated on water quality based effluent limits, and

local governments or businesses need long-term planning certainty before making these investments. The demonstrations supporting SSAC requests for TMDLs should reflect any new relevant information that has become available since the TMDL was developed, including but not limited to the substantial analysis and data considered and made a part of the record for this final rule. For this reason, EPA considers the Federal SSAC procedure to be the appropriate mechanism for determining whether any specific TMDL target should replace the otherwise applicable numeric criteria in this final rule. EPA will work cooperatively with entities requesting SSAC to expedite consideration of TMDL targets and associated TN and/or TP levels as Federal SSAC for purposes of this final rule. As explained in the preamble to the final rule, EPA has delayed the effective date of its numeric criteria for 15 months. EPA encourages any entity wishing to have EPA adopt a particular TMDL target as a SSAC to submit such TMDL to EPA for consideration as a SSAC as soon as possible during these 15 months. When submitting such requests to EPA, such entity must copy FDEP so that FDEP may provide any comments it has to EPA. EPA would then review the SSAC application and prepare the SSAC for public notice once this final rule takes effect. Following this process, the TMDL target, if scientifically and technically justified, could replace the otherwise applicable numeric criteria within a very short period of time after this final rule takes effect. Following any such establishment of site-specific numeric criteria, the State of Florida may review and/or revise the TMDL at its discretion based on the changed criteria and the State’s priorities, resources, and most recent assessments. EPA is still required to approve any changes to a previously approved TMDL.

EPA is extending the effective date of this rule, with the exception of the site-specific alternative criteria provision for reasons discussed below, for 15 months to allow time for the Agency to work with stakeholders and FDEP on important implementation issues and to help the public and all affected parties better understand the final criteria and the bases for those criteria. EPA solicited comment on the rule’s proposed effective date in the preamble to the proposed rule (75 FR 4216 (January 26, 2010)) and received many comments requesting that EPA delay the effective date of the final criteria. A range of commenters suggested delayed effective dates from several months to

several years, including linking the effective date of this rule with the forthcoming estuaries and coastal waters rule to allow closer coordination of the related parts of the two rulemakings. EPA does not agree with some commenters that such an extensive delay is necessary. However, EPA does believe, as discussed below, that these criteria present a unique opportunity for substantial nitrogen and phosphorus loadings reductions in the State that would be greatly facilitated and expedited by strongly coordinated and well-informed stakeholder engagement, planning, and support before a rule of this significance and broad scope begins to take effect and be implemented through the State’s regulatory programs.

EPA believes that it is critical, before the rule becomes effective, to engage and support, in full partnership with FDEP, the general public, stakeholders, local governments, and sectors of the regulated community across the State in a process of public outreach, education, discussion, and constructive planning. EPA solicited comment on the proposed rule in January 2010 and has carefully considered those comments, which numbered more than 22,000, in developing the final rule. However, the nature of rule development has kept EPA from publicly discussing the contents of the final rule until the rule development process, itself, was complete. An investment in outreach, information, coordination, technical assistance and planning following this action may result in far more effective, expeditious, and ultimately effective implementation of appropriate and badly needed nutrient pollution reduction measures leading to public health and environmental improvements, the goals of this rule. EPA recognizes that in order for FDEP to effectively implement the final criteria for nutrients, it needs to plan how to best address the criteria in State programs such as the permits, waterbody assessment and listing, and TMDL programs. The State may need to develop implementation plans and guidance for affected State regulatory programs, train employees, and educate the public and regulated communities. EPA will work with FDEP as a partner over the next 15 months as FDEP takes the steps necessary to implement the new standards in an orderly manner. Moreover, EPA believes it would be useful and beneficial to have discussions with State and local officials, organizations of interested parties, and with the general public to explain the final rule, the bases for that

rule, and respond to implementation questions and concerns.

Several stakeholder groups have provided comments about particular implementation issues that will require time to address before effective implementation of the final rule can be achieved. Florida has a unique local government administration structure that includes county, municipal, and special districts, all which have overlapping authorities with respect to managing water resources. The special districts provide water resource management oversight of flood control and water supply services. These multiple layers of government authorities will require time to coordinate responsibilities. An additional concern for local governments is their budgeting process. Most local governments operate on a fiscal year cycle of October to September; thus they have recently begun a new fiscal year. These local governments engage in multi-year budget planning and have already begun laying the budget foundations for up to five successive years. EPA recognizes that Florida's agricultural community has implemented a variety of best management practices (BMPs) that are effective at reducing nitrogen and phosphorus pollution from farms. However, Florida's agriculture industry is composed of a large number of small farms (about 17,000) that have average annual sales of less than \$10,000 each, and most do not receive any form of government assistance.<sup>162</sup> EPA anticipates that the Natural Resource Conservation Service and the University of Florida/Institute of Food and Agricultural Sciences Extension will need time to educate those not currently enrolled in nutrient management and BMP programs to control nutrient runoff.

A delayed effective date of 15 months for the criteria will also provide time for interested parties to pursue site-specific alternative criteria (SSAC) for a given waterbody. EPA's final rule and associated preamble describe the process by which any entity may seek

a SSAC. A decision to seek a SSAC could not be made, however, until interested parties know what the applicable criteria would be. The Federal SSAC portion of the rule, § 131.43(e), goes into effect 60 days after publication of this rule to allow this important work to proceed in advance of the effective date for the remaining provisions of the rule. During the 15 months before the criteria become effective, parties may evaluate the final criteria, decide whether they want to seek a SSAC, and, if so, submit their SSAC application materials to EPA, copying FDEP. EPA could then review the application, and if complete, public notice the application and technical support document pursuant to the SSAC provision in the final rule. If, after reviewing public comment, EPA believes that the SSAC application meets the requirements of this rule, EPA could determine that such SSAC apply to the specific waterbody in lieu of the criteria in the final rule, even before the criteria in the final rule become effective due to the earlier effective date of the SSAC provision.

EPA believes that the 15-month period of time between publication in the **Federal Register** and the effective date of the criteria will ultimately result in attainment of the criteria in an overall shorter period of time. As EPA frequently points out in its guidance and training materials, criteria are not "self-implementing", that is, it takes knowledgeable and experienced professionals to effectively and properly employ the criteria in monitoring and assessment programs, permit limit derivation and expression, nonpoint source (NPS) control strategies, and other program applications. Without time to develop procedures, there is the risk of ineffective implementation that will not meet the underlying objective of this action—to restore and protect Florida's waters from harm caused by nitrogen and phosphorus pollution. Well designed and mapped out NPS control strategies, in particular, will be critical to gain stakeholder trust and participation.

EPA wishes to actively engage in partnership with FDEP to support FDEP's implementation of these new standards, for example by considering applications for site-specific alternative criteria. After careful consideration of time requirements for critical steps, along with recognition of important planning and accounting mechanisms such as fiscal years, and local and county meeting and planning cycles, EPA has determined that a 15-month time period is both reasonable and will allow time for important

implementation activities to take place. This 15-month period will allow for a four-month education and outreach rollout to cover the major interest sectors and geographic locations throughout the State of Florida; a three-month period of training and guidance concurrent with data synthesis and analysis to support potential SSAC development; a two-month public comment and response period to allow development of effective guidance, training and possible workshops to run concurrent with SSAC submittals; a three-month period for finalizing guidance materials along with development of rollout strategies (e.g., for NPS control) concurrent with notice and comment of SSAC; and finally a 3-month period for statewide education and training on guidance and contingency planning. In short, the 15 months before the criteria become effective will ensure application of programs to achieve criteria in a manner that makes the most efficient use of limited resources and gains the broadest possible support for timely and effective action upon reaching the effective date of the criteria.

#### **IV. Under what conditions will Federal standards be withdrawn?**

Under the CWA, Congress gave States primary responsibility for developing and adopting WQS for their navigable waters. (See CWA section 303(a)-(c)). Although EPA is promulgating numeric criteria for lakes and springs throughout Florida and flowing waters outside the South Florida Region, Florida continues to have the option to adopt and submit to EPA numeric criteria for the State's Class I and Class III waters consistent with CWA section 303(c) and implementing regulations at 40 CFR part 131.

Pursuant to 40 CFR 131.21(c), EPA's promulgated WQS are applicable WQS for purposes of the CWA until EPA withdraws those Federally-promulgated WQS. Withdrawing the Federal standards for the State of Florida would require rulemaking by EPA pursuant to the requirements of the Administrative Procedure Act (5 U.S.C.551 *et seq.*). EPA would undertake such a rulemaking to withdraw the Federal criteria if and when Florida adopts and EPA approves numeric criteria that fully meet the requirements of section 303(c) of the CWA and EPA's implementing regulations at 40 CFR part 131.

<sup>162</sup> NASS. 2009a. 2007 Census of agriculture Florida State and county data, Volume 1, Geographic Area Series, Part 9, AC-07-A-9, Updated December 2009, National Agricultural Statistics Service, U.S. Department of Agriculture, Washington, DC. [http://www.agcensus.usda.gov/Publications/2007/Full\\_Report/Volume\\_1\\_Chapter\\_1\\_State\\_Level/Florida/flv1.pdf](http://www.agcensus.usda.gov/Publications/2007/Full_Report/Volume_1_Chapter_1_State_Level/Florida/flv1.pdf) (retrieved July 15, 2010).

NASS. 2009. 2009 State agriculture overview—Florida. U.S. Department of Agriculture, National Agricultural Statistics Service, Washington, DC, [http://www.nass.usda.gov/Statistics\\_by\\_State/Ag\\_Overview/AgOverview\\_FL.pdf](http://www.nass.usda.gov/Statistics_by_State/Ag_Overview/AgOverview_FL.pdf) (retrieved June 17, 2010).

## V. Alternative Regulatory Approaches and Implementation Mechanisms

### A. Designating Uses

#### (1) Background and Analysis

Under CWA section 303(c), States shall adopt designated uses after taking “into consideration the use and value of water for public water supplies, protection and propagation of fish, shellfish, and wildlife, recreation in and on the water, agricultural, industrial and other purposes including navigation.” Designated uses “shall be such as to protect the public health or welfare, enhance the quality of water and serve the purposes of [the CWA].” (See CWA section 303(c)(2)(A)). EPA’s regulation at 40 CFR 131.3(f) defines “designated uses” as “those uses specified in water quality standards for each waterbody or segment whether or not they are being attained.” A “use” is a particular function of, or activity in, waters of the United States that requires a specific level of water quality to support it. In other words, designated uses are a State’s concise statements of its management objectives and expectations for each of the individual surface waters under its jurisdiction.

In the context of designating uses, States often work with stakeholders to identify a collective goal for their waters that the State intends to strive for as it manages water quality. States may evaluate the attainability of these goals and expectations to ensure they have designated appropriate uses. (See 40 CFR 131.10(g)). Consistent with CWA sections 101(a)(2) and 303(c)(2)(A), EPA’s implementing regulations specify that States adopt designated uses that provide water quality for the protection and propagation of fish, shellfish, and wildlife and for recreation in and on the water, wherever attainable. (See 40 CFR 131.10). Where States do not designate those uses, or remove those uses, they must demonstrate that such uses are not attainable consistent with the use attainability analysis (UAA) provisions of 40 CFR 131.10, specifically 131.10(g). States may determine, based on a UAA, that attaining a designated use is not feasible and propose to EPA to change the use to something that is attainable. This action to change a designated use must be completed in accordance with EPA regulations. (See 40 CFR 131.10(g) and (h)). In implementing these regulations, EPA allows grouping waters together in a watershed in a single UAA, provided that there is site-specific information to show how each individual water fits into the group in the context of any single UAA and how each individual water meets the

applicable requirements of 40 CFR 131.10(g).

EPA’s final numeric criteria for lakes and flowing waters apply to those waters designated by FDEP as Class I (Potable Water Supplies) or Class III (Recreation, Propagation and Maintenance of a Healthy, Well-Balanced Population of Fish and Wildlife). If Florida removes either the Class I and/or Class III designated use for any particular waterbody ultimately affected by this rule, and EPA finds that removal to be consistent with CWA section 303(c) and regulations at 40 CFR part 131, then the Federally-promulgated numeric criteria would not apply to that waterbody because it would no longer be designated Class I or III. Instead, any criteria associated with the newly designated use would apply to that waterbody.

#### (2) Summary of Major Comments

Many commenters took the opportunity to emphasize the need to adhere to the regulations governing the process of modifying or removing a designated use. Some commenters suggested that the process to change a designated use is extremely difficult. EPA’s experience is that UAAs may range from simple to complex, depending on a variety of factors, such as the type of waterbody involved, the size of the segment, the use being changed, the relative degree of change proposed for the designated use, the presence of unique ecological habitats, and the level of public interest/involvement in the designated use decision. EPA agrees that, while a UAA is being conducted, the current designated use and corresponding criteria remain in place. In the case of Florida’s Class I and Class III flowing waters and lakes, EPA’s promulgated numeric criteria will remain the applicable WQS for CWA purposes, including assessments, listings, TMDL development and the issuance of NPDES permits, unless and until the State adopts revised designated uses (with different associated criteria) that are submitted to and approved by EPA under CWA section 303(c).

### B. Variances

#### (1) Final Rule

For purposes of this rule, EPA is promulgating criteria that apply to use designations that Florida has already established. EPA believes that the State has sufficient authority to use its currently EPA-approved variance procedures with respect to a temporary modification of its Class I or Class III uses as it pertains to any Federally-

promulgated criteria. For this reason, EPA did not propose and is not promulgating an alternative Federal variance procedure.

#### (2) Background and Analysis

A variance is a temporary modification to the designated use and associated water quality criteria that would otherwise apply to the receiving water.<sup>163</sup> Variances constitute new or revised WQS subject to the substantive requirements applicable to removing a designated use.<sup>164</sup> Thus, a variance is based on the same factors, set out at 40 CFR 131.10(g), that are required to revise a designated use through a UAA. Typically, variances are time-limited (e.g., three to five years), but renewable. Temporarily modifying the designated use for a particular waterbody through a variance process allows a State to limit the applicability of a specific criterion to that water and to identify an alternative designated use and associated criteria to be met during the term of the variance. A variance should be used instead of removal of a use where the State believes the standard can be attained at some point in the future. By maintaining the designated use for all other criteria and dischargers, and by specifying a point in the future when the designated use will be fully applicable in all respects, the State ensures that further progress will be made in improving water quality and attaining the standard. A variance may be written to address a specified geographic area, a specified pollutant or pollutants, and/or a specified pollutant source. All other applicable WQS not specifically modified by the variance would remain applicable (e.g., any other criteria adopted to protect the designated use). State variance procedures, as part of State WQS, must be consistent with the substantive requirements of 40 CFR part 131. Each variance, as a revised WQS, must be submitted to EPA for review pursuant to CWA section 303(c). A variance allows, among other things, NPDES permits to be written such that reasonable progress is made<sup>165</sup> toward attaining the underlying standards for affected waters without violating section 402(a)(1) of the Act, which requires that NPDES permits

<sup>163</sup> Water Quality Standards Regulation, 40 CFR part 131: Advance notice of proposed rulemaking. USEPA FR 63:129 (July 7, 1998). p. 36741–36806.

<sup>164</sup> *In re Bethlehem Steel Corporation*, General Counsel Opinion No. 58. March 29, 1977 (1977 WL 28245 (E.P.A. G.C.)).

<sup>165</sup> USEPA. 1994. *Water Quality Standards Handbook: Second Edition*. EPA–823–B–94–005a. U.S. Environmental Protection Agency, Office of Water, Washington, DC.

must meet the applicable WQS. (See CWA section 301(b)(1)(C)).

### (3) Summary of Major Comments

In response to comments, EPA agrees that variances could be adopted on a multiple-discharger basis and can be renewed so long as the State and EPA conclude that such variances are consistent with the CWA and implementing regulations. In this regard, EPA allows grouping waters together in a watershed in a single variance application, provided that there is site-specific information to show how each individual water fits into the group in the context of any single variance and how each individual water meets the applicable requirements of 40 CFR 131.10(g). EPA disagrees that Florida law, at 403.201(2), F.S., prohibits the State from issuing variances for waters affected by the Federally-promulgated numeric criteria. Florida law at 403.201(2), F.S., provides that a variance may not be granted that would result in State requirements that are less stringent than a comparable Federal provision or requirement. As discussed above, a variance is a temporary modification to the designated use and thus to the associated water quality criteria that would otherwise apply to the receiving water. EPA's Federal rule, however, does not promulgate or revise any Florida designated uses. EPA's criteria are intended to protect the Class I and Class III designated uses that Florida already has in place. EPA's criteria do not apply where and when the use is something other than Class I or Class III, as would be the case for a variance. Rather, Florida would establish alternative criteria associated with the variance. Any variance would constitute a new or revised WQS subject to EPA review and approval pursuant to section 303(c) of the CWA.

### C. Site-Specific Alternative Criteria

#### (1) Final Rule

EPA believes that there is benefit in establishing a specific procedure in the Federal rule for EPA adoption of Federal site-specific alternative criteria (SSAC) for the numeric chlorophyll *a*, TN, TP, and nitrate+nitrite criteria in this rule. In this rulemaking, EPA is promulgating a procedure whereby the Regional Administrator, Region 4, may establish a SSAC after providing for public comment on the proposed SSAC and the supporting documentation. (See 40 CFR 131.43(e)). This procedure allows any entity, including the State, to submit a proposed Federal SSAC directly to EPA for the Agency's review and assessment

as to whether an adjustment to the applicable Federal numeric criteria is appropriate and warranted. The Federal SSAC process is separate and distinct from the State's SSAC processes in its WQS.

The Federal SSAC procedure allows EPA to determine that a revised site-specific chlorophyll *a*, TN, TP, or nitrate + nitrite numeric criterion should apply in lieu of the generally applicable criteria promulgated in this final rule where that SSAC is demonstrated to be protective of the applicable designated use(s). The promulgated procedure provides that EPA will solicit public comment on its determination. Because EPA's rule establishes this procedure, implementation of this procedure does not require withdrawal of Federally-promulgated criteria for affected water bodies for the Federal SSAC to be effective for purposes of the CWA. EPA has promulgated similar procedures for EPA granting of variances and SSACs in other Federally-promulgated WQS.<sup>166</sup>

EPA is aware of concerns expressed by some commenters that a waterbody may exceed the numeric criteria in this rule and still meet Florida's designated uses related to recreation, public health, and the propagation and maintenance of a healthy, well-balanced population of fish and wildlife. EPA recognizes that there may be certain situations where additional, new, or more specific data related to the local conditions or biology of a particular waterbody may well support an alternate site-specific numeric criteria which may appropriately be more (or less) stringent than the criteria in this final rule in order to ensure maintenance of instream designated uses and protection of downstream waters. EPA believes that the SSAC process is an appropriate mechanism to address such situations and is committed to acting on Federal SSAC applications intended to address such situations as expeditiously as possible.

The process for obtaining a Federal SSAC includes the following steps. First, an entity seeking a SSAC compiles the supporting data, conducts the analyses, develops the expression of the criterion, and prepares the supporting documentation demonstrating that alternative numeric criteria are protective of the applicable designated use. The "entity" may be the State, a city or county, a municipal or industrial discharger, a consulting firm acting on a behalf of a client, or any other individual or organization. The entity

requesting the SSAC bears the burden of demonstrating that any proposed SSAC meets the requirements of the CWA and EPA's implementing regulations, specifically 40 CFR 131.11. Second, if the entity is not the State, the entity must provide notice of the proposed SSAC to the State, including all supporting documentation so that the State may provide comments on the proposal to EPA. Third, the Regional Administrator will evaluate the technical basis and protectiveness of the proposed SSAC and decide whether to publish a public notice and take comment on the proposed SSAC. The Regional Administrator may decide not to publish a public notice and instead return the proposal to the entity submitting the proposal, with an explanation as to why the proposed SSAC application did not provide sufficient information for EPA to determine whether it meets CWA requirements or not. If EPA solicits public comment on a proposed SSAC, upon review of comments, the Regional Administrator may determine that the Federal SSAC is appropriate to account for site-specific conditions and make that determination publicly available together with an explanation of the basis for the decision. The Regional Administrator may also determine that the Federal SSAC is not appropriate and make that determination publicly available together with an explanation of the basis for the decision.

To successfully develop a Federal SSAC for a given lake, stream, or spring, a thorough analysis is necessary that indicates how designated uses are being supported both in the waterbody itself and in downstream water bodies at concentrations of either TN, TP, chlorophyll *a*, or nitrate+nitrite that are either higher or lower than the Federally-promulgated applicable criteria. This analysis should have supporting documentation that consists of examining both indicators of longer-term response to multiple stressors, such as benthic macroinvertebrate health as determined by Florida's Stream Condition Index (SCI), and indicators of shorter-term response specific to nitrogen/phosphorus pollution, such as periphyton algal thickness or water column chlorophyll *a* concentrations. To pursue a Federal SSAC on a watershed-wide basis, the same types of procedures that EPA used to develop the Federally promulgated applicable criteria can be used with further refinements to the categorization of water bodies. For example, an entity could derive alternative instream protective TP and/or TN values using

<sup>166</sup> See 40 CFR 131.33(a)(3), 40 CFR 131.34(c), 40 CFR 131.36(c)(3)(iii), 40 CFR 131.38(c)(2)(v), 40 CFR 131.40(c).



EPA's approach by further sub-delineating the Nutrient Watershed Regions and providing the corresponding data, analysis and documentation to support derivation of an alternative criteria that is protective of the designated use that applies both to the smaller watershed regions as well as to downstream waters. This type of refined reference condition approach is described in EPA guidance manuals<sup>167</sup> and would be consistent with methods used to develop the Federally-promulgated criteria for Florida. In developing either a site-specific or watershed-wide Federal SSAC, it is necessary to ensure that values allowed in an upstream segment as a result of a SSAC provide for the attainment and maintenance of the WQS of downstream waters. It will be important to examine a stream system on a broader basis to ensure that a SSAC established for one segment does not result in adverse effects in nearby segments or downstream waters, such as a downstream lake.

This rule specifically identifies four approaches for developing SSAC. The first two approaches are replicating the approaches EPA used to develop stream and lake criteria, respectively, and applying these methods to a smaller subset of waters. The third approach for developing SSAC is to conduct a biological, chemical, and physical assessment of waterbody conditions. The fourth approach for developing SSAC is a general provision for using another scientifically defensible approach that is protective of the designated use. The first two approaches for developing SSAC replicate EPA's methods in deriving the stream and lake criteria set out in this final rule. To understand the necessary steps in this analysis, interested parties should refer to the complete documentation of these methods in the materials included in the rule docket.

The third approach for developing SSAC is to conduct a biological, chemical, and physical assessment of waterbody conditions. This is a more general approach than the replication approaches and would need additional detail and description of supporting rationale in the documentation submitted to EPA. The components of this approach could include, but not be limited to, evaluation of benthic macroinvertebrate health using the Stream Condition Index (SCI), presence or absence of native flora and fauna,

chlorophyll *a* concentrations or periphyton density, average daily dissolved oxygen fluctuation, organic versus inorganic components of total nitrogen, habitat assessment, and hydrologic disturbance. This approach could apply to any waterbody type, with specific components of analysis tailored for the situation. The fourth approach for developing SSAC is a general provision for using another scientifically defensible approach that is protective of the designated use. This provision allows applicants to make a complete demonstration to EPA using methods not otherwise described in the rule or its statement of basis, consistent with 40 CFR 131.11(b)(1)(iii). This approach could potentially include use of mechanistic models or other data and information.

#### (2) Background and Analysis

A SSAC is an alternative value to criteria set forth in this final rule that would be applied on a watershed, area-wide, or water-body specific basis that meets the regulatory test of protecting the instream designated use, having a basis in sound science, and ensuring the protection and maintenance of downstream WQS. SSAC may be more or less stringent than the otherwise applicable Federal numeric criteria. In either case, because the SSAC must protect the same designated use and must be based on sound science (*i.e.*, meet the requirements of 40 CFR 131.11(a)), there is no need to modify the designated use or conduct a UAA. A SSAC may be appropriate when further scientific data and analyses can bring added precision or accuracy to express the necessary level or concentration of chlorophyll *a*, TN, TP, and/or nitrate+nitrite that protects the designated use for a particular waterbody.

#### (3) Summary of Major Comments

Many commenters expressed support for the concept of EPA's proposed SSAC procedure, although many also expressed concerns about the viability, requirements, expense, and time associated with the process. In EPA's proposed rule, the SSAC process was to be initiated by the State submitting a request to EPA. Many commenters were confused about the relationship between the Federal SSAC process and the State's Type 1 and Type 2 SSAC processes, and how the processes relate for purposes of the Federal rule. The Federal SSAC process is separate and independent from the State SSAC processes. A Federal SSAC is established by the Regional Administrator of EPA Region 4 after due

notice and comment from the public. To resolve this confusion, and to provide a more direct means for entities other than the State to initiate the SSAC process, EPA's final rule provides that any entity may submit a request for a SSAC directly to the Regional Administrator. The final rule adds a requirement that entities submit proposed SSAC and supporting materials to the State at the same time those materials are submitted to EPA to ensure the State has the opportunity to submit comments to EPA.

As several commenters have pointed out, Florida WQS regulations currently do not authorize the State to adopt a SSAC as State WQS except where natural conditions are outside the limits of broadly applicable criteria established by the State (Section 62–302.800, F.A.C.). However, the State may choose to be the entity that submits a SSAC request to EPA under the Federal process described above and set forth at 40 CFR 131.43(e). There is no requirement that the State go through its own State-level Type 1 or Type 2 SSAC process before submitting a proposed SSAC to EPA for consideration under this rule.

Commenters included suggestions for specific approaches for developing SSAC as well as an "expedited" process for determination as a Federal SSAC. EPA agrees that many of the suggested approaches have merit for purposes of developing SSAC, and has adapted many of the suggestions to provide more information on approaches that would meet the general requirements for protective criteria. Many of the comments regarding an "expedited" process suggested a process where SSAC become effective automatically, without need for EPA review and approval. With the exception of State adjustment of lake criteria within a very specific and limited range accompanied by a specified data set and calculation as discussed in Section III.C(2)(e) above, the Agency does not agree with the view that criteria established in this rule can be revised without documentation and public notice and comment process as outlined above.<sup>168</sup> Another commenter asked about the potential to develop a SSAC on a "watershed-scale." EPA does not see any barrier to conducting such an analysis, where it can be demonstrated that the watershed-scale SSAC is protective for all waters in a particular grouping and meets the requirements of 40 CFR 131.11 and 40

<sup>168</sup> EPA's criteria allow for one-time site-specific modifications to the promulgated lake criteria, without requiring those modifications to be submitted as SSAC. See 40 CFR 131.43(c)(1)(ii) and Section III.C(2)(e).

<sup>167</sup> USEPA. 2000b. *Nutrient Criteria Technical Guidance Manual: Rivers and Streams*. EPA-822-B-00-002. U.S. Environmental Protection Agency, Office of Water, Washington, DC.

CFR 131.10(b). Many commenters expressed the desire to defer the applicability of promulgated criteria prior to developing a SSAC. The Federal SSAC portion of the rule, § 131.43(e), goes into effect 60 days after publication of this rule to allow this important work to proceed in advance of the effective date of 15 months after publication for the remaining provisions of the rule. The SSAC review process will depend in substantial part on the nature of the SSAC proposal itself: Its clarity, substance, documentation, and scientific rigor. Some commenters stated that EPA's requirement that Federal SSAC be scientifically defensible and protective of designated uses is too vague; however, it is the same requirement for criteria in the Federal WQS regulation. (See 40 CFR 131.11). EPA will consider the need for further developing supporting technical guidance in the future if it appears at that time that such guidance would help support the process.

#### D. Compliance Schedules

##### (1) Final Rule

Florida has adopted a regulation authorizing compliance schedules. That regulation, Subsection 62–620.620(6), F.A.C., is not affected by this final rule. The complete text of the Florida rules concerning compliance schedules is available at <https://www.flrules.org/gateway/RuleNo.asp?ID=62-620.620>. Florida is, therefore, authorized to grant compliance schedules, as appropriate, under its rule for WQBELs based on EPA's numeric criteria.

##### (2) Background and Analysis

A compliance schedule, or schedule of compliance, refers to “a schedule of remedial measures included in a ‘permit,’ including an enforceable sequence of interim requirements \* \* \* leading to compliance with the CWA and regulations.” (See 40 CFR 122.2, CWA section 502(17)). In an NPDES permit, WQBELs are effluent limits based on applicable WQS for a given pollutant in a specific receiving water (See NPDES Permit Writers Manual, EPA–833–B–96–003, December, 1996). EPA regulations provide that schedules of compliance may only be included in permits if they are determined to be “appropriate” given the circumstances of the discharge and are to require compliance “as soon as possible” (See 40 CFR 122.47).<sup>169</sup>

##### (3) Summary of Major Comments

EPA generally received favorable comment on its description of compliance schedules. Some commenters asked EPA to consider promulgating its own compliance schedule provisions as part of the final rule. Florida's regulations, however, already include an authorizing provision that allows NPDES permit writers to include compliance schedules in permits, where appropriate. Florida's regulations do not limit the criteria which may be subject to compliance schedules. Therefore, Florida may choose to issue permit compliance schedules for nitrogen/phosphorus pollution, as appropriate. As a result, there is no need for EPA to provide an additional compliance schedule authorizing provision in this final rule. EPA disagrees with commenters who assert that Florida's regulation at Subsection 62–620.620(6), F.A.C., authorizing compliance schedules applies only to industrial and domestic wastewater facilities. Chapter 62–620, F.A.C., sets out permit procedures for wastewater facilities or activities that discharge wastes into waters of the State or which will reasonably be expected to be a source of water pollution. (See Subsection 62–620.100(1), F.A.C.). Subsection 62–620.620(6), F.A.C., applies, therefore, more broadly than to just industrial and domestic wastewater facilities. In addition, Chapter 62–4, F.A.C., which sets out procedures on how to obtain a permit from FDEP, provides that permits may include a reasonable time for compliance with new or revised WQS. Subsection 62–4.160(10), F.A.C., does not limit the type of permits that may include such compliance schedules.

#### E. Proposed Restoration Water Quality Standard

##### (1) Final Rule

In EPA's January 2010 proposal, the Agency proposed a new WQS regulatory tool for Florida, referred to as “restoration WQS” for impaired waters. This provision was intended to allow Florida to retain full aquatic life protection (uses and criteria) for its water bodies while establishing a transparent phased WQS process that would result in implementation of enforceable measures and requirements to improve water quality over a specified time period to ultimately meet the long-term designated aquatic life use. For reasons discussed below and in EPA's response to comment document,

EPA has decided not to promulgate a restoration WQS tool specifically for Florida, as proposed.

##### (2) Summary of Major Comments

EPA received a significant number of comments on its proposal that provided constructive and useful information for EPA to consider regarding the proposed restoration WQS provision. Such comments ranged from identifying additional needed requirements to concerns that the restoration WQS tool was so burdensome it would not be helpful. EPA evaluated the current, existing flexibility available to Florida to implement this final rule through variances, compliance schedules, permit reissuance cycles, permit reopener provisions, TMDL scheduling, and workload and administrative prioritization. These are all considerations that FDEP presently brings to the administration of its water quality program. EPA also considered the flexibility that this final rule offers through lake criteria adjustment provisions, alternative approaches to deriving downstream lake protection values and the SSAC process discussed above. The Agency concluded that the range of implementation tools available to the State in combination with a number of the provisions contained in this final rule provide adequate flexibility to implement EPA's numeric criteria finalized in this rule. Florida may use any of these existing tools or exercise its authority to propose additional tools in the future that allow implementation flexibility where demonstrated to be appropriate and consistent with the CWA and implementing regulations. Therefore, EPA believes that its decision not to finalize restoration WQS will not adversely affect Florida's ability to implement the Federal numeric criteria.

#### VI. Economic Analysis

State implementation of this rule may result in new or revised National Pollutant Discharge Elimination System (NPDES) permit conditions for point source dischargers, and requirements for nitrogen/phosphorus pollution treatment controls on other sources (e.g., agriculture, urban runoff, and/or septic systems) through the development of additional Total Maximum Daily Loads (TMDLs) and Basin Management Action Plans (BMAPs). To provide information on the potential incremental costs associated with these related State actions, EPA conducted an analysis to estimate both the additional impaired waters that may be identified as a result of this final rule and the potential State of Florida requirements that may be

<sup>169</sup> Hanlon, Jim, USEPA Office of Wastewater Management. 2007, May 10. Memorandum to Alexis Stauss, Director of Water Division EPA Region 9, on “Compliance Schedules for Water

necessary to assure attainment of applicable State water quality designated uses. EPA's analysis is fully described in the document entitled: "*Economic Analysis of Final Water Quality Standards for Nutrients for Lakes and Flowing Waters in Florida*," which can be found in the docket and record for this final rule.

An economic analysis of a regulation compares a likely scenario absent the regulation (the baseline) to a likely scenario with the regulation. The impacts of the regulation are measured by the resulting differences between these two scenarios (incremental impacts). However, the regulatory effect of this final rule can be interpreted in several ways, which can significantly influence the conditions considered appropriate for representing the baseline. On January 14, 2009 EPA made a determination that numeric nutrient water quality criteria were necessary to meet the requirements of the CWA in the State of Florida. In July 2009 the State of Florida released draft numeric nutrient criteria for lakes and streams.<sup>170</sup> Therefore, when the Agency proposed this rule for lakes and flowing waters in January 2010, EPA evaluated the incremental impacts of the proposed rule in comparison with the provisions of the Florida July 2009 draft criteria. Although the State subsequently did not proceed forward with those numeric criteria provisions, EPA has conducted the same evaluation as part of the economic analysis accompanying this final rule to illustrate the difference between Florida's draft approach and the provisions of this rule. Using this same baseline approach and the refined analysis methodology described below, EPA estimates the potential incremental costs associated with this rule as ranging between \$16.4 million/year and \$25.3 million/year.

An alternative interpretation of the impact of this final rule is that EPA is promulgating numeric criteria to address deficiencies in the State of Florida's current narrative nutrient criteria (current conditions approach), and the incremental impacts of this rule are those associated with the difference between EPA's numeric criteria and Florida's narrative criteria. Under this scenario, the baseline incorporates requirements associated with current water quality, impaired waters, and TMDLs that exist at the time of the analysis. The incremental impacts of

this rule are the costs and benefits associated with additional pollution controls beyond those currently in place or required as a result of Florida's existing narrative criteria. This analysis is principally designed to gain an understanding of the potential costs and benefits associated with implementation of EPA's numeric criteria for lakes and flowing waters above and beyond the costs associated with State implementation of its current narrative nutrient criteria for those waters. For waters that the State of Florida has already identified as impaired, EPA expects that the effect of this final rule will be to shorten the time and reduce the resources necessary for the State of Florida to implement its existing regulatory and nonregulatory framework of tools, limits, measures and BMP guidance to initiate a broader, expedited, more comprehensive, and more effective approach to reducing nutrient loadings necessary to meet the numeric criteria that support current State designated uses. The further effect of this final rule will likely be the assessment and identification of additional waters that are impaired and not meeting the designated use set forth at Section I.B, and new or revised water quality-based effluent limits in NPDES permits. EPA's economic analysis quantifies the costs and cost savings associated with the identification of newly impaired waters and new or revised water quality-based effluent limits, but does not attempt to measure the costs and cost savings associated with addressing waters that are currently listed as impaired under Florida's existing narrative nutrient criteria (these costs are considered part of the baseline).

Although using the State of Florida's draft numeric criteria as a baseline provides one possible measure of the incremental impact associated with this final rule, the current conditions approach can provide valuable information to the State of Florida and the public about other potential costs and benefits that may be realized as a result of this final rule. To provide this additional information, and in part to respond to public comments on the economic analysis at proposal, this economic analysis also measures the incremental costs and benefits of this final rule using current conditions in the State of Florida as the baseline. Using this interpretation of the baseline, EPA estimates the potential incremental costs associated with this final rule as ranging between \$135.5 million per year and \$206.1 million per year. Although analyses using both baselines are

described in EPA's economic analysis document entitled: "*Economic Analysis of Final Water Quality Standards for Nutrients for Lakes and Flowing Waters in Florida*," the analytical methods and results described below highlight the current conditions baseline in detail.

To develop this analysis, EPA first assessed State control requirements associated with current water quality, impaired waters, and total maximum daily loads (the baseline). EPA then assessed the costs and benefits associated with additional pollution controls beyond those currently in place or required to meet EPA's numeric criteria that support Florida designated uses. To estimate incremental point source costs, EPA gathered publicly available information and data on control technologies currently in place at wastewater treatment plants and other industrial facilities, and used Florida Department of Environmental Protection (FDEP) point source implementation procedures to project the potential additional treatment that the State may require as a result of applying the criteria in this final rule. EPA assessed potential non-point source control costs by using publicly available information and data to determine land uses near waters that would likely be identified as impaired under this rule, and using FDEP and the Florida Department of Agriculture and Consumer Services (FDACS) nonpoint source control procedures, estimated costs to implement agricultural best management practices (BMPs) the State may require in order to attain the new numeric criteria. EPA also estimated the potential costs of additional State control requirements for storm water runoff, and potential costs associated with upgrades of homeowner septic systems. EPA also assessed additional potential government regulatory costs of developing additional total maximum daily loads (TMDLs) for waters identified as impaired under this rule. Finally, EPA qualitatively and quantitatively described and estimated some of the potential benefits of complying with the new water quality standards. Because of the inherent uncertainties associated with the benefits analysis, potential benefits are likely underestimated compared to costs. Although it is difficult to predict with certainty how the State of Florida will implement these new water quality standards, the results of these analyses represent EPA's estimates of costs and benefits of this final rule.

#### A. Point Source Costs

Point sources of wastewater must have a National Pollution Discharge

<sup>170</sup> Florida Department of Environmental Protection, 2009, "Draft Technical Support Document: Development of Numeric Nutrient Criteria for Florida Lakes and Streams," available electronically at: [http://www.dep.state.fl.us/water/wqssp/nutrients/docs/tsd\\_nutrient\\_crit.docx](http://www.dep.state.fl.us/water/wqssp/nutrients/docs/tsd_nutrient_crit.docx).

Elimination System (NPDES) permit to discharge into surface waters. EPA identified point sources potentially discharging nitrogen or phosphorus to lakes and flowing waters by evaluating EPA's NPDES Permit Compliance

System (PCS) database. EPA identified all the industry codes associated with any permitted discharger with an existing numeric effluent limit or monitoring requirement for nitrogen or phosphorus. This analysis identified

193 point sources as having the potential to discharge nitrogen and/or phosphorus. The following table summarizes the number of point sources with the potential to discharge nitrogen and/or phosphorus.

TABLE VI(A)—POINT-SOURCES POTENTIALLY DISCHARGING NITROGEN AND/OR PHOSPHORUS TO FLORIDA LAKES AND FLOWING WATERS

Discharger category	Major dischargers <sup>a</sup>	Minor dischargers <sup>b</sup>	Total
Municipal Wastewater .....	43	42	85
Industrial Wastewater .....	57	51	108
Total .....	100	93	193

<sup>a</sup> Facilities discharging greater than one million gallons per day and likely to discharge toxic pollutants in toxic amounts.

<sup>b</sup> Facilities discharging less than one million gallons per day and not likely to discharge toxic pollutants in toxic amounts.

1. Municipal Waste Water Treatment Plant (WWTP) Costs

EPA considered the costs of known nitrogen and phosphorus treatment options for municipal WWTPs. Nitrogen and phosphorus removal technologies that are available can reliably attain an annual average total nitrogen (TN) concentration of approximately 3.0 mg/L or less and an annual average total phosphorus (TP) concentration of approximately 0.1 mg/L or less.<sup>171</sup> Wastewater treatment to these concentrations was considered target levels for the purpose of this analysis.

The NPDES permitting authority determines the need for water quality based effluent limits for point sources on the basis of analysis of reasonable potential to exceed water quality criteria. To estimate the potential incremental costs for WWTPs, the likelihood that WWTPs discharging to Florida lakes and flowing waters have reasonable potential to exceed the numeric criteria in this final rule should be evaluated. However, the site-specific data and information required to precisely determine reasonable potential for each facility was not available. Thus, on the basis that most WWTPs are likely to discharge nitrogen and phosphorus at concentrations above applicable criteria,

EPA made the conservative assumption that all WWTPs have reasonable potential to exceed the numeric criteria.

For municipal wastewater, EPA estimated costs to reduce effluent concentrations to 3 mg/L or less for TN and 0.1 mg/L or less for TP using advanced biological nutrient removal (BNR). Although reverse osmosis and other treatment technologies may have the potential to reduce nitrogen and phosphorus concentrations even further, EPA believes that implementation of reverse osmosis applied on such a large scale has not been demonstrated as practical or necessary.<sup>172</sup> Such treatment has not been required for WWTPs by the State of Florida in the past, even those WWTPs under TMDLs with nutrient targets comparable to the criteria in this final rule. EPA believes that should state-of-the-art BNR technology together with other readily available physical and chemical treatment demonstrated to be effective in municipal WWTP operations not result in compliance with permit limits associated with meeting the new numeric nutrient criteria, then it is reasonable to assume that entities would first seek out other available means of attaining water quality standards such as reuse, nonpoint source reductions,

site-specific alternative criteria, variances, and designated use modifications.

To estimate compliance costs for WWTPs, EPA identified current WWTP treatment performance using information obtained from NPDES permits and/or water quality monitoring reports. EPA assumed that WWTPs under existing TMDLs are currently meeting their wasteload allocation requirements and would not incur additional treatment costs. EPA further assumed that costs to WWTPs discharging to currently impaired waters are not attributable to this final rule because those costs would be incurred absent the rule (under the baseline). However, sufficient location information was not available to insure that all WWTPs discharging to impaired waters were identified. Thus, costs may be overstated to the extent that some WWTPs discharging to currently impaired waters are included in EPA's estimate. The following table summarizes EPA's best estimate of the number of potentially affected municipal WWTPs that may require additional treatment to meet the numeric criteria supporting State designated uses.

TABLE VI(A)(1)(a)—POTENTIAL ADDITIONAL NUTRIENT CONTROLS FOR MUNICIPAL WASTEWATER TREATMENT PLANTS

Discharge type	Number of dischargers				Total
	Additional reduction in TN and TP <sup>a</sup>	Additional reduction in TN only <sup>b</sup>	Additional reduction in TP only <sup>c</sup>	No incremental controls needed <sup>d</sup>	
Major .....	11	2	9	21	43
Minor .....	19	1	3	19	42

<sup>171</sup> U.S. EPA, 2008, "Municipal Nutrient Removal Technologies Reference Document. Volume 1—Technical Report," EPA 832-R-08-006.

<sup>172</sup> Treatment using reverse osmosis also requires substantial amounts of energy and creates disposal

issues as a result of the large volume of concentrate that is generated.

TABLE VI(A)(1)(a)—POTENTIAL ADDITIONAL NUTRIENT CONTROLS FOR MUNICIPAL WASTEWATER TREATMENT PLANTS—Continued

Discharge type	Number of dischargers				Total
	Additional reduction in TN and TP <sup>a</sup>	Additional reduction in TN only <sup>b</sup>	Additional reduction in TP only <sup>c</sup>	No incremental controls needed <sup>d</sup>	
Total .....	30	3	12	40	85

<sup>a</sup> Includes dischargers without treatment processes capable of achieving the target levels or existing WLA for TN and TP, or for which the treatment train description is missing or unclear.

<sup>b</sup> Includes dischargers with chemical precipitation only and those with a wasteload allocations under a TMDL for TP only.

<sup>c</sup> Includes dischargers with MLE, four-stage Bardenpho, and BNR specified to achieve less than 3 mg/L and those with WLA under a TMDL for TN only.

<sup>d</sup> Includes dischargers with A<sup>2</sup>/O, modified Bardenpho, modified UCT, oxidation ditches, or other BNR coupled with chemical precipitation and those with WLAs under a TMDL for both TN and TP.

An EPA study provides unit cost estimates for biological nutrient removal controls for various TN and TP performance levels.<sup>173</sup> To estimate costs for WWTPs, EPA used the average capital and average operation and maintenance (O&M) unit costs for technologies that achieve an annual average of 3 mg/L or less for TN and/or 0.1 mg/L or less for TP. EPA also

estimated a maximum cost for TN and TP reduction by using the highest cost TN and TP removal technology (estimated by finding the maximum of annualized costs for each technology option). Using average and maximum unit costs and multiplying unit costs by flow reported in EPA's PCS database, EPA estimated total capital costs could be approximately \$108 million to \$219

million and operation and maintenance (O&M) costs could be approximately \$12 million per year to \$18 million per year. Total annual costs would be approximately \$22.3 million per year to \$38.1 million per year (capital costs annualized at 7% over 20 years). The following table summarizes estimated costs for municipal WWTPs.

TABLE VI(A)(1)(b)—POTENTIAL INCREMENTAL COSTS FOR MUNICIPAL WASTE WATER TREATMENT PLANTS

Cost component	Capital costs (millions) <sup>a</sup>	O&M costs (millions per year)	Annual costs (millions per year)
Advanced BNR .....	\$108–\$219	\$12–\$18	\$22.3–\$38.1

<sup>a</sup> Low estimate represents average of unit costs; high estimate represents costs for treatment processes that results in the highest annualized costs (annualized capital at 7% over 20 years plus O&M).

Using Florida's 2009 draft criteria as the baseline, municipal WWTP costs associated with this final rule are zero because treatment technologies needed to achieve Florida's 2009 draft criteria are the same as those needed to achieve the criteria in this final rule, even though the criteria themselves are somewhat different.

After EPA published its proposed criteria for Florida (75 FR 4173), several organizations in Florida developed alternative estimates of compliance costs for WWTPs that were substantially higher than EPA's estimated costs. EPA disagrees with these cost estimates because they included costs for nutrient controls that are beyond what would be required by Florida to meet the new numeric criteria. For example, the Florida Water Environment Association Utility Council (FWEAUC) estimated annual costs for WWTPs would be approximately \$2.0 billion per year to \$4.4 billion per year.<sup>174</sup> However, FWEAUC included in their analysis

facilities that discharge to estuaries or coastal waters, and facilities that utilize deep well injection or generate reuse water which are not covered by this rule. FWEAUC also estimated costs to upgrade WWTPs regardless of the treatment that already exists at the facilities. Finally, FWEAUC assumed that all WWTPs will require expensive microfiltration and reverse osmosis control technology to comply with the new standard. EPA is not aware of any WWTPs in Florida that utilize microfiltration or reverse osmosis, even those discharging to currently impaired waters with TMDLs that have nutrient targets comparable to the criteria in this final rule. Thus, as noted above, EPA does not believe that this type of treatment technology for WWTPs in Florida has been demonstrated as practical or necessary. These differences appear to explain the discrepancy between FWEAUC and EPA estimates.

2. Industrial Point Source Costs

Incremental costs for industrial dischargers are likely to be facility-specific and depend on process operations, existing treatment trains, and composition of waste streams. EPA previously estimated that 108 industrial dischargers may potentially be affected by this rule (Table VI(A)). Of those 108 dischargers, EPA identified 38 of them as under an existing TMDL for nitrogen and/or phosphorus and 14 of them as discharging to waters listed as impaired for nutrients and/or dissolved oxygen. As with WWTPs, EPA assumed that industrial dischargers under an existing TMDL are currently meeting their wasteload allocation requirements and would not incur additional treatment costs, and costs at facilities discharging to currently impaired waters are not attributable to this final rule because those costs would be incurred absent the rule (under the baseline). To estimate the potential costs to the remaining 56 potentially affected

<sup>173</sup> U.S. EPA, 2008.

<sup>174</sup> Florida Water Environment Association Utility Council, 2009, "Numeric Nutrient Criteria Cost

Implications for Florida POTWs," available electronically at: <http://www.fweauc.org/PDFs/FWEAUC%20letter%20to%20Crist>

[20re%20NNC%20Cost%20Implications%20for%20Fla%20POTWs%20with%20attachment.pdf](#).

industrial facilities, EPA took a random sample of those facilities from each industry. EPA then analyzed their effluent data obtained from EPA's PCS database and other information in NPDES permits to determine whether or not they have reasonable potential to cause or contribute to an exceedance of the numeric nutrient criteria in this final rule. For those facilities with reasonable potential, EPA further analyzed their effluent data and

estimated potential revised water quality based effluent limits (WQBEL) for TN and TP. If the data indicated that the facility would not be in compliance with the revised WQBEL, EPA estimated the additional nutrient controls those facilities would likely implement to allow receiving waters to meet State designated uses and the costs of those controls. EPA then calculated the average flow-based cost of compliance for the sampled facilities in each

industrial category, and used the average cost to extrapolate to the potential cost for the total flow associated with all facilities in each category (see economic analysis support document for more information). Using this method, EPA estimated the potential costs for industrial dischargers could be approximately \$25.4 million per year.

TABLE VI(A)(2)—POTENTIAL INCREMENTAL COSTS FOR INDUSTRIAL DISCHARGERS

Industrial category	Total number of facilities	Number of facilities sampled	Average sample cost (\$/mgd/yr) <sup>a</sup>		Total annual costs <sup>b</sup>
Chemicals and Allied Products .....	9	2	\$14,100	\$1,116,800	.....
Electric Services .....	9	2	0	.....	\$0
Food .....	7	2	123,300	.....	1,390,000
Mining .....	10	2	160,600	16,442,300	.....
Other .....	17	3	0	0	.....
Pulp and Paper .....	4	1	117,300	6,466,800	.....
<b>Total .....</b>	<b>56</b>	<b>12</b>	.....	<b>25,415,900</b>	.....

<sup>a</sup> Calculated by dividing total annual sample discharger costs by total sample discharger flow. Note that where flow for a sample discharger is not available, EPA used the average flow for dischargers in that category and discharger type (major or minor).

<sup>b</sup> Represents average sample discharger unit cost multiplied by total flow of dischargers affected by the rule in each industrial category.

Using Florida's 2009 draft criteria as the baseline, industrial discharger costs associated with this final rule is zero because treatment technologies needed to achieve the Florida's 2009 draft criteria are the same as those needed to achieve the criteria in this final rule, even though the criteria themselves are somewhat different.

Several organizations in Florida developed alternative estimates of compliance costs for EPA's proposed rule that were substantially higher than EPA's estimated costs for industrial dischargers. EPA disagrees with these cost estimates because they assumed that facilities will need to install treatment technologies that are much more expensive than those that would likely be required by Florida to meet the numeric criteria. For example, FDEP estimated that the costs for industrial dischargers would be approximately \$2.1 billion per year.<sup>175</sup> However, FDEP assumed that every industrial facility would treat their total discharge volume using reverse osmosis which EPA believes is impractical and unnecessary. In addition, FDEP estimated costs for reverse osmosis on the basis of each facility's maximum daily discharge flow

instead of its reported design capacity (in some cases the maximum daily flow was more than double the design capacity). Installing treatment technology to handle maximum daily flows would be unnecessary because equalization basins or storage tanks (used to temporarily hold effluent during peak flows) would be a less expensive compliance strategy. Finally, EPA found no indication that industrial facilities in Florida have installed reverse osmosis for the purpose of complying with a nutrient-related TMDL, even those TMDLs with nutrient targets comparable to the criteria in this final rule. These differences appear to explain the discrepancy between FDEP and EPA estimates.

**B. Incrementally Impaired Waters**

To estimate nonpoint source incremental costs associated with State control requirements that may be necessary to assure attainment of designated uses, EPA first removed from further consideration any waters the State of Florida has already determined to be impaired or has established a TMDL and/or BMAP because these waters were considered part of the

baseline for this analysis. EPA next identified Florida waters that may be identified as incrementally impaired using the criteria of this final rule, and then identified the watersheds surrounding those incrementally impaired waters. EPA analyzed FDEP's database of ambient water quality monitoring data and compared monitoring data for each waterbody with EPA's new criteria for TN and TP in lakes and flowing waters, and nitrate+nitrite concentrations in springs. To account for streams that may have downstream protection values (DPVs) as applicable criteria, streams intersecting lakes were assigned the applicable lake criteria. Costs may be overestimated because the method does not distinguish between upstream and downstream intersecting streams. Thus DPVs and additional controls may have been attributed to streams downstream of an impaired lake. EPA compiled the most recent five years of monitoring data, calculated the annual geometric mean for each waterbody identified by a waterbody identification number (WBID), and identified waters as incrementally impaired if they exceeded the applicable criteria in this final rule.

<sup>175</sup> Florida Department of Environmental Protection, 2010, "FDEP Review of EPA's

Preliminary Estimate of Potential Compliance Costs

and Benefits Associated with EPA's Proposed Numeric Nutrient Criteria for Florida," p. 3.

TABLE VI(B)—SUMMARY OF POTENTIAL INCREMENTALLY IMPAIRED WATERS

Category	Number of water bodies			Total
	Lake	Stream <sup>a</sup>	Spring	
Total in State .....	1,310	3,901	126	5,337
Not Listed/Covered by TMDL <sup>b</sup> .....	1,099	3,608	119	4,826
Water Quality Monitoring Data for Nutrients <sup>c</sup> .....	878	1,273	72	2,223
Sufficient Data Available <sup>d</sup> .....	655	930	72	1,657
Potentially Exceeding Criteria (incrementally impaired) <sup>e</sup> .....	148	153	24	325

<sup>a</sup> Includes blackwater.

<sup>b</sup> As reported in TMDL documents and FDEP.

<sup>c</sup> Data within last 5 years meeting data quality requirements.

<sup>d</sup> Annual geometric means based on at least 4 samples with one sample from May to September and one sample from October to April in a given year.

<sup>e</sup> Annual geometric mean exceeding the applicable criteria more than once in a three year period.

### C. Non-Point Source Costs

To estimate the potential incremental costs associated with controlling nitrogen/phosphorus pollution from non-point sources, EPA identified land areas near incrementally impaired waters using GIS analysis. EPA first identified all the 10-digit hydrologic units (HUCs) in Florida that contain at least a *de minimus* area of an incrementally impaired WBID (WBIDs were GIS polygons), and excluding those HUCs that contain at least a *de minimus* area of a currently impaired WBID. EPA then identified land uses using GIS analysis of data obtained from the State of Florida.<sup>176</sup>

#### 1. Costs for Urban Runoff

EPA's GIS analysis indicates that urban land (excluding land for industrial uses covered under point sources) accounts for approximately seven percent of the land near incrementally impaired waters. EPA's analysis also indicates that urban runoff is already regulated on approximately one half of this land under EPA's storm water program requiring municipal storm sewer system (MS4) NPDES permits. Florida has a total of 28 large (Phase I) permitted MS4s serving greater than 100,000 people and 131 small (Phase II) permitted MS4s serving less than 100,000 people. MS4 permits generally do not have numeric nutrient limits, but instead rely on implementation of BMPs to control pollutants in storm water to the maximum extent practicable. Even those MS4s in Florida discharging to impaired waters or under a TMDL currently do not have numeric limits for any pollutant.

In addition to EPA's storm water program, several existing State rules are intended to reduce pollution from urban runoff. Florida's Urban Turf Fertilizer

rule (administered by FDACS) requires a reduction in the amount of nitrogen and phosphorus that can be applied to lawns and recreational areas. Florida's 1982 storm water rule (Chapter 403 of Florida statutes) requires storm water from new development and redevelopment to be treated prior to discharge through the implementation of BMPs. The rule also requires that older systems be managed as needed to restore or maintain the beneficial uses of waters, and that water management districts establish and implement other storm water pollutant load reduction goals. In addition, Chapter 62–40, F.A.C., "Water Resource Implementation Rule," establishes that storm water design criteria adopted by FDEP and the water management districts shall achieve at least 80% reduction of the average annual load of pollutants that cause or contribute to violations of WQS (95% reduction for outstanding natural resource waters). The rule also states that the pollutant loading from older storm water management systems shall be reduced as necessary to restore or maintain the designated uses of waters.

Although urban runoff is currently regulated under the statutes and rules described above, this final rule may indirectly result in changes to MS4 NPDES permit requirements for urban runoff so that Florida waters meet State designated uses. However, the combination of additional pollution controls required will likely depend on the specific nutrient reduction targets, the controls already in place, and the relative amounts of nitrogen/phosphorus pollution contained in urban runoff at each particular location. Because storm water programs are usually implemented using an iterative approach, with the installation of controls followed by monitoring and re-evaluation to determine the need for additional controls, estimating the complete set of pollution controls required to meet a particular water

quality target would require site-specific analysis.

Although it is difficult to predict the complete set of potential additional storm water controls that may be required to meet the numeric criteria that supports State designated uses in incrementally impaired waters, EPA estimated potential costs for additional treatment by assessing the amount of urban land that may require additional pollution controls for storm water. FDEP has previously assumed that all urban land developed after adoption of Florida's 1982 storm water rule would be in compliance with this final rule.<sup>177</sup> Using this same assumption, EPA used GIS analysis of land use data obtained from the State of Florida<sup>178</sup> to identify the amount of remaining urban land located near incrementally impaired waters. Using this procedure, EPA estimated that up to 48,100 acres of Phase I MS4 urban land, 30,700 acres of Phase II MS4 urban land, and 30,600 acres of non-MS4 urban land may require additional storm water controls. EPA estimated costs of implementing controls for Phase I MS4 urban land based on a range of acres with 48,100 acres as the upper bound and zero acres as the lower bound because Phase I MS4 urban land already must implement controls to the "maximum extent practicable" and may not require additional controls if existing requirements are already fully implemented.

The cost of storm water pollution controls can vary widely. FDEP has assessed the cost of completed storm water projects throughout the State in dollars per acre treated.<sup>179</sup> Capital costs

<sup>177</sup> Florida Department of Environmental Protection, 2010, "FDEP Review of EPA's Preliminary Estimate of Potential Compliance Costs and Benefits Associated with EPA's Proposed Numeric Nutrient Criteria for Florida," p. 9.

<sup>178</sup> Florida Geological Data Library, 2009.

<sup>179</sup> Florida Department of Environmental Protection, 2010, appendix 3.

<sup>176</sup> Florida Geological Data Library, 2009, "GIS Data: WBIDs," available electronically at: <http://www.fgdl.org/download/index.html>.



range from \$62 to \$60,300 per acre treated, with a median cost of \$6,800 per acre. EPA multiplied FDEP's median capital cost per acre by the number of acres identified as requiring controls to estimate the potential additional storm

water control costs that may be needed to meet the numeric criteria in this rule. EPA also used FDEP's estimate of operating and maintenance (O&M) costs as 5% of capital costs, and annualized capital costs using FDEP's discount rate

of 7% over 20 years. EPA estimates the total annual cost for additional storm water controls could range between approximately \$60.5 and \$108.0 million per year. The following table summarizes these estimates.

TABLE VI(C)(1)—POTENTIAL INCREMENTAL URBAN STORM WATER COST SCENARIOS

Land type	Acres needing controls <sup>a</sup>	Capital cost (millions \$) <sup>b</sup>	O&M cost (millions \$) <sup>c</sup>	Annual cost (millions \$) <sup>d</sup>
MS4 Phase I Urban .....	0–48,100 .....	\$0–\$329.1 .....	\$0–\$16.4 .....	\$0–\$47.5
MS4 Phase II Urban .....	30,700 .....	\$210.0 .....	\$10.5 .....	\$30.3
Non-MS4 Urban .....	30,600 .....	\$208.8 .....	\$10.4 .....	\$30.2
Total .....	61,300–109,400	\$418.8–\$747.0	\$20.9–\$37.4 .....	\$60.5–\$108.0

<sup>a</sup>Phase I MS4s range represents implementation of BMPs to the MEP resulting in compliance with EPA's rule or controls needed on all pre-1982 developed land; Phase II MS4s and urban land outside of MS4s represent controls needed on all pre-1982 developed land that is not low density residential.

<sup>b</sup>Represents acres needing controls multiplied by median unit costs of storm water retrofit costs obtained from FDEP.

<sup>c</sup>Represents 5% of capital costs.

<sup>d</sup>Capital costs annualized at 7% over 20 years plus annual O&M costs.

Using Florida's 2009 draft criteria as the baseline, potential incremental costs for urban storm water are estimated to range from \$13.7 million per year to \$27.2 million per year.

Several organizations in Florida developed alternative estimates of compliance costs for EPA's proposed rule that were substantially higher than EPA's estimated costs for urban storm water. EPA disagrees with these cost estimates because they utilized incorrect assumptions about the areas that would have to implement controls. For example, FDEP estimated costs for urban storm water controls at \$1.97 billion per year.<sup>180</sup> However, FDEP estimated costs for pollution controls on urban land in watersheds that may not be listed as impaired, have already been listed as impaired, or will require controls under existing rules (e.g. land currently permitted under EPA's MS4 storm water program). In contrast, EPA estimated costs for urban storm water controls only for urban land with storm water flows to waters that may be listed as impaired as a result of this rule. This difference appears to explain the discrepancy between FDEP and EPA estimates.

2. Agricultural Costs

EPA's GIS analysis of land use indicates that agriculture accounts for about 19 percent of the land near incrementally impaired waters. Agricultural runoff can be a source of

phosphorus and nitrogen to lakes and streams through the application of fertilizer to crops and pastures and from animal wastes. Some agricultural practices may also contribute nitrogen and phosphorus to groundwater aquifers that supply springs. For waters impaired by nitrogen/phosphorus pollution, the 1999 Florida Watershed Restoration Act established that agricultural BMPs should be the primary instrument to implement TMDLs. Thus, additional waters identified by the State as impaired under this rule may result in State requirements or provisions to reduce the discharge of nitrogen and/or phosphorus to incrementally impaired waters through the implementation of BMPs.

EPA estimated the potential costs of additional agricultural BMPs by evaluating land use data obtained from Florida's five water management districts. BMP programs designed for each type of agricultural operation and their costs were taken from a study of agricultural BMPs to help meet TMDL targets in the Caloosahatchee River, St. Lucie River, and Lake Okeechobee watersheds.<sup>181</sup> Three types of BMP programs were identified in this study. The first program, called the "Owner Implemented BMP Program," consists of a set of BMPs that land owners might implement without additional incentives. The second program, called the "Typical BMP Program," is the set of

BMPs that land owners might implement under a reasonably funded cost share program or a modest BMP strategy approach. The third program, called the "Alternative Program," is a more expensive program designed to supplement the "Owner Implemented Program" and "Typical Program" if additional reductions are necessary.

The BMPs in the "Owner Implemented Program" and "Typical Program" are similar to the BMPs adopted by FDACS. EPA has found no indication that the "Alternative BMP Program," which includes storm water chemical treatment, has been required in historically nutrient impaired watersheds with significant contributions from agriculture for which TMDLs have been developed (e.g. Lake Okeechobee). Therefore, for purposes of this analysis, EPA believes it is reasonable to assume that nutrient controls for agricultural sources are best represented by the "Owner Implemented Program" and "Typical Program" described in the study used here.<sup>182</sup> EPA estimated potential incremental costs of BMPs by multiplying the number of acres in each agricultural category by the sum of unit costs for the "Owner Implemented Program" and "Typical Program." The following table summarizes the potential incremental costs of BMPs on agricultural lands near incrementally impaired lakes and streams for each agricultural category.

<sup>180</sup> Florida Department of Environmental Protection, 2010, p. 3.

<sup>181</sup> Soil and Water Engineering Technology, 2008, "Nutrient Loading Rates, Reduction Factors and Implementation Costs Associated with BMPs and

Technologies," (report prepared for South Florida Water Management District).

<sup>182</sup> Soil and Water Engineering Technology, 2008.

TABLE VI(C)(2)(a)—POTENTIAL INCREMENTAL BMP COSTS FOR LAKES AND STREAMS

Agricultural category	Area (acres) <sup>a</sup>	“Owner implemented program” plus “typical program” unit costs (\$/ac/yr) <sup>e</sup>	Total “owner implemented program” and “typical program” costs (\$/yr)
Animal Feeding .....	1,814–1,846	18.56	33,671–34,260
Citrus .....	15,482–27,343	156.80	2,427,652–4,287,343
Cow Calf Production (Improved Pastures) .....	153,978–168,665	15.84	2,439,007–2,671,656
Cow Calf Production (Unimproved Pastures) .....	49,054–51,057	4.22	207,203–215,663
Cow Calf Production (Rangeland and Wooded) .....	74,449–75,790	4.22	314,474–320,136
Row Crop .....	7,846–9,808	70.40	552,352–690,453
Cropland and Pastureland (general). <sup>b</sup> .....	152,976–160,814	27.26	4,169,512–4,383,135
Sod/Turf Grass .....	2,007	35.20	70,631
Ornamental Nursery .....	840	70.00	58,783
Dairies .....	583–621	334.40	194,803–207,777
Horse Farms .....	1,632	15.84	25,857
Field Crop (Hayland) Production .....	194,181–215,168	18.56	3,603,996–3,993,521
Other Areas <sup>c</sup> .....	54,499–67,364	18.56	1,011,500–1,250,281
Total <sup>d</sup> .....	709,340–782,954		15,109,436–18,209,496

<sup>a</sup>Based on GIS analysis of land use data from five water management districts (for entire State) and FDACS BMP program NOI GIS data layer. Low end reflects acres in incrementally impaired HUCs (that are not included in HUCs for baseline impairment) that are not enrolled in BMPs under FDACS; high end reflects all acres in incrementally impaired HUCs, regardless of FDACS BMP enrollment.

<sup>b</sup>“Owner program” and “Typical Program” BMP unit costs based on average costs for improved pastures, unimproved/wooded pasture, row crops, and field crops.

<sup>c</sup>Includes FLUCCS Level 3 codes 2160, 2200, 2230, 2400, 2410, 2500, 2540, and 2550.

<sup>d</sup>Excludes land not in production.

<sup>e</sup>Soil and Water Engineering Technology, 2008, Nutrient Loading Rates, Reduction Factors and Implementation Costs Associated with BMPs and Technologies, Report prepared for South Florida Water Management District.

In addition to estimating potential costs associated with agricultural BMPs to reduce nitrogen/phosphorus pollution to lakes and streams as described above, EPA estimated potential costs associated with BMPs to protect groundwater aquifers that supply water to springs. Fertilizer application and other agricultural practices can significantly increase nutrient loadings to springs, especially those springs supplied by relatively large groundwater aquifers. EPA evaluated the potential incremental costs to meet the numeric criteria in this final rule for springs by assuming that all applicable agricultural operations may be identified for implementation of nutrient management. Nutrient management reduces over application of fertilizers by determining realistic yield expectations, the nitrogen requirements necessary to obtain those yields, and adjusting application methods and timing to minimize nitrogen pollution.

Nutrient management is a cost-effective way to reduce groundwater nitrogen, and may even result in cost savings to some farmers by reducing unnecessary fertilizer application. Therefore, for the purpose of this

analysis, EPA assumed that all agricultural operations applying fertilizer to land would implement a nutrient management program, even those operations that are not associated with incrementally impaired waters. To estimate the potential costs of nutrient management, EPA estimated the amount of agricultural land where nutrient management could be applicable. EPA identified general agriculture<sup>183</sup> and specialty crops<sup>184</sup> as agricultural categories appropriate for nutrient management. EPA then used GIS analysis of land use data obtained from the State of Florida<sup>185</sup> to identify the land areas categorized as general agriculture or specialty crops. Approximately 4.9 million acres of agricultural land was identified as general agriculture and 1 million acres was identified as specialty crops. EPA further analyzed this agricultural land to identify the land near waters already listed as impaired for nutrients or under a TMDL. Similar to point sources, EPA assumed that nonpoint sources under an existing TMDL are currently meeting their load allocation requirements and would not incur additional costs, and costs to nonpoint sources associated

with waters that are currently listed as impaired for nutrients are not attributable to this final rule because those costs would be incurred absent the rule (under the baseline). EPA also removed from this analysis land associated with incrementally impaired waters to avoid double counting the costs of BMPs that were already estimated to protect lakes and streams as described above. As a result of this analysis, approximately 1 million acres of general agriculture and 0.12 million acres of specialty crops was identified as land that may need to implement a nutrient management program to meet the numeric criteria for Florida springs in this final rule. Using unit costs of \$10 per acre for general agriculture and \$20 per acre for specialty crops obtained from Florida’s Environmental Quality Incentive Program,<sup>186</sup> EPA estimated the annual cost of nutrient management could be approximately \$4.7 million per year. The following table summarizes the estimated potential incremental costs of BMPs on agricultural lands to protect State designated uses of springs on the basis of the criteria in this final rule.

<sup>183</sup> Cropland and pastureland, cow calf production (improved pastures), cropland and pastureland (general), dairies, horse farms, and field crop (hayland) production.

<sup>184</sup> Citrus, row crops, sod/turf grass, and ornamental nursery.

<sup>185</sup> Florida Geological Data Library, 2009.

<sup>186</sup> Florida Environmental Quality Incentive Program, 2009, “FY 2009 Statewide Payment Schedules,” available electronically at: [ftp://ftp-fc.sc.egov.usda.gov/FL/eqip/EQIP\\_FY2009PaySched\\_STATEWIDE\\_FINAL.pdf](ftp://ftp-fc.sc.egov.usda.gov/FL/eqip/EQIP_FY2009PaySched_STATEWIDE_FINAL.pdf).

TABLE VI(C)(2)(b)—POTENTIAL INCREMENTAL BMP COSTS FOR SPRINGS

Nutrient management program type	Total acres in Florida <sup>a</sup>	Acres identified for nutrient management <sup>b</sup>	Unit cost (\$/acre)	Total cost	Annual cost (\$/year) <sup>c</sup>
General Agriculture .....	4,885,643	1,003,973	\$10	\$10,039,729	\$3,825,656
Specialty Crop .....	1,057,107	120,558	20	2,411,163	918,778
<b>Total .....</b>	<b>5,942,750</b>	<b>1,124,531</b>	<b>.....</b>	<b>12,450,892</b>	<b>4,744,433</b>

<sup>a</sup> Excludes unimproved and woodland pastures, abandoned groves, aquaculture, tropical fish farms, open rural lands, and fallow cropland.  
<sup>b</sup> Calculated by subtracting agricultural land near incrementally impaired waters needing controls and agricultural land types participating in FDACS BMP program (assuming all Tri-county agricultural area land is regular nutrient management land) from total land use area in Florida.  
<sup>c</sup> Costs annualized at 7% over 3 years on basis of 3 year useful life.

The following table summarizes the costs of BMPs on agricultural lands to meet the numeric criteria.

TABLE VI(C)(2)(c)—POTENTIAL ANNUAL INCREMENTAL COMPLIANCE COSTS FOR AGRICULTURE

Waterbody type	Applicable acres	Annual costs
Lakes and Streams .....	709,340–782,954	\$15,109,400–\$18,209,500
Springs .....	1,124,531	\$4,744,400
<b>Total .....</b>	<b>1,833,871–1,907,485</b>	<b>\$19,853,900–\$22,953,900</b>

Using Florida’s 2009 draft criteria as the baseline, potential incremental costs to agriculture are estimated to range from – \$2.4 million per year (a negative cost represents a cost savings) to \$2.1 million per year.

Several organizations in Florida developed alternative estimates of compliance costs for EPA’s proposed rule that were substantially higher than EPA’s estimated costs for agriculture. EPA disagrees with these cost estimates because they use incorrect assumptions that overestimate costs. For example, the FDACS estimated that costs for agriculture would be approximately \$0.9 billion to \$1.6 billion per year.<sup>187</sup> However, FDACS estimated BMP costs for all 13.6 million acres of agricultural land in the State of Florida. This land includes watersheds where waters are not expected to become listed as impaired due to this final rule (including coastal and estuarine watersheds), have already been listed as impaired, or will require controls under existing rules (e.g. animal feeding operations) and thus are not potentially affected by the rule. A portion of the agricultural land used by FDACS to estimate costs includes 4.8 million acres of forest, 98.1% of which the State of Florida has claimed current BMPs

effectively protect surface waters<sup>188</sup> and thus EPA assumes will not require further controls. FDACS also estimated costs using the highest cost Alternative BMP program. The Alternative BMP Program, which includes storm water chemical treatment, is not yet required in historically nutrient-impaired watersheds with significant contributions from agriculture. Thus, it is uncertain whether such controls would be necessary or required to meet the new numeric criteria which are intended to implement Florida’s existing narrative criteria. In contrast, EPA estimated costs for BMPs that are likely to be necessary, and only on the agricultural land identified as incrementally impaired under this final rule (although costs could be higher in some cases if further reductions are found to be necessary). These differences appear to explain the discrepancy between FDACS and EPA estimates.

The alternative BMP program, which includes storm water chemical treatment, is not yet required in the study basins which have significant contributions from agriculture. Thus, for this analysis, EPA assumed that nutrient controls for agricultural sources are best represented by the owner/typical programs.

3. Septic System Costs

Some nutrient reductions from septic systems may be necessary for incrementally impaired waters to meet the numeric nutrient criteria in this final rule. Several nutrient-related TMDLs in Florida identify septic systems as a significant source of nitrogen/phosphorus pollution. Although properly operated and maintained systems can provide treatment equivalent to secondary wastewater treatment,<sup>189</sup> even properly functioning septic systems can be expected to contribute to nitrogen/ phosphorus pollution at some locations.<sup>190</sup> Some of the ways to address pollution from septic systems may include greater use of inspection programs and repair of failing systems, upgrading existing systems to advanced nutrient removal, installation of decentralized cluster systems where responsible management entities would ensure reliable operation and maintenance, and connecting households and businesses to wastewater treatment plants. On the basis of current practice in the State of

<sup>187</sup> Florida Department of Agriculture and Consumer Services, 2010, “Consolidated Comments on Proposed EPA Numeric Nutrient Criteria for Florida’s Lakes and Flowing Waters,” p. 1, available electronically at: [http://www.floridaagwaterpolicy.com/PDF/FINAL\\_FDACS\\_Consolidated\\_Comments\\_on\\_Docket\\_ID\\_No\\_EPA\\_HQ\\_OW\\_2009\\_0596.pdf](http://www.floridaagwaterpolicy.com/PDF/FINAL_FDACS_Consolidated_Comments_on_Docket_ID_No_EPA_HQ_OW_2009_0596.pdf).

<sup>188</sup> Florida Division of Forestry, Department of Agriculture and Consumer Services, 2010, “Silviculture Best Management Practices: 2009 Implementation Survey Report,” available electronically at: [http://www.fl-dof.com/publications/2009\\_BMP\\_survey\\_report.pdf](http://www.fl-dof.com/publications/2009_BMP_survey_report.pdf).

<sup>189</sup> Petrus, K., 2003, “Total Maximum Daily Load for the Palatamaha River to Address Dissolved Oxygen Impairment, Lake County, Florida,” (Florida Department of Environmental Protection), available electronically at: [http://www.dep.state.fl.us/water/tmdl/docs/tmdls/final/gp1/palatamaha\\_river\\_do\\_tmdl.pdf](http://www.dep.state.fl.us/water/tmdl/docs/tmdls/final/gp1/palatamaha_river_do_tmdl.pdf).

<sup>190</sup> Florida Department of Environmental Protection, 2006, “TMDL Report. Nutrient and Unionized Ammonia TMDLs for Lake Jessup, WBIDs 2981 and 2981A,” available electronically at: [http://www.dep.state.fl.us/water/tmdl/docs/tmdls/final/gp2/lake-jessup-nutr\\_ammonia-tmdl.pdf](http://www.dep.state.fl.us/water/tmdl/docs/tmdls/final/gp2/lake-jessup-nutr_ammonia-tmdl.pdf).

Florida, EPA assumed that the most likely strategy to reduce nutrients loads from septic systems would be to upgrade existing conventional septic systems to advanced nutrient removal systems.

Septic systems in close proximity to surface waters are more likely to contribute nutrient loads to waters than distant septic systems. Florida Administrative Code provides that in most cases septic systems should be located at least 75 feet from surface waters (F.A.C. 64E-6.005(3)). In addition, many of Florida's existing nutrient-related TMDLs identify nearby failing septic systems as contributing to nutrient impairments in surface waters.

For this economic analysis, EPA assumed that some septic systems located near incrementally impaired lakes and streams may be required to upgrade to advance nutrient removal systems. However, the distance that septic systems can be safely located relative to these surface waters depends on a variety of site-specific factors. Because of this uncertainty, EPA conservatively assumed that septic systems located within 500 feet of any lake or stream in watersheds associated with incrementally impaired lakes or streams<sup>191</sup> may be identified for upgrade from conventional to advanced nutrient removal systems.

EPA identified the number of septic systems within 500 feet of any lake or stream in watersheds associated with incrementally impaired lakes and streams using GIS analysis on data obtained from the Florida Department of Health<sup>192</sup> that provides the location of active septic systems in the State. This analysis yielded 8,224 active septic systems that may potentially need to be upgraded from conventional to advanced nutrient removal systems to meet the numeric nutrient criteria in this final rule.

EPA evaluated the cost of upgrading existing septic systems to advanced nutrient removal systems. Upgrade costs range from \$2,000 to \$6,500 per system. For O&M costs, EPA relied on a study that compared the annual costs associated with various septic system treatment technologies including conventional onsite sewage treatment

and disposal system and fixed film activated sludge systems.<sup>193</sup> This study estimated the incremental O&M costs for an advanced system to be \$650 per year. Thus, based on annual O&M costs of \$650 and annualizing capital costs at 7% over 20 years, annual costs could range from approximately \$800 to \$1,300 for each upgrade. EPA estimated the total annual costs of upgrading septic systems by multiplying this range of unit costs with the number of systems identified for upgrade. Using this method, total annual costs for upgrading septic systems to meet State designated uses could range from \$6.6 million per year to \$10.7 million per year.

Using Florida's 2009 draft criteria as the baseline, potential incremental costs to upgrade septic systems are estimated to range from \$1.3 million per year to 2.2 million per year.

Several organizations in Florida developed alternative estimates of compliance costs for septic systems in EPA's proposed rule that were substantially higher than EPA's estimated costs. EPA disagrees with these cost estimates because they used incorrect assumptions that overestimate costs. For example, FDEP estimated that the costs related to septic systems would be approximately \$0.9 billion per year to 2.9 billion per year.<sup>194</sup> However, FDEP assumed that 1,687,500 septic systems would require complete replacement (calculated as the proportion of all septic systems in the State of Florida on lots less than 3 acres assumed to discharge to fresh waters because all urban storm water discharges to freshwaters in that proportion). In contrast, EPA estimated costs to upgrade 8,224 septic systems to advanced nutrient removal systems that GIS analysis identified as located within 500 feet of any water within an incrementally impaired watershed.

#### D. Governmental Costs

This final rule may result in the identification of additional impaired waters that would require the development of additional TMDLs. As the principal State regulatory agency implementing water quality standard, the State of Florida may incur costs related to developing additional TMDLs. EPA's analysis identified 325 incrementally impaired waters potentially associated with this final

rule. Because current TMDLs in Florida include an average of approximately two water bodies each, EPA estimates that the State of Florida may need to develop and adopt approximately 163 additional TMDLs. A 2001 EPA study found that the cost of developing a TMDL could range between \$6,000 and \$154,000, with an average cost of approximately \$28,000.<sup>195</sup> The low end of the range reflects the typical cost associated with TMDLs that are the easiest to develop and/or have the benefit of previous TMDL development for other pollutants. Because most of the incrementally impaired waters in EPA's analysis exceeded the criteria for both nitrogen and phosphorus, EPA assumed that TMDLs would need to be developed for both nitrogen and phosphorus. Under this assumption, EPA estimated the average TMDL cost to be approximately \$47,000 (\$28,000 on average for one pollutant, plus \$6,000 on average for the other pollutant, and adjusting for inflation). For 163 TMDLs, total costs could be approximately \$7.7 million. FDEP currently operates its TMDL schedule on a five-phase cycle that rotates through the five basins over five years. Under this schedule, completion of TMDLs for high priority waters will take 9 years; it will take an additional 5 years to complete the process for medium priority waters. Thus, assuming all the incremental impairments are high priority and FDEP develops the new TMDLs over a 9-year period, annual costs could be approximately \$851,000 per year. Using Florida's 2009 draft criteria as the baseline, potential incremental costs to develop additional TMDLs could be approximately \$261,000 per year.

Should the State of Florida submit current TMDL targets as Federal site specific alternative criteria (SSAC) for EPA review and approval, EPA believes it is reasonable to assume that information used in the development of the TMDLs will substantially reduce the time and effort needed to provide a scientifically defensible justification for such applications. Thus, EPA assumed that incremental costs associated with SSAC, if any, would be minimal.

Similarly, State and local agencies regularly monitor TN and TP in ambient waters. These data are the basis for the extensive IWR database the State of Florida maintains and which provided baseline water quality data for EPA's analyses. Because Florida is currently

<sup>191</sup> In this analysis EPA considered septic systems within 500 feet of any lake or stream in an incrementally impaired watershed rather than only within 500 feet of an incrementally impaired lake or stream to account for the possibility of some downstream transport of nutrients from nearby streams that may not themselves be classified as incrementally impaired.

<sup>192</sup> Florida Department of Health, 2010, "Bureau of Onsite Sewage GIS Data Files," available electronically at: <http://www.doh.state.fl.us/Environment/programs/EhGis/EhGisDownload.htm>.

<sup>193</sup> Chang, N., M. Wanielista, A. Daranpob, F. Hossain, Z. Xuan, J. Miao, S. Liu, Z. Marimon, and S. Debusk, 2010, "Onsite Sewage Treatment and Disposal Systems Evaluation for Nutrient Removal," (Stormwater Management Academy, University of Central Florida).

<sup>194</sup> Florida Department of Environmental Protection, 2010, p. 3.

<sup>195</sup> U.S. EPA, 2001, "The National Costs of the Total Maximum Daily Load Program (Draft Report)," (EPA-841-D-01-003).

<sup>196</sup> EPA did not adjust these estimates to account for potential reductions in resources required to develop TMDLs as a result of this final rule.

monitoring TN, TP, and chlorophyll *a* concentrations in many waters, EPA assumed that this final rule is unlikely to have a significant impact on costs related to water quality monitoring activities.

#### E. Benefits

Elevated concentrations of nutrients in surface waters can result in adverse ecological effects and negative economic impacts. Excess nutrients in water can cause eutrophication, which can lead to harmful (sometimes toxic) algal blooms, loss of rooted plants, and decreased dissolved oxygen, which can lead to adverse impacts on aquatic life, fishing, swimming, wildlife watching, camping, and drinking water. Excess nutrients can also cause nuisance surface scum, reduced food for herbivorous wildlife, fish kills, alterations in fish communities, and unsightly shorelines that can decrease property values. This final rule will help reduce nitrogen and phosphorus concentrations in lakes and flowing waters in Florida, and help improve ecological function and prevent further degradation that can result in substantial economic benefits to Florida citizens. EPA's economic analysis document entitled: *Economic Analysis of Final Water Quality Standards for Nutrients for Lakes and Flowing Waters in Florida* describes many of the potential benefits associated with meeting the water quality standards for nitrogen/phosphorus pollution in this rule.

Florida waters have historically provided an abundance of recreational opportunities that are a vital part of the State's economy. In 2007, over 4.3 million residents and over 5.8 million visitors participated in recreational activities related to freshwater beaches in Florida.<sup>197</sup> Of these residents and visitors, over 2.7 million residents and approximately 1 million visitors used freshwater boat ramps, over 3 million residents and over 900,000 visitors participated in freshwater non-boat fishing, and over 2.6 million residents and almost 1 million visitors participated in canoeing and kayaking. Florida also ranks first in the nation in boat registrations with 973,859 recreational boats registered across the State.

Tourism comprises one of the largest sectors of the Florida economy. In 2000, there were over 80.9 million visitors to the State of Florida, accounting for an estimated \$65 billion in tourism

spending.<sup>198</sup> In 2008, tourism spending resulted in approximately \$3.9 billion in State sales tax revenues and contributed to the direct employment of more than 1 million Florida residents.<sup>199</sup> Florida has ranked first in the nation for the number of in-State anglers, angler expenditures, angler-supported jobs, and State and local tax revenues derived from freshwater fishing.<sup>200</sup> In 2006, total fishing-related expenditures by residents and nonresidents were more than \$4.3 billion.<sup>201</sup> In addition, Florida's freshwater springs are an important inter- and intra-State tourist attraction.<sup>202</sup> In 2002, Blue Springs State Park estimated over 300,000 visitors per year.

Nitrogen/phosphorus pollution has contributed to severe water quality degradation of Florida waters. In 2010, the State of Florida reported approximately 1,918 miles of rivers and streams, and 378,435 acres of lakes that were known to be impaired by nitrogen/phosphorus pollution (the actual number of waters impaired for nutrients may be higher because many waters were not assessed).<sup>203</sup> As water quality declines, water resources have less recreational value. Waters impaired by nitrogen/phosphorus pollution may become unsuitable for swimming and fishing, and in some cases even unsuitable for boating. Nutrient-impaired waters also are less likely to support native plant and animal species, further lowering their value as tourist destinations.<sup>204</sup> Drinking water supplies may also be more expensive to treat as a result of nutrient impairments. Also, Florida citizens that depend on individual wells for their drinking water may need to consider whether on-site

treatment is necessary to reduce elevated nitrate+nitrite levels. Freshwater springs are particularly at risk due to nitrate+nitrite.<sup>205</sup> Silver Springs, the largest of Florida's springs, has experienced reduced ecosystem health and productivity over the past half century, due largely to nitrate+nitrite.<sup>207</sup> Nutrient impairment, characterized by algal blooms, reduced numbers of native species, and lower water quality, in turn leads to reduced demand and lower values for these resources.

Some of the benefits of reducing nitrogen and phosphorus concentrations can be monetized, at least in part, by translating these changes into an indicator of overall water quality (water quality index) and valuing these improvements in terms of willingness to pay (WTP) for the types of uses that are supported by different water quality levels. For this analysis, EPA used a Water Quality Index (WQI) approach to link specific pollutant levels with suitability for particular recreational uses. Using Florida water quality data, available information on WTP, and an analytical approach described in EPA's accompanying economic assessment report and supporting references, EPA estimated potential changes that would result from implementation of this final rule and their value to a distribution of full-time and part-time Florida residents. This approach recognizes that there are differences in WTP among a population and values for households. Using the mid-point WTP and current conditions as the baseline, total monetized benefits are estimated to be approximately \$21.7 million per year for improvements to flowing waters and \$6.6 million per year for improvements to lakes for a total of \$28.2 million per year. Although these monetized benefits estimates do not account for all potential economic benefits, they help to partially demonstrate the economic importance of restoring and protecting Florida waters from the impacts of nitrogen/phosphorus pollution.

<sup>198</sup> VISIT Florida, 2010, available electronically at: <http://media.visitflorida.org/research.php>.

<sup>199</sup> VISIT Florida, 2010.

<sup>200</sup> Bonn, Mark A. and Frederick W. Bell., 2003, Economic Impact of Selected Florida Springs on Surrounding Local Areas. For Florida Department of Environmental Protection. Available electronically at: <http://www.dep.state.fl.us/springs/reports/files/EconomicImpactStudy.doc>.

<sup>201</sup> 2006 National Survey of Fishing, Hunting, and Wildlife-Associated Recreation. Florida. U.S. Department of the Interior, Fish and Wildlife Service, and U.S. Department of Commerce, U.S. Census Bureau. Available electronically at: [http://myfwc.com/docs/Freshwater/2006\\_Florida\\_NationalSurvey.pdf](http://myfwc.com/docs/Freshwater/2006_Florida_NationalSurvey.pdf).

<sup>202</sup> Florida Department of Environmental Protection, 2008.

<sup>203</sup> Florida Department of Environmental Protection, 2010, "Integrated Water Quality Assessment for Florida: 2010 305(b) and 303(d) List Update," available electronically at: [http://www.dep.state.fl.us/water/docs/2010\\_Integrated\\_Report.pdf](http://www.dep.state.fl.us/water/docs/2010_Integrated_Report.pdf).

<sup>204</sup> Zheng, Lei and Michael J. Paul., 2006, *Effects of Eutrophication on Stream Ecosystems*. Available electronically at: [http://n-steps.tetratex-ffx.com/PDF/otherFiles/literature\\_review/Eutrophication%20effects%20on%20streams.pdf](http://n-steps.tetratex-ffx.com/PDF/otherFiles/literature_review/Eutrophication%20effects%20on%20streams.pdf).

<sup>197</sup> Florida Department of Environment, 2008, "State Comprehensive Outdoor Recreation Plan (SCORP)," available electronically at: <http://www.dep.state.fl.us/parks/planning/default.htm>.

<sup>205</sup> Florida Department of Environment, "Deep Trouble: Getting to the Source of Threats to Springs," accessed on October 1, 2010 at: <http://www.floridasprings.org/protection/threats/>.

<sup>206</sup> Munch, D.A., D.J. Toth, C. Huang, J.B. Davis, C.M. Fortich, W.L. Osburn, E.J. Phillips, E.L. Quinlan, M.S. Allen, M.J. Woods, P. Cooney, R.L. Knight, R.A. Clarke and S.L. Knight., 2006, "Fifty-year retrospective study of the ecology of Silver Springs, Florida," (SJ2007-SP4).

<sup>207</sup> Florida Department of Environment, 2008, Summary and Synthesis of the Available Literature on the Effects of Nutrients on Spring Organisms and Systems," available at: [http://www.dep.state.fl.us/springs/reports/files/UF\\_SpringsNutrients\\_Report.pdf](http://www.dep.state.fl.us/springs/reports/files/UF_SpringsNutrients_Report.pdf).

#### F. Summary

The following table summarizes EPA's estimates of potential incremental costs and benefits associated with additional State requirements to meet the numeric criteria that supports State designated uses. Because of uncertainties in the pollution controls ultimately implemented by the State of Florida, actual costs may vary depending on the procedures for assessing waters for compliance and the site-specific source reductions needed to meet the new numeric criteria.

TABLE VI(F)(a)—SUMMARY OF POTENTIAL ANNUAL COSTS  
[millions of 2010 dollars per year]

Source sector	Annual costs
Municipal Waste Water Treatment Plants.	\$22.3–\$38.1
Industrial Dischargers .....	\$25.4
Urban Storm Water .....	\$60.5–\$108.0
Agriculture .....	\$19.9–\$23.0
Septic Systems .....	\$6.6–\$10.7
Government/Program Implementation.	\$0.9
Total .....	\$135.5–\$206.1

#### VII. Statutory and Executive Order Reviews

##### A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order (EO) 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 EO 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action. This final rule does not establish any requirements directly applicable to regulated entities or other sources of nitrogen/phosphorus pollution. Moreover, existing narrative water quality criteria in State law already require that nutrients not be present in waters in concentrations that cause an imbalance in natural populations of flora and fauna in lakes and flowing waters in Florida.

##### B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* Burden is defined at 5 CFR 1320.3(b). It does not include any information collection, reporting, or record-keeping requirements.

##### C. Regulatory Flexibility Act

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 significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of this action on small entities, small entity is 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 that is independently owned and operated and is not dominant in its field.

Under the CWA WQS program, States must adopt WQS for their waters and must submit those WQS to EPA for approval; if the Agency disapproves a State standard and the State does not adopt appropriate revisions to address EPA's disapproval, EPA must promulgate standards consistent with the statutory requirements. EPA also has the authority to promulgate WQS in any case where the Administrator determines that a new or revised standard is necessary to meet the requirements of the Act. These State standards (or EPA-promulgated standards) are implemented through various water quality control programs including the NPDES program, which limits discharges to navigable waters except in compliance with an NPDES permit. The CWA requires that all NPDES permits include any limits on discharges that are necessary to meet applicable WQS.

Thus, under the CWA, EPA's promulgation of WQS establishes standards that the State implements through the NPDES permit process. The State has discretion in developing discharge limits, as needed to meet the standards. This final rule, as explained earlier, does not itself establish any requirements that are applicable to small entities. As a result of this action, the State of Florida will need to ensure that permits it issues include any limitations on discharges necessary to comply with the standards established in the final rule. In doing so, the State will have a number of choices

associated with permit writing. While Florida's implementation of the rule may ultimately result in new or revised permit conditions for some dischargers, including small entities, EPA's action, by itself, does not impose any of these requirements on small entities; that is, these requirements are not self-implementing. Thus, I certify that this rule will not have a significant economic impact on a substantial number of small entities.

##### D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with “Federal mandates” that may result in expenditures to State, local, and Tribal governments, in the aggregate, or to the private sector, of \$100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation of why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

This final rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or Tribal governments or the private sector. The State may use these resulting water quality criteria in implementing its water quality control

programs. This final rule does not regulate or affect any entity and, therefore, is not subject to the requirements of sections 202 and 205 of UMRA.

EPA determined that this final rule contains no regulatory requirements that might significantly or uniquely affect small governments. Moreover, WQS, including those promulgated here, apply broadly to dischargers and are not uniquely applicable to small governments. Thus, this final rule is not subject to the requirements of section 203 of UMRA.

#### *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. EPA's authority and responsibility to promulgate Federal WQS when State standards do not meet the requirements of the CWA is well established and has been used on various occasions in the past. The final rule will not substantially affect the relationship between EPA and the States and territories, or the distribution of power or responsibilities between EPA and the various levels of government. The final rule will not alter Florida's considerable discretion in implementing these WQS. Further, this final rule will not preclude Florida from adopting WQS that EPA concludes meet the requirements of the CWA, after promulgation of the final rule, which would eliminate the need for these Federal standards and lead EPA to withdraw them. Thus, Executive Order 13132 does not apply to this final rule.

Although section 6 of Executive Order 13132 does not apply to this action, EPA had extensive communication with the State of Florida to discuss EPA's concerns with the State's water quality criteria and the Federal rulemaking process.

#### *F. Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments)*

Subject to the Executive Order 13175 (65 FR 67249, November 9, 2000) EPA may not issue a regulation that has Tribal implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by Tribal governments, or EPA consults with Tribal officials early in the process of

developing the proposed regulation and develops a Tribal summary impact statement. EPA has concluded that this action may have Tribal implications. However, the rule will neither impose substantial direct compliance costs on Tribal governments, nor preempt Tribal law.

In the State of Florida, there are two Indian Tribes, the Seminole Tribe of Florida and the Miccosukee Tribe of Indians of Florida, with lakes and flowing waters. Both Tribes have been approved for treatment in the same manner as a State (TAS) status for CWA sections 303 and 401 and have Federally-approved WQS in their respective jurisdictions. These Tribes are not subject to this final rule. However, this rule may impact the Tribes because the numeric criteria for Florida will apply to waters adjacent to the Tribal waters. EPA met with the Seminole Tribe on January 19, 2010 and requested an opportunity to meet with the Miccosukee Tribe to discuss EPA's proposed rule, although a meeting was never requested by the Tribe.

#### *G. Executive Order 13045 (Protection of Children From Environmental Health and Safety Risks)*

This action is not subject to EO 13045 (62 FR 19885, April 23, 1997) because it is not economically significant as defined in EO 12866, and because the Agency's promulgation of this rule will result in the reduction of environmental health and safety risks that could present a disproportionate risk to children.

#### *H. Executive Order 13211 (Actions That Significantly Affect Energy Supply, Distribution, or Use)*

This rule is not a "significant energy action" as defined in Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (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.

#### *I. National Technology Transfer Advancement Act of 1995*

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) 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. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This final rulemaking does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

#### *J. Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations)*

Executive Order (EO) 12898 (Feb. 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 by identifying and addressing, as appropriate, 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 final rule does not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it will afford a greater level of protection to both human health and the environment if these numeric criteria are promulgated for Class I and Class III waters in the State of Florida.

#### *K. Congressional Review Act*

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 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 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). This rule is effective March 6, 2012, except for 40 CFR 131.43(e), which is effective February 4, 2011.

#### **List of Subjects in 40 CFR Part 131**

Environmental protection, Water quality standards, Nitrogen/phosphorus pollution, Nutrients, Florida.



Dated: November 14, 2010.

Lisa P. Jackson,  
Administrator.

■ For the reasons set out in the preamble, 40 CFR part 131 is amended as follows:

**PART 131—WATER QUALITY STANDARDS**

■ 1. The authority citation for part 131 continues to read as follows:

Authority: 33 U.S.C. 1251 *et seq.*

**Subpart D—[Amended]**

■ 2. Section 131.43 is added effective February 4, 2011 to read as follows:

**§ 131.43 Florida.**

(a)–(d) [Reserved]

(e) *Site-specific alternative criteria.* (1) The Regional Administrator may determine that site-specific alternative criteria shall apply to specific surface waters in lieu of the criteria established for Florida waters in this section, including criteria for lakes, criteria for streams, and criteria for springs. Any such determination shall be made consistent with § 131.11.

(2) To receive consideration from the Regional Administrator for a determination of site-specific alternative criteria, an entity shall submit a request that includes proposed alternative numeric criteria and supporting rationale suitable to meet the needs for a technical support document pursuant to paragraph (e)(3) of this section. The entity shall provide the State a copy of all materials submitted to EPA, at the time of submittal to EPA, to facilitate the State providing comments to EPA. Site-specific alternative criteria may be based on one or more of the following approaches.

(i) Replicate the process for developing the stream criteria in this section.

(ii) Replicate the process for developing the lake criteria in this section.

(iii) Conduct a biological, chemical, and physical assessment of waterbody conditions.

(iv) Use another scientifically defensible approach protective of the designated use.

(3) For any determination made under paragraph (e)(1) of this section, the Regional Administrator shall, prior to making such a determination, provide for public notice and comment on a proposed determination. For any such proposed determination, the Regional Administrator shall prepare and make available to the public a technical support document addressing the specific surface waters affected and the justification for each proposed determination. This document shall be made available to the public no later than the date of public notice issuance.

(4) The Regional Administrator shall maintain and make available to the public an updated list of determinations made pursuant to paragraph (e)(1) of this section as well as the technical support documents for each determination.

(5) Nothing in this paragraph (e) shall limit the Administrator's authority to modify the criteria established for Florida waters in this section, including criteria for lakes, criteria for streams, and criteria for springs.

■ 3. Section 131.43 is revised effective March 6, 2012 to read as follows:

**§ 131.43 Florida.**

(a) *Scope.* This section promulgates numeric criteria for nitrogen/phosphorus pollution for Class I and Class III waters in the State of Florida. This section also contains provisions for site-specific alternative criteria.

(b) *Definitions.*—(1) *Canal* means a trench, the bottom of which is normally covered by water with the upper edges of its two sides normally above water.

(2) *Clear, high-alkalinity lake* means a lake with long-term color less than or equal to 40 Platinum Cobalt Units (PCU) and Alkalinity greater than 20 mg/L CaCO<sub>3</sub>.

(3) *Clear, low-alkalinity lake* means a lake with long-term color less than or equal to 40 PCU and alkalinity less than or equal to 20 mg/L CaCO<sub>3</sub>.

(4) *Colored lake* means a lake with long-term color greater than 40 PCU.

(5) *Lake* means a slow-moving or standing body of freshwater that

occupies an inland basin that is not a stream, spring, or wetland.

(6) *Lakes and flowing waters* means inland surface waters that have been classified as Class I (Potable Water Supplies) or Class III (Recreation, Propagation and Maintenance of a Healthy, Well-Balanced Population of Fish and Wildlife) water bodies pursuant to Rule 62–302.400, F.A.C., excluding wetlands, and are predominantly fresh waters.

(7) *Nutrient watershed region* means an area of the State, corresponding to drainage basins and differing geological conditions affecting nutrient levels, as delineated in Table 2.

(8) *Predominantly fresh waters* means surface waters in which the chloride concentration at the surface is less than 1,500 milligrams per liter.

(9) *South Florida Region* means those areas south of Lake Okeechobee and the Caloosahatchee River watershed to the west of Lake Okeechobee and the St. Lucie watershed to the east of Lake Okeechobee.

(10) *Spring* means a site at which ground water flows through a natural opening in the ground onto the land surface or into a body of surface water.

(11) *State* means the State of Florida, whose transactions with the U.S. EPA in matters related to 40 CFR 131.43 are administered by the Secretary, or officials delegated such responsibility, of the Florida Department of Environmental Protection (FDEP), or successor agencies.

(12) *Stream* means a free-flowing, predominantly fresh surface water in a defined channel, and includes rivers, creeks, branches, canals, freshwater sloughs, and other similar water bodies.

(13) *Surface water* means water upon the surface of the earth, whether contained in bounds created naturally or artificially or diffused. Water from natural springs shall be classified as surface water when it exits from the spring onto the Earth's surface.

(c) *Criteria for Florida waters*—(1) *Criteria for lakes.* (i) The applicable criteria for chlorophyll *a*, total nitrogen (TN), and total phosphorus (TP) for lakes within each respective lake class are shown on Table 1.

TABLE 1

A	B	C	
		TN (mg/L)	TP (mg/L)
Lake Color <sup>a</sup> and Alkalinity	Chl-a (mg/L) <sup>b,*</sup>		
Colored Lakes <sup>c</sup> .....	0.020	1.27 [1.27–2.23]	0.05 [0.05–0.16]

TABLE 1—Continued

A Lake Color <sup>a</sup> and Alkalinity	B Chl-a (mg/L) <sup>b,*</sup>	C	
		TN (mg/L)	TP (mg/L)
Clear Lakes, ..... High Alkalinity <sup>d</sup> .....	0.020	1.05 [1.05–1.91]	0.03 [0.03–0.09]
Clear Lakes, ..... Low Alkalinity <sup>e</sup> .....	0.006	0.51 [0.51–0.93]	0.01 [0.01–0.03]

<sup>a</sup>Platinum Cobalt Units (PCU) assessed as true color free from turbidity.

<sup>b</sup>Chlorophyll *a* is defined as corrected chlorophyll, or the concentration of chlorophyll *a* remaining after the chlorophyll degradation product, phaeophytin *a*, has been subtracted from the uncorrected chlorophyll *a* measurement.

<sup>c</sup>Long-term Color > 40 Platinum Cobalt Units (PCU)

<sup>d</sup>Long-term Color ≤ 40 PCU and Alkalinity > 20 mg/L CaCO<sub>3</sub>

<sup>e</sup> Long-term Color ≤ 40 PCU and Alkalinity ≤ 20 mg/L CaCO<sub>3</sub>

\*For a given waterbody, the annual geometric mean of chlorophyll *a*, TN or TP concentrations shall not exceed the applicable criterion concentration more than once in a three-year period.

(ii) Baseline criteria apply unless the State determines that modified criteria within the range indicated in Table 1 apply to a specific lake. Once established, modified criteria are the applicable criteria for all CWA purposes. The State may use this procedure one time for a specific lake in lieu of the site-specific alternative criteria procedure described in paragraph (e) of this section.

(A) The State may calculate modified criteria for TN and/or TP where the chlorophyll *a* criterion-magnitude as an annual geometric mean has not been exceeded and sufficient ambient monitoring data exist for chlorophyll *a* and TN and/or TP for at least the three immediately preceding years. Sufficient data include at least four measurements per year, with at least one measurement between May and September and one measurement between October and April each year.

(B) Modified criteria are calculated using data from years in which sufficient data are available to reflect maintenance of ambient conditions. Modified TN and/or TP criteria may not be greater than the higher value specified in the range of values in column C of Table 1 in paragraph (c)(1)(i) of this section. Modified TP and TN criteria may not exceed criteria applicable to streams to which a lake discharges.

(C) The State shall notify the public and maintain a record of these modified lake criteria, as well as a record supporting their derivation. The State shall notify EPA Region 4 and provide the supporting record within 30 days of determination of modified lake criteria.

(2) *Criteria for streams.* (i) The applicable instream protection value (IPV) criteria for total nitrogen (TN) and total phosphorus (TP) for streams within

each respective nutrient watershed region are shown on Table 2.

TABLE 2

Nutrient watershed region	Instream protection value criteria	
	TN (mg/L)*	TP (mg/L)*
Panhandle West <sup>a</sup> .....	0.67	0.06
Panhandle East <sup>b</sup> .....	1.03	0.18
North Central <sup>c</sup> .....	1.87	0.30
West Central <sup>d</sup> .....	1.65	0.49
Peninsula <sup>e</sup> .....	1.54	0.12

Watersheds pertaining to each Nutrient Watershed Region (NWR) were based principally on the NOAA coastal, estuarine, and fluvial drainage areas with modifications to the NOAA drainage areas in the West Central and Peninsula Regions that account for unique watershed geologies. For more detailed information on regionalization and which WBIDs pertain to each NWR, see the Technical Support Document.

<sup>a</sup>Panhandle West region includes: Perdido Bay Watershed, Pensacola Bay Watershed, Choctawhatchee Bay Watershed, St. Andrew Bay Watershed, and Apalachicola Bay Watershed.

<sup>b</sup>Panhandle East region includes: Apalachee Bay Watershed, and Econfina/Steinhatchee Coastal Drainage Area.

<sup>c</sup>North Central region includes the Suwannee River Watershed.

<sup>d</sup>West Central region includes: Peace, Myakka, Hillsborough, Alafia, Manatee, Little Manatee River Watersheds, and small, direct Tampa Bay tributary watersheds south of the Hillsborough River Watershed.

<sup>e</sup>Peninsula region includes: Waccasassa Coastal Drainage Area, Withlacoochee Coastal Drainage Area, Crystal/Pithlachascotee Coastal Drainage Area, small, direct Tampa Bay tributary watersheds west of the Hillsborough River Watershed, Sarasota Bay Watershed, small, direct Charlotte Harbor tributary watersheds south of the Peace River Watershed, Caloosahatchee River Watershed, Estero Bay Watershed, Kissimmee River/Lake Okeechobee Drainage Area, Loxahatchee/St. Lucie Watershed, Indian River Watershed, Daytona/St. Augustine Coastal Drainage Area, St. John's River Watershed, Nassau Coastal Drainage Area, and St. Mary's River Watershed.

\*For a given waterbody, the annual geometric mean of TN or TP concentrations shall not exceed the applicable criterion concentration more than once in a three-year period.

(ii) *Criteria for protection of downstream lakes.* (A) The applicable criteria for streams that flow into downstream lakes include both the instream criteria for total phosphorus (TP) and total nitrogen (TN) in Table 2 in paragraph (c)(2)(i) and the downstream protection value (DPV) for TP and TN derived pursuant to the provisions of this paragraph. A DPV for stream tributaries (up to the point of reaching water bodies that are not streams as defined by this rule) that flow into a downstream lake is either the allowable concentration or the allowable loading of TN and/or TP applied at the point of entry into the lake. The applicable DPV for any stream shall be determined pursuant to paragraphs (c)(2)(ii)(B), (C), or (D) of this section. Contributions from stream tributaries upstream of the point of entry location must result in attainment of the DPV at the point of entry into the lake. If the DPV is not attained at the point of entry into the lake, then the collective set of streams in the upstream watershed does not attain the DPV, which is an applicable water quality criterion for the water segments in the upstream watershed. The State or EPA may establish additional DPVs at upstream tributary locations that are consistent with attaining the DPV at the point of entry into the lake. The State or EPA also have discretion to establish DPVs to account for a larger watershed area (*i.e.*, include waters beyond the point of reaching water bodies that are not streams as defined by this rule).

(B) In instances where available data and/or resources provide for use of a scientifically defensible and protective lake-specific application of the

BATHTUB model, the State or EPA may derive the DPV for TN and/or TP from use of a lake-specific application of BATHTUB. The State and EPA are authorized to use a scientifically defensible technical model other than BATHTUB upon demonstration that use of another scientifically defensible technical model would protect the lake's designated uses and meet all applicable criteria for the lake. The State or EPA may designate the wasteload and/or load allocations from a TMDL established or approved by EPA as DPV(s) if the allocations from the TMDL will protect the lake's designated uses and meet all applicable criteria for the lake.

(C) When the State or EPA has not derived a DPV for a stream pursuant to paragraph (c)(2)(ii)(B) of this section, and where the downstream lake attains the applicable chlorophyll *a* criterion and the applicable TP and/or TN criteria, then the DPV for TN and/or TP is the associated ambient instream levels of TN and/or TP at the point of entry to the lake. Degradation in water quality from the DPV pursuant to this paragraph is to be considered nonattainment of the DPV, unless the DPV is adjusted pursuant to paragraph (c)(2)(ii)(B) of this section.

(D) When the State or EPA has not derived a DPV pursuant to paragraph (c)(2)(ii)(B) of this section, and where the downstream lake does not attain applicable chlorophyll *a* criterion or the applicable TN and/or TP criteria, or has not been assessed, then the DPV for TN and/or TP is the applicable TN and/or TP criteria for the downstream lake.

(E) The State and EPA shall maintain a record of DPVs they derive based on the methods described in paragraphs (c)(2)(ii)(B) and (C) of this section, as well as a record supporting their derivation, and make such records available to the public. The State and EPA shall notify one another and provide a supporting record within 30 days of derivation of DPVs pursuant to

paragraphs (c)(2)(ii)(B) or (C) of this section.

(3) *Criteria for springs.* The applicable nitrate-nitrite criterion is 0.35 mg/L as an annual geometric mean, not to be exceeded more than once in a three-year period.

(d) *Applicability.* (1) The criteria in paragraphs (c)(1) through (3) of this section apply to lakes and flowing waters, excluding flowing waters in the South Florida Region, and apply concurrently with other applicable water quality criteria, except when:

(i) State water quality standards contain criteria that are more stringent for a particular parameter and use;

(ii) The Regional Administrator determines that site-specific alternative criteria apply pursuant to the procedures in paragraph (e) of this section; or

(iii) The State adopts and EPA approves a water quality standards variance to the Class I or Class III designated use pursuant to § 131.13 that meets the applicable provisions of State law and the applicable Federal regulations at § 131.10.

(2) The criteria established in this section are subject to the State's general rules of applicability in the same way and to the same extent as are the other Federally-adopted and State-adopted numeric criteria when applied to the same use classifications.

(e) *Site-specific alternative criteria.* (1) The Regional Administrator may determine that site-specific alternative criteria shall apply to specific surface waters in lieu of the criteria established in paragraph (c) of this section. Any such determination shall be made consistent with § 131.11.

(2) To receive consideration from the Regional Administrator for a determination of site-specific alternative criteria, an entity shall submit a request that includes proposed alternative numeric criteria and supporting rationale suitable to meet the needs for a technical support document pursuant to paragraph (e)(3) of this section. The

entity shall provide the State a copy of all materials submitted to EPA, at the time of submittal to EPA, to facilitate the State providing comments to EPA. Site-specific alternative criteria may be based on one or more of the following approaches.

(i) Replicate the process for developing the stream criteria in paragraph (c)(2)(i) of this section.

(ii) Replicate the process for developing the lake criteria in paragraph (c)(1) of this section.

(iii) Conduct a biological, chemical, and physical assessment of waterbody conditions.

(iv) Use another scientifically defensible approach protective of the designated use.

(3) For any determination made under paragraph (e)(1) of this section, the Regional Administrator shall, prior to making such a determination, provide for public notice and comment on a proposed determination. For any such proposed determination, the Regional Administrator shall prepare and make available to the public a technical support document addressing the specific surface waters affected and the justification for each proposed determination. This document shall be made available to the public no later than the date of public notice issuance.

(4) The Regional Administrator shall maintain and make available to the public an updated list of determinations made pursuant to paragraph (e)(1) of this section as well as the technical support documents for each determination.

(5) Nothing in this paragraph (e) shall limit the Administrator's authority to modify the criteria in paragraph (c) of this section through rulemaking.

(f) *Effective date.* This section is effective March 6, 2012, except for § 131.43(e), which is effective February 4, 2011.

[FR Doc. 2010-29943 Filed 12-3-10; 8:45 am]

BILLING CODE 6560-50-P



# Federal Register

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Monday,  
December 6, 2010

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## Part IV

### Department of Health and Human Services

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#### Food and Drug Administration

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**Guidance for Industry: Use of Serological Tests To Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components Intended for Transfusion; Availability; Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry: Use of Serological Tests To Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components Intended for Transfusion; Notices**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2009-D-0137]

**Guidance for Industry: Use of Serological Tests To Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components Intended for Transfusion; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: Use of Serological Tests To Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components Intended for Transfusion" dated December 2010. The guidance document notifies establishments that manufacture whole blood and blood components intended for transfusion about FDA approvals of biologics license applications for serological test systems for the detection of antibodies to *Trypanosoma cruzi*. These tests are intended for use as donor screening tests to reduce the risk of transmission of *T. cruzi* infection by detecting antibodies to *T. cruzi* in plasma and serum samples from individual human donors. The guidance document does not apply to the collection of source plasma. Also, the guidance does not apply to establishments that make eligibility determinations for donors of human cells, tissues, and cellular and tissue-based products (HCT/Ps). The guidance announced in this document finalizes the draft guidance entitled "Guidance for Industry: Use of Serological Tests To Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components for Transfusion and Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" dated March 2009. The recommendations for HCT/P donor screening and testing for *T. cruzi* antibodies contained in the draft guidance are not being finalized at this time because FDA believes additional discussion is warranted. Elsewhere in this issue of the **Federal Register**, FDA is publishing a 30-day notice announcing that the proposed collection of information for the guidance has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit either electronic or written comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The 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 guidance document.

Submit electronic comments on the 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:** Valerie A. Butler, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a document entitled "Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components Intended for Transfusion" dated December 2010. The guidance document notifies establishments that manufacture whole blood and blood components intended for transfusion about FDA license approvals for serological test systems for the detection of antibodies to *T. cruzi*. These tests are intended for use as donor screening tests to reduce the risk of transmission of *T. cruzi* infection by detecting antibodies to *T. cruzi* in plasma and serum samples from individual human donors. The guidance document provides recommendations for one time testing of donations of whole blood and blood components for evidence of *T. cruzi* infection, blood donor and product management, labeling of whole blood and blood components, and procedures for reporting the implementation of a licensed *T. cruzi* test. The guidance document does not apply to the collection of source plasma. Also, the guidance does not apply to establishments that make eligibility determinations for donors of HCT/Ps. The recommendations for HCT/P donor

screening and testing for *T. cruzi* antibodies contained in the draft guidance are not being finalized at this time because FDA believes additional consideration of the recommendations is warranted.

At the April 2009 Blood Products Advisory Committee (committee) meeting, FDA sought advice from the committee regarding selective testing strategies for *T. cruzi* infection in repeat blood donors. After discussing the testing strategies presented, the committee voted in favor of a selective testing strategy in which one negative test would qualify a donor for all future donations without further testing or the need to ask questions regarding risk of a newly acquired *T. cruzi* infection.

In the **Federal Register** of March 26, 2009 (74 FR 13211), FDA announced the availability of the draft guidance entitled "Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components for Transfusion and Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" dated March 2009. The guidance announced in this document finalizes only the recommendations concerning testing donations of whole blood and blood components intended for transfusion for *T. cruzi* antibodies.

At this time, FDA is continuing to review public comments on our recommendations for testing HCT/P donors for *T. cruzi*. Therefore, we are not finalizing our recommendations for HCT/Ps in this guidance. We intend to issue guidance for testing HCT/P donors for *T. cruzi* infection in the future.

FDA received numerous comments on the draft guidance and those comments were considered as the guidance was finalized. Editorial changes also were made to improve clarity.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA'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. Paperwork Reduction Act of 1995**

This guidance contains information collection provisions that are subject to review by the OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). Elsewhere in this issue of the **Federal Register**, FDA is publishing a 30-day notice entitled "Agency Information Collection

Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components Intended for Transfusion,” which announces that the proposed collection of information has been submitted to OMB for review and clearance under the Paperwork Reduction Act. FDA will publish a notice concerning OMB approval of these information collection provisions in the **Federal Register** prior to the implementation date provided in the guidance document.

The guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 601.12 have been approved under OMB control number 0910-0338; the collections of information in 21 CFR 606.100, 606.121, 606.122, 606.160(b)(ix), 606.170(b), 610.40, and 630.6 have been approved under OMB control number 0910-0116; the collections of information in 21 CFR 606.171 have been approved under OMB control number 0910-0458.

### III. Comments

Interested persons may submit to the Division of Dockets Management (*see ADDRESSES*) either electronic or written or 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 in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

### IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: November 30, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-30405 Filed 12-3-10; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-D-0137]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry: Use of Serological Tests To Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components Intended for Transfusion

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of the document entitled “Guidance for Industry: Use of Serological Tests To Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components Intended for Transfusion” dated December 2010.

**DATES:** Fax written comments on the collection of information by January 5, 2011.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-NEW and title “Guidance for Industry: Use of Serological Tests To Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components Intended for Transfusion.” Also include the FDA docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3792, [Elizabeth.Berbakos@fda.hhs.gov](mailto:Elizabeth.Berbakos@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed

collection of information to OMB for review and clearance.

#### Guidance for Industry: Use of Serological Tests To Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components Intended for Transfusion—(OMB Control Number 0910-NEW)

The guidance document, announced elsewhere in this issue of the **Federal Register**, would implement the donor screening recommendations for the FDA-approved serological test systems for the detection of antibodies to *Trypanosoma cruzi*. The use of the donor screening tests are to reduce the risk of transmission of *T. cruzi* infection by detecting antibodies to *T. cruzi* in plasma and serum samples from individual human donors, including donors of whole blood and blood components intended for transfusion. The guidance recommends that establishments that manufacture whole blood and blood components intended for transfusion should notify consignees of all previously collected in-date blood and blood components to quarantine and return the blood components to the establishments or to destroy them within 3 calendar days after a donor tests repeatedly reactive by a licensed test for *T. cruzi* antibody. When establishments identify a donor who is repeatedly reactive by a licensed test for *T. cruzi* antibodies and for whom there is additional information indicating risk of *T. cruzi* infection, such as testing positive on a licensed supplemental test (when such test is available) or until such test is available, information that the donor or donor’s mother resided in an area endemic for Chagas disease (Mexico, Central and South America) or as a result of other medical diagnostic testing of the donor indicating *T. cruzi* infection, we recommend that the establishment notify consignees of all previously distributed blood and blood components collected during the lookback period and, if blood or blood components were transfused, encourage consignees to notify the recipient’s physician of record of a possible increased risk of *T. cruzi* infection.

Respondents to this information collection are establishments that manufacture whole blood and blood components intended for transfusion. We believe that the information collection provisions for consignee notification and for consignees to notify the recipient’s physician of record in the guidance do not create a new burden for respondents and are part of usual and customary business practices. Since the end of January 2007, a number of blood

centers representing a large proportion of U.S. blood collections have been testing donors using a licensed assay. We believe these establishments have already developed standard operating procedures for notifying consignees and the consignees to notify the recipient's physician of record.

The guidance also refers to previously approved collections of information found in FDA regulations. The

collections of information in 21 CFR 601.12 have been approved under OMB control number 0910-0338; the collections of information in 21 CFR 606.100, 606.121, 606.122, 606.160(b)(ix), 606.170(b), 610.40, and 630.6 have been approved under OMB control number 0910-0116; the collections of information in 21 CFR 606.171 have been approved under OMB control number 0910-0458.

In the **Federal Register** of March 26, 2009 (74 FR 13211), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received on the information collection.

Dated: November 30, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-30404 Filed 12-3-10; 8:45 am]

**BILLING CODE 4160-01-P**





# Federal Register

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**Monday,  
December 6, 2010**

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**Part V**

## **Federal Communications Commission**

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**47 CFR Parts 0 and 15  
Unlicensed Operation in the TV Broadcast  
Bands; Final Rule**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Parts 0 and 15

[ET Docket No. 04–186 and 02–380; FCC 10–174]

### Unlicensed Operation in the TV Broadcast Bands

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This document finalizes rules to make the unused spectrum in the TV bands available for unlicensed broadband wireless devices. This particular spectrum has excellent propagation characteristics that allow signals to reach farther and penetrate walls and other structures. Access to this spectrum could enable more powerful public Internet connections—super Wi-Fi hot spots—with extended range, fewer dead spots, and improved individual speeds as a result of reduced congestion on existing networks. This type of “opportunistic use” of spectrum has great potential for enabling access to other spectrum bands and improving spectrum efficiency. The Commission’s actions here are expected to spur investment and innovation in applications and devices that will be used not only in the TV band but eventually in other frequency bands as well.

**DATES:** Effective January 5, 2011 except for amendments to §§ 15.713, 15.714, 15.715 and 15.717, which contain information collection requirements that are not effective until approved by the Office of Management and Budget. The Commission will publish a document in the **Federal Register** announcing the effective dates for those amendments.

**FOR FURTHER INFORMATION CONTACT:** Hugh Van Tuyl, Policy and Rules Division, Office of Engineering and Technology, (202) 418–7506 or via e-mail [Hugh.VanTuyl@fcc.gov](mailto:Hugh.VanTuyl@fcc.gov).

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission’s Second Memorandum Opinion and Order, ET Docket No. 04–186 and 02–380, adopted September 23, 2010 and released September 23, 2010. The full text of this document is available on the Commission’s Internet site at <http://www.fcc.gov>. It is also available for inspection and copying during regular business hours in the FCC Reference Center (Room CY–A257), 445 12th Street, SW., Washington, DC 20554. The full text of this document also may be purchased from the Commission’s duplication contractor, Best Copy and

Printing Inc., Portals II, 445 12th St., SW., Room CY–B402, Washington, DC 20554; telephone (202) 488–5300; fax (202) 488–5563; e-mail [FCC@BCPIWEB.COM](mailto:FCC@BCPIWEB.COM).

### Paperwork Reduction Act of 1995 Analysis

This document adopts new or revised information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13 (44 U.S.C. 3501–3520). The requirements will be submitted to the Office of Management and Budget (OMB) for review under section 3507(d) of the PRA. The Commission will publish a separate notice in the **Federal Register** inviting comment on the new or revised information collection requirements adopted herein. The requirements will not go into effect until OMB has approved them and the FCC has published a notice announcing the effective date of the information collection requirements. In addition, we note that pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4), we previously sought specific comment on how the Commission might “further reduce the information collection burden for small business concerns with fewer than 25 employees.”

### Summary of the Second Memorandum Opinion and Order

1. In this Second Memorandum Opinion and Order, the Commission addresses on reconsideration a wide variety of issues relating to unlicensed use of the TV bands. These issues include protection criteria for incumbent authorized services, technical rules for TV bands devices, TV bands database requirements, the channels that can be used by TV bands devices, and several miscellaneous issues. The Commission is generally upholding the decisions it made in the *Second Report and Order* and *Memorandum Opinion and Order (Second Report and Order)* in this proceeding, 74 FR 7314, February 17, 2009, with some specific revisions and clarifications. In this regard the actions taken here are consistent with and continue the approach towards authorization of unlicensed devices in the TV bands that the Commission enunciated in the *Second Report and Order*—its actions in this proceeding are to be a conservative first step that includes many safeguards to prevent harmful interference to incumbent communications services. The Commission does, however, agree with petitioners with regard to a number of the requested changes to the rules and

are modifying and clarify our rules as appropriate in granting those requests. The Commission believes these changes and clarifications will provide for improved protection of licensed services in the TV bands, resolve certain uncertainties in the rules and provide manufacturers with greater flexibility in designing products to meet market demands. The Commission decisions granting and denying the various requests for changes to our rules for TV bands devices are discussed.

2. With the issuance of this decision and the forthcoming decision by the Commission’s Office of Engineering and Technology on selection of one or more database managers, manufacturers will be able to begin to make unlicensed TV bands devices and systems available to consumers, business and government users for general use. The Commission intends to closely oversee the introduction of these devices to the market and will take whatever actions may be necessary to avoid, and if necessary correct, any harmful interference that may occur. Further, the Commission will consider in the future any changes to the rules that may be appropriate to provide greater flexibility for development of this technology and protect against harmful interference to incumbent communications services.

3. Specifically, the Commission is resolving on reconsideration certain legal and technical issues in order to provide certainty concerning the rules for operation of unlicensed transmitting devices in the television broadcast frequency bands (unlicensed TV bands devices, or TVBDs). Resolution of these issues will allow manufacturers to begin marketing unlicensed communications devices and systems that operate on frequencies in the TV bands in areas where they are not used by licensed services (“TV white spaces”). The opening of these bands for unlicensed use, which represents the first significant increase in unlicensed spectrum below 5 GHz in over 20 years, will have significant benefits for both businesses and consumers and will promote more efficient spectrum use.

4. The Commission responds to seventeen petitions for reconsideration that were filed in response to the *Second Report and Order* in this proceeding. These petitions collectively request numerous changes in the rules for TV bands devices. The Commission is upholding the majority of its prior decisions on the issues raised therein. In this regard, the Commission continues to believe that the approach it followed in the *Second Report and Order* is desirable and appropriate for this first step in allowing unlicensed operations

in the TV bands. The Commission does, however, find merit in a number of the requests for changes to the rules for TVBDs and is granting those requests by modifying and clarifying the rules in four areas. Specifically, the Commission is taking the following actions:

- Protection Criteria for Incumbent Services
  - Modifying the protection criteria for low power auxiliary stations such as wireless microphones to reduce the required separation between such devices and unlicensed personal/portable devices operating in Mode II.
  - Modifying the definition of the receive sites entitled to protection outside of a television station's service area to include all multi-channel video programming distributors as defined by our rules.
  - Reserving two vacant UHF channels for wireless microphones and other low power auxiliary service devices in all areas of the country.
  - Allowing operators of event and production/show venues that use large numbers of wireless microphones on an unlicensed basis that cannot be accommodated in the two reserved channels and any others available at that location to register the sites of those venues on TV bands databases to receive the same geographic spacing protections afforded licensed wireless microphones.
  - Restricting fixed TV bands devices from operating on locations where the ground level is more than 76 meters above the average terrain level in the area.
- TV Bands Devices
  - Eliminating the requirement that TV bands devices that incorporate geo-location and database access must also listen (sense) to detect the signals of TV stations and low power auxiliary service stations (wireless microphones). As part of that change the Commission is also revising and amending the rules in several aspects to reflect use of that method as the only means for determining channel availability. While the Commission is eliminating the sensing requirement for TVBDs, it is encouraging continued development of this capability because it believes that it holds promise to further improvements in spectrum efficiency in the TV spectrum in the future and will be a vital tool for providing opportunistic access to other spectrum bands.
  - Adopting power spectral density limits for unlicensed TV bands devices.
  - Modifying the rules governing measurement of adjacent channel emissions.
  - Restricting fixed TV bands devices from operating at locations

where the height above average terrain of the ground level is greater than 76 meters.

- TV Bands Database
    - Requiring that communications between TV bands devices and TV bands databases, and between multiple databases, are secure.
    - Requiring that all information that is required by the Commission's rules to be in the TV bands databases be publicly available.
    - Use of TV Channels
      - Amending the rules to protect Canadian and Mexican stations in the border areas by including those stations in the TV bands database as protected services.
      - Changing the protection zone for the radio astronomy facility near Socorro, New Mexico to a rectangular area.
      - Declining to grant a request by FiberTower to set aside TV channels for fixed licensed backhaul use.
5. The Commission also makes other minor changes and refinements to its rules for TV bands devices. With these changes and clarifications, the rules will better ensure that licensed services are protected from interference while retaining flexibility for unlicensed devices to share the TV bands with them.

#### Protection Criteria for Incumbent Services

##### TV Stations

6. In the *Second Report and Order*, the Commission adopted technical criteria for determining when a TV channel is considered vacant for the purpose of allowing operation of an unlicensed device on that channel. It protected full service TV stations and Class A TV, low power TV, TV translator and TV booster stations from interference within defined signal contours. The signal level defining a television station's protected contour varies depending on the type of station, *e.g.*, analog or digital TV, and the band in which a TV station operates, *e.g.*, VHF or UHF. The protected contours for analog TV stations are calculated in accordance with the F(50,50) curves specified in the Commission's rules, and the protected contours for digital TV stations are calculated in accordance with the F(50,90) curves. While part 74 of the rules protects low power stations to a higher signal strength contour, and therefore to a shorter distance, than full service TV stations, the Commission decided to require TV bands devices to protect low power stations to the same contour as full service TV stations.

7. *Decision.* The Commission affirms its decisions regarding the protection

contours for TV stations. First, the Commission declines to change the method that must be used to calculate TV station protected contours. No party has described an alternative model that will provide more accurate calculations of TV station contours than the Commission's current method. The current method of calculating TV station contours in § 73.684 of the rules using the FCC curves in § 73.699 of the rules is straightforward, well understood and has proven sufficiently accurate over time. Given the lack of compelling information to the contrary, the Commission believes that calculations of channel availability relying on that methodology will provide satisfactory protection of TV services. Further, with respect to Adaptrum's request that TV signal information be incorporated into the TV bands databases, the Commission is removing the requirement that TV bands devices that include a geo-location capability and access to a database must sense television and low power auxiliary stations. Thus, sensing information on the location of TV signals would not be available to incorporate into the database. The Commission agrees with Rudman/Ericksen that the TV bands device database should include information on transmit antenna beam tilt to permit TV contour calculations to be made consistent with part 73 of the rules and is modifying § 15.713(h) of the rules accordingly.

8. The Commission also affirms its decision to protect low power television stations to the same signal contour as full service TV stations. Low power stations may provide the only over-the-air broadcast services in rural areas, and the Commission disagrees that viewers of those stations should receive less protection than viewers of full service stations. Further, low power stations by their nature cover only a relatively small area, so a modest increase in the protected area beyond the defined part 74 contour for these stations will not significantly impact the deployment of TV bands devices.

9. The Commission disagrees with SBE and Community Broadcasters that the rules fail to protect analog TV stations. While the D/U protection ratios for analog TV stations are higher than for digital stations, the protected service contours for analog stations are also higher than for digital stations. The net result is that the level of an undesired signal from a TVBD that will cause interference to an analog station is higher than the level that will cause interference to a digital station. Thus, the Commission's standards for protection of digital TV stations from

interference caused by TVBDs when applied for protection of analog TV stations provide somewhat greater protection of analog TV stations than would standards produced from a similar analysis that specifically considered protection of analog TV stations. The Commission also finds that an analysis focusing on digital operation is appropriate for low power television stations because these stations will eventually convert to digital operation.

10. The Commission declines to adopt any new requirements related to the use of TV bands devices in close proximity to amplified indoor antennas. A TV bands device and a TV receiver in close proximity would be under the control of the same party who could take steps to eliminate interference. The Commission previously adopted a requirement in the *Second Report and Order* requiring manufacturers to provide information to consumers on possible methods to resolve interference to television in the event it occurs, so the Commission finds no need to adopt any additional requirements.

#### *Wireless Microphones and Other Low Power Auxiliary Stations*

11. In the *Second Report and Order*, the Commission decided that the locations where licensed part 74 low power auxiliary stations, including wireless microphones, are used can be registered in the TV bands device database and will be protected from interference from TV bands devices. TV bands devices may not operate co-channel to a registered low power auxiliary station within a distance of 1 kilometer of the registered coordinates.

12. *Decision.* The Commission continues to recognize that wireless microphones are currently used in many different venues where people gather for events large and small and many consumers and businesses have come to rely on these devices. The Commission has previously limited use of channels 2 and 5–20 to communications between fixed TVBDs and reserved two channels in the range 14–51 in the 13 markets where PLMRS and CMRS systems operate to make sure that frequencies are available for wireless microphones. The Commission herein expands the reservation of two channels in the range 14–51 to all markets nationwide as suggested by several petitioners. This will provide frequencies where a limited but substantial number of wireless microphones can be operated on any basis without the potential for interference from TV bands devices. It will also ensure that frequencies are available everywhere for licensed wireless microphones used on a roving

basis to operate without risk of receiving harmful interference from TVBDs. The Commission has also provided for a nominal separation distance between TVBDs and sites of venues and events where large numbers of unlicensed wireless microphones used by permitting such sites to be registered in the TV bands databases. Further, it notes that at any particular location a number of TV channels will not be available for use by TVBDs due to the application of the various interference protection requirements under our rules. Thus, a significant amount of spectrum will be available on which wireless microphones can be operated as they have in the past without concern for interference from TVBDs. The Commission believes that this spectrum will provide sufficient frequencies to support wireless microphone operations at the great majority of events. The Commission disagrees with those who argue that more spectrum should be reserved for wireless microphones. It observes that wireless microphones generally have operated very inefficiently, perhaps in part due to the luxury of having access to a wealth of spectrum. While there may be users that believe they need access to more spectrum to accommodate more wireless microphones, the Commission finds that any such needs must be accommodated through improvements in spectrum efficiency. The Commission underscored this point in the currently pending wireless microphone proceeding and sought comment on solutions that could enable wireless microphones to operate more efficiently and/or improve their immunity to harmful interference, *See Report and Order and Further Notice of Proposed Rule Making* in WT Docket Nos. 08–166 and 08–167 and ET Docket No. 10–24, 25 FCC Rcd 643, 702 (2010), FCC 10–16, 75 FR 9113, March 1, 2010. The Commission will continue to pursue this issue as it considers possible repurposing of the TV spectrum.

13. The Commission disagrees with the petitioners that argue unlicensed wireless microphones should be subject to the same requirements as TVBDs under the rules. There are many important differences that make it impractical to apply the same rules to both types of devices. For example, TVBDs are expected to be data devices that will have access to the Internet. Wireless microphones do not typically include geo-location technology nor do they connect to the Internet, so requiring these devices to check for channel availability through a database would be impractical. Also, TVBDs

generally should be able to tolerate some latency, whereas wireless microphones operate in real time and generally cannot tolerate significant latency. Most importantly, unlicensed wireless microphones have been operating for quite some time without causing harmful interference. Accordingly, the Commission concludes that unlicensed wireless microphones should not be subject to the more confined approach it has applied to TVBDs.

14. With regard to registration of unlicensed devices in the TV bands databases, the Commission first observes that unlicensed wireless microphones operate under the same general conditions of operation in § 15.5 of the rules as TV bands devices, meaning they may not cause interference to authorized services and must accept any interference received, including interference from other non-licensed devices. As a general matter, the Commission therefore finds that it would be inappropriate to protect unlicensed wireless microphones against harmful interference from other unlicensed devices, and in particular TV bands devices. The Commission observes that there are a wide variety of applications for wireless microphones ranging from a single wireless microphone used by a performer or presenter, to small theatrical productions using perhaps 10–20 microphones, to large scale productions and events such as professional sports events and Broadway style productions that may use well over 100 wireless microphones. The overwhelming majority of such use does not merit registration in the TV bands database. In cases where the number of wireless microphones needed for an event is relatively low, the operator of unlicensed microphones can avoid receiving harmful interference from TVBDs by simply using the reserved channels or other channels in each market where TVBDs are not allowed to operate. The two reserved TV channels will accommodate a minimum of at least 16 wireless microphones, and the additional channels that are not available for TVBDs at most locations will accommodate many additional wireless microphones. On the other hand, the Commission recognizes that certain events, such as major sporting contests or live theatrical productions/shows, may use scores of wireless microphones and therefore may not be able to be accommodated in the two reserved channels and other channels that may be available for wireless microphones at that location.

15. Accordingly, the Commission is addressing unlicensed wireless microphones and low power auxiliary devices in our rules for TV band devices as follows. As the general rule, it is not allowing unlicensed wireless microphones and other low power auxiliary devices operating without a license to be registered in the database; these devices will not be afforded protection from interference from TV bands devices on channels where TV bands devices are allowed to operate. Entities desiring to operate wireless microphones on an unlicensed basis without potential for interference from TVBDs may use the two channels in each market area where TVBDs are not allowed to operate, as well as other TV channels that will be available in the vast majority of locations. Such entities may consult with a TV bands database to identify the reserved channels at their location, as well as the TV channels that may not be available for TV band devices. Entities operating or otherwise responsible for the audio systems at major events where large numbers of wireless microphones will be used and cannot be accommodated in the available channels at that location may request registration of the site in the TV bands databases. The registration requests must be filed with the Commission. Entities filing registration requests will be required to certify that they are using the reserved channels and all other available channels from 7–51 (except channel 37) that are not available for use by TV band devices and are practicable for use by wireless microphones. The request to be registered must be filed with the Commission at least 30 days in advance and include the hours, dates or days of the week and specific weeks on which those microphones will be in actual use (on dates where events are not taking place, those sites will not be protected) and other identifying information also required of low power auxiliary licensees. Unlicensed microphones at event sites qualifying for registration in TV bands databases will be afforded the same geographic spacing from TVBDs as licensed microphones. The Commission also advises entities responsible for event sites qualifying for registration in TV bands databases that registration does not create or establish any form or right or assurance of continued use of the spectrum in the future.

16. To allow it to better identify registered wireless microphone licensed operations and unlicensed sites, the Commission adopted the following registration procedures. Operators of licensed wireless microphones may

register sites directly with one of the designated database administrators and provide the information required by the rules, which the Commission is amending to include the wireless microphone call sign. As indicated, operators of venues using unlicensed wireless microphones will be required to register their sites with the Commission, which will transmit the information to the TV bands device database administrators. For the purpose of this registration, the Commission will develop a form that will allow the information to be filed through one of the Commission's electronic filing systems, such as the Universal Licensing System (ULS). The applicant will be required to certify that it complies with the requirements for registration of unlicensed wireless microphones, including that it will first make use of all TV channels not available for TV bands devices that are practicable for wireless microphone use, including channels 7–51 (except channel 37), and submit the information specified by the rules, which we are amending to include the name of the venue where the equipment is operated. As a benchmark, at least 6–8 wireless microphones must be operating in each channel that is being used for the event. Registration requests that do not meet these criteria will not be registered in the TV bands databases. The Commission will take actions against parties that file inaccurate or incomplete information, such as denial of registration in the database, removal of information from the database pursuant to § 15.713(i), or other sanctions as appropriate to ensure compliance with the rules. The Commission will make requests for registration of sites that use unlicensed wireless microphones public and will provide an opportunity for public comment or objections. The Commission has delegated authority for administering this registration process jointly to its Office of Engineering and Technology and Wireless Telecommunications Bureaus.

17. The Commission is maintaining the requirement that fixed TV bands devices may not operate co-channel with low power auxiliary stations within 1 km of their coordinates registered in the TV bands databases. The Commission recognizes the arguments of Shure and CWMU about the difference in power levels between fixed TV bands devices and wireless microphones. However, whether harmful interference occurs in a particular situation depends on many factors, including the undesired signal power, antenna directivity and

separation distance, as well as the level of the desired signal at the receiver, the receive antenna and receiver characteristics, and any intervening structures or terrain that could attenuate the undesired signal. Neither Shure nor CWMU provided an analysis with their petitions demonstrating that the 1 km separation distance adopted in the *Second Report and Order* is inadequate for fixed devices when taking all relevant factors into account. In cases where licensed low power auxiliary stations are being used at large outdoor venues, such as racetracks or golf courses, the Commission will permit the party registering the devices to specify the coordinates of multiple locations within the site to ensure that protection is provided over the entire facility where microphones are being used.

18. However, the Commission agrees with petitioners that argue that it is not necessary to provide low power auxiliary stations the same protection from personal/portable TV bands devices because the latter operate with power levels at least forty times lower than the maximum power permitted for fixed TV bands devices. Therefore, it is modifying the rules to require that Mode II (independent) personal/portable devices not operate co-channel with low power auxiliary stations within 400 meters (0.4 km) of their coordinates registered in the TV bands device database. A 100 mW transmitter will produce a lower signal at 400 meters than a 4 watt transmitter at 1 km using a free space calculation, so this shorter distance will provide greater protection for low power auxiliary devices from 100 mW TV bands devices than a 1 km separation from 4 watt devices. The Commission will use this same 400 meters distance for personal/portable devices that operate with less than 100 mW of power.

19. The Commission finds that it is not practical to protect wireless microphones using information obtained from the ULS and declines to require that that information be used in defining such protection as suggested by Rudman/Ericksen. Some wireless microphones are licensed using specific coordinates, while others are licensed to a wide area such as the entire service area of a TV station, and a license may specify multiple operating channels. The Commission also observes that wireless microphones can be operated intermittently at discrete locations, rather than continuously over a wide area. Thus, the use of ULS licensing data could preclude TV bands devices from operating on multiple channels and at locations where no wireless microphones are in operation.

*Translators, Cable Headends and Multichannel Video Program Distributors*

20. In the *Second Report and Order*, the Commission adopted rules to protect TV translator receive sites and cable TV headends that are located outside the protected contours of the TV stations being received. TV translator receive sites are often located on high towers or at high elevations and use high gain antennas to receive a full service station's signal well beyond the station's service area. Cable headends are facilities that acquire and distribute video service signals over a cable television system. Broadcast TV signals are often received off-the-air at a cable headend for retransmission over the cable system. In many cases, the cable headend will use an antenna with high gain antenna mounted high on a tower to receive a TV station's signals well beyond the station's service area in a manner similar to that used by TV translators. The Commission found that it is important to avoid disruption of TV service to viewers who are located beyond TV station service areas and able to receive those signals through retransmission on TV translators and cable systems. While those viewers are in fact located beyond the areas where the Commission normally protects TV services, in these cases TV services have *de facto* been extended and valuable service is being provided to a significant number of households. If a TV bands device were to be located between the TV translator/cable headend and TV station and then operate on one or more of the channels being received by those facilities in a manner that results in harmful interference, TV reception to the households and the cable system services could be disrupted.

21. To protect cable headends and TV translator receive sites which are not listed in Commission databases, the Commission allowed operators of TV translator receive sites and cable headends that are located within 80 km of the service contour of the received TV station to register their location and the channel(s) they receive in the TV bands device database. To prevent unnecessary entries into the database, the Commission permitted translator receive sites and cable headends to be registered only if they are outside the protected contour of the TV station being received. The rules limit operation of TV bands devices co-channel and adjacent to the channel(s) being received over an arc of  $\pm 30$  degrees from a line between the receive site and the TV station(s) being received. Within this arc, TV bands

devices operating co-channel to the received station may not operate within 80 km of the receive site, and TV bands devices on channels adjacent to the received station may not operate within 20 km of the receive site. The protection radius extends only as far as the protected contour of the station being received, so the co-channel protection distance would be less than 80 km for receive sites closer than this distance from a protected contour, and both the co-channel and adjacent channel protection distances would be less than 20 km for receive sites closer than this distance from a protected contour. In addition, to prevent interference to TV translators and cable headends from TV bands devices outside the main beam of the receive antenna, the Commission prohibited TV bands devices from operating co-channel to the channel(s) being received by these facilities within 8 kilometers and from operating on adjacent channels within 2 kilometers in all directions off the  $\pm 30$  degree arc.

22. *Decision.* The Commission modified the rules to expand and more clearly define the types of receive facilities that may be registered in the TV bands database and are making certain changes to the protection criteria for these receive facilities. The purpose of permitting the registration of receive sites is to protect the reception of over-the-air TV signals that are redistributed through another means. Consistent with this intent, the Commission will permit the registration of TV receive sites for other types of video service providers besides cable systems and is modifying the rules in this regard to more clearly and completely define the types of facilities that may be registered. The Commission therefore specifies that receive sites of all multi-channel video programming distributors (MVPDs) as defined by section 602(13) of the Communications Act may be voluntarily registered in the database, in addition to TV translator receive sites.

23. The Commission recognizes that there are cable headends that receive TV station signals located at distances beyond 80 km from the edge of a television station's protected service contour and understand NCTA's concern for possible disruption service to cable subscribers. These same considerations would apply to other MVPDs and to TV translator, low power TV and Class A TV stations that retransmit programming from another TV station. The Commission does not believe that the requested change would have significant impact on the availability of TV white space because these facilities are generally in remote areas where many channels will be

available for white space devices. However, the Commission also recognizes that parties may wish to have an opportunity to review such requests to confirm the assessment. We are therefore providing that current MVPD operators, TV translator, low power TV and Class A TV stations with receive sites located beyond the 80 km co-channel protection distance in the rules may apply for a waiver of that distance during a period that will end 90 days after the effective date of the rules adopted herein. Such waiver requests would also involve shifting the 20 km adjacent channel protection distance so that it is measured from the actual receive site. The Commission will then issue a public notice requesting comment on requests it receives and issue decisions. MVPD operators and TV translator, low power TV and class A TV stations that commence operation in the future with receive sites located beyond the co-channel and adjacent protection distances may apply for a waiver of those distances within 90 days of commencing operation. Following receipt of such request(s), the Commission will then issue a public notice asking for comment on the request(s) and issue decision(s).

24. The Commission declines to increase the width of the  $\pm 30$  degree protected arc as requested by NCTA. A receive site located outside the protected contour of a TV station would need to incorporate a high gain receive antenna, which has a narrow beamwidth. While it recognizes NCTA's argument that an antenna has side lobes that will allow it to receive signals outside its main beam, this does not in itself demonstrate that the current protection requirement is inadequate or that a wider protected arc is necessary. Adaptrum provides no information to support its argument that the protection distance outside of the main lobe of the receive antenna should be significantly reduced and we therefore deny that request. The Commission further declines to require operators of fixed TV bands devices to coordinate with operators of receive sites. The requirements it has adopted are extremely conservative and will adequately protect receive sites, so a coordination requirement is unnecessary and would be cumbersome to implement.

25. The Commission finds it unnecessary to provide for registration of receive sites within the protected contour of a TV station being received and thus declines to allow such registrations. Within a station's protected service contour, receive sites are protected from interference by the

same provisions that protect reception by consumers. The rules require that TV bands devices be located outside the contour of a co-channel TV station, so a TV bands device located near a contour that is communicating with another TV bands device would not be directing its signal into the contour where the receive site is located. Further, a receive site inside, but near the edge of a protected contour, would have its receive antenna directed toward the TV station and not at the TV bands device outside the contour. Therefore, the orientation of the antennas in this situation makes interference highly unlikely. Additionally, a TV bands device operating on a channel adjacent to an occupied TV channel is permitted to operate within the service contour, but at a lower power level not to exceed 40 mW. This lower power level combined with the fact that a receive site within a contour will receive a higher signal level than a receive site outside the contour makes adjacent channel interference from that source again unlikely. Furthermore, in the event that interference does occur, the operator of the TV bands device is required to cease operation.

26. Finally, the Commission is modifying the text of the rules to clarify that registration for receive sites is limited to channels that are received over-the-air and are used as part of service of the MVPD, TV translator, low power TV station or Class A TV station. The Commission is not limiting registration to local channels so as not to preclude the possibility that an MVPD or TV translator/low power television station may retransmit out-of-market channels if it is authorized to do so.

#### TV Bands Devices

##### *Spectrum Sensing*

27. In addition to requiring that TV bands devices access a database to determine available channels, the Commission decided in the *Second Report and Order* to require that TV bands devices be capable of sensing analog TV signals, digital TV signals and wireless microphone signals at a level of  $-114$  dBm within defined receiver bandwidths. This level is referenced to an omni-directional receive antenna with a gain of 0 dBi. If a receive antenna with a minimum directional gain of less than 0 dBi is used, the detection threshold must be reduced by the amount in dB that the minimum directional gain of the antenna is less than 0 dBi. Alternative approaches for the sensing antenna are permitted that provide at least the same

performance as an omni-directional antenna with 0 dBi gain. The Commission also required that the receive antenna used by fixed devices be located at least 10 meters above the ground to maximize the likelihood that its reception is not blocked from receiving signals originating from any direction. It found that receive antenna height requirements are impractical for personal/portable devices and declined to impose such requirements on those devices.

28. Under the rules adopted in the *Second Report and Order*, a TV bands device is permitted to begin operating on a TV channel if no wireless microphone or other low power auxiliary device signals above the detection threshold are detected within a minimum time interval of 30 seconds. A TV bands device must also perform in-service monitoring of channels on which it operates a minimum of once every 60 seconds. There is no minimum channel availability check time for in-service monitoring. If a device detects a wireless microphone or other low power auxiliary device signal on a channel it is using, the device must cease all transmissions on that channel within two seconds. If a TV signal is detected on a channel indicated as available for use by the database, the TV bands device must provide a notice of that detection to the operator of the device and provide a means for the operator to remove the channel from the device's list of available channels. However, with respect to TV signals, the database is the controlling factor in determining whether a channel is available, and there is no requirement for a TV bands device to avoid operating on a channel where it detects a TV signal, since it is possible to detect a signal outside a station's protected service contour.

29. A personal/portable device operating in Mode I must identify (report) those TV channels on which it senses a wireless microphone or television signal above the detection threshold to the fixed or Mode II personal/portable device that provides it with a list of available channels. The fixed or Mode II device must respond as if it had detected the signal itself, *i.e.*, it must not use the occupied channel if the Mode I device detects a wireless microphone and must report the TV signal detection to the operator of the device. In addition, TV bands devices communicating either directly with one another or linked through a base station must share information on channel occupancy determined by sensing. If any device in a local area group or network determines that a channel is occupied and notifies other devices

with which it is linked, all the other linked devices will be required to respond as if they had detected the signal themselves.

30. *Decision.* The Commission eliminated the requirement for TV bands devices that rely on geo-location and database access to sense analog and digital TV signals and also wireless microphones and other low power auxiliary stations. Much of this proceeding has focused on the central question of whether spectrum sensing is a viable tool for providing access to spectrum. The Commission has noted the benefits and limitations of spectrum sensing through testing conducted by its engineers and extensive discussion in the *Second Report and Order*. The Commission continues to believe that spectrum sensing will continue to develop and improve. It anticipates that some form of spectrum sensing may very well be included in TVBDs on a voluntary basis for purposes such as determining the quality of each channel relative to real and potential interference sources and enhancing spectrum sharing among TVBDs. However, at this juncture, the Commission does not believe that a mandatory spectrum sensing requirement best serves the public interest. As petitioners and responding parties indicate, the geo-location and database access method and other provisions of the rules will provide adequate and reliable protection for television and low power broadcast auxiliary services, so that spectrum sensing is not necessary. With respect to protection of television services, the Commission observes that the geo-location and database method is already the primary means for preventing interference to TV stations. The sensing requirement adopted in the *Second Report and Order* only requires that a TV bands device inform the user when a TV signal above a threshold is detected and provide an opportunity for the user to change channel, but it does not preclude operation on a channel where a TV signal is detected. That is, the *Second Report and Order* essentially relied on geo-location and the TV bands databases to protect over-the-air TV broadcasting, not spectrum sensing.

31. The Commission also now concludes that inclusion of a spectrum sensing capability is not necessary to protect wireless microphone operations. Parties operating part 74 licensed low power auxiliary stations at fixed locations are eligible to register those operations in the TV bands device database to obtain interference protection from TV bands devices. As indicated, for parties ineligible for part



74 licensing, the Commission, in its *Wireless Microphone R&O/FNPRM* permitted the operation of low power auxiliary service stations on an unlicensed basis under part 15 of the rules pending a final decision on its proposals to expand eligibility for part 74 licensing and to allow a new category of wireless audio devices to operate in the core TV bands under part 15. Based on the Commission's informal observations of the marketing and uses of wireless microphones, it appears that the number of wireless microphones operating under the part 15 waiver significantly outnumbered those operating as part 74 licensed devices. Unlicensed devices operate on a non-interference basis, meaning they may not cause interference to authorized services, and must accept any interference received, including interference from other unlicensed devices such as TV bands devices. Requiring TV bands devices to sense low power auxiliary stations such as wireless microphones would inappropriately give interference protection to a large number of other unlicensed, unprotected devices because there is no way for the sensing feature of a TV bands device to distinguish licensed from unlicensed devices. The Commission recognizes that there will be some licensed low power auxiliary stations that can be used in roving applications for which the location cannot be known in advance and therefore cannot be registered in the TV bands device database. The Commission has reserved two channels at all locations on which unlicensed TV bands devices will not be allowed to operate in order to ensure that there are frequencies on which licensed microphones used in roving applications such as electronic news gathering can operate. The availability of the frequencies in these channels will make it unnecessary to provide special protection from interference for such applications.

32. With the elimination of the spectrum sensing requirement for TV bands devices that use geo-location and database access, there is collaterally no longer a need for a minimum receive antenna height for fixed devices, and the Commission consequently is removing that requirement from the rules. The Commission also revised and amended certain elements of the rules so that they continue to provide comparable assurance of protection against interference in the absence of sensing capabilities and to clarify and simplify the rules as they pertain to interference protection. In addition to

revisions of the geo-location and database access rules, the changes include revision of certain terms used in the rules and elimination of the terms "client device," "client mode," "master device," and "master mode."

33. As part of these changes, the Commission eliminated the requirements for devices operating in Mode I to use distributed sensing. It also observes that some of the comments on this issue appear to reflect an understanding that the rules permit extensive networks of devices that would all be linked together using a commonly identified list of available channels. The Commission wishes to correct any misconceptions that, at least at this stage, the rules contemplate or permit such networks and sharing of channel availability information. Rather, as stated in the *Second Report and Order*, the Commission will permit personal/portable TVBDs to be used in the operation of networks only where a means is provided to ensure that each device is operating consistent with the channels available at its particular location. The rules do not permit personal/portable devices operating in Mode I to relay channel availability information from one Mode I device to another Mode I device unless some means is used to ensure that each device is operating within the parameters for its particular location.

34. The Commission's elimination of the general requirement that all TV bands devices perform spectrum sensing at least once per minute and report channel availability information to other devices in a network removes the only existing requirement in the rules for a Mode I device to maintain contact with a fixed or Mode II device. In reviewing this provision, the Commission also observed that the rules currently do not require that a Mode I device periodically re-establish its list of available channels through either device that uses geo-location and database access; however, such re-checks for channel availability are necessary to ensure that a Mode I device does not continue to operate on a channel that becomes unavailable. To address these concerns, the Commission is adding a requirement that a device operating in Mode I must either receive a special signal from the Mode II or fixed device that provided its current list of available channels to verify that it is still in reception range of that device or contact a Mode II or fixed device at least once per minute to re-verify/re-establish channel availability. This new requirement, including the special signal for verifying contact with the Mode II or fixed device that provided

the Mode I device's list of available channels, is described in more detail in the section below on Re-check Procedures. This requirement is necessary because a Mode I device is not generally expected to be able to determine when it has moved, and it could possibly be moved to a location where the operating channel is occupied. Maintaining regular contact with a Mode II or fixed device will ensure that Mode I devices operate only on channels available at their location and that they cease operation when they move out of range of the device from which they obtained their list of available channels, in which case their list of available channels would no longer be valid. This requirement will also address situations where a Mode I device is no longer able to maintain contact with an operating fixed or Mode II device (for example, if the fixed or Mode II device with which the Mode I device has been communicating ceases operation and the Mode I device is not able to contact a replacement).

35. In reviewing the rules in this context, the Commission also observes that § 15.711(b)(3)(ii) of the rules requires that a Mode II personal/portable device access the database for a list of available channels each time it is activated from a power-off condition and re-check its location and the database for available channels if it changes location during operation. It is the Commission's intent that a Mode II device monitor its location regularly to determine if its location has changed under this requirement. The Commission therefore amended this section of the rules to clarify that a Mode II device must use its geo-location capability to check its location at least once every 60 seconds, except when in "sleep mode," *i.e.*, in a mode in which the device is inactive but is not powered-down. This clarification will ensure that Mode II devices re-check their list of available channels within a short interval if their location changes. It will also provide clarity with respect to the re-check requirements for devices that operate on a mobile basis within a bounded geographic area in which the same channels are available at all locations.

36. While the Commission eliminated spectrum sensing for TVBDs that use geo-location and database access, it continues to believe that this technology offers significant promise for improving spectrum access and efficiency both in the TV bands and in providing access to other spectrum. Spectrum sensing has come a long way and some have expressed the view that even today it is sufficiently developed that it can be

relied upon for determining access to the TV bands and other spectrum. The Commission is therefore leaving open the opportunity to submit applications for certification of sensing-only devices. It acknowledges that the process for approval of such devices is rigorous. However, the Commission continues to believe that an open and transparent review as provided by that process is appropriate for sensing-only devices. Accordingly, the Commission retained the provisions in the rules that permit the authorization and operation of personal/portable TV bands devices that rely on sensing alone under a “proof-of-performance” standard. The Commission invites parties that submit such applications when they are ready to do so. The Commission takes this opportunity to clarify that devices that use sensing alone may initiate and participate in a network of TVBDs and may communicate with fixed, Mode I, Mode II and other sensing-only TVBDs but may not provide a Mode I device with a list of available channels. The Commission is also re-locating the existing spectrum sensing technical provisions that previously applied to all TVBDs into the rule section on sensing-only devices.

37. The Commission is also increasing the minimum required detection threshold for wireless microphones and other LPAS stations of sensing-only devices from  $-114$  dBm to  $-107$  dBm. It is making this change for two reasons. First, sensing-only devices must operate with lower power than fixed or other personal/portable devices (except for personal/portable devices operating on channels adjacent to television stations), so a higher detection threshold would provide a level of protection that is approximately comparable to a lower threshold in a higher power device. Second, the rules for such devices specify that although compliance with the detection threshold for spectrum sensing is required, it is not necessarily sufficient for demonstrating reliable interference avoidance. Thus, the required detection threshold we are adopting serves as a minimum performance criteria for a device.

38. Authorization of a sensing only TVBD under the proof-of-performance standard also requires that a manufacturer submit a prototype device that will be tested by the Commission to ensure that the device is capable of operating without interference prior to certification. The decision on whether to certify a sensing-only device will be based on its performance, and in particular its ability to reliably detect the presence of authorized transmissions. If the Commission

determines through testing that a lower detection threshold is necessary to prevent interference then it will require the device to meet the lower threshold before it could be certified. The Commission believes that these requirements for sensing-only devices are sufficiently conservative to prevent interference to TV reception and low power auxiliary stations. The Commission sees no basis for increasing the threshold for sensing of television signals.

#### Technical Requirements

##### *Antenna Height*

39. Because the range at which a TV bands device can cause interference increases as the height of the device’s antenna increases, the Commission adopted a maximum antenna height limit of 30 meters above ground for fixed devices. This height limit was intended to balance unlicensed fixed TV bands device transmission range with the distance at which those operations could impact licensed services. The Commission did not impose height restrictions on personal/portable devices because it found that it is not practical to administer an antenna height limit for those devices and the lower power and limited antenna gain of personal/portable devices would generally result in propagation over a shorter range than fixed devices. Further, the Commission observed that personal/portable devices, unlike fixed devices which have gain antennas mounted outdoors to maximize the propagation range of their signals, will likely typically be used indoors where their signals will be attenuated by exterior walls. These factors will significantly reduce the range at which signals from a personal/portable device will be of sufficient field strength to cause interference.

40. *Decision.* The Commission declines to increase the maximum permitted transmit antenna height above ground for fixed TV bands devices. As the Commission stated in the *Second Report and Order*, the 30 meters above ground limit was established as a balance between the benefits of increasing TV bands device transmission range and the need to minimize the impact on licensed services. Consistent with the Commission’s stated approach in the *Second Report and Order* of taking a conservative approach in protecting authorized services, it finds the prudent course of action is to maintain the previously adopted height limit. If, in the future, experience with TV bands devices indicates that these devices

could operate at higher transmit heights without causing interference, the Commission could revisit the height limit.

41. While the Commission expects that specifying a limit on antenna height above ground rather than above average terrain is satisfactory for controlling interference to authorized services in the majority of cases, it also recognizes petitioners’ concerns about the increased potential for interference in instances where a fixed TV bands device antenna is located on a local geographic high point such as a hill or mountain. In such cases, the distance at which a TV bands device signal could propagate would be significantly increased, thus increasing the potential for interference to authorized operations in the TV bands. The Commission therefore concludes that it is necessary to modify our rules to limit the antenna HAAT of a fixed device as well as its antenna height above ground. In considering a limit for antenna HAAT, the Commission needs to balance the concerns for long range propagation from high points against the typical variability of ground height that occurs in areas where there are significant local high points—the Commission does not want to preclude fixed devices from a large number of sites in areas where there are rolling hills or a large number of relatively high points that do not generally provide open, line-of-sight paths for propagation over long distances. The Commission finds that limiting the fixed device antenna HAAT to 106 meters (350 feet), as calculated by the TV bands database, provides an appropriate balance of these concerns. It will therefore restrict fixed TV bands devices from operating at locations where the HAAT of the ground is greater than 76 meters; this will allow use of an antenna at a height of up to 30 meters above ground level to provide an antenna HAAT of 106 meters. Accordingly, the Commission specifies that a fixed TV bands device antenna may not be located at a site where the ground HAAT is greater than 75 meters (246 feet). The ground HAAT is to be calculated by the TV bands database using computational software employing the methodology in § 73.684(d) of the rules to ensure that fixed devices comply with this requirement.

42. In reexamining this issue, the Commission also notes that the rules currently do not indicate that fixed device antenna heights must be provided to the database for use in determining available channels. It was clearly the Commission’s intent that fixed devices include their height when

querying the database because the available channels for fixed devices cannot be determined without this information. The Commission is therefore modifying §§ 15.711(b)(3) and 15.713(f)(3) to indicate that fixed devices must submit their antenna height above ground to the database.

43. The Commission continues to decline to establish height limits for personal/portable devices. As the Commission stated in the *Second Report and Order*, there is no practical way to enforce such limits, and such limits are not necessary due to the different technical and operational characteristics of personal/portable devices.

#### *Power and Power Spectral Density Limits*

44. In the *Second Report and Order*, the Commission allowed fixed TV bands devices to operate with a peak transmitter output power of one watt with a maximum antenna gain of 6 dBi, and required that the transmitter power be reduced by the same amount in dB that the maximum antenna gain exceeds 6 dBi. This allows unlicensed TV bands fixed devices to operate with the equivalent of 4 watts EIRP. The Commission found that 4 watts EIRP is sufficient to allow fixed devices to communicate at ranges that will serve community and rural users while minimizing the potential for interference to broadcast television and other authorized services in the TV bands. Fixed TV bands devices were not permitted to operate adjacent to occupied TV channels, although the Commission decided to defer a final decision on this issue and to keep the record open pending the development of additional information demonstrating that a reliable method can be developed to allow adjacent channel operation while protecting authorized services.

45. The Commission allowed personal/portable TV bands devices to operate with a peak transmitter output power of 100 mW with a maximum antenna gain of 0 dBi, and required that the transmitter power of such devices be reduced by the same amount in dB that the maximum antenna gain exceeds 0 dBi. This allows personal/portable TV bands devices to operate with an equivalent of 100 mW EIRP. In cases where a personal/portable device is operating adjacent to an occupied TV channel, the maximum permitted EIRP is 40 mW. Personal/portable devices that rely on spectrum sensing without the use of geo-location and a TV bands device database may be authorized at a power level up to 50 mW EIRP. The Commission did not specify minimum bandwidth limits for transmissions by

TV bands devices or power spectral density (PSD) limits in the *Second Report and Order*.

46. *Decision.* The Commission is not convinced by the petitions for reconsideration that the power limits for unlicensed TV bands can be increased without also increasing the potential for interference to authorized services and is therefore affirming the power limits for fixed and personal/portable devices that it adopted in the *Second Report and Order*. In addition, the Commission does not find that the power level of TV bands devices should be restricted to protect against direct pick-up interference to cable and satellite TV services. The Commission does, however, recognize the need to address power considerations in TV bands device signals that occupy less than the full bandwidth of a TV channel and is therefore amending the rules to include power spectral density limits.

47. The Commission declines to increase the 4 watt EIRP power limit for fixed devices and notes that it also considered and rejected a higher power limit for fixed devices in the *Second Report and Order*. While the Commission previously observed that there are advantages to higher power levels for fixed devices, such as reduced infrastructure costs and increased service range, it did not adopt a higher power limit due to concerns about increased risk of interference in congested areas and a lack of experience with unlicensed wireless broadband operations in the TV bands. The Commission also recognizes the increased range provided by operation at higher power levels would be particularly desirable for some applications, including rural service and mobile operations as suggested by Motorola. The Commission also understands that there may be situations where radio communications facilities could operate at higher power in TV white spaces without causing interference. However, the Commission continues to conclude that because the extended range of such devices would significantly increase the potential for interference and also make it more difficult to identify sources of interference, it would not be appropriate to allow higher power for unlicensed TV bands devices at this time. Indeed, such operation would be more appropriate under a licensed regime of regulation. The Commission therefore affirms its previous decision on fixed device power levels, but could re-visit the issue of higher power levels for TV bands devices on a licensed or unlicensed basis at some point in the future as may be appropriate.

48. The Commission retained the current 100 mW maximum transmitter power limit for Mode I and Mode II personal/portable devices and decline to establish a new class of higher power vehicle mounted portable devices. As the Commission noted in the *Second Report and Order*, personal/portable devices generally pose a greater risk of harmful interference to authorized operations than fixed devices because these devices will change locations, making identification of both unused TV frequencies and the devices themselves, if interference occurs, more complex and difficult. The Commission also noted the significant distances at which interference could occur from a personal/portable device operating at greater than 100 mW would make it very difficult to identify a device that is the source of interference. The Commission therefore declines to increase the power limit for personal/portable devices at this time.

49. Additionally, the Commission is retaining the 50 mW power limit for sensing-only devices. The Commission stated in the *Second Report and Order* that the prototype TV bands devices it tested were able to sense the presence of signals from incumbent services under some conditions, but were unable to do so in others, such as in noisy environments or in the presence of strong adjacent channel signals. It further stated that these factors made it difficult to fully validate the performance of sensing technology and develop standards to ensure that devices relying on sensing alone would not cause interference. While the Commission believed that these problems could be solved and decided to permit sensing-only devices, it decided to limit these devices to 50 mW rather than 100 mW as permitted for other personal/portable devices out of an abundance of caution with regard to their interference potential. The Commission finds that it provided an adequate rationale for the 50 mW power limit for sensing-only devices and declines to change the power limit for these devices at this time.

50. The Commission also declines to reduce the maximum permitted power for personal/portable devices that operate adjacent to occupied TV channels. In the *Second Report and Order*, the Commission recognized that there is a potential for TV bands devices to interfere with TV reception on adjacent channels, but found that such interference is unlikely to occur in the majority of situations if the power level is kept low. As with any interference analysis, certain assumptions were made concerning factors such as the

separation distance from the potential source of interference to the receive antenna, the characteristics of the receiver, the type of transmit and receive antennas and any intervening terrain or obstacles. The petitioners are essentially challenging the assumptions the Commission used in its analysis in the *Second Report and Order*. We find that the Commission made reasonable assumptions and are upholding the 40 mW adjacent channel power limit. Specifically, the Commission observes that interference to TV reception from a transmitter on adjacent channel would occur only when an adjacent channel signal level is substantially greater than the received TV signal level. Thus, adjacent channel interference would be most likely to occur in weak signal areas where an outdoor rooftop antenna is needed. In such situations, we find the Commission's assumed separation distance of 16 meters from a TV bands device to a rooftop TV antenna to be reasonable, as well as its assumption that the receive antenna will have horizontal polarization while the TV bands device has vertical polarization and that such a configuration will have a 3 dB polarization mismatch.

51. The Commission agrees that a PSD limit would help protect authorized services in the TV bands and is therefore requiring that the conducted output power of fixed and personal/portable TV bands devices comply with PSD limits. In the absence of a PSD limit, multiple devices with transmit bandwidths of significantly less than 6 megahertz could share a single channel, resulting in a total transmitted power within a channel significantly greater than the power limits for fixed or personal/portable devices. A PSD limit will prohibit high power concentrations in a single channel, which will reduce the interference potential to TV stations and other services in the TV bands. The Commission bases the PSD limit on the maximum permissible conducted output power spread across a transmit bandwidth of 6.0 megahertz, the full bandwidth of a TV channel. The resulting conducted PSD limits in a 100 kilohertz bandwidth are 16.7 mW (12.2 dBm) for fixed devices, 1.67 mW (2.2 dBm) for personal/portable devices, 0.83 mW (-0.8 dBm) for sensing-only personal/portable devices and 0.7 mW (-1.8 dBm) for personal/portable devices operating adjacent to occupied channels. The Commission adopted these PSD limits. The Commission declines, however, to adopt minimum bandwidth requirements as requested by IEEE 802 and SBE. It finds that a

minimum bandwidth requirement could unnecessarily constrain the types of modulation that could be used with TV bands devices and is not necessary because the PSD limit has the same effect of preventing high power levels in a TV channel. The Commission also clarified that a device that operates across more than one 6 MHz TV channel is still subject to the maximum power limits in § 15.709(a)(1) and (a)(2) of the rules per channel—the allowable power per channel does not increase with use of additional bandwidth beyond 6 megahertz.

#### *Out of Band Emission (OOBE) Limits*

52. In the *Second Report and Order*, the Commission required that TV bands device emissions in channels adjacent to the occupied channel be attenuated at least 55 dB below the highest average power in the occupied channel. Emission measurements in both the occupied channel and the adjacent channels are to be made with a minimum resolution bandwidth of 100 kHz and an average detector.

53. *Decision*. The Commission modified the rule for adjacent channel emissions to require that emissions be measured relative to the total in-band power in a 6 megahertz bandwidth, rather than in a 100 kHz bandwidth. This change will address the concerns raised by petitioners that the measured in-band power in a narrow bandwidth will vary depending upon the bandwidth of the transmitted signal. The Commission will continue to require that the adjacent channel emissions be measured with a 100 kHz bandwidth, because a wider bandwidth would not be able to resolve emissions located just outside the channel of operation without being affected by the in-band power. The use of a 6 megahertz bandwidth for measuring the in-band power means that a higher reading will be obtained as compared to using a 100 kHz bandwidth, because the wider bandwidth will capture all the energy in a channel rather than only a portion of that energy. The 55 dB attenuation that the Commission adopted for adjacent channel emissions was based on the assumption that identical bandwidths would be used to measure both in-band and adjacent channel power, so we agree with IEEE that the currently required 55 dB attenuation should be increased to reflect the increased in-band measuring bandwidth while providing the same level of adjacent channel protection. As noted, the Commission will assume the maximum transmit bandwidth used to be the full 6 MHz channel. We will therefore base the increase in adjacent channel

attenuation on a bandwidth ratio of 6.0 megahertz/100 kHz or 17.8 dB. Thus, the Commission revised the required adjacent channel attenuation to be 72.8 dB.

54. The Commission declines to reduce the required adjacent channel attenuation as requested by Motorola and the Wi-Fi Alliance. Adjacent channel emissions from a TV bands device appear as co-channel emissions in an adjacent channel used by a TV station or other authorized service. Personal/portable TV bands devices are permitted to operate within the protected contours of adjacent channel TV stations, and fixed TV bands devices can operate as close as 0.1 kilometers outside the contours of adjacent channel stations and at significantly higher power than personal/portable TV bands devices. For these reasons, the Commission finds it necessary to limit adjacent channel emissions to the extent practicable to prevent interference to adjacent channel TV stations and other authorized services. The Commission declines to modify the adjacent channel emissions limits for the VHF band as requested by Rudman/Ericksen because they failed to describe or provide a justification for any specific changes to the rules.

#### *Direct Pickup Interference*

55. In the *Second Report and Order*, the Commission recognized the concerns of cable interests regarding the potential for direct pickup interference and their position that power levels should be limited to a lesser value. It noted that FCC staff tests of three digital cable ready receivers, and anecdotal tests performed by the FCC staff in the laboratory and field, indicated that there is some potential for direct pickup interference to cable service from TV bands devices. The Commission observed that this direct pickup interference occurred at relatively close distances within the user's premises and could be corrected by removing consumer-installed splitters and wiring that effectively reduce the shielding of interfering signals as well as reduce the desired signal levels available at the user's TV receiver. It also observed that in the FCC staff tests when just a cable converter box was used to connect directly to the TV receiver, interference declined dramatically and was virtually non-existent on the digital tier of channels. The Commission further observed in tests by the staff with a 10 meter separation between devices on separate sides of a wall, such as in a townhouse, interference did not occur at undesired signal levels below 100 mW for two receivers and slightly under 50

mW for a third. Based upon these observations and the fact the TV bands devices must incorporate transmit power control to limit their operating power to the minimum necessary for successful communications, the Commission decided that the risk of direct pickup interference is not sufficiently great to warrant a reduction in power that could impede the viability of certain TV bands device applications.

56. *Decision.* The Commission declines to reduce the maximum permissible power for personal/portable devices or to impose power and separation limits for fixed devices as requested by NCTA and DIRECTV. It notes that direct pickup interference is different from interference that can be received at the antenna of licensed over-the-air radio services such as broadcast television, low power auxiliary services or the PLRMS/CMRS. Interference can be caused to off-air reception of these services when an undesired signal on the same frequency as the transmitted signal exceeds some threshold at a receiver. By contrast, a cable system or satellite in-home wiring is a closed system in which the operator is not licensed to transmit on the frequencies used. No signal is transmitted over-the-air in those applications; rather direct pickup interference occurs when an undesired signal leaks into some part of the otherwise closed system, such as the cable, connectors, set top box or TV set. Thus, direct pickup interference results from a lack of immunity to undesired signals at some point(s) in the closed system of wiring and equipment. As noted, the Commission has standards for regarding the ability of analog cable ready TV receivers to reject direct pickup interference. However, there are no rules regarding the ability of other components in a system to reject direct pickup interference, and selection of appropriate system components is the owner or cable/satellite TV operator's responsibility. In this regard, the Commission generally does not believe it is appropriate to protect the operations of closed systems that use radiofrequency (RF) signaling from interference from radio services and operations that use the airways. In this regard, the Commission observes that the operators/users of such systems have full discretion to design their equipment to be immune to ambient RF energy transmitted by radio systems that use the airways.

57. The Commission is not persuaded that direct pickup interference is a significant problem as NCTA states. Its testing revealed many of the same characteristics of direct pickup interference that the Commission's staff

discovered during its testing. Specifically, NCTA determined that the cables in a system are a significant source of direct pickup and that low quality (inadequately shielded) cables and connectors can result in substantially increased signal ingress. It also determined that analog systems are significantly more sensitive to direct pickup interference than digital systems. The Commission previously considered these factors when it established the power limits for TV bands devices in the *Second Report and Order*. It notes that the NCTA tests assumed a worst case scenario in which the cable signal level to a home is at the minimum level required by the rules, the TV bands device operates at the maximum power permitted by the rules and the maximum signal level is directed towards a TV receiver. In real world situations, the cable signal level may be greater than the minimum required, the TV bands device may operate at less than the maximum power due to the requirement to incorporate transmit power control, and the maximum TV bands device signal may not be directed toward a TV receiver, depending on the antenna directivity and orientation. These factors can have a greater impact on the potential for direct pickup interference than the power reductions requested by NCTA. The Commission also notes that NCTA's testing showed that some TV receivers can withstand signals levels greater than 100 mW without interference on digital channels, even assuming minimum cable signal input levels. The Commission further notes that NCTA did not perform any tests using a cable converter box, which the Commission's testing showed, and which NCTA agrees, could further reduce the potential for direct pickup interference. In any event, notwithstanding NCTA's concerns for direct pickup interference and the possible mitigation of those concerns by elements in rules for TV bands devices, the Commission finds it inappropriate to limit the utility of TV bands devices by limiting their power to protect cable installations with inadequately shielded wiring or TV receivers that do not comply with the Part 15 shielding requirements.

#### TV Bands Database

58. In the *Second Report and Order*, the Commission required all fixed and Mode II TV bands devices to access a database to obtain information on the available channels at their location and required all unlicensed fixed TV bands devices to register their operations in this database. The Commission stated that it will designate one or more

entities to create and operate the TV bands database(s) and, has invited interested parties to apply for selection as database administrators. The database(s) will be a privately owned and operated service that unlicensed TV bands devices must contact to obtain information on channel availability at the locations where they are operated and, in the case of fixed devices, to register their operation at those locations. In the case that multiple database administrators are selected, each device must contact a database service that the user or the manufacturer of the device selects. Database administrators are permitted to charge fees for registering fixed devices and providing lists of available channels to fixed devices and personal/portable devices. A TV bands database will be required to contain information on: (1) All of the authorized services that operate in the TV bands using fixed transmitters with designated service areas, including full service and low power TV stations, (2) the service paths of broadcast auxiliary point-to-point facilities, (3) the geographic regions served by PLMRS/CMRS operations on channels 14–20, (4) regions served by the Offshore Radiotelephone Service, and (5) the locations of cable headends and low power TV receive sites that are outside the protected contours of the TV stations whose signals they receive. In addition, a TV bands database will be required to contain the locations of registered sites where wireless microphones and other low power auxiliary devices are used on a regular or scheduled basis. The Commission did not establish any specific security requirements or protocols for communications between TV bands devices and the TV bands database.

59. The Commission required fixed and Mode II TV bands devices to re-check the database, at a minimum, on a daily basis to provide for timely protection of wireless microphones and other new or modified licensed facilities. If a device fails to make contact with its database on any given day, it will be required to cease operating at 11:59 p.m. on the following day. Mode II devices are also required to re-establish their location coordinates and to access a TV bands database for a list of available channels each time they are activated or moved. The Commission further required that, if multiple database administrators are authorized, the database administrators are to cooperate to develop a standardized process for sharing data on a daily basis or more often, as appropriate, to ensure consistency in

the records of protected facilities. Finally, the Commission required that a database administrator make its services available to all unlicensed TV bands device users on a non-discriminatory basis.

#### Security

60. *Decision.* On reconsideration, the Commission found that it is important and necessary for TV bands devices and TV bands databases to incorporate reasonable and reliable security measures to minimize the possibility that TV bands devices will operate on occupied channels and cause interference to licensed services, and to protect the operation of the databases and the devices they serve from outside manipulation. While the Commission did not explicitly require the incorporation of security measures in the *Second Report and Order*, it noted that virtually all online transactions involving financial or other confidential information currently use security measures to protect against unauthorized viewing and/or alteration of information being sent and to ensure that only authorized users have access to information. The Commission therefore expects that device manufacturers and database administrators will have access to and be able to incorporate the reliability and security measures needed to protect the contents of databases and communications between databases and TV bands devices or other databases. The Commission is concerned that if a device uses channels provided through other than legitimate contact with a TV bands database or if a database administrator does not include appropriate security to avoid serving unauthorized devices or to prevent outside parties from altering its processing system and data records, there could be interference consequences ranging from mild to severe.

61. To achieve the necessary protection of databases and connections between devices and databases regarding channel availability, the Commission will require that TV bands devices and database systems employ security measures follows. First, it will require that, for purposes of obtaining a list of available channels and related matters, fixed and Mode II TVBDs only be capable of contacting databases operated by administrators designated by the Commission. This will prevent TV bands devices from obtaining channel lists from unauthorized databases which may be invalid or inaccurate—the Commission is particularly concerned about potential

cases where a database would indicate as available channels that are used by authorized services. The Commission will also specify that TV bands databases must not provide lists of available channels to uncertified TV bands devices for purposes of operation (is acceptable for a TV bands database to distribute lists of available channels by means other than contact with TVBDs) in order to avoid facilitating the operation of unapproved and non-compliant devices. To facilitate these restrictions, the Commission will require that database(s) verify that the FCC identification number (FCC ID) supplied by a fixed or personal/portable TV bands device is for a certified device. To implement this provision, the Commission will also require that database administrators obtain a list of certified TVBDs from its Equipment Authorization System.

62. The Commission will further require that communications between TV bands devices and databases be transmitted using secure methods to prevent corruption or unauthorized modification of data. This requirement includes communications of channel availability and other spectrum access information between fixed and Mode II devices (it is not necessary for TVBDs to apply security coding to channel availability and channel access information that they simply pass through as such information will already be protected by the sending device). The Commission will require that when Mode I devices communicate with fixed or Mode II devices for purposes of obtaining a list of available channels, they are to use a secure method that ensures against corruption or unauthorized modification of the data. In addition, a fixed or Mode II device must check with its database that the Mode I device has a valid FCC Identifier before providing a list of available channels. The Commission will also require that contact verification signals transmitted for Mode I devices be encoded with encryption to secure the identity of the transmitting device and that Mode I devices using such signals accept as valid for authorization only the signals of the device from which they obtained their list of available channels. Finally, the Commission will require that databases be protected from unauthorized data input or alteration of stored data. In order to accomplish this goal, the database administrator is to establish communications authentication procedures that allow the fixed or Mode II devices to be assured

that the data they receive is from an authorized source.

63. The Commission will not require the use of specific technologies to meet these requirements, as it believes that database administrators and device manufacturers are in the best position to determine the appropriate methods to ensure compliance. Rather, the Commission will require that applications for certification of TV bands device include a high level operational description of the technologies and measures that are incorporated in the device to comply with the security requirements. In addition, the Commission will require that applications for certification of fixed and Mode II devices identify at least one of the designated TV bands databases that the device will have the ability to access for channel availability information and affirm that the device will conform to the communications security methods used by that database. With regard to MSTV/NAB's concerns about the possible problems with protocols developed after a database administrator is selected, there is no practical way the Commission could review a communication protocol in advance to provide absolute assurance that there are no security flaws with it. The Commission will, however, take all reasonable steps in its examination of applications for certification to ensure that communications protocols are secure. In the event that flaws are discovered in a TVBD's security measures, the Commission will take steps to ensure that those measures are quickly corrected by device manufacturers and database administrators or to withhold or withdraw the authorization for operation of any affected devices.

#### Database Administrators

64. *Decision.* The Commission will uphold its decision to allow the designation of multiple database administrators and will rely on market forces to shape the structure of the database administration functions and service offerings, subject to the various requirements set forth in the rules. Under this approach, some providers may choose to provide a full panoply of services and others may choose to provide only a repository function or "look-up" service. As the Commission stated in the *Second Report and Order*, multiple database administrators could offer services on a competitive basis. This would prevent a single party from obtaining monopoly control over the database, could provide an incentive for database operators to provide additional services beyond those required by the

rules and could result in lower costs to consumers. The Commission will permit the database functions, such as a data repository, registration and query services, to be split among multiple entities. This approach will allow for competition between providers of specific elements of the database function and encourage the provision of enhanced services not specifically required by the rules. The Commission recognizes Key Bridge's concerns about creating a situation in which some parties engaged in the process do not have full competency in all aspects of database administration, but no parties would be provide all the necessary database functions. Therefore, the Commission will require that entities selected as database administrators will be held accountable for all aspects of database administration, including any functions performed by third parties. The nine proposals received in response to the Commission's November 25, 2009 public notice indicate that there are multiple parties seeking to be designated as TV bands device database managers, some as full-service operations and others as partial service providers. The Commission is confident that market forces will result in the necessary and appropriate mix of database providers and third party entities that perform some aspect of the database function.

65. The Commission disagrees with SBE that designating multiple database administrators would complicate equipment design or limit the Commission's ability to control unauthorized database operators. Manufacturers would only have to design equipment to communicate with a single database, although they could design equipment to communicate with multiple databases if they choose. Further, designating only a single database administrator would not prevent unscrupulous parties from attempting to establish an unauthorized and inaccurate database, as parties could attempt this whether the Commission designates a single or multiple database administrators. Rather, the requirement to incorporate security in communications between TV bands devices and the databases will thwart unauthorized database operators.

66. The Commission recognizes that a complication of designating multiple database administrators is the need to synchronize licensing and registration information between databases. However, the rules already require this, and no party has shown that it is impractical to share information between TV bands device databases. The Commission declines to establish

an advisory panel to oversee the database as requested by CWMU. It finds that this approach is unnecessary given that the Commission has already started the process for selecting the database administrators, and it is concerned that disagreements between panel members could potentially slow the development of the database. Rather, the Commission will expect entities selected as a database administrator to cooperate in complying with the requirements for database coordination. The Commission also declines to state a preference for a non-profit organization to run the database, as there is no evidence that a non-profit organization would administer a database better than a for-profit company.

67. In the *Second Report and Order*, the Commission stated that the database manager or managers would be selected by its Office of Engineering and Technology. Once the selection of a database manager or managers is completed there will need to be Commission oversight and management of the database administrator(s) and their functions. The Commission is delegating authority for this oversight to the Chief, Office of Engineering and Technology under part 0 of the rules.

#### *Re-Check Procedures*

68. *Decision.* The Commission affirms the current requirement that fixed and Mode II personal/portable TV bands device check the database at least once per day. The majority of entries in the database will be fixed services, such as TV stations, TV translator receive sites, cable and satellite headends, fixed BAS links, and the PLMRS/CMRS facilities. These fixed services change channels or service areas infrequently, so we find that requiring a daily database check by TV bands devices is quite adequate to protect these services. The concerns expressed in the record about the need to increase the frequency of database contact relate primarily to protecting LPAS stations and wireless microphones in particular. Even in the case of wireless microphones, most events for which users can register wireless microphones in the database occur at fixed locations where the required registration information will be known more than a day in advance. Thus, the main concern appears to be how to protect licensed wireless microphones that are used in applications where the location and/or channel are not known at least a day in advance, such as electronic news gathering. As discussed, the Commission is taking steps to ensure that some channels remain available for wireless microphones by prohibiting

personal/portable devices from operating below channel 21, designating two channels in each market from among channels 14–51 where TV bands devices cannot operate, and prohibiting fixed devices from operating adjacent to occupied TV bands channels. The Commission finds that these measures will ensure that adequate spectrum is available for licensed itinerant wireless microphone users in the vast majority of situations. In this context, the Commission also must consider that in most locations many channels will be available for wireless microphone use that are not available for TVBD use. Those channels can be used by wireless microphones for unscheduled events. The Commission also observes that in the case of a major unplanned news event, broadcasters already coordinate their use of frequencies for wireless microphones and that at a site can share frequencies by avoiding operation of wireless microphones at the same time. The Commission therefore declines to require more frequent database checks by TV bands devices which would substantially increase the amount of database traffic without significant benefit.

69. In re-affirming the daily re-check requirement, the Commission also observes that the rules currently do not specify that a database provide the TVBD with information on changes in channel availability that occur over the course of the 24 hours before the next re-check. For example, if a database were to provide a TVBD with only a list of the channels that are available at 9 a.m. and there is a scheduled use of wireless microphones on one or more of those channels during the period 3 p.m. to midnight, the TVBD would not cease operating on the channels that became unavailable later in the day. It is the Commission's intention that a database provide TVBDs with information on the full schedule of channel availability over the course of the 24 hour re-check period plus the additional period of up to 24 hours that a device may continue to operate if it is not able to contact its database at the end of the re-check period. This is necessary to ensure that TVBDs do not cause interference to protected operations that use channels during part of a 24 hour period. Accordingly, the Commission is amending its rules to provide that (1) a database must provide fixed and Mode II TVBDs with channel availability information that includes scheduled changes in channel availability over the course of the 48 hour period beginning at the time the TVBDs make a re-check contact and (2) fixed and Mode II



TVBDs must adjust their use of channels in accordance with channel availability schedule information provided by their database.

70. As indicated, because they have no geo-location capability to identify their location, the Commission is requiring Mode I personal/portable devices to either receive a signal to verify contact from the Mode II or fixed device that provided its current list of available channels or contact a Mode II or fixed device at least once per minute to re-verify/re-establish channel availability. Under the new contact verification option, a "contact verification signal" will be an encoded identification signal that may be broadcast by a fixed or Mode II device for reception by Mode I devices to which the fixed or Mode II device has provided a list of available channels for operation. Such signal will be for the purpose of establishing that a Mode I device is still within the reception range of the fixed or Mode II device from which it received a list of available channels; reception of a contact verification signal will be presumed to verify that the list of available channels used by the Mode I device remains valid for purposes of the once per minute re-check requirement. The Commission expects that this feature will be especially useful for improving efficiency in cases where several Mode I devices receive lists of available channels from the same fixed or Mode II device. The Commission is not requiring that Mode II and fixed devices transmit contact verification signals in support of Mode I devices they serve; however, use of this option is strongly suggested. The Commission requires that contact verification signals be encoded to ensure that they originate from the TV bands device that provided the list of available channels; the fixed or Mode II device transmitting a contact verification signal would need to provide a Mode I device it serves with decoding information at the time it makes an exchange contact with the Mode I device to provide a list of available channels. Mode I devices that receive contact verification signals will still be required to re-check with a fixed or Mode II device at least once a day. In addition, Mode II devices will be required to re-check/reestablish contact to obtain a list of available channels if they lose power. Collaterally, if a Mode II device loses power and obtains a new channel list, it must signal all Mode I devices it is serving to acquire new channel list. The Commission also clarifies the requirement that Mode II devices re-check with their database

when they move to specify that such devices must re-check only when they are moved more than 100 meters from the location at which they performed their last re-check. This will avoid the need for re-checking when a device is moved very short distances that would have a de minimis impact on potential interference and reduce the burden of the re-check function on the database and the Mode II TVBD.

71. The Commission will permit database administrators and device manufacturers to develop a system to "push" channel availability changes and other information to TV bands devices if they choose. This capability could, for example, be used in the development of standards that allow more efficient sharing of TV spectrum by networks of TV bands devices. The Commission will not require that databases or devices incorporate this capability. To guard against the possibility that a device may miss updates pushed by the database and continue transmitting on a channel that becomes unavailable, devices that incorporate this capability must still function in the same manner as other TV bands devices and validate their channel at least once per day and cease operation no later than 11:59 p.m. the following day if they cannot validate the operating channel. The operation of such an information "push" system must be described in the application for certification. Any other clearing of channels, such as marking particular channels as unavailable in the database, may only be done under authorization by the Commission.

72. The Commission also will permit Mode II personal/portable devices to load available channel information for locations beyond their current position and use that information in their operation. Mode II devices will be allowed to use such additional available channel information to define a geographic area within which they could operate on the same available channels at all locations. Allowing channel lists to be stored for more than a single location will allow for more efficient operation of portable devices by reducing the number of queries to the database and to support mobile operation. For example a Mode II TVBD could calculate a bounded area in which a channel or channels are available at all locations within the area and operate on a mobile basis within that area. Mode II TVBDs that use such an approach must contact the database when they have moved beyond the boundary of the area where their channel availability data is valid, and must re-check the database at least once each day like other Mode II devices even if they have not moved

beyond the range where the data is valid. Parties that incorporate the ability to load channel lists for multiple locations and operate within an area bounded into a device must describe in the application for certification how they will ensure the device operates only on available channels within the bounded area.

#### *Additional Service Features*

73. *Decision.* Database administrators may perform additional functions besides those required by the rules, such as tracking active channel use if reported by the TV bands device, or sending additional information to a TV bands device to enable it to determine the "best" available channel to use. Such functions are not prohibited by the rules, and the ability to add additional functionality could allow multiple database operators to distinguish their services and could be useful in the development of industry standards to enable more efficient spectrum sharing. However, in the interest of keeping the rules simple and avoiding the imposition of unnecessary requirements that could hamper innovation, the Commission declines to require TV bands devices to report additional information to the database beyond what the rules currently require. It also declines to require the incorporation of different (and currently unspecified) TV service area prediction models into the database as requested by Motorola. The rules currently prohibit adjacent channel operations by fixed devices, and there is insufficient record to change that requirement at this time.

#### *Database Information*

74. *Decision.* The Commission will require that all information that is required by the Commission's rules to be in a TV bands device database be publicly available, including fixed TV bands device registration and voluntarily submitted protected entity (e.g., cable head ends) information. The Commission will not require the public disclosure of information that a database manager may collect to support additional services, provided that this information also is not required to be provided by our rules. The Commission notes that the registration of a protected entity in the database will preclude operation of TV bands devices on one or more channels over specific areas, and that there is the possibility of errors in the registration information. Although much of the data will come from Commission databases that already are public sources, errors could result from the inadvertent entry of incorrect data, or as a result of a party deliberately

entering false data. The Commission finds that it is appropriate to permit public examination of protected entity registration information to allow the detection and correction of errors. It also finds that making fixed TV bands device registration information publicly available could assist parties in locating the source of any interference that occurs and contacting the device operator to correct it. With regard to Key Bridge's request concerning the Commission's requirement to provide or delete information from the database, the Commission clarifies that this requirement applies only to the information that the Commission requires to be placed in the database and not any other information that a database administrator collects beyond what the rules require.

75. The Commission declined to require fixed TV bands device operators to access and review the database prior to network deployment and to select a channel that is not in use, because one of the general conditions of operation for part 15 is that a party's use of a particular frequency does not give it rights over other parties to continued use of that frequency. In addition, a TV bands device may need to operate on more than one available channel and may do so. However, the Commission will permit database administrators to allow prospective operators of TV bands devices to query the database to verify whether there are vacant channels at a site where they wish to operate, and operators of TV bands devices may use information from the database to voluntarily coordinate their channel usage to avoid conflicts.

76. In reviewing the rules for the information to be included in a TV bands database, the Commission observes that in the case of full power TV, Class A TV, low power TV and TV translator stations the Commission's Consolidated Broadcast Data Base System (CDBS) from which the TV station database records will be extracted in many cases includes multiple types of records for each station. For example, the database may include license, license application, special temporary authorization and construction permit applications for the same station and may also include more than one of each of these types of records for the same station. These multiple records can pose confusion in administering a TV bands database with respect to which records to extract for the database. It is our intention that the records in a TV bands database only reflect stations that are serving viewers. In the CDBS, only records for licenses and license applications imply that a

station is providing service to viewers. The Commission therefore clarifies that a TV bands database is to include only TV station information from license or license application records. Given that a license application implies a change that is to the station's ongoing operations, the Commission finds that in cases where a station has records for both a license application and a license, a TV bands database should include the information from the license application rather than the license. The Commission amended its rules to add these clarifications.

#### *Database Fees*

77. *Decision.* The Commission declines to establish a particular fee structure for database administrators. It finds that database administrators are in the best position to manage their costs and fees. The Commission disagrees with SBE that registering protected entities with the database will have a significant impact on licensees or others. Many of the registrations will be for services at fixed locations such as fixed BAS links or satellite, MVPD or TV translator receive sites, and these only need to be registered once, and in the case of receive sites, only if they are located outside the protected contour of the TV station being received. Information for licensed services will come from Commission databases. Further, all such registrations are voluntary, so a party may choose not to register sites where it believes that interference from TV bands devices is unlikely to occur. The Commission modified § 15.714(a) to remove the provision that database administrators may charge to register temporary BAS links. The Commission did not state in the *Second Report and Order* that database administrators could charge for registering temporary BAS links, and a provision stating that they could was inadvertently added to the rules.

#### *Other Database Issues*

78. *Decision.* Fixed and Mode II TV bands devices are allowed to contact a database for a list of available channels through other TV bands devices, provided they follow the rules and connect to an authorized database using the appropriate protocol, send their geographic coordinates and other required information and operate only on channels that the database indicates are available. The rules already permit this practice but do not allow the formation of "chains" of devices that did not access the database but merely pass on a list of available channels. Therefore, no rule changes are necessary in this regard. The Commission will not

require Mode II personal/portable devices to register in the database, because this would substantially increase the number of registrations in the database, and each of these registrations would have to be updated as device changes locations, thus substantially increasing the database traffic. The Commission also sees no need for registration of these devices as a means to help identify a source of interference, as the interference range of personal/portable devices is in general relatively short. In this regard, the Commission is correcting an error in § 15.713(e)(4) of the rules which incorrectly states that Mode II devices must register on initialization. The Commission will not require devices to provide coordinates accurate to  $\pm 5$  meters because that is a higher degree of precision than necessary, and such accuracy may not be readily achievable by most devices.

#### **Use of TV Channels**

##### *TV Bands Devices, Wireless Microphones and Low Power Auxiliary Stations*

79. In the *Second Report and Order*, the Commission prohibited fixed TV bands devices from operating adjacent to occupied TV channels at this time, although it deferred a final decision on this issue and kept the record open pending the development of additional information demonstrating that a reliable method can be developed to allow adjacent channel operation. The Commission decided to allow both fixed and personal/portable unlicensed TV bands devices to operate on channels 21–36 and 38–51. In addition, the Commission allowed only fixed TV bands devices to operate on channels 2 and 5–13 and on channels 14–20 outside of areas where PLMRS/CMRS services operate. The Commission stated that allowing only fixed TV bands devices to operate below channel 20 would ensure that some channels remain available for use by wireless microphones and eliminate the possibility of interference from TV bands devices to public safety and other important communications operations in the PLMRS. While it believed that the geo-location/database and Mode I operation provisions of the rules would provide a high degree of assurance that PLMRS/CMRS, Offshore Radiotelephone Service and other authorized services on channels 14–20 are protected, the Commission chose a more conservative approach to protect the PLMRS/CMRS services from expected high numbers of nomadic personal/portable devices and affirmed

its decision from the *First Report and Order and Further Notice of Proposed Rule Making*, 71 FR 66897, November 17, 2006, in this proceeding to prohibit personal/portable devices from operating on channels 14–20. In addition, in 13 major markets where certain channels between 14 and 20 are allocated for land mobile operations, the Commission designated two channels between 21 and 51—*i.e.*, the first vacant channels above and below channel 37—where personal/portable TV bands devices could not operate, leaving those two channels available for low power auxiliary stations.

80. *Decision.* The Commission affirms its initial decision to prohibit fixed devices from operating on channels adjacent to occupied TV channels. While Adaptrum and Motorola provided general information on possible ways that fixed devices could operate adjacent to occupied TV channels, neither party provided sufficiently detailed information on the technical requirements that would be necessary to allow adjacent channel operation without interference and still permit operation of TVBDs. The Commission also declines to change the designated channels where TV bands devices are prohibited from operating and, in this regard, it also affirms its decision to prohibit personal/portable devices from operating below channel 21. As the Commission noted in both the *First Report and Order*, 71 FR 66897, November 17, 2006, and *Second Report and Order*, 74 FR 7314, February 17, 2009, there is some potential for interference to PLMRS/CMRS services on channels 14–20 due to the nomadic nature of personal/portable devices, and it took a conservative approach to protect these services from interference and prohibit operation of personal/portable devices on these channels. In addition, the Commission affirms the prohibition on personal/portable devices on channels below 14 as well to help ensure that unused channels remain available for wireless microphones and other LPAS devices.

81. The Commission is revising its rules to reserve two channels nationwide where TV devices are not permitted to operate to ensure that some spectrum remains available for wireless microphones and other LPAS stations. Reserving two channels nationwide will ensure that at least two channels remain available for wireless microphones in all markets. These channels will be the first channels on either side of channel 37 that are unoccupied by broadcast television stations or, if no channels are available on one side of channel 37, the first two channels nearest to channel 37.

These reservations will provide channels to accommodate LPAS operations that are not at fixed locations that would have been protected under the spectrum sensing provisions we are eliminating. Such LPAS operations include electronic news gathering and other temporary on-site applications, where the operating channels and locations are not known sufficiently far in advance to register them in the database. The Commission believes that the reservation of two channels nationwide, along with the additional channels that will be available at the vast majority of locations that cannot be used by TVBDs, will provide more than sufficient spectrum to accommodate the vast majority of wireless microphone usage. This will allow protected operation of a minimum of 12–16 wireless microphones and other LPAS stations in a small geographic area. Further, the relatively low power of these stations limits their operating range to about 100 meters, allowing each vacant TV channel to be used at many locations in a TV market. The Commission notes that in many areas more than two channels will likely remain available for LPAS stations because fixed TV bands devices are not permitted to operate adjacent to occupied TV channels and personal/portable devices are not permitted to operate below channel 21.

82. Recently the Broadband Action Agenda announced an intention for the Commission to initiate rule making proceedings to increase spectrum efficiency and innovation in various frequency bands, including broadcast TV spectrum. In addition, the Commission has initiated a proceeding to consider changes to the rules for wireless microphones that operate in the TV bands. If the Commission makes changes to the rules concerning the channels available for operation for TV and other authorized services, the channels available for use by unlicensed TV bands devices and wireless microphones could change, and any TV bands device or wireless microphone that operates on a channel that is later designated for another use would have to cease operation on that channel. Depending on the tuning range of the TV bands device, particularly personal/portable devices, or wireless microphone, these radios could have a reduced operating range. The Commission recognizes that the anticipated proceedings introduce some uncertainty for manufacturers of TV bands devices and could delay their deployment. To avoid this problem, manufacturers can design devices that

have the capability to tune over a wider range of frequencies than the rules currently permit, but that incorporate measures to limit operation to the frequency range over which the device is certified. Manufacturers would therefore not have to redesign their equipment if the Commission modifies the permitted operating frequency range and could modify their equipment certification through a streamlined procedure. The Commission also observes that manufacturers are contemplating that devices that connect to CMRS services, mobile and personal/portable devices, whole-home wireless networks and other wireless data systems that will use TV white space spectrum will also include Wi-Fi and Bluetooth communications technologies.

#### *Fixed Licensed Point-to-Point Backhaul Use*

83. In the *Second Report and Order*, the Commission decided that it would not be practicable to authorize the use of TV white spaces on a licensed basis. It concluded that the attributes supporting successful use of licensing—spectrum rights that are clearly defined, exclusive, flexible and transferable—would be difficult to accomplish in the TV bands if the Commission were to maintain its goal of not affecting the interference protection status of existing services. The frequencies and amount of unused TV bands spectrum will vary at each location and could change as other primary users enter the band. Instead, the Commission decided to allow low power unlicensed devices to operate on the TV white spaces at power levels no greater than 4 watts EIRP. First, it was concerned that operation at higher power levels would increase the risk of interference in congested areas and thus could make sharing spectrum between TV bands device users more difficult. Second, because the Commission did not have experience with unlicensed wireless broadband operations in the TV bands, it decided to take a cautious approach in setting power limits to minimize the risk of interference to authorized users of the TV bands.

84. *Decision.* The Commission has declined to set aside TV channels for fixed licensed backhaul use as requested by FiberTower at this time. The Broadband Action Agenda recently indicated an intention that the Commission initiate rule making proceedings to increase spectrum efficiency and innovation in various frequency bands including the broadcast TV spectrum. The Commission intends to consider FiberTower's requests for spectrum for fixed licensed backhaul to

support broadband services in the broader context of these future proceedings in order to better ensure a comprehensive approach to wireless rural backhaul in these bands. The Commission disagrees with FiberTower's contention that it should not delay in addressing its request for access to the TV bands because it would be impossible for the Commission to authorize licensed uses after unlicensed devices occupy the TV bands. Both fixed and personal/portable devices are to rely on a TV bands device database as their primary method for determining available channels. If the Commission makes changes to the rules concerning permissible channels of operation, imposes geographic area restrictions or makes other changes to the technical parameters for TV bands devices, these will be taken into account by the database administrator in determining available channels for TV bands devices. Therefore, any TV bands device that operates on a channel that is later designated for another use would cease operation on that channel after it performs its daily database check and the database indicates that the channel is no longer available for use. As the Commission moves forward, it is interested in pursuing the question of whether it can accommodate licensed rural backhaul in the white spaces within the UHF bands. Therefore, Commission staff will evaluate this possibility over the coming months, and will formulate and submit a recommendation on next steps to the Commissioners by the end of 2010.

#### Other Issues

##### *Canada/Mexico Border Areas*

85. The allotment and assignment of TV channels in the border areas with Canada and Mexico are subject to agreements with each of those countries. Low power TV assignments within 32 kilometers (20 miles) of the Canadian border must be referred to the Canadian authorities for approval. In addition, low power UHF TV stations that are located less than 40 kilometers (25 miles) from the Mexican border, and low power VHF TV stations that are less than 60 kilometers (37 miles) from the Mexican border, must be referred to the Mexican government for approval.

86. In the *Second Report and Order*, the Commission decided that fixed TV bands devices should not be permitted to operate within the border areas specified in the Canadian and Mexican agreements until it has an opportunity "to negotiate any necessary changes to those agreements with Canada and Mexico." The Commission stated that

fixed TV bands devices that operate with outdoor antennas at an EIRP of up to 4 watts "will be somewhat similar in operation to low power TV stations," and thus decided "in keeping with the low power broadcasting agreements with Canada and Mexico" that TV bands devices must comply with the distance separations from the border specified in the agreements. The Commission also applied the same distance restrictions on the use of lower powered unlicensed personal/portable TV bands devices within the border areas "to avoid any uncertainty in administering the agreements with Canada and Mexico." These border distance restrictions will be enforced for fixed devices and Mode II personal/portable devices through the use of their geo-location and database access capabilities. Devices operating in Mode I without a geo-location/database access capability will be prevented from operating in the border areas in that they will operate relatively close to an associated base station (fixed or personal/portable) that uses a geo-location/database access capability that will keep it from operating in the border areas.

87. *Decision.* The Commission modified the requirements for the operation of TV bands devices in border areas with Canada and Mexico. The Commission clarified that unlicensed devices are not covered by the TV broadcast agreements with Canada and Mexico, and thus it does not need to negotiate changes to those agreements as stated in the *Second Report and Order*. The Commission historically applied these agreements to licensed operations which are well-defined and readily identified under its rules and in its databases, characteristics which do not apply to unlicensed devices. Nonetheless, because TV bands devices will operate in the same frequency bands and on the same channels as TV stations in those countries as well as in the U.S., albeit at lower power than licensed stations, the Commission is sensitive to the need to avoid causing interference to TV broadcast operations in Canada and Mexico. The Commission finds merit in Tribal Digital Village's suggested option to protect Canadian and Mexican stations in the border areas by including information on the Canadian and Mexican stations in the TV bands database as protected services within those countries. The Commission will do so, thereby ensuring that stations in those countries will be protected to the same level as stations in the U.S. The Commission will discuss its decision with Canada and Mexico to ensure that information on

their operations in the database will be timely and accurate.

##### *Transmitter IDs*

88. In the *Second Report and Order*, the Commission required fixed TV bands devices to transmit identifying information to ensure that they can be identified if interference occurs. It required the identification signal to conform to a standard established by a recognized industry standards setting organization and stated that it expects the identification signal to carry sufficient information to identify the device and its location.

89. *Decision.* The Commission affirms its decision to require fixed TV bands devices to transmit an identification signal to identify the specific device and its location. The Commission concluded previously that an identification signal will provide a useful means to help locate a specific device in the event that it causes interference. Although it has not specified the type of information that should be transmitted, it anticipates that, because fixed devices also have to register in the TV bands database, the transmitted identification information will be correlated, perhaps identical, with the database information to facilitate the location of a specific device.

90. The Commission recognizes the concerns of Motorola and Adaptrum about possible delays in development of a standard for the identification signal. Although the rules require that the signal conform to a standard established by a "recognized industry standards setting organization," the Commission does not specify beyond this general criterion the type of organization that could develop such a standard, nor limit the number of organizations that might participate in the development of the standard. If necessary, the Commission will work with industry groups to ensure development of a standard in a timely fashion. Accordingly, the Commission anticipates that the development of a standard, at worst, will result in relatively little delay in the entry into the market of new TV bands devices. This slight potential downside is more than outweighed by the benefits of standardizing the delivery of the identification information.

91. Adaptrum is mistaken in asserting that the Commission's reliance on a non-governmental group for developing a standard for the identification signal constitutes an improper delegation of authority. The Commission established minimum requirements for the identification information in the *Second Report and Order*, and it retained

authority to determine whether fixed TV bands device operators comply with this requirement. The referral to an industry standards-setting organization in the *Second Report and Order* of the task to develop a standard for the identification signal only involves issues related to the details of the identifying information to be transmitted, such as format. To the extent the standard fails to facilitate the intended use of the identification information that the device operators are required to provide, the Commission can easily address this failing by revisiting the sufficiency of the device operators' compliance with the underlying identification requirements and the framework for ensuring such compliance. Under these circumstances, the Commission's instruction that the device operators conform their identification signals to an industry standard established by a non-governmental standards-setting group does not come close to crossing the line drawn by the courts against improper delegations of agency authority.

92. The Commission declines to require that personal/portable devices operating in Mode I transmit an identification signal. Personal/portable devices operate at lower power than fixed devices and have a lower interference potential so there is less need for them to transmit identification information. Also, a personal/portable device operating in Mode I will not "know," and therefore cannot transmit, its geographic coordinates, making an identification signal from such a device significantly less useful.

#### *Professional Installation*

93. The geographic coordinates of a fixed TV bands device are to be determined by either an incorporated geo-location capability or a professional installer. In the case of professional installation, the party who registers the device in the database will be responsible for assuring the accuracy of the entered coordinates.

94. *Decision.* The Commission sees no need to modify the rules concerning the requirements for professional installation. The rules provide professional installation as an alternative to including a geo-location capability in the devices, and the intended purpose is to ensure that the geographic coordinates are correctly ascertained. The Commission generally intended that a "professional installer" mean an entity consisting of an individual or team of individuals with experience in installing radio communications equipment and that provides service on a fee basis—such an individual or team can generally be

expected to be capable of ascertaining the geographic coordinates of a site and entering them into the device for communication to a database. The task of ascertaining geographic coordinates and entering them into a device is not particularly difficult or complex and the Commission therefore does not believe it is necessary to define the qualifications of a professional installer in the rules. In this context, the Commission finds it adequate to simply provide that a professional installer may be responsible for assuring the accuracy of the entered coordinates. Further, the rules already recognize professional installation for certain categories of part 15 transmitters, and if professional installation is deemed appropriate for a device, the grant of certification is conditioned accordingly.

#### **Section 301 Licensing**

95. *Decision.* The Commission considered and rejected SBE's contention that the rules adopted in the *Second Report and Order* do not provide adequate protection against interference. Accordingly, the Commission need not address SBE's assertion that section 301 of the Act requires licensing in this case. In addition, it declines to modify the rules to provide a private right of action if interference occurs. The Commission's statutory authority and its rules provide for a range of enforcement actions that could be relied upon to eliminate and prevent interference.

#### **Radio Astronomy**

96. In the *Second Report and Order*, the Commission prohibited both fixed and personal/portable TV bands devices from operating on any channel within 2.4 kilometers (1.5 miles) of certain radio astronomy receive sites, including the Very Large Array (VLA) observatory located approximately 50 miles west of Socorro, New Mexico. This observatory consists of 27 moveable antennas laid out in a Y-shaped configuration. The Commission's rules list the coordinates of the center of the array, but each segment of the array is 13 miles long, so the protection zone of 2.4 kilometers around the center point does not encompass large portions of the array. The National Telecommunications and Information Administration (NTIA) requested that the Commission change the protected coordinates from a single point to a rectangular area that encompasses the entire VLA. To ensure that this facility is protected from interference from TV bands devices, the Commission is adopting the change requested by NTIA. The rectangular area recommended by NTIA is

approximately 19 miles by 22.5 miles, but because the observatory is in a generally unpopulated area, this change will affect few potential users of TV bands devices.

#### **Other Rule Clarifications**

97. Upon review of the rules adopted in the *Second Report and Order*, the Commission discovered a number of minor inconsistencies between the text of the *Second Report and Order* and the rules. In addition, it noted a number of cases where it believes it is appropriate to clarify the rules, consistent with the *Second Report and Order*. Because these changes are not substantive, the Commission may make them on its own motion without prior notice and comment. A summary of the changes is provided as follows.

- Changes to definitions:

- The Commission is correcting an erroneous cross-reference in the definition of available channel and removing text that is not necessary as part of this definition; it is also clarifying the definition of a television channel.

- The Commission is removing the specific definitions of client mode, client device, master mode and master device and revising the text of other portions of the TV white space rules to reflect these changes.

- The Commission is incorporating the concepts of master and client in the definitions of fixed, Mode I and Mode II personal/portable devices.

- The Commission is indicating that a TV receive site may be used to provide signals to a Multiple Video Program Distributor (MVPD) and making minor wording edits to the definition of receive site.

- The Commission is indicating in the definition of TV bands devices that they operate on an unlicensed basis.

- The Commission is indicating that TV bands device databases used by TV bands devices to obtain lists of available channels must be authorized by the Commission.

- Clarifications of the requirements for Mode I TV bands devices.

- The Commission is specifying that the list of channels provided to a Mode I device must be the same as the list of channels that are available to the fixed or Mode II device that provides the list.

- The Commission is clarifying that a Mode I device may operate only on channels that are permissible for its use, even if there are available channels outside the permitted range for Mode I devices, e.g., channels below 21, where only fixed devices may operate.

○ The Commission is clarifying that a fixed device or a Mode II device has the option to provide a supplemental list of available channels to Mode I devices (*i.e.*, a list of available channels in addition to the list of channels available to the fixed or Mode II device) that includes channels that are adjacent occupied TV channels and therefore not available to the fixed or Mode II device.

#### Final Paperwork Reduction Act of 1995 Analysis

98. The *Second Memorandum Opinion and Order* contains new or modified information collections subject to the Paperwork Reduction Act of 1995 (PRA) and will be submitted to the Office of Management and Budget (OMB) for review under section 3507(d) of the PRA, Public Law 104–13. A modification is required to the Form 731 (OMB 3060–0057). OMB, the general public, and other Federal agencies are invited to comment on the new or modified information collection requirements contained in this proceeding. In addition, we note that pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), we previously sought specific comment on how the Commission might further reduce the information collection burden for small business concerns with fewer than 25 employees.

#### Final Regulatory Flexibility Analysis

99. As required by the Regulatory Flexibility Act (RFA),<sup>1</sup> an Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the *Notice of Proposed Rule Making* (NPRM) in ET Docket No. 04–186,<sup>2</sup> 69 FR 34103, June 18, 2004, and an additional IRFA was incorporated in the *First Report and Order and Further Notice of Proposed Rule Making* (Further NPRM) in ET Docket No. 04–186,<sup>3</sup> 71 FR 66897, November 17, 2006. The Commission sought written public comment on the proposals in the *NPRM* and in the *Further NPRM*, including comment on the IRFAs. No comments were received in response to either IRFA. This Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.<sup>4</sup>

<sup>1</sup> See 5 U.S.C. 603. The RFA, see 5 U.S.C. 601–612, has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Public Law 104–121, Title II, 110 Stat. 857 (1996).

<sup>2</sup> *NPRM*, 19 FCC Rcd at 10018.

<sup>3</sup> *Further NPRM*, 21 FCC Rcd at 12299.

<sup>4</sup> See 5 U.S.C. 604.

#### A. Need for, and Objectives of, the Second Memorandum Opinion and Order

100. This *Second Memorandum Opinion and Order* responds to seventeen petitions for reconsideration that were filed in response to the *Second Report and Order and Memorandum Opinion and Order* (Second Report and Order) in this proceeding.<sup>5</sup> It upholds the majority of the Commission's prior decisions permitting unlicensed broadband operations in the TV bands and also makes other minor changes and refinements to the rules for TV bands devices. The Commission believes that these changes and clarifications to the rules will better ensure that licensed services are protected from interference while retaining flexibility for unlicensed devices to share spectrum with new services or to change frequencies if TV spectrum is reallocated for other purposes.

101. In the *Second Memorandum Opinion and Order*, the Commission is taking steps to provide access to unused TV spectrum that will fuel innovation and investment in new unlicensed wireless technologies, such as Wi-Fi and Bluetooth have changed the landscape of communications in recent years. It is resolving on reconsideration certain legal and technical issues in order to provide certainty concerning the rules for operation of unlicensed transmitting devices in the television broadcast frequency bands (unlicensed TV bands devices, or TVBDs). The steps being taken will make a significant amount of currently unused spectrum with very desirable propagation characteristics available for new and innovative products and services, particularly broadband data and other services for businesses and consumers. Resolution of these issues will allow manufacturers to begin marketing unlicensed communications devices and systems that operate on frequencies in the TV bands in areas where they are not used by licensed services (TV white spaces). The opening of these bands for unlicensed use, which represents the first significant increase in unlicensed spectrum below 5 GHz in over 20 years, will spur manufacturers to develop new radio technologies that will have wide ranging applicability for spectrum sharing in many frequency bands, will have significant benefits for both

<sup>5</sup> We are addressing seventeen petitions for reconsideration that were filed in response to the *Second Report and Order and Memorandum Opinion and Order* (Second Report and Order) in this proceeding. See *Second Report and Order and Memorandum Opinion and Order* in ET Docket Nos. 02–380 and 04–186, 23 FCC Rcd 16807 (2008).

businesses and consumers and will promote more efficient spectrum use. The technology that enables access to TV white spaces will also serve as a foundation for a model that can be extended to provide opportunistic access to other spectrum bands.

#### B. Summary of Significant Issues Raised by Public Comments in Response to the IRFA

102. Richard A. Rudman and Dane E. Ericksen (Rudman/Ericksen) argue that the Final Regulatory Flexibility Analysis (FRFA) in the *Second Report and Order* is deficient because it did not address certain burdens on industry.<sup>6</sup> Specifically, they argue that the FRFA failed to consider the burden of every one of the 6,635 cable television systems in the United States having to register with the TV bands device database to protect the multiple TV receivers typically installed at a cable headend. Rudman/Ericksen state that because the rules permit the registration of receive sites only if they are outside the protected contour of the station being received, and only at distances up to 80 km from the protected contour, a cable system operator will have to calculate the contour for each station being received to determine if the receive site is eligible for registration. They state that there are 8,126 cable headends in the United States, and that if each headend receives ten stations, then over 80,000 contour calculations must be performed. Similarly, Rudman/Ericksen argue that thousands of TV translator licensees will have to perform contour calculations to determine whether their receive sites are at locations that are eligible for registration in the TV bands device database.

103. The Commission disagrees with Rudman/Ericksen that voluntary registration of receive sites for cable headends and TV translators poses a significant burden. As the Commission noted in the *Second Report and Order*, the receive sites that may be registered in the TV bands device database are located in areas where TV services are normally not protected, but the Commission decided to provide parties the option of registering sites if they choose to minimize the potential for interference from TV bands devices. However, there is no requirement to register a site. Further, operators of cable systems or other multi-channel video programming distributors (MVPDs) typically already have information on the location of the protected contours of TV stations in their service areas, so they can quickly

<sup>6</sup> See Rudman/Ericksen petition at 7.

determine whether a particular receive site is eligible for registration. Even if the operator of a receive site does not know its location with respect to the protected contour of the station being received, such information can be readily obtained. The Commission notes that it received petitions for reconsideration from the cable and TV translator industries and two MVPDs, and none of these parties claimed that registration of receive sites is unduly burdensome as Rudman/Ericksen allege.<sup>7</sup>

### C. Description and Estimate of the Number of Small Entities To Which Rules Will Apply

104. The RFA directs agencies to provide a description of, and, where feasible, an estimate of, the number of small entities that may be affected by the rules adopted herein.<sup>8</sup> The RFA generally defines the term “small entity” as having the same meaning as the terms “small business,” “small organization,” and “small governmental jurisdiction.”<sup>9</sup> In addition, the term “small business” has the same meaning as the term “small business concern” under the Small Business Act.<sup>10</sup> A “small business concern” is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA).<sup>11</sup>

105. *Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing.* The Census Bureau defines this category as follows: “This industry comprises establishments primarily engaged in manufacturing radio and television broadcast and wireless communications equipment. Examples of products made by these establishments are: transmitting and receiving antennas, cable television equipment, GPS equipment, pagers, cellular phones, mobile communications equipment, and radio

and television studio and broadcasting equipment.”<sup>12</sup> The SBA has developed a small business size standard for Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing, which is: all such firms having 750 or fewer employees.<sup>13</sup> According to Census Bureau data for 2002, there were a total of 1,041 establishments in this category that operated for the entire year.<sup>14</sup> Of this total, 1,010 had employment of under 500, and an additional 13 had employment of 500 to 999.<sup>15</sup> Thus, under this size standard, the majority of firms can be considered small.

106. *Wireless Telecommunications Carriers (except Satellite).* Since 2007, the Census Bureau has placed wireless firms within this new, broad, economic census category.<sup>16</sup> Prior to that time, such firms were within the now-superseded categories of “Paging” and “Cellular and Other Wireless Telecommunications.”<sup>17</sup> Under the present and prior categories, the SBA has deemed a wireless business to be small if it has 1,500 or fewer employees.<sup>18</sup> Because Census Bureau data are not yet available for the new category, we will estimate small business prevalence using the prior categories and associated data. For the category of Paging, data for 2002 show that there were 807 firms that operated

<sup>12</sup> U.S. Census Bureau, 2002 NAICS Definitions, “334220 Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing”; <http://www.census.gov/epcd/naics02/def/NDEF334.HTM#N3342>.

<sup>13</sup> 13 CFR 121.201, NAICS code 334220.

<sup>14</sup> U.S. Census Bureau, American FactFinder, 2002 Economic Census, Industry Series, Industry Statistics by Employment Size, NAICS code 334220 (released May 26, 2005); <http://factfinder.census.gov>. The number of “establishments” is a less helpful indicator of small business prevalence in this context than would be the number of “firms” or “companies,” because the latter take into account the concept of common ownership or control. Any single physical location for an entity is an establishment, even though that location may be owned by a different establishment. Thus, the numbers given may reflect inflated numbers of businesses in this category, including the numbers of small businesses. In this category, the Census breaks-out data for firms or companies only to give the total number of such entities for 2002, which was 929.

<sup>15</sup> *Id.* An additional 18 establishments had employment of 1,000 or more.

<sup>16</sup> U.S. Census Bureau, 2007 NAICS Definitions, “517210 Wireless Telecommunications Categories (Except Satellite)”; <http://www.census.gov/naics/2007/def/ND517210.HTM#N517210>.

<sup>17</sup> U.S. Census Bureau, 2002 NAICS Definitions, “517211 Paging”; <http://www.census.gov/epcd/naics02/def/NDEF517.HTM>; U.S. Census Bureau, 2002 NAICS Definitions, “517212 Cellular and Other Wireless Telecommunications”; <http://www.census.gov/epcd/naics02/def/NDEF517.HTM>.

<sup>18</sup> 13 CFR 121.201, NAICS code 517210 (2007 NAICS). The now-superseded, pre-2007 CFR citations were 13 CFR 121.201, NAICS codes 517211 and 517212 (referring to the 2002 NAICS).

for the entire year.<sup>19</sup> Of this total, 804 firms had employment of 999 or fewer employees, and three firms had employment of 1,000 employees or more.<sup>20</sup> For the category of Cellular and Other Wireless Telecommunications, data for 2002 show that there were 1,397 firms that operated for the entire year.<sup>21</sup> Of this total, 1,378 firms had employment of 999 or fewer employees, and 19 firms had employment of 1,000 employees or more.<sup>22</sup> Thus, we estimate that the majority of wireless firms are small.

### D. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

107. TV bands devices are required to be authorized under the Commission’s certification procedure as a prerequisite to marketing and importation, and the Second Memorandum Opinion and Order makes no change to that requirement. However, it makes certain changes to the technical requirements for TV bands devices, which are discussed below. In addition, the Second Memorandum Opinion and Order makes certain changes to the requirements for TV bands device databases, which are also discussed.

### E. Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

108. The RFA requires an agency to describe any significant alternatives that it has considered in developing its approach, which may include the following four alternatives (among others): “(1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities; (3) the use of performance rather than design standards; and (4) an exemption

<sup>19</sup> U.S. Census Bureau, 2002 Economic Census, Subject Series: Information, “Establishment and Firm Size (Including Legal Form of Organization,” Table 5, NAICS code 517211 (issued Nov. 2005).

<sup>20</sup> *Id.* The census data do not provide a more precise estimate of the number of firms that have employment of 1,500 or fewer employees; the largest category provided is for firms with “1000 employees or more.”

<sup>21</sup> U.S. Census Bureau, 2002 Economic Census, Subject Series: Information, “Establishment and Firm Size (Including Legal Form of Organization,” Table 5, NAICS code 517212 (issued Nov. 2005).

<sup>22</sup> *Id.* The census data do not provide a more precise estimate of the number of firms that have employment of 1,500 or fewer employees; the largest category provided is for firms with “1000 employees or more.”

<sup>7</sup> See petitions of the National Cable and Telecommunications Association (March 19, 2009), Community Broadcasters Association (March 19, 2009) and DirecTV and Dish Network (March 19, 2009).

<sup>8</sup> 5 U.S.C. 604(a)(3).

<sup>9</sup> 5 U.S.C. 601(6).

<sup>10</sup> 5 U.S.C. 601(3) (incorporating by reference the definition of “small-business concern” in the Small Business Act, 15 U.S.C. 632). Pursuant to 5 U.S.C. 601(3), the statutory definition of a small business applies “unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the Federal Register.”

<sup>11</sup> 15 U.S.C. 632.



from coverage of the rule, or any part thereof, for such small entities.”<sup>23</sup>

109. The Second Memorandum Opinion and Order generally upholds the rules adopted in the *Second Report and Order*. However, the Commission agreed with petitioners with regard to a number of the requested changes to the rules and modified and clarified the rules as appropriate in granting those requests. It believed those changes and clarifications will provide for improved protection of licensed services in the TV bands, resolve certain uncertainties in the rules and provide manufacturers with greater flexibility in designing products to meet market demands.

110. The Commission eliminated the requirement for TV bands devices that rely on geo-location and database access to sense analog and digital TV signals and also wireless microphones and other low power auxiliary stations. In reaching this decision, it considered the competing views from various parties on whether spectrum sensing is a viable tool for providing access to spectrum. The Commission believes that spectrum sensing will continue to develop and improve and anticipates that some form of spectrum sensing may very well be included in TVBDs on a voluntary basis for purposes such as determining the quality of each channel and enhancing spectrum sharing among TVBDs. However, the Commission did not believe that a mandatory spectrum sensing requirement best serves the public interest. It found that the geo-location and database access method and other provisions of the rules will provide adequate and reliable protection for television and low power broadcast auxiliary services, so that spectrum sensing is not necessary. These other rule provisions include: (1) Reserving two vacant UHF channels for wireless microphones and other low power auxiliary service devices in all areas of the country, and (2) allowing operators of the venues of large events and productions/shows that use large numbers of wireless microphones on an unlicensed basis to register the sites of those venues with the Commission to receive the same geographic spacing protections afforded licensed wireless microphones.

111. The Commission also adopted changes to the requirements for the databases that TV bands devices must contact to contain lists of available channels. Specifically, it required that communications between TV bands devices and TV bands databases, and between multiple databases, are secure. The Commission found that it is

important and necessary for TV bands devices and TV bands databases to incorporate reasonable and reliable security measures to minimize the possibility that TV bands devices will operate on occupied channels and cause interference to licensed services and to protect the operation of the databases and the devices they serve from outside manipulation. The Commission noted that virtually all online transactions involving financial or other confidential information currently use security measures to protect against unauthorized viewing and/or alteration of information being sent and to ensure that only authorized users have access to information. It therefore expects that device manufacturers and database administrators will have access to and be able to incorporate the reliability and security measures needed to protect the contents of databases and communications between databases and TV bands devices or other databases. In addition, the Commission required that all information that is required by the Commission's rules to be in a TV bands device database be publicly available, including fixed TV bands device registration and voluntarily submitted protected entity (e.g., cable head ends) information. Although much of the data will come from Commission databases that already are public sources, errors could result from the inadvertent entry of incorrect data, or as a result of a party deliberately entering false data. The Commission found it is appropriate to permit public examination of protected entity registration information to allow the detection and correction of errors.

112. The Commission made certain changes to the technical requirements for TV bands devices. It adopted a power spectral density (PSD) limit, which is a measure of transmitter power per unit of bandwidth. In the absence of a PSD limit, multiple devices with transmit bandwidths of significantly less than the width of a TV channel (6 megahertz) could share a single channel, resulting in a total transmitted power within a channel significantly greater than the power limits for fixed or personal/portable devices. A PSD limit will prohibit high power concentrations in a single channel, which will reduce the interference potential to TV stations and other services in the TV bands. The Commission also adopted changes to the measurement procedure for TV bands device emissions that fall into a TV channel adjacent to the operating channel to ensure that consistent measurement results are obtained regardless of the bandwidth of the transmitted signal.

113. The Commission also removed the prohibition on TV bands devices operating within the border areas near Canada and Mexico. It found that TV stations in Canada and Mexico could be protected by including them in the TV bands device database rather than by a blanket exclusion on TV bands device operation within the border areas.

#### F. Report to Congress

114. The Commission will send a copy of the Second Memorandum Opinion and Order, including this FRFA, in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act.<sup>24</sup> A copy of the Second Memorandum Opinion and Order and FRFA (or summaries thereof) will also be published in the **Federal Register**.<sup>25</sup>

#### Ordering Clauses

115. Pursuant to the authority contained in sections 4(i), 302, 303(e), 303(f), and 307 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 302, 303(c), 303(f), and 307 this Second Memorandum Opinion and Order *is hereby adopted*.

116. Pursuant to sections 4(i), 302, 303(e), 303(f), 303(g), 303(r) and 405 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 302, 303(e), 303(f), 303(g), 303(r) and 405, the petitions for reconsideration addressed *are granted* to the extent discussed and the remainder of requests in the petitions for reconsideration *are denied* as discussed.

117. Part 15 of the Commission's rules *is amended* as specified in Appendix B, and such rule amendments shall be effective January 5, 2011 except for §§ 15.713, 15.714, 15.715 and 15.717, which contains information collection requirements that require approval by the Office of Management and Budget (OMB) under the PRA. The Federal Communications Commission will publish a document in the **Federal Register** announcing such approval and the relevant effective date.

118. Pursuant to sections 4(i), 302, 303(e), 303(f), 303(g), 303(r) and 405 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 302, 303(e), 303(f), 303(g), 303(r) and 405, the remainder of requests in the petitions for reconsideration addressed herein *are denied*.

119. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of the Second Memorandum Opinion and Order, including the Final Regulatory

<sup>23</sup> 5 U.S.C. 603(c)(1) through (c)(4).

<sup>24</sup> See 5 U.S.C. 801(a)(1)(A).

<sup>25</sup> See 5 U.S.C. 604(b).

Flexibility Analysis, to the Chief Counsel for Advocacy of the U.S. Small Business Administration.

#### List of Subjects

##### 47 CFR Part 0

Organization and functions (government agencies), Reporting and recordkeeping requirements.

##### 47 CFR Part 15

Communications equipment.  
Federal Communications Commission.

**Marlene H. Dortch,**  
Secretary.

#### Final Rules

■ For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR parts 0 and 15 to read as follows:

#### PART 0—COMMISSION ORGANIZATION

■ 1. The authority citation for part 0 continues to read as follows:

**Authority:** Sec. 5, 48 Stat. 1068, as amended; 47 U.S.C. 155, 225, unless otherwise noted.

■ 2. Section 0.241 is amended by redesignating paragraph (h) as paragraph (i) and adding new paragraph (h) to read as follows:

##### § 0.241 Authority delegated.

\* \* \* \* \*

(h) The Chief of the Office of Engineering and Technology is delegated authority to administer the database functions for unlicensed devices operating in the television broadcast bands (TV bands) as set forth in subpart H of part 15 of this chapter. The Chief is delegated authority to develop specific methods that will be used to designate TV bands database managers, to designate these database managers; to develop procedures that these database managers will use to ensure compliance with the requirements for database operations; to make determinations regarding the continued acceptability of individual database managers; and to perform other functions as needed for the administration of the TV bands databases. The Chief is also delegated authority jointly with the Chief of the Wireless Telecommunications Bureau to administer provisions of § 15.713(h)(8) of this chapter pertaining to the registration of event sites where large numbers of wireless microphones that operate on frequencies specified in § 74.802 of this chapter are used.

\* \* \* \* \*

■ 3. Section 0.331 is amended by revising the introductory text and adding new paragraph (e) to read as follows:

##### § 0.331 Authority delegated.

The Chief, Wireless Telecommunications Bureau, is hereby delegated authority to perform all functions of the Bureau, described in § 0.131, subject to the exceptions and limitations in paragraphs (a) through (d) of this section, and also the functions described in paragraph (e) of this section.

\* \* \* \* \*

(e) The Chief of the Wireless Telecommunications Bureau is delegated authority jointly with the Chief of the Office of Engineering and Technology to administer provisions of § 15.713(h)(8) of this chapter pertaining to the registration of event sites where large numbers of wireless microphones that operate on frequencies specified in § 74.802 of this chapter are used.

#### PART 15—RADIO FREQUENCY DEVICES

■ 4. The authority citation for part 15 continues to read as follows:

**Authority:** 47 U.S.C. 154, 302a, 303, 304, 307, 336, and 544a.

■ 5. Section 15.701 is revised to read as follows:

##### § 15.701 Scope.

This subpart sets forth the regulations for unlicensed Television Band Devices (TVBDs). These devices are unlicensed intentional radiators that operate on available TV channels in the broadcast television frequency bands at 54–60 MHz (TV channel 2), 76–88 MHz (TV channels 5 and 6), 174–216 MHz (TV channels 7–13), 470–608 MHz (TV channels 14–36) and 614–698 MHz (TV channels 38–51).

■ 6. Section 15.703 is revised to read as follows:

##### § 15.703 Definitions.

(a) *Available channel.* A six-megahertz television channel, as specified in § 73.603 of this chapter, which is not being used by an authorized service at or near the same geographic location as the TVBD and is acceptable for use by an unlicensed device under the provisions of this subpart.

(b) *Contact verification signal.* An encoded signal broadcast by a fixed or Mode II device for reception by Mode I devices to which the fixed or Mode II device has provided a list of available channels for operation. Such signal is for the purpose of establishing that the

Mode I device is still within the reception range of the fixed or Mode II device for purposes of validating the list of available channels used by the Mode I device and shall be encoded to ensure that the signal originates from the device that provided the list of available channels. A Mode I device may respond only to a contact verification signal from the fixed or Mode II device that provided the list of available channels on which it operates. A fixed or Mode II device shall provide the information needed by a Mode I device to decode the contact verification signal at the same time it provides the list of available channels.

(c) *Fixed device.* A TVBD that transmits and/or receives radiocommunication signals at a specified fixed location. A fixed TVBD may select channels for operation itself from a list of available channels provided by a TV bands database, initiate and operate a network by sending enabling signals to one or more fixed TVBDs and/or personal/portable TVBDs. Fixed devices may provide to a Mode I personal/portable device a list of available channels on which the Mode I device may operate under the rules, including available channels above 512 MHz (above TV channel 20) on which the fixed TVBD also may operate and a supplemental list of available channels above 512 MHz (above TV channel 20) that are adjacent to occupied TV channels on which the Mode I device, but not the fixed device, may operate.

(d) *Geo-location capability.* The capability of a TVBD to determine its geographic coordinates within the level of accuracy specified in § 15.711(b)(1), *i.e.* 50 meters. This capability is used with a TV bands database approved by the FCC to determine the availability of TV channels at a TVBD's location.

(e) *Mode I personal/portable device.* A personal/portable TVBD that does not use an internal geo-location capability and access to a TV bands database to obtain a list of available channels. A Mode I device must obtain a list of available channels on which it may operate from either a fixed TVBD or Mode II personal/portable TVBD. A Mode I device may not initiate a network of fixed and/or personal/portable TVBDs nor may it provide a list of available channels to another Mode I device for operation by such device.

(f) *Mode II personal/portable device.* A personal/portable TVBD that uses an internal geo-location capability and access to a TV bands database, either through a direct connection to the Internet or through an indirect connection to the Internet by way of fixed TVBD or another Mode II TVBD,

to obtain a list of available channels. A Mode II device may select a channel itself and initiate and operate as part of a network of TVBDs, transmitting to and receiving from one or more fixed TVBDs or personal/portable TVBDs. A Mode II personal/portable device may provide its list of available channels to a Mode I personal/portable device for operation on by the Mode I device.

(g) *Network initiation.* The process by which a fixed or Mode II TVBD sends control signals to one or more fixed TVBDs or personal/portable TVBDs and allows them to begin communications.

(h) *Operating channel.* An available channel used by a TVBD for transmission and/or reception.

(i) *Personal/portable device.* A TVBD that transmits and/or receives radiocommunication signals at unspecified locations that may change. Personal/portable devices may only transmit on available channels in the frequency bands 512–608 MHz (TV channels 21–36) and 614–698 MHz (TV channels 38–51).

(j) *Receive site.* The location where the signal of a full service television station is received for rebroadcast by a television translator or low power TV station, including a Class A TV station, or for distribution by a Multiple Video Program Distributor (MVPD) as defined in 47 U.S.C. 602(13).

(k) *Sensing only device.* A personal/portable TVBD that uses spectrum sensing to determine a list of available channels. Sensing only devices may transmit on any available channels in the frequency bands 512–608 MHz (TV channels 21–36) and 614–698 MHz (TV channels 38–51).

(l) *Spectrum sensing.* A process whereby a TVBD monitors a television channel to detect whether the channel is occupied by a radio signal or signals from authorized services.

(m) *Television band device (TVBD).* Intentional radiators that operate on an unlicensed basis on available channels in the broadcast television frequency bands at 54–60 MHz (TV channel 2), 76–88 MHz (TV channels 5 and 6), 174–216 MHz (TV channels 7–13), 470–608 MHz (TV channels 14–36) and 614–698 MHz (TV channels 38–51).

(n) *TV bands database.* A database system that maintains records of all authorized services in the TV frequency bands, is capable of determining the available channels as a specific geographic location and provides lists of available channels to TVBDs that have been certified under the Commission's equipment authorization procedures. TV bands databases that provide lists of available channels to TVBDs must receive approval by the Commission.

■ 7. Section 15.706 is amended by revising paragraph (a) to read as follows:

**§ 15.706 Information to the user.**

(a) In addition to the labeling requirements contained in § 15.19, the instructions furnished to the user of a TVBD shall include the following statement, placed in a prominent location in the text of the manual:

This equipment has been tested and found to comply with the rules for TV bands devices, pursuant to part 15 of the FCC rules. These rules are designed to provide reasonable protection against harmful interference. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

(1) Reorient or relocate the receiving antenna.

(2) Increase the separation between the equipment and receiver.

(3) Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

(4) Consult the manufacturer, dealer or an experienced radio/TV technician for help.

\* \* \* \* \*

■ 8. Section 15.707 is revised to read as follows:

**§ 15.707 Permissible channels of operation.**

(a) All TVBDs are permitted to operate available channels in the frequency bands 512–608 MHz (TV channels 21–36) and 614–698 MHz (TV channels 38–51), subject to the interference protection requirements in §§ 15.711 and 15.712, except that operation of TVBDs is prohibited on the first channel above and the first channel below TV channel 37 (608–614 MHz) that are available, *i.e.*, not occupied by an authorized service. If a channel is not available both above and below channel 37, operation is prohibited on the first two channels nearest to channel 37. These channels will be identified and protected in the TV bands database(s).

(b) Operation on available channels in the bands 54–60 MHz (TV channel 2), 76–88 MHz (TV channels 5 and 6), 174–216 MHz (TV channels 7–13) and 470–512 MHz (TV channels 14–20), subject to the interference protection requirements in §§ 15.711 and 15.712, is permitted only for fixed TVBDs that communicate only with other fixed TVBDs.

(c) Fixed and Mode II TVBDs shall operate only on available channels as identified in paragraphs (a) and (b) of

this section and as determined by a TV bands database in accordance with the interference avoidance mechanisms of §§ 15.711 and 15.712.

(d) Mode I TVBDs shall operate only on available channels as identified in paragraphs (a) and (b) of this section and provided from a fixed or Mode II TVBD in accordance with § 15.711(b)(3)(iv).

■ 9. Section 15.709 is amended by revising paragraphs (a) and (b); removing paragraph (c) introductory text and adding a heading to paragraph (c) in its place; and revising paragraphs (c) (1) through (c)(3) to read as follows:

**§ 15.709 General technical requirements.**

(a) *Power limits for TVBDs.* (1) For fixed TVBDs, the maximum power delivered to the transmitting antenna shall not exceed one watt per 6 megahertz of bandwidth on which the device operates. The power delivered to the transmitting antenna is the maximum conducted output power reduced by the signal loss experienced in the cable used to connect the transmitter to the transmit antenna. If transmitting antennas of directional gain greater than 6 dBi are used, the maximum conducted output power shall be reduced by the amount in dB that the directional gain of the antenna exceeds 6 dBi.

(2) For personal/portable TVBDs, the maximum EIRP shall not exceed 100 milliwatts (20 dBm) per 6 megahertz of bandwidth on which the device operates with the following exceptions; Mode II personal/portable TVBDs that do not meet the adjacent channel separation requirements in § 15.712(a) and Mode I personal/portable TVBDs that operate on available channels (provided by a Mode II TVBD) that do not meet the adjacent channel separation requirements of § 15.712(a) are limited to a maximum EIRP of 40 milliwatts (16 dBm) per 6 megahertz of bandwidth on which the device operates.

(3) TVBDs shall incorporate transmit power control to limit their operating power to the minimum necessary for successful communication. Applicants for equipment certification shall include a description of a device's transmit power control feature mechanism.

(4) Maximum conducted output power is the total transmit power over the occupied bandwidth delivered to all antennas and antenna elements averaged across all symbols in the signaling alphabet when the transmitter is operating at its maximum power control level. Power must be summed across all antennas and antenna elements. The average must not include

any time intervals during which the transmitter is off or is transmitting at a reduced power level. If multiple modes of operation are possible (e.g., alternative modulation methods), the maximum conducted output power is the highest total transmit power occurring in any mode.

(5) The power spectral density conducted from the TVBD to the antenna shall not be greater than the following values when measured in any 100 kHz band during any time interval of continuous transmission:

(i) Fixed devices: 12.2 dBm.

(ii) Personal/portable devices operating adjacent to occupied TV channels: -1.8 dBm.

(iii) Sensing-only devices: -0.8 dBm.

(iii) All other personal/portable devices: 2.2 dBm.

(6) TVBDs shall incorporate adequate security measures to prevent the TVBD from accessing databases not approved by the FCC and to ensure that unauthorized parties can not modify the TVBD or configure its control features to operate inconsistent with the rules and protection criteria set forth in this subpart.

(b) *Antenna requirements.* (1) All transmit and receive antenna(s) of personal/portable devices shall be permanently attached.

(2) The transmit antenna used with fixed devices may not be more than 30 meters above the ground. In addition, fixed devices may not be located at sites where the height above average terrain (HAAT) at ground level is more than 76 meters. The ground level HAAT is to be calculated by the TV bands database that the device contacts for available channels using computational software employing the methodology in § 73.684(d) of this chapter.

(3) For personal/portable TVBDs operating under § 15.717, the provisions of § 15.204(c)(4) do not apply to an antenna used for transmission and reception/spectrum sensing.

(4) For personal/portable TVBDs operating under § 15.717 that incorporate a separate sensing antenna, compliance testing shall be performed using the lowest gain antenna for each type of antenna to be certified.

(c) *Emission limits for TVBDs.* (1) In the television channels immediately adjacent to the channel in which a TVBD is operating, emissions from the TVBD shall be at least 72.8 dB below the highest average power in the TV channel in which the device is operating.

(2) Emission measurements in the channel of operation shall be performed over a reference bandwidth of 6 megahertz with an average detector.

Emission measurements in the adjacent channels shall be performed using a minimum resolution bandwidth of 100 kHz with an average detector. A narrower resolution bandwidth may be employed near the band edge, when necessary, provided the measured energy is integrated to show the total power over 100 kHz.

(3) At frequencies beyond the television channels immediately adjacent to the channel in which the TVBD is operating, the radiated emissions from TVBDs shall meet the requirements of § 15.209.

\* \* \* \* \*

■ 10. Section 15.711 is amended by revising the section heading, adding introductory text, and revising paragraphs (a) through (f) to read as follows:

**§ 15.711 Interference avoidance methods.**

Except as provided in § 15.717, television channel availability for a TVBD is determined based on the geo-location and database access method described in paragraphs (a) and (b) of this section.

(a) *Geo-location and database access.* A TVBD shall rely on the geo-location and database access mechanism to identify available television channels consistent with the interference protection requirements of § 15.712. Such protection will be provided for the following authorized and unlicensed services: digital television stations, digital and analog Class A, low power, translator and booster stations; translator receive operations; fixed broadcast auxiliary service links; private land mobile service/commercial radio service (PLMRS/CMRS) operations; offshore radiotelephone service; low power auxiliary services authorized pursuant to §§ 74.801 through 74.882 of this chapter, including wireless microphones and MVPD receive sites; and unlicensed wireless microphones used by venues of large events and productions/shows as provided under § 15.713(h)(8). In addition, protection shall be provided in border areas near Canada and Mexico in accordance with § 15.712(g).

(b) *Geo-location and database access requirements.* (1) The geographic coordinates of a fixed TVBD shall be determined to an accuracy of  $\pm 50$  meters by either an incorporated geo-location capability or a professional installer. In the case of professional installation, the party who registers the fixed TVBD in the database will be responsible for assuring the accuracy of the entered coordinates. The geographic coordinates of a fixed TVBD shall be

determined at the time of installation and first activation from a power-off condition, and this information may be stored internally in the TVBD. If the fixed TVBD is moved to another location or if its stored coordinates become altered, the operator shall re-establish the device's:

(i) Geographic location and store this information in the TVBD either by means of the device's incorporated geo-location capability or through the services of a professional installer; and

(ii) Registration with the database based on the device's new coordinates.

(2) A Mode II personal/portable device shall incorporate a geo-location capability to determine its geographic coordinates to an accuracy of  $\pm 50$  meters. A Mode II device must also re-establish its position each time it is activated from a power-off condition and use its geo-location capability to check its location at least once every 60 seconds while in operation, except while in sleep mode, i.e., in a mode in which the device is inactive but is not powered-down.

(3)(i) Fixed devices must access a TV bands database over the Internet to determine the TV channels that are available at their geographic coordinates, taking into consideration the fixed device's antenna height, prior to their initial service transmission at a given location. Operation is permitted only on channels that are indicated in the database as being available for such TVBDs. Fixed TVBDs shall access the database at least once a day to verify that the operating channels continue to remain available. Operation on a channel must cease immediately if the database indicates that the channel is no longer available. Fixed TVBD must adjust their use of channels in accordance with channel availability schedule information provided by their database for the 48-hour period beginning at the time of the device last accessed the database for a list of available channels.

(ii) Mode II personal/portable devices must access a TV bands database over the Internet to determine the TV channels that are available at their geographic coordinates prior to their initial service transmission at a given location. Operation is permitted only on channels that are indicated in the database as being available for personal/portable TVBDs. A Mode II personal/portable device must access the database for a list of available channels each time it is activated from a power-off condition and re-check its location and the database for available channels if it changes location during operation by more than 100 meters from the

location at which it last accessed the database. A Mode II personal/portable device that has been in a powered state shall re-check its location and access the database daily to verify that the operating channel(s) continue to be available. Mode II personal/portable devices must adjust their use of channels in accordance with channel availability schedule information provided by their database for the 48-hour period beginning at the time of the device last accessed the database for a list of available channels. A Mode II personal/portable device may load channel availability information for multiple locations around, *i.e.*, in the vicinity of, its current location and use that information in its operation. A Mode II TVBD may use such available channel information to define a geographic area within which it can operate on the same available channels at all locations, for example a Mode II TVBD could calculate a bounded area in which a channel or channels are available at all locations within the area and operate on a mobile basis within that area. A Mode II TVBD using such channel availability information for multiple locations must contact the database again if/when it moves beyond the boundary of the area where the channel availability data is valid, and must access the database daily even if it has not moved beyond that range to verify that the operating channel(s) continue to be available. Operation must cease immediately if the database indicates that the channel is no longer available.

(iii) If a fixed or Mode II personal/portable TVBD fails to successfully contact the TV bands database during any given day, it may continue to operate until 11:59 p.m. of the following day at which time it must cease operations until it re-establishes contact with the TV bands database and re-verifies its list of available channels.

(iv) A Mode I personal/portable TVBD may only transmit upon receiving a list of available channels from a fixed or Mode II TVBD that has contacted a database and verified that the FCC identifier (FCC ID) of the Mode I device is valid. The list of channels provided to the Mode I device must be the same as the list of channels that are available to the fixed or Mode II device, except that a Mode I device may operate only on channels that are permissible for its use under § 15.707. A fixed device may also obtain from a database a separate list of available channels that includes adjacent channels that would be available to a Mode I personal/portable device and provide that list to the Mode I device. A fixed or Mode II

device may provide a Mode I device with a list of available channels only after it contacts its database, provides the database the FCC Identifier (FCC ID) of the Mode I device requesting available channels, and receives verification that the FCC ID is valid for operation. To initiate contact with a fixed or Mode II device, a Mode I device may transmit on an available channel used by the fixed or Mode II TVBD or on a channel the fixed or Mode II TVBD indicates is available for use by a Mode I device on a signal seeking such contacts. At least once every 60 seconds, except when in sleep mode, *i.e.*, a mode in which the device is inactive but is not powered-down, a Mode I device must either receive a contact verification signal from the Mode II or fixed device that provided its current list of available channels or contact a Mode II or fixed device to re-verify/re-establish channel availability. A Mode I device must cease operation immediately if it does not receive a contact verification signal or is not able to re-establish a list of available channels through contact with a fixed or Mode II device on this schedule. In addition, a Mode II device must re-check/reestablish contact with a fixed or Mode II device to obtain a list of available channels if they lose power. Collaterally, if a Mode II device loses power and obtains a new channel list, it must signal all Mode I devices it is serving to acquire new channel list.

(v) Device manufacturers and database administrators may implement a system that pushes updated channel availability information from the database to TVBDs. However, the use of such systems is not mandatory, and the requirements for TVBDs to validate the operating channel at least daily and to cease operation in accordance with paragraph (b)(3)(iii) of this section continue to apply if such a system is used.

(vi) TV bands devices shall incorporate adequate security measures to ensure that they are capable of communicating for purposes of obtaining lists of available channels only with databases operated by administrators authorized by the Commission, and to ensure that communications between TV bands devices and databases between TV bands devices are secure to prevent corruption or unauthorized interception of data. This requirement includes implementing security for communications between Mode I personal portable devices and fixed or Mode II devices for purposes of providing lists of available channels.

(4) All geographic coordinates shall be referenced to the North American Datum of 1983 (NAD 83).

(c) *Display of available channels.* A TVBD must incorporate the capability to display a list of identified available channels and its operating channels.

(d) *Identifying information.* Fixed TVBDs shall transmit identifying information. The identification signal must conform to a standard established by a recognized industry standards setting organization. The identification signal shall carry sufficient information to identify the device and its geographic coordinates.

(e) *Fixed devices without a direct connection to the Internet.* If a fixed TVBD does not have a direct connection to the Internet and has not yet been initialized and registered with the TV bands database consistent with § 15.713, but can receive the transmissions of another fixed TVBD, the fixed TVBD needing initialization may transmit to that other fixed TVBD on either a channel that the other TVBD has transmitted on or on a channel which the other TVBD indicates is available for use to access the database to register its location and receive a list of channels that are available for it to use. Subsequently, the newly registered TVBD must only use the television channels that the database indicates are available for it to use. A fixed device may not obtain lists of available channels from another fixed device as provided by a TV bands database for such other device, *i.e.*, a fixed device may not simply operate on the list of available channels provided by a TV bands database for another fixed device with which it communicates but must contact a database to obtain a list of available channels on which it may operate.

(f) *Security.* (1) For purposes of obtaining a list of available channels and related matters, fixed and Mode II TVBDs shall only be capable of contacting databases operated by FCC designated administrators.

(2) Communications between TV bands devices and TV bands databases are to be transmitted using secure methods that ensure against corruption or unauthorized modification of the data; this requirement applies to communications of channel availability and other spectrum access information between fixed and Mode II devices (it is not necessary for TVBDs to apply security coding to channel availability and channel access information where they are not the originating or terminating device and that they simply pass through).

(3) Communications between a Mode I device and a fixed or Mode II device for purposes of obtaining a list of available channels shall employ secure methods that ensure against corruption or unauthorized modification of the data. When a Mode I device makes a request to a fixed or Mode II device for a list of available channels the receiving device shall check with the TV bands database that the Mode I device has a valid FCC Identifier before providing a list of available channels. Contact verification signals transmitted for Mode I devices are to be encoded with encryption to secure the identity of the transmitting device. Mode I devices using contact verification signals shall accept as valid for authorization only the signals of the device from which they obtained their list of available channels.

(4) A TV bands database shall be protected from unauthorized data input or alteration of stored data. To provide this protection, the administrator of the TV bands database administrator shall establish communications authentication procedures that allow the fixed or Mode II devices to be assured that the data they receive is from an authorized source.

(5) Applications for certification of TV bands devices are to include a high level operational description of the technologies and measures that are incorporated in the device to comply with the security requirements of this section. In addition, applications for certification of fixed and Mode II devices are to identify at least one of the TV bands databases operated by a designated TV bands database administrator that the device will access

for channel availability and affirm that the device will conform to the communications security methods used by that database.

\* \* \* \* \*

■ 11. Section 15.712 is amended by revising paragraphs (a)(1), (a)(2), (b), (d), (f), (g), paragraph (h) introductory text and (h)(3) to read as follows:

**§ 15.712 Interference protection requirements.**

(a) \* \* \*

(1) *Protected contour.* TVBDs must protect digital and analog TV services within the contours shown in the following table. These contours are calculated using the methodology in § 73.684 of this chapter and the R-6602 curves contained in § 73.699 of this chapter.

Type of station	Protected contour		
	Channel	Contour (dBu)	Propagation curve
Analog: Class A TV, LPTV, translator and booster .....	Low VHF (2-6) .....	47	F(50,50)
	High VHF (7-13) .....	56	F(50,50)
	UHF (14-69) .....	64	F(50,50)
Digital: Full service TV, Class A TV, LPTV, translator and booster .....	Low VHF (2-6) .....	28	F(50,90)
	High VHF (7-13) .....	36	F(50,90)
	UHF (14-51) .....	41	F(50,90)

(2) *Required separation distance.* TVBDs must be located outside the contours indicated in paragraph (a)(1) of this section of co-channel and adjacent channel stations by at least the minimum distances specified in the

following table. Personal/portable TVBDs operating in Mode II must comply with the separation distances specified for an unlicensed device with an antenna height of less than 3 meters. Alternatively, Mode II personal/portable

TVBDs may operate at closer separation distances, including inside the contour of adjacent channel stations, provided the power level is reduced to 40 mW or less as specified in § 15.709(a)(2).

Antenna height of unlicensed device	Required separation (km) from digital or analog TV (full service or low power) protected contour	
	Co-channel (km)	Adjacent channel (km)
Less than 3 meters .....	6.0	0.1
3—Less than 10 meters .....	8.0	0.1
10-30 meters .....	14.4	0.74

(b) *TV translator, Low Power TV (including Class A) and Multi-channel Video Programming Distributor (MVPD) receive sites.* MVPD, TV translator station and low power TV (including Class A) station receive sites located outside the protected contour of the TV station(s) being received may be registered in the TV bands database if they are no farther than 80 km outside the nearest edge of the relevant contour(s). Only channels received over the air and used by the MVPD, TV translator station or low power/Class A TV station may be registered. TVBDs

may not operate within an arc of ± - 30 degrees from a line between a registered receive site and the contour of the TV station being received in the direction of the station's transmitter at a distance of up to 80 km from the edge of the protected contour of the received TV station for co-channel operation and up to 20 km from the registered receive site for adjacent channel operation, except that the protection distance shall not exceed the distance from the receive site to the protected contour. Outside of this ± / - 30 degree arc, TVBDs may not operate within 8 km from the receive

site for co-channel operation and 2 km from the receive site for adjacent channel operation. For purposes of this section, a TV station being received may include a full power TV station, TV translator station or low power TV/Class A TV station.

\* \* \* \* \*

(d) *PLMRS/CMRS operations:* TVBDs may not operate at distances less than 134 km for co-channel operations and 131 km for adjacent channel operations from the coordinates of the metropolitan areas and on the channels listed in § 90.303(a) of this chapter. For PLMRS/

CMRS operations authorized by waiver outside of the metropolitan areas listed in § 90.303(a) of this chapter, co-channel and adjacent channel TVBDs may not operate closer than 54 km and 51 km, respectively from a base station.

\* \* \* \* \*

(f) *Low power auxiliary services, including wireless microphones:* (1) Fixed TVBDs are not permitted to operate within 1 km, and personal/portable TVBDs will not be permitted to operate within 400 meters, of the

coordinates of registered low power auxiliary station sites on the registered channels during the designated times they are used by low power auxiliary stations.

(2) TVBDs are not permitted to operate on the first channel on each side of TV channel 37 (608–614 MHz) that is not occupied by a licensed service.

(g) *Border areas near Canada and Mexico:* Fixed and personal/portable TVBDs shall comply with the required separation distances in § 15.712(a)(2) from the protected contours of TV

stations in Canada and Mexico. TVBDs are not required to comply with these separation distances from portions of the protected contours of Canadian or Mexican TV stations that fall within the United States.

(h) *Radio astronomy services:* Operation of fixed and personal/portable TVBDs is prohibited on all channels within 2.4 kilometers at the following locations.

\* \* \* \* \*

(3) The following facilities:

Observatory	Longitude (deg/min/sec)	Latitude (deg/min/sec)
Allen Telescope Array .....	121 28 24 W .....	40 49 04 N
Arecibo Observatory .....	066 45 11 W .....	18 20 46 N
Green Bank Telescope (GBT) .....	079 50 24 W .....	38 25 59 N
Very Large Array (VLA) .....	Rectangle between latitudes 33 58 22 N and 34 14 56 N, and longitudes 107 24 40 W and 107 48 22 W	
Very Long Baseline Array (VLBA) Stations:		
Pie Town, AZ .....	108 07 07 W .....	34 18 04 N
Kitt Peak, AZ .....	111 36 42 W .....	31 57 22 N
Los Alamos, NM .....	106 14 42 W .....	35 46 30 N
Ft. Davis, TX .....	103 56 39 W .....	30 38 06 N
N. Liberty, IA .....	091 34 26 W .....	41 46 17 N
Brewster, WA .....	119 40 55 W .....	48 07 53 N
Owens Valley, CA .....	118 16 34 W .....	37 13 54 N
St. Croix, VI .....	064 35 03 W .....	17 45 31 N
Hancock, NH .....	071 59 12 W .....	42 56 01 N
Mauna Kea, HI .....	155 27 29 W .....	19 48 16 N

■ 11. Section 15.713 is amended by revising paragraphs (a)(1), (b)(2)(i), (c)(2), (d), (e), (f)(3), (h) introductory text, (h)(1), and (h)(6) through (h)(9), and adding new paragraph (j) to read as follows:

**§ 15.713 TV bands database.**

(a) \* \* \*  
 (1) To determine and provide to a TVBD, upon request, the available TV channels at the TVBD's location. Available channels are determined based on the interference protection requirements in § 15.712. A database must provide fixed and Mode II personal portable TVBDs with channel availability information that includes scheduled changes in channel availability over the course of the 48 hour period beginning at the time the TVBDs make a re-check contact. In making lists of available channels available to a TVBD, the TV bands database shall ensure that all communications and interactions between the TV bands database and the TVBD include adequate security measures such that unauthorized parties cannot access or alter the TV bands database or the list of available channels sent to TVBDs or otherwise affect the

database system or TVBDs in performing their intended functions or in providing adequate interference protections to authorized services operating in the TV bands. In addition, a TV bands database must also verify that the FCC identifier (FCC ID) of a device seeking access to its services is valid; under this requirement the TV bands database must also verify that the FCC ID of a Mode I device provided by a fixed or Mode II device is valid. A list of devices with valid FCC IDs and the FCC IDs of those devices is to be obtained from the Commission's Equipment Authorization System.

\* \* \* \* \*

(b) \* \* \*  
 (2) \* \* \*  
 (i) MVPD receive sites.

\* \* \* \* \*

(c) \* \* \*  
 (2) MVPD receive sites within the protected contour or more than 80 kilometers from the nearest edge of the protected contour of a television station being received are not eligible to register that station's channel in the database.

(d) *Determination of available channels.* The TV bands database will determine the available channels at a location using the interference

protection requirements of § 15.712, the location information supplied by a TVBD, and the data for protected stations/locations in the database.

(e) *TVBD initialization.* (1) Fixed and Mode II TVBDs must provide their location and required identifying information to the TV bands database in accordance with the provisions of this subpart.

(2) Fixed and Mode II TVBDs shall not transmit unless they receive, from the TV bands database, a list of available channels and may only transmit on the available channels on the list provided by the database.

(3) Fixed TVBDs register and receive a list of available channels from the database by connecting to the iInternet, either directly or through another fixed TVBD that has a direct connection to the Internet.

(4) Mode II TVBDs receive a list of available channels from the database by connecting to the Internet, either directly or through a fixed or Mode II TVBD that has a direct connection to the Internet.

(5) A fixed or Mode II TVBD that provides a list of available channels to a Mode I device shall notify the database of the FCC identifier of such



Mode I device and receive verification that that FCC identifier is valid before providing the list of available channels to the Mode I device.

(6) A fixed device located at a site where the ground level height above average terrain (HAAT) is greater than 76 meters shall not be provided a list of available channels. The ground level HAAT of sites occupied by fixed TVBDs is to be calculated using computational software employing the methodology in § 73.684(d) of this chapter.

(f) \* \* \*

(3) The TVBD registration database shall contain the following information for fixed TVBDs:

(i) FCC identifier (FCC ID) of the device;

(ii) Manufacturer's serial number of the device;

(iii) Device's geographic coordinates (latitude and longitude (NAD 83) accurate to  $\pm/ - 50$  m);

(iv) Device's antenna height above ground level (meters);

(v) Name of the individual or business that owns the device;

(vi) Name of a contact person responsible for the device's operation;

(vii) Address for the contact person;

(viii) E-mail address for the contact person;

(ix) Phone number for the contact person.

\* \* \* \* \*

(h) *TV bands database information.*

The TV bands database shall contain the listed information for each of the following:

(1) Digital television stations, digital and analog Class A, low power, translator and booster stations, including stations in Canada and Mexico that are within the border coordination areas as specified in § 73.1650 of this chapter (a TV bands database is to include only TV station information from station license or license application records. In cases where a station has records for both a license application and a license, a TV bands database should include the information from the license application rather than the license. In cases where there are multiple license application records or license records for the same station, the database is to include the most recent records, and again with license applications taking precedence over licenses.):

(i) Transmitter coordinates (latitude and longitude in NAD 83);

(ii) Effective radiated power (ERP);

(iii) Height above average terrain of the transmitting antenna (HAAT);

(iv) Horizontal transmit antenna pattern (if the antenna is directional);

(v) Amount of electrical and mechanical beam tilt (degrees depression below horizontal) and orientation of mechanical beam tilt (degrees azimuth clockwise from true north);

(vi) Channel number; and

(vii) Station call sign.

\* \* \* \* \*

(6) MVPD receive sites. Registration for receive sites is limited to channels that are received over-the-air and are used as part of the MVPD service.

(i) Name and address of MVPD company;

(ii) Location of the MVPD receive site (latitude and longitude in NAD 83, accurate to  $\pm/ - 50$  m);

(iii) Channel number of each television channel received, subject to the following condition: channels for which the MVPD receive site is located within the protected contour of that channel's transmitting station are not eligible for registration in the database;

(iv) Call sign of each television channel received and eligible for registration;

(v) Location (latitude and longitude) of the transmitter of each television channel received;

(7) Television translator, low power TV and Class A TV station receive sites. Registration for television translator, low power TV and Class A receive sites is limited to channels that are received over-the-air and are used as part of the station's service.

(i) Call sign of the TV translator station;

(ii) Location of the TV translator receive site (latitude and longitude in NAD 83, accurate to  $\pm/ - 50$  m);

(iii) Channel number of the retransmitted television station, subject to the following condition: a channel for which the television translator receive site is located within the protected contour of that channel's transmitting station is not eligible for registration in the database;

(iv) Call sign of the retransmitted television station; and

(v) Location (latitude and longitude) of the transmitter of the retransmitted television station.

(8) Licensed low power auxiliary stations, including wireless microphones and wireless assist video devices. Use of licensed low power auxiliary stations at well defined times and locations may be registered in the database. Multiple registrations that specify more than one point in the facility may be entered for very large sites. Registrations will be valid for no more than one year, after which they may be renewed. Registrations must include the following information:

(i) Name of the individual or business responsible for the low power auxiliary device(s);

(ii) An address for the contact person;

(iii) An email address for the contact person (optional);

(iv) A phone number for the contact person;

(v) Coordinates where the device(s) are used (latitude and longitude in NAD 83, accurate to  $\pm/ - 50$  m);

(vi) Channels used by the low power auxiliary devices operated at the site;

(vii) Specific months, weeks, days of the week and times when the device(s) are used (on dates when microphones are not used the site will not be protected); and

(viii) The stations call sign.

(9) Unlicensed wireless microphones at venues of events and productions/shows that use large numbers of wireless microphones that cannot be accommodated in the two reserved channels and other channels that are not available for use by TVBDs at that location. Such sites of large events and productions/shows with significant wireless microphone use at well defined times and locations may be registered in the database. Entities responsible for eligible event venues registering their site with a TV bands data base are required to first make use of the two reserved channels and other channels that are not available for use by TVBDs at that location. As a benchmark, at least 6–8 wireless microphones should be operating in each channel used at such venues (both licensed and unlicensed wireless microphones used at the event may be counted to comply with this benchmark). Multiple registrations that specify more than one point in the facility may be entered for very large sites. Sites of eligible event venues using unlicensed wireless microphones must be registered with the Commission at least 30 days in advance and the Commission will provide this information to the data base managers. Parties responsible for eligible event venues filing registration requests must certify that they are making use of all TV channels not available to TV bands devices and on which wireless microphones can practicably be used, including channels 7–51 (except channel 37). The Commission will make requests for registration of sites that use unlicensed wireless microphones public and will provide an opportunity for public comment or objections. Registrations will be valid for one year, after which they may be renewed. The Commission will take actions against parties that file inaccurate or incomplete information, such as denial of registration in the database, removal of

information from the database pursuant to paragraph (i) of this section, or other sanctions as appropriate to ensure compliance with the rules. Registrations must include the following information:

- (i) Name of the individual or business that owns the unlicensed wireless microphones;
- (ii) An address for the contact person;
- (iii) An e-mail address for the contact person (optional);
- (iv) A phone number for the contact person;
- (v) Coordinates where the device(s) are used (latitude and longitude in NAD 83, accurate to ±/ - 50 m);
- (vi) Channels used by the wireless microphones operated at the site and the number of wireless microphones used in each channel. As a benchmark, least 6–8 wireless microphones must be used in each channel. Registration requests that do not meet this criteria will not be registered in the TV bands data bases;
- (vii) Specific months, weeks, days of the week and times when the device(s) are used (on dates when microphones are not used the site will not be protected); and
- (viii) The name of the venue.

\* \* \* \* \*

(j) *Security.* The TV bands database shall employ protocols and procedures to ensure that all communications and interactions between the TV bands database and TVBDs are accurate and secure and that unauthorized parties cannot access or alter the database or the list of available channels sent to a TVBD.

(1) Communications between TV bands devices and TV bands databases, and between different TV bands databases, shall be secure to prevent corruption or unauthorized interception of data. A TV bands database shall be protected from unauthorized data input or alteration of stored data.

(2) A TV bands database shall verify that the FCC identification number supplied by a fixed or personal/portable TV bands device is for a certified device and may not provide service to an uncertified device.

(3) A TV bands database must not provide lists of available channels to uncertified TV bands devices for purposes of operation (it is acceptable for a TV bands database to distribute lists of available channels by means other than contact with TVBDs to provide list of channels for operation). To implement this provision, a TV bands database administrator shall obtain a list of certified TVBDs from the FCC Equipment Authorization System.

■ 12. Section 15.714 is amended by revising paragraph (a) to read as follows:

**§ 15.714 TV bands database administration fees.**

(a) A TV bands database administrator may charge a fee for provision of lists of available channels to fixed and personal/portable TVBDs and for registering fixed TVBDs.

\* \* \* \* \*

■ 13. Section 15.715 is amended by revising the introductory text, revising paragraphs (c), (d), and (e), redesignating paragraphs (f) through (k) as paragraphs (g) through (l), revising newly designated paragraphs (h) through (l), and adding new paragraph (f) to read as follows:

**§ 15.715 TV bands database administrator.**

The Commission will designate one or more entities to administer the TV bands database(s). The Commission may, at its discretion, permit the functions of a TV bands database, such as a data repository, registration, and query services, to be divided among multiple entities; however, it will designate specific entities to be a database administrator responsible for coordination of the overall functioning of a database and providing services to TVBDs. Each database administrator designated by the Commission shall:

\* \* \* \* \*

(c) Establish a process for registering fixed TVBDs and registering and including in the database facilities entitled to protection but not contained in a Commission database, including MVPD and TV translator receive sites.

(d) Establish a process for registering facilities where part 74 low power auxiliary stations are used on a regular basis.

(e) Provide accurate lists of available channels to fixed and personal/portable TVBDs that submit to it the information required under §§ 15.713(e), (f), and (g) based on their geographic location and provide accurate lists of available channels to fixed and Mode II devices requesting lists of available channels for Mode I devices. Database administrators may allow prospective operators of TV bands devices to query the database and determine whether there are vacant channels at a particular location.

(f) Establish protocols and procedures to ensure that all communications and interactions between the TV bands database and TVBDs are accurate and secure and that unauthorized parties cannot access or alter the database or the list of available channels sent to a TVBD consistent with the provisions of § 15.713(i).

\* \* \* \* \*

(h) Provide service for a five-year term. This term can be renewed at the Commission's discretion.

(i) Respond in a timely manner to verify, correct and/or remove, as appropriate, data in the event that the Commission or a party brings claim of inaccuracies in the database to its attention. This requirement applies only to information that the Commission requires to be stored in the database.

(j) Transfer its database along with the IP addresses and URLs used to access the database and list of registered Fixed TVBDs, to another designated entity in the event it does not continue as the database administrator at the end of its term. It may charge a reasonable price for such conveyance.

(k) The database must have functionality such that upon request from the Commission it can indicate that no channels are available when queried by a specific TVBD or model of TVBDs.

(l) If more than one database is developed, the database administrators shall cooperate to develop a standardized process for providing on a daily basis or more often, as appropriate, the data collected for the facilities listed in § 15.713(b)(2) to all other TV bands databases to ensure consistency in the records of protected facilities.

■ 14. Section 15.717 is revised to read as follows:

**§ 15.717 TVBDs that rely on spectrum sensing.**

(a) *Applications for certification.* Parties may submit applications for certification of TVBDs that rely solely on spectrum sensing to identify available channels. Devices authorized under this section must demonstrate with an extremely high degree of confidence that they will not cause harmful interference to incumbent radio services.

(1) In addition to the procedures in subpart J of part 2 of this chapter, applicants shall comply with the following.

(i) The application must include a full explanation of how the device will protect incumbent authorized services against interference.

(ii) Applicants must submit a pre-production device, identical to the device expected to be marketed.

(2) The Commission will follow the procedures below for processing applications pursuant to this section.

(i) Applications will be placed on public notice for a minimum of 30 days for comments and 15 days for reply comments. Applicants may request that portions of their application remain

confidential in accordance with § 0.459 of this chapter. This public notice will include proposed test procedures and methodologies.

(ii) The Commission will conduct laboratory and field tests of the pre-production device. This testing will be conducted to evaluate proof of performance of the device, including characterization of its sensing capability and its interference potential. The testing will be open to the public.

(iii) Subsequent to the completion of testing, the Commission will issue by public notice, a test report including recommendations. The public notice will specify a minimum of 30 days for comments and, if any objections are received, an additional 15 days for reply comments.

(b) *Power limit for devices that rely on sensing.* The TVBD shall meet the requirements for personal/portable devices in this subpart except that it will be limited to a maximum EIRP of 50 mW per 6 megahertz of bandwidth on which the device operates and it does not have to comply with the requirements for geo-location and database access in § 15.711(b). Compliance with the detection threshold for spectrum sensing in

§ 15.717(c), although required, is not necessarily sufficient for demonstrating reliable interference avoidance. Once a device is certified, additional devices that are identical in electrical characteristics and antenna systems may be certified under the procedures of Part 2, Subpart J of this chapter.

(c) *Sensing requirements.*

(1) *Detection threshold.*

(i) The required detection thresholds are:

(A) ATSC digital TV signals: -114 dBm, averaged over a 6 MHz bandwidth;

(B) NTSC analog TV signals: -114 dBm, averaged over a 100 kHz bandwidth;

(C) Low power auxiliary, including wireless microphone, signals: -107 dBm, averaged over a 200 kHz bandwidth.

(ii) The detection thresholds are referenced to an omnidirectional receive antenna with a gain of 0 dBi. If a receive antenna with a minimum directional gain of less than 0 dBi is used, the detection threshold shall be reduced by the amount in dB that the minimum directional gain of the antenna is less than 0 dBi. Minimum directional gain shall be defined as the antenna gain in

the direction and at the frequency that exhibits the least gain. Alternative approaches for the sensing antenna are permitted, e.g., electronically rotatable antennas, provided the applicant for equipment authorization can demonstrate that its sensing antenna provides at least the same performance as an omnidirectional antenna with 0 dBi gain.

(2) *Channel availability check time.* A TVBD may start operating on a TV channel if no TV, wireless microphone or other low power auxiliary device signals above the detection threshold are detected within a minimum time interval of 30 seconds.

(3) *In-service monitoring.* A TVBD must perform in-service monitoring of an operating channel at least once every 60 seconds. There is no minimum channel availability check time for in-service monitoring.

(4) *Channel move time.* After a TV, wireless microphone or other low power auxiliary device signal is detected on a TVBD operating channel, all transmissions by the TVBD must cease within two seconds.

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To designate the facility of the United States Postal Service located at 100 Broadway in Lynbrook, New York, as the "Navy Corpsman Jeffrey L. Wiener Post Office Building". (Nov. 30, 2010; 124 Stat. 3061)

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