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**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

**14 CFR Part 39**

**[Docket No. FAA–2008–1118; Directorate Identifier 2007–NM–318–AD; Amendment 39–16792; AD 2011–18–10]**

**RIN 2120–AA64**

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

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

**ACTION:** Final rule.

**SUMMARY:** We are superseding an existing airworthiness directive (AD) for the products listed above. The existing AD currently requires reviewing the airplane maintenance records to determine whether an engine has been removed from the airplane since the airplane was manufactured. For airplanes on which an engine has been removed, the existing AD also requires an inspection of the aft engine mount to determine if the center link assembly is correctly installed, and follow-on actions if necessary. This new AD expands the applicability to include airplanes on which the engine has not been previously removed, and Model 737–900ER airplanes. This AD was prompted by reports indicating that operators found that the center link assembly for the aft engine mount was reversed on several airplanes that had not had an engine removed since delivery. We are issuing this AD to prevent increased structural loads on the aft engine mount, which could result in failure of the aft engine mount and consequent separation of the engine from the airplane.

**DATES:** This AD is effective November 7, 2011.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in the AD as of November 7, 2011.

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

### Examining the AD Docket

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

**FOR FURTHER INFORMATION CONTACT:** Alan Pohl, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6450; fax (425) 917–6590.

**SUPPLEMENTARY INFORMATION:**

### Discussion

We issued a supplemental notice of proposed rulemaking (SNPRM) to amend 14 CFR part 39 to supersede airworthiness directive (AD) 2003–03–01, Amendment 39–13025 (68 FR 4367, January 29, 2003). That AD applies to the specified products. The SNPRM published in the **Federal Register** on January 11, 2011 (76 FR 1552). The original NPRM (73 FR 64568, October 30, 2008) proposed to continue to require reviewing the airplane maintenance records to determine whether an engine has been removed from the airplane since the airplane was manufactured. For airplanes on which an engine has been removed, the original NPRM also requires an inspection of the aft engine mount to determine if the center link assembly is correctly installed, and follow-on actions if necessary. The original NPRM also proposed to require those same actions on airplanes on which the engine has not previously been removed. The SNPRM proposed to further expand the applicability to include Model 737–900ER airplanes.

### Comments

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

### Supportive Comments

Boeing and Continental Airlines concur with the SNPRM (76 FR 1552, January 11, 2011).

### Request for Information

American Airlines stated that it has accomplished the actions required by AD 2003–03–01 (68 FR 4367, January 29, 2003) and the SNPRM (76 FR 1552, January 11, 2011), and although it will no longer be affected by the requirements in the SNPRM, asked the following questions:

- What action has the original equipment manufacturer, Boeing, taken to prevent incorrect aft mount assembly installations?
- Can Boeing specifically identify the procedures and/or best practices incorporated into their production process to prevent a recurrence of this type of event?

We acknowledge the commenter's concerns and provide the following responses:

- Boeing Alert Service Bulletin 737–71A1462, Revision 2, dated May 29, 2003; and Revision 3, dated May 20, 2004; specify marking of the hangar fitting (pylon structure) and center link (engine structure) assembly, which is the same as the marking incorporated previously in production. These marks ''L,'' ''AFT,'' and ''R,'' applied to both the hangar fitting and center link assembly will only be in close proximity if the center link is installed correctly.
- Boeing has advised us that it has revised the instructions in its component maintenance manuals

(assembly level) and aircraft maintenance manuals (installation level) to put special emphasis on the center link installation. Boeing also advised us that it implemented drawing changes affecting both production assembly and field installation of this part; these changes incorporated specific markings on both the center link assembly and the hanger fitting to which it is attached. Boeing noted that after 2003 the parts were marked with an ''L'' and ''R'' (left and right) to indicate the part orientation when assembled, and the hanger assembly was marked with 'AFT' at the center line. Boeing has also developed a shop aid for use at the facility where the parts are fabricated and assembled which helps the assembler confirm the correct orientation of the parts. We have made no change to the AD in this regard.

**Conclusion**

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

**Costs of Compliance**

We estimate that this AD affects 854 airplanes of U.S. registry. There are no new requirements in this AD; however, we have expanded the applicability of this AD. The current costs for this AD are recalculated for the convenience of affected operators, as follows:

ESTIMATED COSTS

| Action | Work hours | Parts | Cost per airplane | Fleet cost |
|---|---|---|---|---|
| Maintenance records review (required by AD 2003–03–01, Amendment 39–13025 (68 FR 4367, January 29, 2003)) | 1 | $0 | $85 | $72,590 |
| Inspection for correct installation of center link assembly (new required action) | 1 | 0 | 85 | 72,590 |

**Authority for This Rulemaking**

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

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

**Regulatory Findings**

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

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

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

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

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

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

**List of Subjects in 14 CFR Part 39**

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

**Adoption of the Amendment**

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

## PART 39—AIRWORTHINESS DIRECTIVES

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

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

**§ 39.13 [Amended]**

■ 2. The FAA amends § 39.13 by removing airworthiness directive (AD) 2003–03–01, Amendment 39–13025 (68 FR 4367, January 29, 2003), and by adding the following new AD:

**2011–18–10 The Boeing Company:** Amendment 39–16792; Docket No. FAA–2008–1118; Directorate Identifier 2007–NM–318–AD.

**Effective Date**

(a) This AD is effective November 7, 2011.

**Affected ADs**

(b) This AD supersedes AD 2003–03–01, Amendment 39–13025 (68 FR 4367, January 29, 2003).

**Applicability**

(c) This AD applies to all The Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes, certificated in any category.

**Subject**

(d) Air Transport Association (ATA) of America Code 71: Powerplant.

**Unsafe Condition**

(e) This AD was prompted by reports indicating that operators found that the center link assembly for the aft engine mount was reversed on several airplanes that had not had an engine removed since delivery. We are issuing this AD to prevent increased structural loads on the aft engine mount, which could result in failure of the aft engine mount and consequent separation of the engine from the airplane.

**Compliance**

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

**Restatement of Requirements of AD 2003–03–01 (68 FR 4367, January 29, 2003): Review of Maintenance Records**

(g) For Model 737–600, –700, –700C, –800, and –900 series airplanes: Within 90 days after February 13, 2003 (the effective date of AD 2003–03–01 (68 FR 4367, January 29, 2003)), review the airplane maintenance records to determine whether either engine has been removed since the airplane's date of manufacture. If neither engine has been removed since the airplane's date of manufacture, no further action is required by this paragraph.

**Inspection of Engines That Have Been Removed To Determine If Center Link Assembly Is Installed Correctly**

(h) For Model 737–600, –700, –700C, –800, and –900 series airplanes on which any installed engine has been removed from the airplane since the airplane's date of manufacture: Within 90 days after February 13, 2003, do a one-time general visual inspection to determine if the center link

assembly of the aft engine mount is installed correctly, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–71A1462, Revision 1, dated November 7, 2002; or Revision 3, dated May 20, 2004. If the center link assembly is installed correctly, no further action is required by paragraph (h) or (i) of this AD for that engine. As of the effective date of this AD, use only Boeing Alert Service Bulletin 737–71A1462, Revision 3, dated May 20, 2004.

**Note 1:** For the purposes of this AD, a general visual inspection is: ''A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made from within touching distance unless otherwise specified. A mirror may be necessary to ensure visual access to all surfaces in the inspection area. This level of inspection is made under normally available lighting conditions such as daylight, hanger lighting, flashlight, or droplight and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked.''

**Follow-On and Corrective Actions**

(i) For airplanes on which any center link assembly is found installed incorrectly during any inspection required by paragraph (h), (k), or (l) of this AD: Before further flight, do the actions specified in paragraphs (i)(1), (i)(2), and (i)(3) of this AD, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–71A1462, Revision 1, dated November 7, 2002; or Revision 3, dated May 20, 2004; except that it is not necessary to submit a report of findings to the airplane manufacturer. As of the effective date of this AD, use only Boeing Alert Service Bulletin 737–71A1462, Revision 3, dated May 20, 2004.

(1) Remove the center link assembly and install it correctly.

(2) Perform a detailed inspection of the engine mounting lugs and engine turbine rear frame for cracking, yielding, buckling, or wear damage.

(3) Perform a detailed inspection of the hardware for the aft engine mount; including the center link assembly, right link assembly, aft mount hanger assembly, and link pins; for cracking, yielding, buckling, or wear damage.

**Note 2:** For the purposes of this AD, a detailed inspection is: ''An intensive examination of a specific item, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at an intensity deemed appropriate. Inspection aids such as mirror, magnifying lenses, etc., may be necessary. Surface cleaning and elaborate procedures may be required.''

**Repair**

(j) If any cracking, yielding, buckling, or wear damage is found during the inspections required by paragraphs (i)(2) and (i)(3) of this AD: Before further flight, replace the discrepant part with a new or serviceable part, or repair in accordance with a method approved in accordance with the procedures specified in paragraph (o) of this AD.

**New Requirements of This AD**

**Inspection of Engines That Have Not Been Removed To Determine If Center Link Assembly Is Installed Correctly**

(k) For airplanes identified in Boeing Alert Service Bulletin 737–71A1462, Revision 3, dated May 20, 2004, on which any installed engine has not been removed from the airplane since the airplane's date of manufacture: Within 90 days after the effective date of this AD, do a detailed inspection to determine if the center link assembly of the aft engine mount is installed correctly, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–71A1462, Revision 3, dated May 20, 2004. If the center link is installed correctly, no further action is required by this paragraph for that engine.

**Follow-On and Corrective Actions**

(l) For airplanes on which any center link assembly is found installed incorrectly during the inspection required by paragraph (k) of this AD: Before further flight, do the follow-on and corrective actions required by paragraph (i) of this AD.

**Credit for Actions Done Using Previous Service Information**

(m) Inspections and corrective actions done before the effective date of this AD in accordance with a Boeing service bulletin listed in Table 1 of this AD are acceptable for compliance with the corresponding requirements of this AD.

TABLE 1—PREVIOUS SERVICE BULLETINS

| Boeing Alert Service Bulletin— | Revision— | Dated— |
|---|---|---|
| 737–71A1462 | Original | August 29, 2002. |
| 737–71A1462 | 1 | November 7, 2002. |
| 737–71A1462 | 2 | May 29, 2003. |

**Parts Installation**

(n) As of the effective date of this AD, no person may install an engine on any airplane identified in paragraph (c) of this AD unless the actions required by paragraph (n)(1) or (n)(2) of this AD are accomplished.

(1) The inspection is accomplished in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–71A1462, Revision 3, dated May 20, 2004, and the center link assembly of the aft engine mount is found to be installed correctly.

(2) The hanger fitting and center link assembly are marked and part marked in accordance with Part 2 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–71A1462, Revision 3, dated May 20, 2004.

**Note 3:** For hanger fittings and center link assemblies marked and part marked in production, as specified in Part 2 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–71A1462, Revision 3, dated May 20, 2004, the actions specified in paragraph (n)(2) of this AD do not apply.

**Alternative Methods of Compliance (AMOCs)**

(o) The certification office specified in paragraph (o)(1) or (o)(2) of this AD, as applicable, has the authority to approve AMOCs for paragraphs (i) and (j) of this AD, if requested using the procedures found in 14 CFR 39.19.

(1) For the structure identified in paragraph (i)(2) of this AD: The Manager, Engine Certification Office (ECO), FAA. Send information to ATTN: Antonio Cancelliere, Aerospace Engineer, ANE–141, FAA, ECO, 12 New England Executive Park, Burlington, Massachusetts 01803–5299; telephone 781–238–7751; fax 781–238–7199.

(2) For the structure identified in paragraph (i)(3) of this AD: The Manager, Seattle Aircraft Certification Office (ACO), FAA. Send information to ATTN: Alan Pohl, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle ACO, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6450; fax (425) 917–6590. Information may be e-mailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(3) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(4) An AMOC that provides an acceptable level of safety may be used for any repair required by paragraph (i)(3) of this AD if it is approved by Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

**Material Incorporated by Reference**

(p) You must use Boeing Alert Service Bulletin 737–71A1462, Revision 3, dated

May 20, 2004, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of Boeing Alert Service Bulletin 737–71A1462, Revision 3, dated May 20, 2004, under 5 U.S.C. 552(a) and 1 CFR part 51.

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

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

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

Issued in Renton, Washington on September 8, 2011.

**Ali Bahrami,**

*Manager, Transport Airplane Directorate, Aircraft Certification Service.*

**Peter A. White,**

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

[FR Doc. 2011–24681 Filed 9–30–11; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

**[Docket No. FAA–2011–0646; Directorate Identifier 2010–NM–224–AD; Amendment 39–16814; AD 2011–20–04]**

**RIN 2120–AA64**

## Airworthiness Directives; Gulfstream Aerospace LP Model Galaxy and Gulfstream 200 Airplanes

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

**ACTION:** Final rule.

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

Cracked nuts * * * were found on aircraft's production line during routine post assembly inspection. Investigation revealed that the cracks resulted from hydrogen embrittlement combined with high hardness. Non-conformity with certified mechanical properties of this fastener can potentially lead to an unsafe condition.

The unsafe condition is cracked nuts in multiple locations (including aileron fittings, rudder tab assembly and mounting structure for power drive units) could result in failure of affected locations and consequent reduced controllability or reduced structural capability of the airplane. We are issuing this AD to require actions to correct the unsafe condition on these products.

**DATES:** This AD becomes effective November 7, 2011.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of November 7, 2011.

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

**FOR FURTHER INFORMATION CONTACT:** Mike Borfitz, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–2677; fax (425) 227–1149.

**SUPPLEMENTARY INFORMATION:**

### Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on June 29, 2011 (76 FR 38062). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

> Cracked nuts (P/N [part number] MS–21042L3) were found on aircraft's production line during routine post assembly inspection. Investigation revealed that the cracks resulted from hydrogen embrittlement combined with high hardness. Non-conformity with certified mechanical properties of this fastener can potentially lead to an unsafe condition.

The unsafe condition of cracked nuts in multiple locations (including aileron fittings, rudder tab assembly and mounting structure for power drive units) could result in failure of affected locations and consequent reduced controllability or reduced structural capability of the airplane. The required actions include replacing nuts having P/N MS21042L3, and in certain locations, a one time radiographic inspection for cracked nuts and replacing any cracked nuts. You may obtain further information by examining the MCAI in the AD docket.

### Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM (76 FR 38062, June 29, 2011) or on the determination of the cost to the public.

### Conclusion

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

### Differences Between This AD and the MCAI or Service Information

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

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

### Costs of Compliance

We estimate that this AD will affect 2 products of U.S. registry. We also estimate that it will take about 227 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour. Required parts will cost about $0 per product. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these parts. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here. Based on these figures, we estimate the cost of this AD to the U.S. operators to be $38,590, or $19,295 per product.

### Authority for This Rulemaking

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

detail the scope of the Agency's authority.

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

**Regulatory Findings**

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

For the reasons discussed above, I certify this AD:

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

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

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

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

**Examining the AD Docket**

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM (76 FR 38062, June 29, 2011), the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

**List of Subjects in 14 CFR Part 39**

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

**Adoption of the Amendment**

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

## PART 39—AIRWORTHINESS DIRECTIVES

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

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

**§ 39.13 [Amended]**

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

**2011–20–04 Gulfstream Aerospace LP:** Amendment 39–16814. Docket No. FAA–2011–0646; Directorate Identifier 2010–NM–224–AD.

**Effective Date**

(a) This airworthiness directive (AD) becomes effective November 7, 2011.

**Affected ADs**

(b) None.

**Applicability**

(c) This AD applies to Gulfstream Aerospace LP Model Galaxy and Gulfstream 200 airplanes, certificated in any category, serial numbers 219 through 231 inclusive.

**Subject**

(d) Air Transport Association (ATA) of America Code 51: Standard Practices/Structures.

**Reason**

(e) The mandatory continuing airworthiness information (MCAI) states:

Cracked nuts * * * were found on aircraft's production line during routine post assembly inspection. Investigation revealed that the cracks resulted from hydrogen embrittlement combined with high hardness. Non-conformity with certified mechanical properties of this fastener can potentially lead to an unsafe condition.

The unsafe condition is cracked nuts in multiple locations (including aileron fittings, rudder tab assembly and mounting structure for power drive units) could result in failure of affected locations and consequent reduced controllability or reduced structural capability of the airplane.

**Compliance**

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

**Actions**

(g) Within 12 months after the effective date of this AD, do the applicable actions specified in paragraphs (g)(1) and (g)(2) of this AD, in accordance with the Accomplishment Instructions in Gulfstream Service Bulletin 200–51–366, dated March 30, 2010, including Appendix A: Israel Aircraft Industries Document IS951400E, Radiographic Inspection of Self-Locking Nut P/N MS21042L3, Revision A, dated January 25, 2010.

(1) For all airplanes: Replace nuts having part number (P/N) MS21042L3 in the applicable areas identified in Steps 4, 5, 6, and 7 of the Accomplishment Instructions of Gulfstream Service Bulletin 200–51–366, dated March 30, 2010, including Appendix A: Israel Aircraft Industries Document IS951400E, Radiographic Inspection of Self-Locking Nut P/N MS21042L3, Revision A, dated January 25, 2010.

(2) For airplanes having serial numbers 224 through 231 inclusive: Do the actions in paragraphs (g)(2)(i) and (g)(2)(ii).

(i) Replace nuts having P/N MS21042L3 at the location specified in Step 8.H. of the Accomplishment Instructions of Gulfstream Service Bulletin 200–51–366, dated March 30, 2010, including Appendix A: Israel Aircraft Industries Document IS951400E, Radiographic Inspection of Self-Locking Nut P/N MS21042L3, Revision A, dated January 25, 2010.

(ii) Do a radiographic inspection for cracking of nuts having P/N MS21042L3 at the location specified in Step 8.J. of the Accomplishment Instructions of Gulfstream Service Bulletin 200–51–366, dated March 30, 2010, including Appendix A: Israel Aircraft Industries Document IS951400E, Radiographic Inspection of Self-Locking Nut P/N MS21042L3, Revision A, dated January 25, 2010. Before further flight replace all cracked nuts.

**FAA AD Differences**

**Note 1:** This AD differs from the MCAI and/or service information as follows: No differences.

**Other FAA AD Provisions**

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

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Mike Borfitz, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–2677; fax (425) 227–1149. Information may be e-mailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

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

**Related Information**

(i) Refer to MCAI Civil Aviation Authority of Israel (CAAI) Airworthiness Directive 57–10–06–18, dated July 27, 2010; and Gulfstream Service Bulletin 200–51–366, dated March 30, 2010, including Appendix A: Israel Aircraft Industries Document IS951400E, Radiographic Inspection of Self-Locking Nut P/N MS21042L3, Revision A, dated January 25, 2010; for related information.

**Material Incorporated by Reference**

(j) You must use Gulfstream Service Bulletin 200–51–366, dated March 30, 2010, including Appendix A: Israel Aircraft Industries Document IS951400E, Radiographic Inspection of Self-Locking Nut P/N MS21042L3, Revision A, dated January 25, 2010, to do the actions required by this AD, unless the AD specifies otherwise. The document number specified on pages 1 through 14 of Appendix A of this document is identified as ''IS951400.''

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

(2) For service information identified in this AD, contact Gulfstream Aerospace Corporation, P.O. Box 2206, Mail Station D–25, Savannah, Georgia 31402–2206; telephone 800–810–4853; fax 912–965–3520; e-mail pubs@gulfstream.com; Internet *http://www.gulfstream.com/product_support/technical_pubs/pubs/index.htm.*

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

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

Issued in Renton, Washington on September 16, 2011.

**Ali Bahrami,**

*Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 2011–24683 Filed 9–30–11; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 97

**[Docket No. 30803; Amdt. No. 3444]**

## Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

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

**ACTION:** Final rule.

**SUMMARY:** This establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

**DATES:** This rule is effective October 3, 2011. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 3, 2011.

**ADDRESSES:** Availability of matters incorporated by reference in the amendment is as follows:

*For Examination—*

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;

2. The FAA Regional Office of the region in which the affected airport is located;

3. The National Flight Procedures Office, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

*Availability*—All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit *http://www.nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

**FOR FURTHER INFORMATION CONTACT:** Richard A. Dunham III, Flight Procedure Standards Branch (AFS–420), Flight Technologies and Programs Divisions, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082, Oklahoma City, OK 73125) *Telephone:* (405) 954–4164.

**SUPPLEMENTARY INFORMATION:** This rule amends Title 14 of the Code of Federal Regulations, Part 97 (14 CFR part 97), by establishing, amending, suspending, or revoking SIAPS, Takeoff Minimums and/or ODPS. The complete regulators description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR part 97.20. The applicable FAA Forms are FAA Forms 8260–3, 8260–4, 8260–5, 8260–15A, and 8260–15B when required by an entry on 8260–15A.

The large number of SIAPs, Takeoff Minimums and ODPs, in addition to their complex nature and the need for a special format make publication in the **Federal Register** expensive and impractical. Furthermore, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their depiction on charts printed by publishers of aeronautical materials. The advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA forms is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAPs and the effective dates of the, associated Takeoff Minimums and ODPs. This amendment also identifies the airport and its location, the procedure, and the amendment number.

**The Rule**

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as contained in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPS and Takeoff

Minimums and ODPS, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPS contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPS and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedures before adopting these SIAPS, Takeoff Minimums and ODPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

**Conclusion**

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule '' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26,1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

**List of Subjects in 14 CFR Part 97**

Air traffic control, Airports, Incorporation by reference, and Navigation (air).

Issued in Washington, DC, on September 16, 2011.

**Ray Towles,**

*Deputy Director, Flight Standards Service.*

**Adoption of the Amendment**

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures and/or Takeoff Minimums and/or Obstacle Departure Procedures effective at 0902 UTC on the dates specified, as follows:

## PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

**Effective 20 OCT 2011**

West Memphis, AR, West Memphis Muni, ILS OR LOC RWY 17, Amdt 5
Windsor Locks, CT, Bradley Intl, ILS OR LOC RWY 6, ILS RWY 6 (SA CAT I), ILS RWY 6 (CAT II), ILS RWY 6 (CAT III), Amdt 37
Windsor Locks, CT, Bradley Intl, ILS OR LOC RWY 24, ILS RWY 24 (SA CAT I), ILS RWY 24 (SA CAT II), Amdt 12
Windsor Locks, CT, Bradley Intl, ILS OR LOC RWY 33, Amdt 10
Windsor Locks, CT, Bradley Intl, RNAV (GPS) Y RWY 6, Amdt 2
Windsor Locks, CT, Bradley Intl, RNAV (GPS) Y RWY 15, Amdt 2
Windsor Locks, CT, Bradley Intl, RNAV (GPS) Y RWY 24, Amdt 3
Windsor Locks, CT, Bradley Intl, RNAV (GPS) Y RWY 33, Amdt 2
Windsor Locks, CT, Bradley Intl, RNAV (RNP) Z RWY 6, Orig
Windsor Locks, CT, Bradley Intl, RNAV (RNP) Z RWY 24, Orig
Windsor Locks, CT, Bradley Intl, VOR OR TACAN RWY 6, Orig-B, CANCELLED
Windsor Locks, CT, Bradley Intl, VOR OR TACAN RWY 15, Amdt 2A, CANCELLED
Windsor Locks, CT, Bradley Intl, VOR OR TACAN RWY 24, Orig-A, CANCELLED
Windsor Locks, CT, Bradley Intl, VOR OR TACAN RWY 33, Orig-C, CANCELLED
Wilmington, DE, New Castle, ILS OR LOC RWY 1, Amdt 23
Daytona Beach, FL, Daytona Beach Intl, ILS OR LOC RWY 25R, Orig
Daytona Beach, FL, Daytona Beach Intl, LOC BC RWY 25R, Amdt 16, CANCELLED
Daytona Beach, FL, Daytona Beach Intl, RNAV (GPS) RWY 25R, Amdt 3
Fitzgerald, GA, Fitzgerald Muni, Takeoff Minimums and Obstacle DP, Amdt 1
Greenfield, IA, Greenfield Muni, NDB OR GPS RWY 32, Amdt 1, CANCELLED
Lamoni, IA, Lamoni Muni, Takeoff Minimums and Obstacle DP, Orig
Driggs, ID, Driggs-Reed Memorial, RNAV (GPS) RWY 3, Amdt 1A, CANCELLED
Driggs, ID, Driggs-Reed Memorial, RNAV (GPS) RWY 3, Orig
Carmi, IL, Carmi Muni, GPS RWY 36, Orig-A, CANCELLED
Carmi, IL, Carmi Muni, RNAV (GPS) RWY 36, Orig
Carmi, IL, Carmi Muni, Takeoff Minimums and Obstacle DP, Amdt 2
Belleville, KS, Belleville Muni, NDB RWY 18, Amdt 5
Belleville, KS, Belleville Muni, NDB RWY 36, Amdt 5
Belleville, KS, Belleville Muni, RNAV (GPS) RWY 18, Orig
Belleville, KS, Belleville Muni, RNAV (GPS) RWY 36, Orig
Belleville, KS, Belleville Muni, Takeoff Minimums and Obstacle DP, Orig
Ottawa, KS, Ottawa Muni, GPS RWY 17, Orig-A, CANCELLED
Ottawa, KS, Ottawa Muni, GPS RWY 35, Orig, CANCELLED
Ottawa, KS, Ottawa Muni, RNAV (GPS) RWY 17, Orig
Ottawa, KS, Ottawa Muni, RNAV (GPS) RWY 35, Orig
Ottawa, KS, Ottawa Muni, Takeoff Minimums and Obstacle DP, Amdt 1
Topeka, KS, Forbes Field, NDB RWY 13, Amdt 7
Abbeville, LA, Abbeville Chris Crusta Memorial, LOC RWY 16, Orig
Great Barrington, MA, Walter J. Koladza, NDB–A, Amdt 6
Gladwin, MI, Gladwin Zettel Memorial, Takeoff Minimums and Obstacle DP, Amdt 3
Hastings, MI, Hastings, RNAV (GPS) RWY 12, Orig
Hastings, MI, Hastings, RNAV (GPS) RWY 30, Orig
Hannibal, MO, Hannibal Rgnl, NDB RWY 35, Amdt 4, CANCELLED
Salem, MO, Salem Memorial, Takeoff Minimums and Obstacle DP, Orig
Wayne, NE, Wayne Muni/Stan Morris Field, RNAV (GPS) RWY 18, Amdt 2
Wayne, NE, Wayne Muni/Stan Morris Field, RNAV (GPS) RWY 23, Amdt 1
Wayne, NE, Wayne Muni/Stan Morris Field, RNAV (GPS) RWY 36, Amdt 2
Morristown, NJ, Morristown Muni, Takeoff Minimums and Obstacle DP, Amdt 6
Pedricktown, NJ, Spitfire Aerodrome, Takeoff Minimums and Obstacle DP, Amdt 1
New York, NY, John F. Kennedy Intl, Takeoff Minimums and Obstacle DP, Amdt 8
New York, NY, La Guardia, Takeoff Minimums and Obstacle DP, Amdt 9
Memphis, TN, Memphis Intl, Takeoff Minimums and Obstacle DP, Amdt 3
Dallas, TX, Dallas-Love Field, Takeoff Minimums and Obstacle DP, Amdt 16
Laredo, TX, Laredo Intl, ILS OR LOC/DME RWY 17R, Amdt 11
Laredo, TX, Laredo Intl, RNAV (GPS) RWY 17R, Amdt 1
Laredo, TX, Laredo Intl, Takeoff Minimums and Obstacle DP, Amdt 4
Palacios, TX, Palacios Muni, Takeoff Minimums and Obstacle DP, Orig
Sweetwater, TX, Avenger Field, NDB RWY 17, Amdt 4
Sweetwater, TX, Avenger Field, RNAV (GPS) RWY 4, Orig
Sweetwater, TX, Avenger Field, RNAV (GPS) RWY 17, Orig
Sweetwater, TX, Avenger Field, RNAV (GPS) RWY 22, Orig
Sweetwater, TX, Avenger Field, RNAV (GPS) RWY 35, Orig
Richlands, VA, Tazewell County, LOC/DME RWY 25, Amdt 1
Richlands, VA, Tazewell County, RNAV (GPS) RWY 25, Amdt 1
Milwaukee, WI, General Mitchell Intl, ILS OR LOC RWY 7R, Amdt 16
Milwaukee, WI, General Mitchell Intl, LOC RWY 25L, Amdt 5
Milwaukee, WI, General Mitchell Intl, RNAV (GPS) RWY 7R, Amdt 1
Milwaukee, WI, General Mitchell Intl, RNAV (GPS) RWY 19R, Amdt 2
Milwaukee, WI, General Mitchell Intl, RNAV (GPS) RWY 25L, Amdt 1

New Holstein, WI, New Holstein Muni, RNAV (GPS) RWY 14, Orig
New Holstein, WI, New Holstein Muni, RNAV (GPS) RWY 32, Orig
New Holstein, WI, New Holstein Muni, Takeoff Minimums and Obstacle DP, Orig
New Holstein, WI, New Holstein Muni, VOR/DME–A, Amdt 2

RESCINDED: On September 15, 2011 (76 FR 56970), the FAA published an Amendment in Docket No. 30801, Amdt No. 3442 to Part 97 of the Federal Aviation Regulations under section 97.25. The following entry, effective September 22, 2011, is hereby rescinded in its entirety:

Abbeville, LA, Abbeville Chris Crusta Memorial, LOC RWY 16, Orig

[FR Doc. 2011–24724 Filed 9–30–11; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 97

**[Docket No. 30804; Amdt. No. 3445]**

## Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

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

**ACTION:** Final rule.

**SUMMARY:** This rule establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

**DATES:** This rule is effective October 3, 2011. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 3, 2011.

**ADDRESSES:** Availability of matter incorporated by reference in the amendment is as follows:

*For Examination*—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;

2. The FAA Regional Office of the region in which the affected airport is located;

3. The National Flight Procedures Office, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

*Availability*—All SIAPs are available online free of charge. Visit *http://nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

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

**SUPPLEMENTARY INFORMATION:** This rule amends Title 14, Code of Federal Regulations, part 97 (14 CFR part 97) by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (FDC)/Permanent Notice to Airmen (P–NOTAM), and is incorporated by reference in the amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of Title 14 of the Code of Federal Regulations.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAP and the corresponding effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

### The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP as modified by FDC/P–NOTAMs.

The SIAPs, as modified by FDC P–NOTAM, and contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for all these SIAP amendments requires making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making these SIAPs effective in less than 30 days.

### Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

### List of Subjects in 14 CFR Part 97

Air traffic control, Airports, Incorporation by reference, and Navigation (air).

Issued in Washington, DC on September 16, 2011.

**Ray Towles,**

*Deputy Director, Flight Standards Service.*

### Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97, 14 CFR part 97, is amended by amending Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

## PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

**§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33 and 97.35 [Amended]**

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

** * * Effective Upon Publication*

| AIRAC date | State | City | Airport | FDC No. | FDC Date | Subject |
|---|---|---|---|---|---|---|
| 20–Oct–11 .... | NJ | Readington ..... | Solberg-Hunterdon ..... | 1/0833 | 9/1/11 | RNAV (GPS) RWY 4, Orig |
| 20–Oct–11 .... | NJ | Readington ..... | Solberg-Hunterdon ..... | 1/0834 | 9/1/11 | RNAV (GPS) RWY 22, Orig |
| 20–Oct–11 .... | NJ | Readington ..... | Solberg-Hunterdon ..... | 1/0835 | 9/1/11 | VOR RWY 4, Amdt 1 |
| 20–Oct–11 .... | NJ | Readington ..... | Solberg-Hunterdon ..... | 1/0836 | 9/1/11 | VOR A, Amdt 9 |
| 20–Oct–11 .... | TX | Brownsville ..... | Brownsville/South Padre Island Intl. | 1/1141 | 9/8/11 | VOR/DME RNAV OR GPS RWY 35, Amdt 3 |
| 20–Oct–11 .... | TX | Brownsville ..... | Brownsville/South Padre Island Intl. | 1/1142 | 9/8/11 | VOR OR TACAN OR GPS A, Amdt 1A |
| 20–Oct–11 .... | TX | Brownsville ..... | Brownsville/South Padre Island Intl. | 1/1143 | 9/8/11 | LOC BC RWY 31L, Amdt 11B |
| 20–Oct–11 .... | AL | Bay Minette ..... | Bay Minette Muni ..... | 1/1453 | 9/1/11 | RNAV (GPS) RWY 26, Orig-B |
| 20–Oct–11 .... | IL | Marion ..... | Williamson County Rgnl ..... | 1/2688 | 9/1/11 | RNAV (GPS) RWY 2, Orig |
| 20–Oct–11 .... | IL | Marion ..... | Williamson County Rgnl ..... | 1/2689 | 9/1/11 | RNAV (GPS) RWY 20, Orig |
| 20–Oct–11 .... | IL | Marion ..... | Williamson County Rgnl ..... | 1/2690 | 9/1/11 | VOR RWY 2, Amdt 13 |
| 20–Oct–11 .... | IL | Marion ..... | Williamson County Rgnl ..... | 1/2691 | 9/1/11 | NDB RWY 20, Amdt 10 |
| 20–Oct–11 .... | IL | Marion ..... | Williamson County Rgnl ..... | 1/2692 | 9/1/11 | VOR RWY 20, Amdt 17 |
| 20–Oct–11 .... | NY | Albany ..... | Albany Intl ..... | 1/3420 | 9/1/11 | ILS OR LOC RWY 1, Amdt 11 ; ILS RWY 1 (SA CAT II), Amdt 11 |
| 20–Oct–11 .... | FL | Tallahassee ..... | Tallahassee Rgnl ..... | 1/3426 | 9/1/11 | RADAR–1, Amdt 5A |
| 20–Oct–11 .... | MA | Nantucket ..... | Nantucket Memorial ..... | 1/4378 | 9/1/11 | RNAV (GPS) RWY 24, Orig |
| 20–Oct–11 .... | MA | Nantucket ..... | Nantucket Memorial ..... | 1/4379 | 9/1/11 | ILS OR LOC RWY 6, Amdt 1 |
| 20–Oct–11 .... | MA | Nantucket ..... | Nantucket Memorial ..... | 1/4380 | 9/1/11 | ILS OR LOC RWY 24, Amdt 15E |
| 20–Oct–11 .... | MA | Nantucket ..... | Nantucket Memorial ..... | 1/4381 | 9/1/11 | RNAV (GPS) RWY 6, Orig |
| 20–Oct–11 .... | MA | Nantucket ..... | Nantucket Memorial ..... | 1/4382 | 9/1/11 | VOR RWY 24, Amdt 14 |
| 20–Oct–11 .... | WI | Milwaukee ..... | Milwaukee/Lawrence J. Timmerman. | 1/4409 | 9/1/11 | RNAV (GPS) RWY 4L, Orig |
| 20–Oct–11 .... | WI | Milwaukee ..... | Milwaukee/Lawrence J. Timmerman. | 1/4410 | 9/1/11 | RNAV (GPS) RWY 22R, Orig |
| 20–Oct–11 .... | IN | Gary ..... | Gary/Chicago Intl ..... | 1/4565 | 9/8/11 | NDB OR GPS RWY 30, Amdt 7B |
| 20–Oct–11 .... | NY | New York ..... | La Guardia ..... | 1/5043 | 9/1/11 | ILS OR LOC RWY 22, Amdt 20; ILS RWY 22 (SA CAT I), Amdt 20; ILS RWY 22 (SA CAT II), Amdt 20 |
| 20–Oct–11 .... | IL | Mount Vernon ..... | Mount Vernon ..... | 1/7201 | 9/8/11 | RNAV (GPS) RWY 5, Orig |
| 20–Oct–11 .... | IL | Mount Vernon ..... | Mount Vernon ..... | 1/7202 | 9/8/11 | RNAV (GPS) RWY 23, Orig |
| 20–Oct–11 .... | IL | Mount Vernon ..... | Mount Vernon ..... | 1/7233 | 9/8/11 | VOR RWY 5, Amdt 16B |
| 20–Oct–11 .... | IL | Mount Vernon ..... | Mount Vernon ..... | 1/7270 | 9/8/11 | VOR RWY 23, Amdt 16 |
| 20–Oct–11 .... | IA | Pocahontas ..... | Pocahontas Muni ..... | 1/7324 | 9/8/11 | RNAV (GPS) RWY 12, Orig |
| 20–Oct–11 .... | IA | Pocahontas ..... | Pocahontas Muni ..... | 1/7325 | 9/8/11 | NDB RWY 12, Amdt 5 |
| 20–Oct–11 .... | TX | Dallas ..... | Dallas Executive ..... | 1/8190 | 8/25/11 | ILS OR LOC RWY 31, Amdt 8A |

[FR Doc. 2011–24720 Filed 9–30–11; 8:45 am]

**BILLING CODE 4910–13–P**

**DEPARTMENT OF COMMERCE**

**International Trade Administration**

**19 CFR Part 351**

**[Docket No. 110420253–1577–02]**

**RIN 0625–AA88**

## Modification of Regulations Regarding the Practice of Accepting Bonds During the Provisional Measures Period in Antidumping and Countervailing Duty Investigations

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**ACTION:** Final rule.

**SUMMARY:** The Department of Commerce (the Department) is amending its regulations governing the effect of an affirmative preliminary determination in antidumping or countervailing duty proceedings to establish that the provisional measures will normally take the form of a cash deposit. Requiring that provisional measures will normally take the form of a cash deposit will help to strengthen the administration of the nation's antidumping (AD) and countervailing duty (CVD) laws by making importers directly responsible for the payment of AD and CVD duties.

**DATES:** This Final Rule is effective November 2, 2011. This rule will apply to all investigations initiated on the basis of petitions filed on or after this effective date.

**FOR FURTHER INFORMATION CONTACT:** Thomas Futtner at (202) 482–3814, Mark Ross at (202) 482–4794, or Joanna Theiss at (202) 482–5052.

**SUPPLEMENTARY INFORMATION:**

### Background

On April 26, 2011, the Department published a proposed modification to its regulations regarding the practice of accepting bonds during the provisional measures period in AD and CVD investigations. *See Modification of Regulations Regarding the Practice of Accepting Bonds During the Provisional Measures Period in Antidumping and Countervailing Duty Investigations,* 76 FR 23225 (April 26, 2011) (Proposed Rule). The Proposed Rule explained the Department's proposal to modify its regulations to establish that the provisional measures during an AD or CVD investigation will normally take the form of a cash deposit. The Department received numerous comments on the Proposed Rule and has addressed these comments below. The Proposed Rule, comments received, and this Final Rule can be accessed using the Federal eRulemaking Portal at *http://www.Regulations.gov* under Docket Number ITA–2011–0005. After analyzing and carefully considering all of the comments that the Department received in response to the Proposed Rule, the Department has adopted the modification and amended its regulations to establish that the provisional measures during an AD or CVD investigation will normally take the form of a cash deposit.

### Explanation of Regulatory Provision

Our regulations describe the preliminary determination in AD and CVD investigations as the first point at which the Department may provide a remedy if we preliminarily find that dumping or countervailable subsidization has occurred. The regulations at 19 CFR 351.205(a) stated that, ''[t]he remedy (sometimes referred to as 'provisional measures') usually takes the form of a bonding requirement to ensure payment if antidumping or countervailing duties ultimately are imposed.'' Section 351.205(d) of the Department's regulations states that, ''[i]f the preliminary determination is affirmative, the Secretary will take the actions described in section 703(d) or section 733(d) (whichever is applicable).''

The provisional measures period is the period between the publication of the Department's preliminary affirmative determination and the earlier of (1) The expiration of the applicable time period set forth in sections 703(d) and 733(d) of the Tariff Act of 1930, as amended (the Act), or (2) the publication of the International Trade Commission (Commission)'s final affirmative injury determination.[1] During this time the Department is instructed by the Act to order ''the posting of a cash deposit, bond, or other security, as the administering authority deems appropriate.'' *See* Sections 703(d)(1)(B) and 733(d)(1)(B) of the Act.

Requiring that provisional measures will normally take the form of a cash deposit will help to strengthen the administration of the nation's AD and CVD laws by making importers directly responsible for the payment of AD and CVD duties. This change will help to ensure that the U.S. Government collects the full amount of the duties owed should an investigation result in the imposition of an AD or CVD order and, further, it will reduce some of the burdens that U.S. Customs and Border Protection (CBP) faces when trying to collect AD and CVD duties. Certain parties commented on the explanation the Department provided for this change in the Proposed Rule, and the Department has addressed those comments in the section entitled ''Response to Comments on the Proposed Rule''.

### Explanation of Final Modification to 19 CFR 351.205

Prior to this modification to the regulations, the second sentence of 19 CFR 351.205(a) stated that ''[t]he remedy (sometimes referred to as 'provisional measures') usually takes the form of a bonding requirement to ensure payment if antidumping or countervailing duties ultimately are imposed.'' The Department deleted most of the sentence to no longer permit under normal circumstances, U.S. importers to post bonds during the provisional measures period. However, the Department retained the phrase ''(sometimes referred to as 'provisional measures')'' but moved it to the first sentence of 19 CFR 351.205(a). We view this phrase as a useful link between this part of our regulations and the terminology under Article 7 of the WTO Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994 (''ADA'') and Article 17 of the Agreement on Subsidies and Countervailing Measures (''ASCM'').

Further, to clarify that provisional measures will take the form of cash deposits, the Department added a sentence to 19 CFR 351.205(d) that states, ''With respect to section 703(d)(1)(B) and 733(d)(1)(B) of the Act, the Secretary will normally order the posting of cash deposits to ensure payment if antidumping or countervailing duties ultimately are imposed.'' This change, in our view, places the requirement for cash deposits in the appropriate part of 19 CFR part 351 (*i.e.,* in the part that explains the effects of an affirmative preliminary determination). This amendment reflects the Department's change in practice to now normally require cash deposits rather than bonds during the provisional measures period. This modification is also in line with 19 CFR 351.205(d), which provides that ''if the preliminary determination is affirmative, the Secretary will take the actions described in section 703(d) or section 733(d) of the Act (whichever is applicable)'' because these sections of the Act provide that the Department

[1] Also, pursuant to sections 703(e)(2) and 733(e)(2) of the Act, if the Department makes an affirmative determination of critical circumstances, then provisional measures shall apply on or after the later of (A) The date which is 90 days before the date on which the suspension of liquidation was first ordered, or (B) the date on which notice of the determination to initiate the investigation is published in the **Federal Register**.

shall order the posting of cash deposits or bonds, as the Department deems appropriate.

**Response to Comments on the Proposed Rule**

The Department received numerous comments on its Proposed Rule. As indicated in the ''Background'' section, these comments can be accessed using the Federal eRulemaking Portal at *http://www.Regulations.gov* under Docket Number ITA–2011–0005. The Department has analyzed and carefully considered all of the comments received. Below is a summary of the comments, grouped by issue category, and followed by the Department's response.

*Issue 1—U.S. Law, the WTO Agreements, and Cash Deposits During the Provisional Measures Period*

Several commenters assert that section 703(d)(l)(B) and 733(d)(1)(B) of the Act provide the Department discretion to collect cash deposits as provisional measures. Some of the same parties also note that Article 7 of the ADA and Article 17 of the ASCM indicate that WTO members may require importers to post cash deposits as provisional measures. Another commenter asserts that Article 7 of the ADA and Article 17 of the ASCM indicate no hierarchy between cash and bond requirements for provisional measures, and that allowing the importer to choose the kind of guarantee that is suitable for them reduces the chance of default. Another commented that the ADA and ASCM clearly provide for the acceptance of bonds as one of the options for the purpose of covering provisional duties.

*Response:* It is within the Department's discretion to require that provisional measures will normally take the form of a cash deposit. The Act does not specify a preference for cash deposits or bonds, nor does it provide the importer with the option of selecting which method the importer prefers. For the provisional measures period in AD and CVD investigations, the Act provides for ''the posting of a cash deposit, bond, or other security, as the administering authority deems appropriate.'' *See* sections 703(d)(1)(B) and 733(d)(1)(B) of the Act.

The modification to our regulations is also consistent with the ADA and the ASCM. Article 7.2 of the ADA states that, ''[p]rovisional measures may take the form of a provisional duty or, preferably, a security *by cash deposit or bond* equal to the amount of the antidumping duty provisionally estimated, being not greater than the provisionally estimated margin of dumping.'' (emphasis added). Article 17.2 of the ASCM states that, ''[p]rovisional measures may take the form of provisional countervailing duties guaranteed *by cash deposits or bonds* equal to the amount of the provisionally calculated amount of subsidization.'' (emphasis added). U.S. law and the WTO Agreements provide that the Department may require either the posting of cash deposits or bonds, and do not prohibit the Department from normally requiring the posting of cash deposits only during the provisional measures period.

*Issue 2—Use of Bonding by Other Countries*

Several commenters assert that the practice of most, if not all, other WTO members is to require cash deposits during the provisional measures period, and that the proposed modification will bring the United States in line with the practices of other WTO members. Other commenters assert that the laws of certain WTO members provide for an option to post bonds or other security as provisional measures.

*Response:* The Department has considered the information the commenters provided on the practice of various countries of permitting or not permitting importers the option of posting bonds during the provisional measures period of AD and CVD investigations. As detailed in the above section entitled *''Issue 1—U.S. Law, the WTO Agreements, and Cash Deposits During the Provisional Measures Period,''* requiring cash deposits is permissible under the WTO Agreements and this also appears to be the practice of many WTO members. While certain WTO members may provide for an option to post bonds, sections 703(d)(1)(B) and 733(d)(1)(B) of the Act grant the Department the discretion to select the form of security that it deems appropriate as a provisional measure. After considering all the comments received, and for the reasons outlined in the Proposed Rule and this Final Rule, we have decided to proceed with the modifications to our regulations specified in the Proposed Rule. Accordingly, we are modifying our regulations to normally require cash deposits rather than bonds during the provisional measures period of AD and CVD duty investigations.

*Issue 3—Effective Date of Rule Change*

Several commenters urged the Department to make the change effective immediately. Two of these parties asked that we apply the change not only in future investigations, but to all pending AD or CVD proceedings for which a final determination has not yet been issued. One commenter asserted that implementation of this modification to the Department's regulations will involve minimal administrative burden in light of the very limited number of pending proceedings.

*Response:* As indicated in the **DATES** section above, this Final Rule will apply to all investigations initiated on the basis of petitions filed on or after November 2, 2011. The Department believes that this is a reasonable approach to the effective date issue for this particular rule change. Importantly, implementing the Final Rule in this manner will provide parties (*e.g.,* importers of merchandise that are subject to an AD or CVD investigation) time to prepare for the new requirement to normally post cash deposits upon the publication of an affirmative preliminary determination.

*Issue 4—Financial Consequences of Cash Deposits*

Several commenters assert that the change would have significant adverse consequences for importers. They argue that it would be burdensome for the importers, some of which are small businesses, because their cash flow would be negatively impacted. Certain supporters of the change assert that any burden placed on importers by the cash deposit requirement is mitigated by the fact that provisional measures are in place for a short period of time.

*Response:* The Department acknowledges that, in the past, certain importers may have benefited from the option of posting bonds during the provisional measures period and that upon implementation of this Final Rule that option will no longer be readily available to them. Nonetheless, the Act clearly provides the Department with discretion to require either cash deposits or bonds should a company choose to import merchandise that has been preliminarily determined to be dumped or subsidized and likely to be causing injury to an industry in the United States. The Department considers the security for provisional measures to be an important matter for the collection of duties. The requirement of a cash deposit will better ensure that importers bear full responsibility for any future AD and CVD duties they may owe, as the Department and CBP have learned from the agencies' extensive experience in the administration of the AD and CVD laws.

The provisional measures period lasts, at most, six months. The Department considers this to be a

relatively short period in the context of an AD or CVD proceeding. Further, importers will receive the cash deposit back in full if the imports at issue are not dumped (sold in the United States at less than the normal value of the merchandise) or not found to benefit from a countervailable subsidy (or the Commission issues a negative injury finding). If the margin calculated for the final determination ends up lower than the margin calculated at the preliminary determination, the statute requires that the difference be refunded to the importer. *See* Sections 707(a)(2) (CVD) and 737(a)(2) (AD) of the Act. However, if the margin calculated for the final determination is higher than the margin calculated at the preliminary determination, the difference is disregarded. *See* Sections 707(a)(1) (CVD) and 737(a)(1) (AD) of the Act. In other words, in no circumstance will an importer be required to post cash deposits which equal more than the margin determined at the preliminary determination, and in fact will be refunded its cash deposit to the extent the deposit is higher than the duty that is determined to be due.

*Issue 5—Significance of Change to the Regulation*

One commenter stated that the Department's reasoning as to why the change is not significant is ''subjective and without factual basis, especially since the Department ignores the market impact of preliminary determinations on small business industrial users/consumers.'' Certain supporters of the change argued that the percentage of U.S. imports subject to AD or CVD orders is extremely small.

*Response:* In determining whether this change to its regulations is significant, the Department first considered the fact that less than two percent of all entries of merchandise into the United States are subject to AD or CVD duties. Next, the Department examined the number of affirmative preliminary determinations which were issued in both AD and CVD investigations in 2007, 2008 and 2009. For instance, if an affirmative preliminary determination was published in June 2007, importers were required to post cash deposits or bonds generally beginning on the date of publication for a four to six month period. For each year, we also examined how many AD and CVD proceedings were ongoing, accounting for orders which had been revoked during a particular year. We then compared the number of affirmative preliminary determinations published in a given year to the number of ongoing proceedings in that year, to find the percentage of ongoing proceedings in each year where provisional measures were applied. We found that the average of the results of this comparison for 2007, 2008 and 2009 was less than ten percent. This analysis was used for the proposed regulatory change, and it demonstrates that the change is not significant because the change in the security requirement will impact less than ten percent of ongoing AD/CVD proceedings.

For the Final Rule, our analysis included data from 2010, which we did not include in our initial analysis. The 2010 data further supports our initial analysis: in 2010, there were 15 preliminary affirmative AD determinations and six preliminary affirmative CVD determinations, in comparison to 260 ongoing AD proceedings and 46 ongoing CVD proceedings. For 2010, approximately seven percent of all AD and CVD proceedings involved the application of provisional measures during the year. Also, the simple average of the results for each year from 2007 through 2010 is less than ten percent. Thus, we find that the market impact of altering the provisional measures security requirement is not significant for purposes of making a regulatory change. Finally, we disagree with the assertion that the Department is required to make an analysis of the significance of the change with regard to ''small business industrial users/consumers.'' The analytical requirements of 5 U.S.C. 605(b), requires that the Department consider the ''economic impact on a substantial number of small business entities,'' which requires the Department to analyze the economic impact on all small business entities, and is not limited to industrial users/consumers.

*Issue 6—Requiring Cash Deposits Based on a Preliminary Determination*

Several commenters argue that it is unfair to require cash deposits based on a preliminary determination, when a final order may not be issued. Some commenters assert that this change will serve as a trade barrier, and one party commented that the Department's true intention is to benefit petitioners in response to recent unfavorable WTO and court decisions. Several supporters of the change assert that importers are protected by the fact that provisional measures are not imposed without a preliminary determination of dumping (or countervailable subsidization) and injury. The parties also assert that the change will better ensure that the U.S. government can collect the full amount of duties owed, should the investigation result in the imposition of an AD or CVD order.

*Response:* We disagree with the assertion that it is unfair to require cash deposits based on a preliminary determination in an AD or CVD investigation. Before imposing provisional measures, the Department must make an affirmative preliminary determination of dumping or countervailable subsidization and the Commission must also make a preliminary determination as to whether dumping or subsidization are likely to be causing material injury. While a preliminary determination may occur without an order being issued, in such a circumstance any cash deposits are completely refunded to the importer(s). We also disagree with the assertion that the change would act as a trade barrier because AD and CVD measures, when applied consistent with WTO rules, remedy injury and harm caused by market-distorting unfair trade practices.

On August 26, 2010, in support of President Obama's National Export Initiative (NEI), the Department announced a number of proposals to strengthen the agency's administration of the nation's AD and CVD laws. One of those proposals is the modification of the regulations regarding the acceptance of bonds during the provisional measures period in AD and CVD investigations. Specifically, the Department indicated that it is ''[c]onsidering whether importers will be required to post cash deposits rather than bonds for imports that fall within the scope of an AD/CVD investigation starting with the issuance of the Department's preliminary determination (rather than following the imposition of an AD/CVD order).'' *See* ''NEI Trade Law Enforcement Package Fact Sheet'' at *http://ia.ita.doc.gov/tlei/fachsheet-tlei-20101108.pdf.* As indicated in the above section entitled ''*Explanation of Final Modification to 19 CR 351.205,''* the posting of cash deposits rather than bonds will make importers directly responsible for the payment of AD and CVD duties. It will also help to ensure that the U.S. Government collects the full amount of the duties owed should an investigation result in the imposition of an AD or CVD order. Further, the change will reduce some of the burdens that CBP faces when trying to collect AD and CVD duties.

*Issue 7—Whether Bonds Will Be Accepted in Any Circumstance*

One commenter argues that the Proposed Rule would still allow bonding as an option for provisional measures, and suggests that the

Department should set forth guidelines of circumstances in which bonding is permitted. Another argues that the Department should consider other options to address the issues it has experienced with the use of bonding during the provisional measures period (such as those used in new shipper reviews).

*Response:* The change to the regulation provides that ''the Secretary will normally order the posting of cash deposits to ensure payment if antidumping or countervailing duties ultimately are imposed.'' The Department considers that this change appropriately addresses the concerns identified with the use of bonding during the provisional measures period of AD and CVD investigations. The use of the term ''normally'' provides the Department flexibility to address those rare and unusual circumstances that the Department may find warrant the acceptance of bonds. The Department intends to make such exceptional determinations on a case-by-case basis (depending on the particular facts of each case) as warranted rather than attempting to articulate a rule that predicts what unusual circumstances may arise in the future. With regard to the comment about new shipper reviews, unlike in investigations, bonding in new shipper reviews is required by the Act.

*Issue 8—Administrative Burdens of Permitting Bonding*

One commenter asserts that the Department cites a subjective and unsubstantiated conclusion regarding the burden the bonding requirement imposes on CBP. Another commenter asserts that by requiring cash deposits, the administrative burdens and expenses, such as ensuring adequate bond coverage and handling claims for mitigation or relief from the bond requirement, will be minimized.

*Response:* In the Proposed Rule the Department stated that, ''[w]hile most of the duties on entries secured by a bond during the provisional measures period are ultimately collected, these collections can be very slow and involve burdensome administrative problems for (CBP).'' This conclusion was based on the U.S. Government Accountability Office's (GAO) Report to Congress on Antidumping and Countervailing Duties (GAO–08–391) (March 2008), in which the GAO stated that when an importer fails to pay supplemental AD or CVD duties, CBP frequently faces a lengthy process of trying to collect from bonding agents. Additionally, CBP reports bonding is more burdensome than collecting cash deposits because Single Transaction Bonds (STBs), which are required for the posting of bonds in AD and CVD investigations, must be reviewed for sufficiency and adequacy. Further, since bonds are legal documents, CBP must keep paper copies of STBs. CBP also has to manually enter an electronic note in its Automated Commercial System for STBs. Conversely, cash deposits are recorded electronically in ACS and are usually transmitted to CBP electronically and, thus, are recorded automatically.

*Issue 9—The Use of Bonds in a Retrospective Duty Assessment System*

One commenter asserted that bonds are a more appropriate form of provisional measures for the United States since it has a retrospective duty collection system, and requests that the Department not modify the current regulations and practice of accepting bonds during the provisional measures period.

*Response:* The Department disagrees with the assertion that bonds are a more appropriate form of provisional measures, and notes that no information or argument was provided to support this assertion. The ADA and ASCM permit the application of provisional measures in the form of cash or bond, regardless of whether the WTO member is operating a prospective or retrospective system. In either system, provisional measures serve the same function—to provide adequate security for the payment of AD or CVD duties pending the final determination of whether such duties are owed and in what amount.

**Classification**

*Executive Order 12866*

This rule has been determined to be not significant for purposes of Executive Order 12866.

*Regulatory Flexibility Act*

The Chief Counsel for Regulation has certified to the Chief Counsel for Advocacy of the Small Business Administration under the provisions of the Regulatory Flexibility Act, 5 U.S.C. 605(b), that this rule, if promulgated, would not have a significant economic impact on a substantial number of small business entities. The factual basis for the certification was published in the Proposed Rule. The Department received a comment regarding the factual basis for this decision, which appears in *Issue 5—Significance of Change to the Regulation.* Based upon the Department's analysis, as discussed above, the factual basis used in the Proposed Rule to determine that the rule, if promulgated, would not have a significant economic impact on a substantial number of small business entities did not change. *See Issue 5—Significance of Change to the Regulation.* As a result, a Final Regulatory Flexibility analysis is not required and has not been prepared.

*Paperwork Reduction Act*

This rule does not contain a collection of information for purposes of the Paperwork Reduction Act of 1980, as amended (44 U.S.C. 3501 *et seq.*).

**List of Subjects in 19 CFR Part 351**

Administrative practice and procedure, Antidumping, Business and industry, Cheese, Confidential business information, Countervailing duties, Freedom of information, Investigations, Reporting and recordkeeping requirements.

Dated: September 15, 2011.

**Ronald K. Lorentzen,**

*Deputy Assistant Secretary for Import Administration.*

For the reasons stated, 19 CFR part 351 is amended as follows:

## PART 351—ANTIDUMPING AND COUNTERVAILING DUTIES

■ 1. The authority citation for 19 CFR part 351 continues to read as follows:

**Authority:** 5 U.S.C. 301; 19 U.S.C. 1202 note; 19 U.S.C. 1303 note; 19 U.S.C. 1671 *et seq.;* and 19 U.S.C. 3538.

**§ 351.205 [Amended]**

■ 2. In § 351.205, revise paragraphs (a) and (d) to read as follows:

(a) *Introduction.* A preliminary determination in an antidumping or countervailing duty investigation constitutes the first point at which the Secretary may provide a remedy (sometimes referred to as ''provisional measures'') if the Secretary preliminarily finds that dumping or countervailable subsidization has occurred. Whether the Secretary's preliminary determination is affirmative or negative, the investigation continues. This section contains rules regarding deadlines for preliminary determinations, postponement of preliminary determinations, notices of preliminary determinations, and the effects of affirmative preliminary determinations.

* * * * *

(d) *Effect of affirmative preliminary determination.* If the preliminary determination is affirmative, the Secretary will take the actions described in section 703(d) or section 733(d) of the Act (whichever is applicable). With

respect to section 703(d)(1)(B) and 733(d)(1)(B) of the Act, the Secretary will normally order the posting of cash deposits to ensure payment if antidumping or countervailing duties ultimately are imposed. In making information available to the Commission under section 703(d)(3) or section 733(d)(3) of the Act, the Secretary will make available to the Commission and to employees of the Commission directly involved in the proceeding the information upon which the Secretary based the preliminary determination and which the Commission may consider relevant to its injury determination.

* * * * *

[FR Doc. 2011–24666 Filed 9–30–11; 8:45 am]

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## DEPARTMENT OF THE TREASURY

### 31 CFR Part 31

**RIN 1505–AC05**

### TARP Conflicts of Interest

**AGENCY:** Departmental Offices, Treasury.

**ACTION:** Final rule.

**SUMMARY:** On January 21, 2009, the Department issued an interim rule that provided guidance on conflicts of interest pursuant to Section 108 of the Emergency Economic Stabilization Act of 2008 (''EESA''), which was enacted on October 3, 2008. This final rule takes into account the public comments received and adopts revisions to the interim rule.

**DATES:** *Effective date:* November 2, 2011.

**FOR FURTHER INFORMATION CONTACT:** For further information regarding this final rule contact the Troubled Asset Relief Program Compliance Office, Office of Financial Stability, Department of the Treasury, 1500 Pennsylvania Avenue, Washington, DC, 20220, (202) 622–2000, or *TARP.COI@do.treas.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. Background

Pursuant to Section 108 of EESA (Pub. L. 110–343; 122 Stat. 3765), which authorizes the Secretary of the Treasury to issue regulations or guidelines necessary to address and manage or to prohibit conflicts of interest that may arise in connection with the administration and execution of the EESA authorities, Treasury promulgated an interim final rule on conflicts of interest on January 21, 2009 (''Interim Rule'') (74 FR 3431). Treasury invited the public to submit comments on the Interim Rule and received requests from several commentators requesting that Treasury modify aspects of the Interim Rule. Treasury carefully considered all comments received and, in section II of this rule, discusses the comments received and sets out modifications in this final rule.

The January 21, 2009, interim rule's provisions are available at 74 FR 3431. The interim rule defines organizational and personal conflicts of interest. Further, the interim rule sets forth: (1) The requirements for retained entities to search for, disclose, certify to, and mitigate organizational or personal conflicts of interest, (2) general standards related to the handling of conflicts of interest, favors, gifts, Treasury property, and items of monetary value, (3) limits on retained entities' activities concurrently with providing services to Treasury, (4) limits on retained entities' communications with Treasury employees, (5) requirements with respect to the receipt and handling of nonpublic information, and (6) enforcement powers with respect to the interim rule.

### II. Summary of Comments, Treasury's Resulting Changes, and Final Rule

Treasury is promulgating this rule to finalize the Interim Rule issued on January 21, 2009. Interested members of the public submitted several comments to the Interim Rule. The comments have been carefully considered. Comments are described below, as are the approaches that Treasury has taken in addressing them.

Commentators asked Treasury to eliminate the reference to ''management officials'' in 31 CFR 31.201 and 31 CFR 31.212. One commentator took issue with what they felt was the presumption, by defining management official, that such officials had knowledge related to the Treasury arrangement by virtue of status, rather than by virtue of having a substantive role in the arrangement. Treasury agrees, and decided to limit various obligations previously required of management officials to those key individuals who are personally and substantially involved in providing services under an arrangement with Treasury. Management officials performing a substantive role under an arrangement will be subsumed in the definition of key individual, rendering the definition of management official unnecessary.

Treasury received a comment that inquired whether Treasury considered the examples listed in the definitional provisions in 31 CFR 31.201 to *per se* constitute organizational conflict of interests. The illustrations set forth in the definitional provisions in section 31.201 are examples of situations that may give rise to a conflict of interest. They are not pronouncements that a particular set of facts will necessarily give rise to a conflict of interest, or that such conflict of interest cannot be mitigated. Treasury also received a comment suggesting the rule include specific mitigation plans for some of the conflicts examples. Treasury believes that including specific mitigation plans as part of the regulation would not be useful because the facts and circumstances of each potential or actual conflict determine whether a conflict of interest exists and dictate the appropriate mitigation controls. Treasury notes that it routinely interfaces directly with retained entities to formulate conflicts of interest mitigation plans that are dependent on the particular facts underlying the potential conflict.

Treasury also received comments questioning the relationship of the rule to contractors versus financial agents. To clarify, this final rule applies to both financial agency agreements and procurement contracts. Of course, procurement contracts are also subject to the Federal Acquisition Regulation (the ''FAR'') along with other regulatory requirements. Treasury also notes that the TARP Chief Compliance Officer lacks the direct or delegated authority to waive FAR rules related to organizational conflicts of interests. Thus, a waiver issued under 31 CFR part 31 does not itself ensure compliance with the applicable FAR requirements.

Treasury notes that pursuant to section 31.200(b), vendors hired under an arrangement to perform purely administrative services (*e.g.,* parking services for Treasury) are not subject to this rule because, in Treasury's estimation, the providers of such services are not likely to exercise the discretion core to Treasury's mission under the Troubled Asset Relief Program (''TARP'') which would likely create conflicts of interest and, therefore, the burden of subjecting such vendors to the rule is unnecessary.

Treasury added a specific reference to the appearance of a conflict of interest to sections 31.200, 31.211 and 31.212 to clarify that facts or situations that give rise to the appearance of a conflict of interest are also considered potential conflicts. This clarification is consistent with the overall approach of, and policy underlying, the regulation.

One commentator advocated the adoption of a rule that a retained entity which is an SEC-registered investment

adviser is *per se* deemed to have complied with the federal securities laws mentioned in section 31.211(a) or that, in the alternative, the rule should require that the compliance programs only be ''reasonably designed'' to detect and prevent violations of federal securities laws and organizational conflicts of interest. Treasury does not agree with the first suggestion but agrees with the latter, and has revised section 31.211(a) accordingly.

Treasury also received comments that the standards related to gifts in section 31.213(a)(1) should be limited to individuals deployed for Treasury and include reasonable scope limitations. In response, Treasury agreed to limit application of section 31.213(a)(1) to individuals performing work under the arrangement and added specific dollar figures to the restriction on accepting or soliciting favors, gifts, or other items of monetary value (above $20 per gift or $50 for the year) to make it consistent with the standards used by the Office of Government Ethics.

Treasury clarifies that it intends to follow the same standard for ''credible evidence'' in section 31.213 that is used in relation to FAR Clause 52.203–13(b)(3).

One commentator believed that the definition of ''retained entity'' was overly broad, in that it included subcontractors and consultants hired to perform services under the arrangement, and that the reference to subcontractors and consultants should be removed or, in the alternative, limited to those providing substantive services under the arrangement. Treasury disagrees and notes that subcontractors and vendors may possess conflicts of interest that could cause a reasonable person with knowledge of the relevant facts to question the retained entity's objectivity or judgment. As stated previously, pursuant to section 31.200(b), administrative contracts are excluded from the rule, thus avoiding application of the rule to entities unlikely to possess organizational conflicts of interest.

A commentator also recommended that ''related entities'' be defined more narrowly, to eliminate parents, subsidiaries, *etc.* which operate independently from the retained entity. It was noted that some conflict mitigation procedures, such as barriers to eliminate the sharing of information, may also inhibit the discovery of conflicts of interest involving related entities. Treasury understands the commentator's concern, but believes revising the related entity definition is unnecessary as the conflict mitigation measures listed in section 31.211(c) are provided for illustrative purposes only and can be tailored as necessary in the actual mitigation plan agreed upon by the retained entity and Treasury.

One comment maintained that the rule inappropriately places too much of the burden of discovering conflicts of interest, both organizational and personal, on the retained entity, and that the rule should be amended to explicitly state the burden falls on both the retained entity and the Treasury. Treasury does not agree. Although Treasury takes independent steps to identify conflicts of interest and determine appropriate mitigants, the rule focuses on the obligation of the retained entity, pursuant to section 31.211(a), to identify conflicts and formulate a conflicts of interest mitigation plan.

One commentator stated the rule should specify the level of employee within the retained entity that must learn of an organizational conflict of interest before a reporting obligation is triggered. Treasury believes that such a limitation would be opposed to its policy objectives that any employee of a retained entity who knows of a conflict should be required to report it.

Treasury also received a comment in favor of a materiality threshold in judging what constitutes an organizational conflict of interest. Treasury was directed to look to applicable case law concerning Rule 10b–5 of the Securities Exchange Act of 1934. Treasury has not adopted a materiality threshold because Treasury should be alerted to any possible conflict of interest, and post-notification Treasury can decide whether a conflict is material. Additionally, the adoption of a materiality threshold could invite abuse.

Treasury received a comment expressing the view that, since the American Bar Association's (ABA) Rules of Professional Conduct already contain conflicts of interest provisions, that Treasury should disregard organizational conflicts of interest concerns when the retained entity is a law firm that has complied with the standards set forth in either these rules or applicable case law. Treasury does not adopt this change because this regulation is specifically related to the requirements of EESA and the ABA Rules of Professional Conduct may not adequately address all conflicts of interest.

Treasury received comments suggesting that the continuing obligation to search for any potential organizational and personal conflicts of interest and to report new conflicts of interest within five business days of learning of them is unreasonable and invites failure. It was requested that Treasury adopt a more flexible standard, and one commentator even recommended eliminating the notification requirement altogether and relying only upon the periodic certifications. Treasury believes such a five day timeframe is appropriate and does not need to be revised or lengthened. Experience has shown five days is not too short of a period as the retained entity need only provide Treasury notification of the conflict and the initial proposal for mitigating the conflict. In addition, it is important for mitigation controls to be implemented without delay. Eliminating the notification requirement and relying solely upon the periodic certification may result in situations in which certain conflicts of interest have not been mitigated adequately and, thus, Treasury's ability to monitor such conflicts in a timely manner would be undercut.

One comment requested the clarification that the notification requirement applies only to conflicts of interest not yet identified, and not to new conflicts that can be addressed by a previously-approved conflicts mitigation plan. The notification requirement applies to all new conflicts.

The same comment questioned whether the five day timeframe begins at the time the new conflicts arises, or when the retained entity's TARP Compliance Officer is informed of the new conflict. For avoidance of doubt, the five day timeframe begins when any person at the retained entity becomes aware of the new conflict (not just the TARP Compliance Officer).

Treasury also received comments to the effect that the section 31.212(b) concept of identifying and monitoring close personal relationships was improperly subjective because the phrase ''close personal relationship'' is open to broad interpretation. Treasury agrees and revised the definition of a personal conflict of interest in section 31.201 and the requirements of section 31.212(b) to include ''an individual, or any dependent child (meaning son, daughter, stepson or stepdaughter who is either (a) Unmarried, under age 21, and living in the individual's house, or (b) considered a ''dependent'' of the individual under the U.S. tax code),'' In making this modification, Treasury adopted the standards used in completing the Office of Government Ethics (''OGE'') Form 450.

Treasury received many comments expressing the view that requiring the use of OGE Form 278 as a disclosure standard in the personal conflicts inquiry process (section 31.212(b))

presented an overly invasive, unwarranted burden, in that it took too long to fill out the form and that the form asked intrusive questions regarding personal activities. Treasury reviewed these comments in light of its own experience, and also in light of having received an official recommendation from the Government Accountability Office (GAO) suggesting that Form 450 would be a more appropriate model on which vendors should base their inquiries into the personal conflicts of their employees than Form 278. The GAO believed that the using Form 450 as a model could appropriately reduce the burden of providing financial information as opposed to the Form 278. *See TROUBLED ASSET RELIEF PROGRAM: March 2009 Status of Efforts to Address Transparency and Accountability Issues, GAO March 2009 p. 45, available at http://www.gao.gov/new.items/d09504.pdf.* On these bases, Treasury agrees that Form 450 is more appropriate than Form 278 as a personal conflicts inquiry model, and has substituted Form 450 for Form 278 in the rule.

Treasury received a comment asserting the rule did not provide enough detail in regard to what would constitute a personal conflict of interest, and what the related mitigation steps would be. Since the Interim Rule has been released, Treasury has found that the definition of ''personal conflicts of interest'' is sufficiently broad to encompass the wide range of personal conflicts of interest that may arise, but yet provides enough guidance for retained entities to recognize which circumstances could constitute a personal conflict of interest, and that the variables that would determine a sufficient mitigation plan are such that providing specific examples would be of limited value.

Some commentators expressed concern that the ten-business day timeframe for submitting the personal conflicts of interest certification is too little time for a sound submission, contending it is unlikely a retained entity would be able to gather, process, and certify the required information in that time. Treasury disagrees because it has found in its experience in applying the Interim Rule that ten business days is sufficient time to gather the information required to submit the personal conflicts of interest certification, particularly since the retained entity can begin at least part of the process before the arrangement is signed. If a retained entity feels ten business days may not be adequate (for example, if the retained entity has a large number of key individuals), it may request an extension.

Treasury also received a comment that the three-year document retention requirement in sections 31.211(h) and 31.212(h) should be shortened. Treasury believes the three-year document retention requirement is necessary in case any question should surface regarding a past determination or mitigation as to a particular personal conflict of interest.

One commentator felt that section 31.213(c) should be revised so that Treasury would no longer refer all violations of 18 U.S.C. 1001 to the Department of Justice and to SIGTARP, but would instead refer only those violations relating to services under EESA and related certifications. Treasury sees no reason to limit which violations it refers to the Department of Justice or to SIGTARP, as Treasury does not wish for any false statements to go unreported.

Treasury received a comment that the phrase ''impermissible conflicts of interest'' referred to in section 31.214 should be limited so that it only relates to activities in connection with buying or selling assets under the TARP program, and not to ''customary'' business activities such as managing client accounts that hold securities or other financial instruments issued by TARP-funded entities. Treasury was also urged to limit the prohibitions set forth in section 31.214(a) and (b) to concurrent activities involving the specific assets for which the retained entity has entered into an arrangement with Treasury, and further, to adopt a *de minimis* exception in order to permit a retained entity to engage in certain incidental market activities involving TARP securities without such activities rising to the level of an ''impermissible'' conflict of interest. Treasury believes that because such activities can be addressed in the retained entity's conflicts mitigation plan agreed upon by Treasury, and because section 31.214 specifically states its restrictions do not apply if ''Treasury agrees in writing to specific mitigation measures,'' including these exceptions in the rule is unnecessary.

The same commentator argued that section 31.217(a)'s treatment of all information provided by Treasury to a retained entity under an arrangement as non-public until Treasury determines otherwise is overbroad. It was recommended that the confidentiality requirement apply only to information pertaining to a TARP beneficiary or its assets, or that is otherwise marked by Treasury as proprietary or confidential. Treasury understands the commentator's concern, but believes the consequences of sensitive information becoming public are such that maintaining a broad determination of confidentiality is warranted and appropriately protective of confidential information.

Treasury also received comments recommending that only management officials and key personnel be subject to a duty to report violations of confidentiality obligations. As stated earlier, Treasury believes that any employee of the retained entity should be required to report a breach of confidentiality.

Treasury received one comment expressing the view that the penalties contemplated by section 31.218(a) are overly broad and not reasonably calculated to address the nature and severity of the perceived transgression. Treasury believes that the appropriateness of the sanction will depend heavily on the violation, such that leaving the potential penalties listed in the rule broad is appropriate.

Treasury received a comment recommending that section 31.218(b) be eliminated due to perceived uncertainty regarding Treasury's expectations regarding the times and extent of the disclosure requirements found in the rule. Treasury believes section 31.218(b) encourages prompt disclosure of violations of the rule, and thus rejects the recommendation.

The definition of ''key individual'' in section 31.201 has been changed to clarify that the list of actions that may constitute personal and substantial participation in a matter provides examples and is not necessarily an exclusive list of such actions. This change is made to more closely track the language of 5 CFR 2635.402(b)(4), upon which the list is based. It should be stressed that while § 2635.402(b)(4), which applies to Government employees, covers participation in a Government matter, personal and substantial participation in a decision or other matter under consideration by the retained entity itself will satisfy the criteria for a key individual under this part 31. For example, an employee of the retained entity who provides advice to other employees of the retained entity concerning performance of the arrangement qualifies as a key individual if the other elements of the definition are satisfied.

For consistency, Treasury replaced the previous definition of ''troubled assets'' (in section 31.201) with a reference to the definition given in EESA, 12 U.S.C. 5209(9).

## III. Procedural Requirements

*Regulatory Planning and Review*

Executive Orders 13563 and 12866 direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a ''significant regulatory action'' although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

*Regulatory Flexibility Act*

Because no notice of proposed rulemaking is required, this rule is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. chapter 6).

*Paperwork Reduction Act*

The information collections contained in the rule have been reviewed and approved by OMB under the Paperwork Reduction Act (44 U.S.C. chapter 35) and assigned OMB control number 1505–0209. Under the Paperwork Reduction Act, an agency may not conduct or sponsor and a person is not required to respond to, a collection of information unless it displays a valid OMB control number.

**List of Subjects in 31 CFR Part 31**

Conflicts of interest, Contracts, Troubled assets.

For the reasons set out in the preamble, Title 31 of the Code of Federal Regulations is amended as follows:

■ 1. Revise part 31 to read as follows:

## PART 31—TROUBLED ASSET RELIEF PROGRAM

Sec.

31.1 General.

**Subpart A—[Reserved]**

**Subpart B—Conflicts of Interest**

31.200 Purpose and scope.
31.201 Definitions.
31.211 Organizational conflicts of interest.
31.212 Personal conflicts of interest.
31.213 General standards.
31.214 Limitations on concurrent activities.
31.215 Grant of waivers.
31.216 Communications with Treasury employees.
31.217 Confidentiality of information.
31.218 Enforcement.

**Authority:** 31 U.S.C. 321; Pub. L. 110–343; 122 Stat. 3765.

### § 31.1 General.

This part sets forth regulations to implement and administer the Emergency Economic Stabilization Act of 2008 (Pub. L. 110–343; 122 Stat. 3765).

### Subpart A—[Reserved]

### Subpart B—Conflicts of Interest

### § 31.200 Purpose and scope.

(a) *Purpose.* This regulation sets forth standards to address and manage or to prohibit conflicts of interest that may arise in connection with the administration and execution of the authorities under the Troubled Asset Relief Program (TARP), established under sections 101 and 102 of the Emergency Economic Stabilization Act of 2008 (EESA).

(b) *Scope.* This regulation addresses actual and potential conflicts of interest, or circumstances that give rise to the appearance of a conflict of interest, that may arise from contracts and financial agency agreements between private sector entities and the Treasury for services under the TARP, other than administrative services identified by the TARP Chief Compliance Officer.

### § 31.201 Definitions.

As used in this part:

*Arrangement* means a contract or financial agency agreement between a private sector entity and the Treasury for services under the TARP, other than administrative services identified by the TARP Chief Compliance Officer.

*Dependent child* means a son, daughter, stepson or stepdaughter who is either (a) Unmarried, under age 21, and living in the individual's house, or (b) considered a ''dependent'' of the individual under the U.S. tax code.

*EESA* means the Emergency Economic Stabilization Act of 2008, as amended.

*Key individual* means an individual providing services to a private sector entity who participates personally and substantially, through, for example, decision, approval, disapproval, recommendation, or the rendering of advice, in the negotiation or performance of, or monitoring for compliance under, the arrangement with the Treasury. For purposes of the definition of key individual, the words ''personally and substantially'' shall have the same meaning and interpretation as such words have in 5 CFR 2635.402(b)(4).

*Organizational conflict of interest* means a situation in which the retained entity has an interest or relationship that could cause a reasonable person with knowledge of the relevant facts to question the retained entity's objectivity or judgment to perform under the arrangement, or its ability to represent the Treasury. Without limiting the scope of this definition, organizational conflicts of interest may include the following situations:

(1) A prior or current arrangement between the Treasury and the retained entity that may give the retained entity an unfair competitive advantage in obtaining a new arrangement with Treasury.

(2) The retained entity is, or represents, a party in litigation against the Treasury relating to activities under the EESA.

(3) The retained entity provides services for Treasury relating to the acquisition, valuation, disposition, or management of troubled assets at the same time it provides those services for itself or others.

(4) The retained entity gains, or stands to gain, an unfair competitive advantage in private business arrangements or investments by using information provided under an arrangement or obtained or developed pursuant to an arrangement with Treasury.

(5) The retained entity is a potential candidate for relief under EESA, is currently participating in an EESA program, or has a financial interest that could be affected by its performance of the arrangement.

(6) The retained entity maintains a business or financial relationship with institutions that have received funds from Treasury pursuant to the EESA.

*Personal conflict of interest* means a personal, business, or financial interest of an individual, his or her spouse or any dependent child that could adversely affect the individual's ability to perform under the arrangement, his or her objectivity or judgment in such performance, or his or her ability to represent the interests of the Treasury.

*Related entity* means the parent company and subsidiaries of a retained entity, any entity holding a controlling interest in the retained entity, and any entity in which the retained entity holds a controlling interest.

*Retained entity* means the individual or entity seeking an arrangement with the Treasury or having such an arrangement with the Treasury, but does not include special government employees. A ''retained entity'' includes the subcontractors and consultants it

hires to perform services under the arrangement.

*Special government employee* means an officer or employee serving the Treasury, serving with or without compensation, for a period not to exceed 130 days during any 365-day period on a full-time or intermittent basis.

*Treasury* means the United States Department of the Treasury.

*Treasury employee* means an officer or employee of the Treasury, including a special government employee, or an employee of any other government agency who is properly acting on behalf of the Treasury.

*Troubled assets,* for purposes of this rule, shall have the same meaning as set forth in 12 U.S.C. 5202(9).

**§ 31.211 Organizational conflicts of interest.**

(a) *Retained entity's responsibility.* A retained entity working under an arrangement shall not permit an actual or potential organizational conflict of interest (including a situation in which the retained entity has an interest or relationship that could cause a reasonable person with knowledge of the relevant facts to question the retained entity's objectivity or judgment to perform under the arrangement or its ability to represent the Treasury), unless the conflict has been disclosed to Treasury under this Section and mitigated under a plan approved by Treasury, or Treasury has waived the conflict. With respect to arrangements for the acquisition, valuation, management, or disposition of troubled assets, the retained entity shall maintain a compliance program reasonably designed to detect and prevent violations of federal securities laws and organizational conflicts of interest.

(b) *Information required about the retained entity.* As early as possible before entering an arrangement to perform services for Treasury under the EESA, a retained entity shall provide Treasury with sufficient information to evaluate any organizational conflicts of interest. The information shall include the following:

(1) The retained entity's relationship to any related entities.

(2) The categories of troubled assets owned or controlled by the retained entity and its related entities, if the arrangement relates to the acquisition, valuation, disposition, or management of troubled assets.

(3) Information concerning all other business or financial interests of the retained entity, its proposed subcontractors, or its related entities, which could conflict with the retained entity's obligations under the arrangement with Treasury.

(4) A description of all organizational conflicts of interest and potential conflicts of interest.

(5) A written detailed plan to mitigate all organizational conflicts of interest, along with supporting documents.

(6) Any other information or documentation about the retained entity, its proposed subcontractors, or its related entities that Treasury may request.

(c) *Plans to mitigate organizational conflicts of interest.* The steps necessary to mitigate a conflict may depend on a variety of factors, including the type of conflict, the scope of work under the arrangement, and the organizational structure of the retained entity. Some conflicts may be so substantial and pervasive that they cannot be mitigated. Retained entities should consider the following measures when designing a mitigation plan:

(1) Adopting, implementing, and enforcing appropriate information barriers to prevent unauthorized people from learning nonpublic information relating to the arrangement and isolate key individuals from learning how their performance under the arrangement could affect the financial interests of the retained entity, its clients, and related entities.

(2) Divesting assets that give rise to conflicts of interest.

(3) Terminating or refraining from business relationships that give rise to conflicts of interest.

(4) If consistent with the terms of the arrangement and permitted by Treasury, refraining from performing specific types of work under the arrangement.

(5) Any other steps appropriate under the circumstances.

(d) *Certification required.* When the retained entity provides the information required by paragraph (b) of this section, the retained entity shall certify that the information is complete and accurate in all material respects.

(e) *Determination required.* Prior to entering into any arrangement, the Treasury must conclude that no organizational conflict of interest exists that has not been adequately mitigated, or if a conflict cannot be adequately mitigated, that Treasury has expressly waived it. Once Treasury has approved a conflicts mitigation plan, the plan becomes an enforceable term under the arrangement.

(f) *Subsequent notification.* The retained entity has a continuing obligation to search for, report, and mitigate any and all potential organizational conflicts of interest that have not already been disclosed to Treasury under a plan approved by Treasury or previously waived by Treasury. The retained entity shall search regularly for conflicts and shall, within five (5) business days after learning of a potential organizational conflict of interest, disclose the potential conflict of interest in writing to the TARP Chief Compliance Officer. The disclosure shall describe the steps it has taken or proposes to take to mitigate the potential conflict or request a waiver from Treasury.

(g) *Periodic Certification.* No later than one year after the arrangement's effective date, and at least annually thereafter, the retained entity shall certify in writing that it has no organizational conflicts of interest, or explain in detail the extent to which it can certify, and describe the actions it has taken and plans to take to mitigate any conflicts. Treasury may require more frequent certifications, depending on the arrangement.

(h) *Retention of information.* A retained entity shall retain the information needed to comply with this section and to support the certifications required by this section for three (3) years following termination or expiration of the arrangement, and shall make that information available to Treasury upon request. Such retained information shall include, but is not limited to, written documentation regarding the factors the retained entity considered in its mitigation plan as well as written documentation addressing the results of the retained entities' periodic review of the mitigation plan.

**§ 31.212 Personal conflicts of interest.**

(a) *Retained entity's responsibility.* A retained entity shall ensure that all key individuals have no personal conflicts of interest (including a situation that would cause a reasonable person with knowledge of the relevant facts to question the individual's ability to perform, his or her objectivity or judgment in such performance, or his or her ability to represent the interests of the Treasury), unless mitigation measures have neutralized the conflict, or Treasury has waived the conflict.

(b) *Information required.* Before key individuals begin work under an arrangement, a retained entity shall obtain information from each of them in writing about their personal, business, and financial relationships, as well as those of their spouses and dependent children that would cause a reasonable person with knowledge of the relevant facts to question the individual's ability to perform, his or her objectivity or judgment in such performance, or his or her ability to represent the interests of

the Treasury. When the arrangement concerns the acquisition, valuation, management, or disposition of troubled assets, the information shall be no less extensive than that required of certain new federal employees under Office of Government Ethics Form 450. Treasury may extend the time necessary to meet these requirements in urgent and compelling circumstances.

(c) *Disqualification.* The retained entity shall disqualify key individuals with personal conflicts of interest from performing work pursuant to the arrangement unless mitigation measures have neutralized the conflict to the satisfaction of the TARP Chief Compliance Officer. The retained entity may seek a waiver from the TARP Chief Compliance Officer to allow a key individual with a personal conflict of interest to work under the arrangement.

(d) *Initial certification.* No later than ten business days after the effective date of the arrangement, the retained entity shall certify to the Treasury that all key individuals performing services under the arrangement have no personal conflicts of interest, or are subject to a mitigation plan or waiver approved by Treasury. In making this certification, the retained entity may rely on the information obtained pursuant to paragraph (b) of this section, unless the retained entity knows or should have known that the information provided is false or inaccurate. Treasury may extend the time necessary to meet these requirements where the retained entity has a large number of key individuals, or in other appropriate circumstances.

(e) *Periodic certification.* No later than one year after the arrangement's effective date, and at least annually thereafter, the retained entity shall renew the certification required by paragraph (d) of this section. The retained entity shall provide more frequent certifications to Treasury when requested.

(f) *Retained entities' responsibilities.* The retained entity shall adopt and implement procedures designed to search for, report, and mitigate personal conflicts of interest on a continuous basis.

(g) *Subsequent notification.* Within five business days after learning of a personal conflict of interest, the retained entity shall notify Treasury of the conflict and describe the steps it has taken and will take in the future to neutralize the conflict.

(h) *Retention of information.* A retained entity shall retain the information needed to comply with this section and to support the certifications required by this section for three years following termination or expiration of the arrangement, and shall make that information available to Treasury upon request.

**§ 31.213 General standards.**

(a) During the time period in which a retained entity is seeking an arrangement and during the term of any arrangement:

(1) The retained entity's officers, partners, or employees performing work under the arrangement shall not accept or solicit favors, gifts, or other items of monetary value above $20 from any individual or entity whom the retained entity, officer, partner, or employee knows is seeking official action from the Treasury in connection with the arrangement or has interests which may be substantially affected by the performance or nonperformance of duties to the Treasury under the arrangement, provided that the total value of gifts from the same person or entity does not exceed $50 in any calendar year.

(2) The retained entity and its officers and partners, and its employees shall not improperly use or allow the improper use of Treasury property for the personal benefit of any individual or entity other than the Treasury.

(3) The retained entity and its officers and partners, and its employees shall not make any unauthorized promise or commitment on behalf of the Treasury.

(b) Any individual who acts for or on behalf of the Treasury pursuant to an arrangement shall comply with 18 U.S.C. 201, which generally prohibits the direct or indirect acceptance by a public official of anything of value in return for being influenced in, or because of, an official act. Violators are subject to criminal penalties.

(c) Any individual or entity that provides information or makes a certification to the Treasury that is relating to services under EESA or required pursuant to 31 CFR Part 31 is subject to 18 U.S.C. 1001, which generally prohibits the making of any false or fraudulent statement to a federal officer. Upon receipt of information indicating that any individual or entity has violated any provision of title 18 of the U.S. Code or other provision of criminal law, Treasury shall refer such information to the Department of Justice and the Special Inspector General for the Troubled Asset Relief Program (SIGTARP).

(d) A retained entity shall disclose to the SIGTARP, any credible evidence, in connection with the designation, services, or closeout of the arrangement, that an employee, or contractor of the retained entity has committed a violation of Federal criminal law involving fraud, conflict of interest, bribery, or gratuity violations found in Title 18 of the United States Code, or a violation of the civil False Claims Act (31 U.S.C. 3729–3733).

**§ 31.214 Limitations on concurrent activities.**

Treasury has determined that certain market activities by a retained entity during the arrangement are likely to cause impermissible conflicts of interest. Accordingly, the following restrictions shall apply unless waived pursuant to section 31.215, or Treasury agrees in writing to specific mitigation measures.

(a) If the retained entity assists Treasury in the acquisition, valuation, management, or disposition of specific troubled assets, the retained entity and key individuals shall not purchase or offer to purchase such assets from Treasury, or assist anyone else in purchasing or offering to purchase such troubled assets from the Treasury, during the term of its arrangement.

(b) If the retained entity advises Treasury with respect to a program for the purchase of troubled assets, the retained entity and key individuals shall not, during the term of the arrangement, sell or offer to sell, or act on behalf of anyone with respect to a sale or offer to sell, any asset to Treasury under the terms of that program.

**§ 31.215 Grant of waivers.**

The TARP Chief Compliance Officer may waive a requirement under this Part that is not otherwise imposed by law when it is clear from the totality of the circumstances that a waiver is in the government's interest.

**§ 31.216 Communications with Treasury employees.**

(a) *Prohibitions.* During the course of any process for selecting a retained entity (including any process using non-competitive procedures), a retained entity participating in the process and its representatives shall not:

(1) Directly or indirectly make any offer or promise of future employment or business opportunity to, or engage directly or indirectly in any discussion of future employment or business opportunity with, any Treasury employee with personal or direct responsibility for that procurement.

(2) Offer, give, or promise to offer or give, directly or indirectly, any money, gratuity, or other thing of value to any Treasury employee, except as permitted by the Standards of Conduct for Employees of the Executive Branch, 5 CFR part 2635.

(3) Solicit or obtain from any Treasury employee, directly or indirectly, any

information that is not public and was prepared for use by Treasury for the purpose of evaluating an offer, quotation, or response to enter into an arrangement.

(b) *Certification.* Before a retained entity enters a new arrangement, the retained entity must certify to the following:

(1) The retained entity is aware of the prohibitions of paragraph (a) of this section and, to the best of its knowledge after making reasonable inquiry, the retained entity has no information concerning a violation or possible violation of paragraph (a) of this section.

(2) Each officer, employee, and representative of the retained entity who participated personally and substantially in preparing and submitting a bid, offer, proposal, or request for modification of the arrangement has certified that he or she:

(i) Is familiar with and will comply with the requirements of paragraph (a) of this section; and

(ii) Has no information of any violations or possible violations of paragraph (a) of this section, and will report immediately to the retained entity any subsequently gained information concerning a violation or possible violation of paragraph (a) of this section.

**§ 31.217 Confidentiality of information.**

(a) *Nonpublic information defined.* Any information that Treasury provides to a retained entity under an arrangement, or that the retained entity obtains or develops pursuant to the arrangement, shall be deemed nonpublic until the Treasury determines otherwise in writing, or the information becomes part of the body of public information from a source other than the retained entity.

(b) *Prohibitions.* The retained entity shall not:

(1) Disclose nonpublic information to anyone except as required to perform the retained entity's obligations pursuant to the arrangement, or pursuant to a lawful court order or valid subpoena after giving prior notice to Treasury.

(2) Use or allow the use of any nonpublic information to further any private interest other than as contemplated by the arrangement.

(c) *Retained entity's responsibility.* A retained entity shall take appropriate measures to ensure the confidentiality of nonpublic information and to prevent its inappropriate use. The retained entity shall document these measures in sufficient detail to demonstrate compliance, and shall maintain this documentation for three years after the arrangement has terminated. The retained entity shall notify the TARP Chief Compliance Officer in writing within five business days of detecting a violation of the prohibitions in paragraph (b), above. The security measures required by this paragraph shall include:

(1) Security measures to prevent unauthorized access to facilities and storage containers where nonpublic information is stored.

(2) Security measures to detect and prevent unauthorized access to computer equipment and data storage devices that store or transmit nonpublic information.

(3) Periodic training to ensure that persons receiving nonpublic information know their obligation to maintain its confidentiality and to use it only for purposes contemplated by the arrangement.

(4) Programs to ensure compliance with federal securities laws, including laws relating to insider trading, when the arrangement relates to the acquisition, valuation, management, or disposition of troubled assets.

(5) A certification from each key individual stating that he or she will comply with the requirements in section 31.217(b). The retained entity shall obtain this certification, in the form of a nondisclosure agreement, before a key individual performs work under the arrangement, and then annually thereafter.

(d) *Certification.* No later than ten business days after the effective date of the arrangement, the retained entity shall certify to the Treasury that it has received a certification form from each key individual stating that he or she will comply with the requirements in § 31.217(b). In making this certification, the retained entity may rely on the information obtained pursuant to paragraph (b) of this section, unless the retained entity knows or should have known that the information provided is false or inaccurate.

**§ 31.218 Enforcement.**

(a) Compliance with these rules concerning conflicts of interest is of the utmost importance. In the event a retained entity or any individual or entity providing information pursuant to 31 U.S.C. part 31 violates any of these rules, Treasury may impose or pursue one or more of the following sanctions:

(1) Rejection of work tainted by an organizational conflict of interest or a personal conflict of interest and denial of payment for that work.

(2) Termination of the arrangement for default.

(3) Debarment of the retained entity for Federal government contracting and/or disqualification of the retained entity from future financial agency agreements.

(4) Imposition of any other remedy available under the terms of the arrangement or at law.

(5) In the event of violation of a criminal statue, referral to the Department of Justice for prosecution of the retained entity and/or its officers or employees. In such cases, the Department of Justice may make direct and derivative use of any statements and information provided by any entity, its representatives and employees or any individual, to the extent permitted by law.

(b) To the extent Treasury has discretion in selecting or imposing a remedy, it will give significant consideration to a retained entity's prompt disclosure of any violation of these rules.

Dated: September 19, 2011.

**Timothy G. Massad,**

*Assistant Secretary for Financial Stability.*

[FR Doc. 2011–25443 Filed 9–30–11; 8:45 am]

**BILLING CODE 4810–25–P**

## POSTAL SERVICE

## 39 CFR Part 122

## Service Standards for Market-Dominant Special Services Products

**AGENCY:** Postal Service.

**ACTION:** Final rule.

**SUMMARY:** This rule adds a service standard for Stamp Fulfillment Services to the set of service standards for stand-alone market-dominant special services products set forth in our regulations.

**DATES:** *Effective date:* November 2, 2011.

**FOR FURTHER INFORMATION CONTACT:** Khalid Hussain at 816–545–1250.

**SUPPLEMENTARY INFORMATION:** Section 301 of the Postal Accountability and Enhancement Act of 2006, Public Law 109–435, 120 Stat. 3198 *et seq.,* requires the Postal Service to establish modern service standards for its market-dominant products within a year of the law's December 20, 2006, enactment. Section 301 also requires that these service standards be revised ''from time to time.'' With this final rule, the Postal Service adds a set of service standards for Stamp Fulfillment Services (SFS) to the previously-established set of modern service standards.

After extensive consultations with the Postal Regulatory Commission (PRC),

the Postal Service established modern service standards for market-dominant products at 39 CFR Parts 121 and 122. See 72 FR 58946–70 (October 17, 2007) (proposed rule); 72 FR 72216–31 (December 19, 2007) (final rule).[1] The Postal Service also requested the PRC's approval of proposed systems for the measurement of service standard achievement for its market-dominant products. See PRC Docket No. PI2008–1, Notice of Request for Comments on Service Performance Measurement Systems for Market Dominant Products (December 4, 2007).

Since the establishment of the Postal Service's service standards, the PRC added SFS to the market-dominant products list. PRC Order No. 487 (July 13, 2010). As a result of SFS' classification as a market-dominant product, the Postal Service now considers it necessary to add a set of service standards for SFS to 39 CFR Part 122.

SFS provides the fulfillment of stamp and product orders received by mail, phone, fax, or Internet at the Postal Service's SFS center in Kansas City, Missouri. Orders can include stamps, stamped cards, envelopes, and stationery, and other philatelic items such as First Day Covers and stamp collecting materials. The Postal Service charges a fee for order processing and handling.

Based on the nature of the fee, the distinct aspect of SFS service consists of SFS' intake, processing, and handling of orders for stamps (both mail use and philatelic), stamp products, and retail items. Once the order is processed, the Postal Service transmits the items as First-Class Mail, Priority Mail, Express Mail, Certified Mail, or Registered Mail, depending on the nature and priority of the order. These mail channels are subject to their own service standards, performance measurement, and reporting, where applicable, and so the Postal Service does not consider it necessary or reasonable to add a separate standard for the time that SFS is in transit as a mail shipment. Due to the variety of customer orders received at SFS (mail use stamps, collectible stamps, retail product, etc.), the Postal Service establishes a set of service standards for SFS based upon order profiles.

STAMP FULFILLMENT SERVICES—SERVICE STANDARDS FOR FULFILLMENT PROCESS

| Customer order | Service standard [1] |
|---|---|
| Internet Orders: Non-Philatelic/Non-Custom | ≤2 Business Days. |
| Business Level Orders | ≤5 Business Days. |
| Philatelic/Custom and All Other Order Sources | ≤10 Business Days. |

These service standards apply to the period from receipt of the order with payment in Stamp Fulfillment Services' order intake system thru order completion for entry (pick up by mail truck) into USPS mail stream. These standards exclude orders which may be comprised of pre-orders, backorders, or orders where merchandise is not fulfilled at SFS.

The service standards for SFS reflects thorough consideration of the objectives listed in 39 U.S.C. 3691(b)(1) and the factors listed in 39 U.S.C. 3691(c), with an emphasis on customer satisfaction and customer needs.

39 U.S.C. 3691(b) requires that market-dominant product service standard performance be measured by some objective external system, or by internal methods approved by the PRC under 39 U.S.C. 3691(b)(2). The Postal Service will submit a plan for service performance measurement to the PRC for review.

**List of Subjects in 39 CFR Part 122**

Mail, Postal service.

For the reasons stated in the preamble, the Postal Service amends 39 CFR Part 122 as follows:

## PART 122—[AMENDED]

■ 1. The authority citation for 39 CFR Part 122 continues to read as follows:

**Authority:** 39 U.S.C. 101, 401, 403, 404, 1001, 3691.

■ 2. Section 122.2 is amended by adding paragraph (e) to read as follows:

**§ 122.2 Stand-Alone Special Services.**

* * * * *

(e) The service standards for Stamp Fulfillment Services order fulfillment service is shipment of orders within the following timeframes, based from the time of order receipt within SFS systems, excluding designated postal holidays.

STAMP FULFILLMENT SERVICES—SERVICE STANDARDS FOR FULFILLMENT PROCESS

| Customer order | Service standard [1] |
|---|---|
| Internet Orders: Non-Philatelic/Non-Custom | ≤2 Business Days. |
| Business Level Orders | ≤5 Business Days. |
| Philatelic/Custom and All Other Order Sources | ≤10 Business Days. |

[1] By operation of 39 U.S.C. 410(a), the Postal Service is exempt from the notice and comment requirements of the Administrative Procedure Act (5 U.S.C. 553 (b), (c)) regarding proposed rule makings. The Postal Service determined that public comment was appropriate for the initial service standards rulemaking in light of its unprecedented role. Given the limited scope of the rules issued in this notice, however, the Postal Service is exercising its discretion to forego notice-and-comment rulemaking in this instance.

**Stanley F. Mires,**

*Attorney, Legal Policy & Legislative Advice.*

[FR Doc. 2011–25336 Filed 9–30–11; 8:45 am]

**BILLING CODE 7710–12–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

**[EPA–R08–OAR–2007–0649; FRL–9290–2]**

## Approval and Promulgation of State Implementation Plans; State of Colorado Regulation Number 3: Revisions to the Air Pollutant Emission Notice Requirements and Exemptions

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

**ACTION:** Final rule.

**SUMMARY:** EPA is partially approving and partially disapproving State Implementation Plan (SIP) revisions regarding the Air Pollutant Emission Notice (APEN) regulations submitted by the State of Colorado on September 16, 1997, June 20, 2003, July 11, 2005, August 8, 2006 and August 1, 2007. The APEN provisions in Sections II.A. through II.D., Part A of Colorado's Regulation Number 3, specify the APEN filing requirements for stationary sources and exemptions from such requirements. This action is being taken under section 110 of the Clean Air Act (CAA).

**DATES:** This final rule is effective November 2, 2011.

**ADDRESSES:** EPA has established a docket for this action under Docket ID No. EPA–R08–OAR–2007–0649. All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Air Program, Environmental Protection Agency (EPA), Region 8, 1595 Wynkoop Street, Denver, Colorado 80202–1129. EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8 a.m. to 4 p.m., excluding Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Crystal Freeman, Air Program, U.S. Environmental Protection Agency, Region 8, Mailcode 8P–AR, 1595 Wynkoop, Denver, Colorado 80202–1129, (303) 312–6602, *freeman.crystal@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

### Definitions

For the purpose of this document, we are giving meaning to certain words or initials as follows:

(i) The words or initials *Act* or *CAA* mean or refer to the Clean Air Act, unless the context indicates otherwise.

(ii) The words *EPA, we, us* or *our* mean or refer to the United States Environmental Protection Agency.

(iii) The initials *SIP* mean or refer to State Implementation Plan.

(iv) The words *State* or *Colorado* mean the State of Colorado, unless the context indicates otherwise.

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II. Response to Comments
III. Section 110(l) of the CAA
IV. Final Action
V. Statutory and Executive Order Reviews

### I. Background

The State of Colorado submitted formal revisions to their SIP between 1997 and 2007 with Governor's letters dated as follows: September 16, 1997; June 20, 2003; July 11, 2005; August 8, 2006; and August 1, 2007. These submittals included revisions to the Colorado APEN provisions in Regulation Number 3, Part A, Sections II.A. through II.D. The Colorado APEN provisions in Regulation Number 3, Part A, Sections II.A. through II.C., specify requirements for stationary sources (major and minor) to file emission notices. These notices provide information such as the location where a source's emissions will occur, the nature of the source or of the activity generating the expected emissions, and an estimate of the emissions' quantity and composition. The Colorado APEN provisions in Regulation Number 3, Part A, Section II.D. exempt specific categories of sources from APEN requirements.

EPA's last final rulemaking action addressing revisions to Colorado's APEN provisions was published January 21, 1997 (62 FR 2910). The final rule today addresses the APEN SIP revisions discussed above. EPA's final rule action on the revisions submitted by the State does not trace the APEN provision changes through each of the submissions noted above. For reasons of efficiency and clarity, EPA compared the language of each APEN provision as submitted by the State on August 1, 2007 with the EPA-approved text of the same APEN provision in the 1997 Colorado SIP. These changes are detailed in the technical support document available in the docket for this action. In Table 1 of Section IV. below, EPA provides the approvals, disapprovals and no actions being taken for each provision number as of the August 1, 2007 submittal. The reasons for EPA's final action are discussed in our notice proposing action on these revisions and in the associated technical support document. (76 FR 4271 (Jan. 25, 2011)). Through this approach to the cumulative revisions, EPA is taking final action on all APEN revisions—with certain exceptions noted below—as submitted by the State of Colorado on September 16, 1997, June 20, 2003, July 11, 2005, August 8, 2006, and August 1, 2007.

### II. Response to Comments

EPA did not receive comments on our January 25, 2011 **Federal Register** proposed action regarding the partial approval and partial disapproval of Colorado's SIP revisions to their Regulation Number 3, Part A, Sections II.A. through II.D.

### III. Section 110(l) of the CAA

Section 110(l) of the CAA states that a SIP revision cannot be approved if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress toward attainment of the National Ambient Air Quality Standards (NAAQS) or any other applicable requirements of the Act. Those portions of the revisions to Colorado's Regulation Number 3, Part A, Sections II.A. through II.D. that we are approving satisfy section 110(l), because those portions do not relax existing SIP requirements. Instead, the revisions that EPA is approving increase stringency of existing provisions, clarify existing provisions, or remove obsolete provisions. Therefore, section 110(l) is satisfied for the provisions that EPA is approving. However, EPA is disapproving some exemptions in part because those provisions relax existing SIP requirements. (See 76 FR 4271.) Because EPA is disapproving those provisions, section 110(l) is satisfied.

### IV. Final Action

EPA is partially approving and partially disapproving the Colorado SIP revisions for APEN requirements and exemptions submitted by the State on September 16, 1997, June 20, 2003, July 11, 2005, August 8, 2006, and August 1, 2007. As noted above, EPA's evaluation of the revisions submitted by the State

does not track the APEN provision changes through each of the submissions, but instead, for each provision, compared the textual changes between the EPA-approved Colorado APEN provisions effective February 21, 1997, and the Colorado-adopted APEN provisions included with the August 1, 2007 submittal. Below is a comprehensive summary of EPA's final action—approval, disapproval or no action—for each of the Colorado APEN provisions in Regulation Number 3, Part A, Section II. The APEN provision numbers are as codified in the August 1, 2007 submission.

In addition to Table 1 below, EPA is approving revisions to the following provisions in Regulation Number 3, Part A, Section II: (1) Deletion of provisions II.B.8., II.B.10., and II.D.4.b.; and (2) renumbering of APEN requirements, the entirety of the language and their new location in Section I.B. The provision references, before the renumbering, were: II.B.5. and II.B.9. The references, after the renumbering, are, respectively, I.B.43 and I.B.16.

EPA is disapproving revisions to the following provisions in Regulation Number 3, Part A, Section II, which can also be found in Table 1 below: (1) A revision to II.D.1.q., regarding the APEN exemption for open burning activities; [1] (2) new exemption II.D.1.sss. and its subprovisions, which would exempt three tiers of stationary internal combustion engines from APEN requirements; (3) new exemption II.D.1.ttt. and its subprovisions, which would exempt three tiers of emergency power generators from APEN requirements; (4) new exemption II.D.1.xxx., which exempts deaerator/vacuum pump exhausts; and (5) new exemption II.D.1.ffff., applicable to Air Curtain Destructors.

EPA is taking no action on the following provisions, also found in Table 1 below, in Regulation Number 3, Part A, Section II: (1) II.D.1.m; II.D.1.ee; II.D.1.uu; II.D.1.ddd; and II.D.1.eeee., because EPA already proposed approval of the repeal of these exemptions in a separate action published on July 21, 2010 (75 FR 42346); and (2) the revision to APEN exemption II.D.1.uuu., because we proposed approval of the revision in the same July 21, 2010 proposal. The remaining provisions listed in the ''No Action'' section of the table were not revised by the State in any of the submittals that are the subject of this action.

TABLE 1—LIST OF COLORADO APEN PROVISIONS (REQUIREMENTS AND EXEMPTION IN SECTIONS II.A THROUGH II.D OF PART A, REGULATION NUMBER 3) BY EPA—FINAL RULE

| EPA's final rule | APEN provision number in August 1, 2007 submission |
|---|---|
| Approval | II.A; II.B.1; II.B.1.b; II.B.2; II.B.3; II.B.3.a; II.B.4.a. through II.B.4.f; II.B.5; II.B.6 [2]; II.C., II.C.1, II.C.1.a; II.C.1.h; II.C.2; II.C.2.b; II.C.2.b.(i) through II.C.2.b.(iv); II.C.3; II.C.3.a through II.C.3.d; II.D; II.D.1; II.D.1.a; II.D.1.f through II.D.1.i; II.D.1.j; II.D.1.k; II.D.1.n; II.D.1.x; II.D.1.y; II.D.1.aa; II.D.1.bb; II.D.1.kk; II.D.1.nn; II.D.1.oo; II.D.1.aaa; II.D.1.bbb; II.D.1.ccc; II.D.1.fff; II.D.1.ggg; II.D.1.lll; II.D.1.nnn. through II.D.1.rrr; II.D.1.vvv; II.D.1.www; II.D.1.yyy through II.D.1.dddd; II.D.2 through II.D.6. |
| Disapproval | II.D.1.q; II.D.1.sss; II.D.1.sss(i); II.D.1.sss(ii); II.D.1.sss(iii); II.D.1.ttt; II.D.1.ttt(i); II.D.1.ttt(ii); II.D.1.ttt(iii); II.D.1.xxx; II.D.1.ffff. |
| No Action | II.B; II.B.1.a; II.B.3.b; II.B.4; II.C.1.b. through II.C.1.g; II.C.2.a; II.D.1.b. through II.D.1.e; II.D.1.i.(i). through II.D.1.i.(iii); II.D.1.l; II.D.1.m; II.D.1.o; II.D.1.p; II.D.1.r. through II.D.1.w; II.D.1.z; II.D.1.cc; II.D.1.dd; II.D.1.ee; II.D.1.ff. through II.D.1.jj; II.D.1.ll; II.D.1.mm; II.D.1.pp. through II.D.1.tt; II.D.1.uu; II.D.1.vv. through II.D.1.zz; II.D.1.ddd; II.D.1.eee; II.D.1.hhh. through II.D.1.kkk; II.D.1.mmm; II.D.1.uuu; II.D.1.eeee. |

[2] For provisions II.B.5. and II.B.6., we are approving the renumbering.

## V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have Tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on Tribal governments or preempt Tribal law.

[1] The revision changes the reference from Regulation Number 1 to Regulation Number 9, which is enforceable only by the State.

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by December 2, 2011. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

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

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

Dated: March 24, 2011.

**Carol Rushin,**

*Deputy Regional Administrator, Region 8.*

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 G—Colorado

■ 2. Section 52.320 is amended by adding paragraphs (c)(72)(i)(F) and (c)(119) to read as follows:

**§ 52.320 Identification of plan.**

* * * * *

(c) * * *

(72) * * *

(i) * * *

(F) Previously approved in paragraph (c)(72)(i)(D) under Regulation No. 3, Air Contaminant Emissions Notices, 5 CCR 1001–5. These sections are now deleted without replacement: II.B.7., II.B.8., II.B.9., II.B.10., and II.D.7, effective October 30, 2006.

* * * * *

(119) The State of Colorado submitted revisions on September 16, 1997, June 20, 2003, July 11, 2005, August 8, 2006 and August 1, 2007 to Colorado's 5 CCR 1001–5 Regulation Number 3, Part A, Section II. The August 1, 2007 submittal included a renumbering of sections in II.B and II.D. The incorporation by reference in (c)(119)(i)(A) reflects the renumbered provisions as of the August 1, 2007 submittal. Additionally, the State of Colorado deleted sections II.B.7., II.B.8., II.B.9., II.B.10., and II.D.7. without replacement. The deletion of these provisions has been incorporated by reference at (c)(72)(i)(F) of this section, the paragraph containing the original incorporation by reference of the provisions.

(i) Incorporation by reference.

(A) 5 CCR 1001–5, Regulation 3, *Stationary Source Permitting and Air Pollutant Emission Notice Requirements,* Part A, *Concerning General Provisions Applicable to Reporting and Permitting,* Section II, *Air Pollutant Emission Notice (APEN) Requirements,* Sections II.A, *Air Pollutant Emission Notices for New, Modified, and Existing Sources;* II. B, *General;* II.B.1, *Emission Estimate;* II.B.1.b, *Other engineering calculations;* II.B.2, *Air Pollutant Emission Notice Term;* II.B.3, *APEN Applicability;* II.B.3.a, *Criteria Pollutants;* II.B.4.a; II.B.4.b; II.B.4.c; II.B.4.d; II.B.4.e; II.B.4.f; the undesignated text immediately following II.B.4.f and preceding II.B.5; II.B.5; II.B.6; II.C, *Revised Air Pollutant Emission Notices;* II.C.1; II.C.1.a; II.C.1.h; II.C.2; II.C.2.b; II.C.3; II.D, *Exemptions from Air Pollutant Emission Notice Requirements;* II.D.1; the undesignated text immediately following II.D.1 and preceding II.D.1.a; II.D.1.a; II.D.1.f; II.D.1.g; II.D.1.h; II.D.1.i (excluding subprovisions); II.D.1.j; II.D.1.k; II.D.1.n; II.D.1.x; II.D.1.y; II.D.1.aa; II.D.1.bb; II.D.1.kk; II.D.1.nn; II.D.1.oo; II.D.1.aaa; II.D.1.bbb; II.D.1.ccc; II.D.1.fff; II.D.1.ggg; II.D.1.lll; the undesignated text immediately following II.D.1.lll and preceding II.D.1.mmm; II.D.1.nnn., II.D.1.ooo; II.D.1.ppp; II.D.1.qqq; II.D.1.rrr; II.D.1.vvv; II.D.1.www; II.D.1.yyy; II.D.1.zzz; II.D.1.aaaa; II.D.1.bbbb; II.D.1.cccc; II.D.1.dddd; II.D.2; II.D.3; II.D.4; II.D.5; II.D.6; effective October 30, 2006.

■ 3. Add paragraph (e) to § 52.329 as follows:

**§ 52.329 Rules and regulations.**

* * * * *

(e) The State of Colorado submitted revisions on September 16, 1997, June 20, 2003, July 11, 2005, August 8, 2006 and August 1, 2007 to Colorado's 5 CCR 1001–5 Regulation Number 3, Part A, Section II. One of the revisions deleted two provisions from Section II and moved them to Section I of Regulation Number 3, Part A. The revised regulatory provisions read as follows:

(1) 5 CCR 1001–5, Regulation 3, *Stationary Source Permitting and Air Pollutant Emission Notice Requirements,* Part A, *Concerning General Provisions Applicable to Reporting and Permitting,* Section I, *Applicability,* Section I.B.16, *Criteria Pollutants,;* effective June 30, 2004:

(i) Those pollutants for which the U.S. EPA has established national ambient air quality standards, including: carbon monoxide, nitrogen dioxide, sulfur dioxide, $PM_{10}$, total suspended particulate matter, ozone, volatile organic compounds (as a precursor to ozone), and lead. For the purposes of Air Pollutant Emission Notice reporting, criteria pollutants shall also include nitrogen oxides, fluorides, sulfuric acid mist, hydrogen sulfide, total reduced sulfur, reduced sulfur compounds, municipal waste combustor organics, municipal waste combustor metals, and municipal waste combustor acid gases.

(2) 5 CCR 1001–5, Regulation 3, *Stationary Source Permitting and Air Pollutant Emission Notice Requirements,* Part A, *Concerning General Provisions Applicable to Reporting and Permitting,* Section I, *Applicability,* Section I.B.43, *Uncontrolled Actual Emissions;* effective June 30, 2004:

(i) The annual emission rate corresponding to the annual process rate listed on the Air Pollutant Emission Notice form, without consideration of any emission control equipment or procedures. The division may allow a source to forego calculating or estimating its uncontrolled actual emissions of hazardous air pollutants upon a showing by the source and a determination by the division that the creation of such data is unreasonably costly, technically impractical or not reasonably related to information necessary for making regulatory decisions with respect to that source. The division's final determination may be appealed to the commission by the source.

[FR Doc. 2011–25292 Filed 9–30–11; 8:45 am]

**BILLING CODE 6560–50–P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

**[EPA–R09–OAR–2011–0580; FRL–9468–2]**

## Revisions to the California State Implementation Plan, Sacramento Metropolitan Air Quality Management District, Ventura County Air Pollution Control District, and Placer County Air Pollution Control District

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

**ACTION:** Direct final rule.

**SUMMARY:** EPA is taking direct final action to approve revisions to the Sacramento Metropolitan Air Quality Management District (SMAQMD), Ventura County Air Pollution Control District (VCAPCD), and Placer County Air Pollution Control District (PCAPCD) portion of the California State Implementation Plan (SIP). These revisions concern volatile organic compound (VOC) emissions from organic chemical manufacturing, soil decontamination, and polyester resin operations. We are approving local rules that regulate these emission sources under the Clean Air Act as amended in 1990 (CAA or the Act).

**DATES:** This rule is effective on December 2, 2011 without further notice, unless EPA receives adverse comments by November 2, 2011. If we receive such comments, we will publish a timely withdrawal in the **Federal Register** to notify the public that this direct final rule will not take effect.

**ADDRESSES:** Submit comments, identified by docket number EPA–R09–OAR–2011–0580, by one of the following methods:

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

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

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

*Instructions:* All comments will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *http://www.regulations.gov* or e-mail. *http://www.regulations.gov* is an ''anonymous access'' system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send e-mail directly to EPA, your e-mail address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

*Docket:* Generally, documents in the docket for this action are available electronically at *http://www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed at *http://www.regulations.gov,* some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material, large maps), and some may not be publicly available in either location (*e.g.,* CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

**FOR FURTHER INFORMATION CONTACT:** David Grounds, EPA Region IX, (415) 972–3019, *grounds.david@epa.gov.*

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

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### I. The State's Submittal

*A. What rules did the State submit?*

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

TABLE 1—SUBMITTED RULES

| Local agency | Rule No. | Rule title | Adopted | Submitted |
|---|---|---|---|---|
| SMAQMD | 464 | Organic Chemical Manufacturing Operations | 09/25/08 | 09/15/09 |
| VCAPCD | 74.29 | Soil Decontamination Operations | 04/08/08 | 01/10/10 |
| PCAPCD | 243 | Polyester Resin Operations | 04/10/03 | 12/07/10 |

On 01/21/10, EPA determined that the submittal for SMAQMD Rule 464 met the completeness criteria in 40 CFR Part 51 Appendix V, which must be met before formal EPA review. On 02/04/10, EPA determined that the submittal for VCAPCD Rule 74.29 met the completeness criteria, and on 01/13/11, EPA determined that the submittal for PCAPCD Rule 243 met the completeness criteria.

*B. Are there other versions of these rules?*

There are no previous versions of PCAPCD Rules 243 in the SIP. We approved an earlier version of SMAQMD Rule 464 into the SIP on 04/19/00 (65 FR 20912). We approved an earlier version of VCAPCD Rule 74.29 into the SIP on 07/16/02 (67 FR 46596). While we can act on only the most recently submitted version, we have reviewed materials provided with previous submittals.

*C. What is the purpose of the submitted rules?*

VOCs help produce ground-level ozone and smog, which harm human health and the environment. Section 110(a) of the CAA requires States to submit regulations that control VOC emissions. SMAQMD Rule 464 limits VOC emissions from organic chemical plants. VCAPCD Rule 74.29 establishes procedures for the treatment of soil contaminated with gasoline, diesel fuel or jet fuel. PCAPCD Rule 243 reduces the emissions of VOC from polyester resin operations. EPA's technical

support documents (TSDs) have more information about these rules.

**II. EPA's Evaluation and Action**

*A. How is EPA evaluating these rules?*

Generally, SIP rules must be enforceable (see section 110(a) of the Act), must require Reasonably Available Control Technology (RACT) for each category of sources covered by a Control Techniques Guidelines (CTG) document as well as each major source in nonattainment areas (see sections 182(a)(2) and (b)(2)), and must not relax existing requirements (see sections 110(l) and 193). SMAQMD regulates an ozone nonattainment area (see 40 CFR part 81). SMAQMD has no major sources for this category but is covered by relevant CTGs. The stringency of requirements in submitted Rule 464 is generally consistent with the relevant guidance that help define RACT. VCAPCD and PCAPCD also regulate ozone nonattainment areas, but have no relevant major sources and no CTGs so RACT is not required for these rules.

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

1. ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations,'' EPA, May 25, 1988 (the Bluebook).
2. ''Guidance Document for Correcting Common VOC & Other Rule Deficiencies,'' EPA Region 9, August 21, 2001 (the Little Bluebook).
3. ''Control of Volatile Organic Emissions from Batch Processes—Alternative Control Techniques Information Document'' (EPA–453–93–017, 02/94).
4. ''Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products'' (EPA–450–2–78–029, 12/78).
5. ''Control Techniques Guidelines for Industrial Cleaning Solvents'' (EPA–453/R–06–001, 09/06).
6. ''Control of VOC Emissions from Manufacture of High-Density Polyethylene, Polypropylene, and Polystyrene Resins'' (EPA–450/3–83–008, 11/83).
7. ''Control of VOC Fugitive Emissions from Synthetic Organic Chemical Polymer and Resin Manufacturing Equipment'' (EPA–450/3–83–006, 03/84).
8. ''Control Techniques Guidelines for Fiberglass Boat Manufacturing Materials'' (EPA–453/R–08–004, 09/08).

*B. Do the rules meet the evaluation criteria?*

We believe these rules are consistent with the relevant policy and guidance regarding enforceability, RACT, and SIP relaxations. The TSDs have more information on our evaluation.

*C. EPA Recommendations To Further Improve the Rules*

The TSDs for VCAPCD and PCAPCD describe additional rule revisions that we recommend for the next time the local agency modifies the rule.

*D. Public Comment and Final Action*

As authorized in section 110(k)(3) of the Act, EPA is fully approving the submitted rules because we believe they fulfill all relevant requirements. We do not think anyone will object to this approval, so we are finalizing it without proposing it in advance. However, in the Proposed Rules section of this **Federal Register**, we are simultaneously proposing approval of the same submitted rules. If we receive adverse comments by November 2, 2011, we will publish a timely withdrawal in the **Federal Register** to notify the public that the direct final approval will not take effect and we will address the comments in a subsequent final action based on the proposal. If we do not receive timely adverse comments, the direct final approval will be effective without further notice on December 2, 2011. This will incorporate these rules into the Federally enforceable SIP.

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

**III. Statutory and Executive Order Reviews**

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve State choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, these rules do not have Tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIPs are not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on Tribal governments or preempt Tribal law.

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United

States Court of Appeals for the appropriate circuit by December 2, 2011. Filing a petition for reconsideration by the Administrator of these final rules does not affect the finality of these actions 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 rules or actions. Parties with objections to these direct final rules are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the Proposed Rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of these direct final rules, so that EPA can withdraw these direct final rules and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

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

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

Dated: August 16, 2011.

**Keith Tekata,**

*Acting Regional Administrator, Region IX.*

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

## PART 52—[AMENDED]

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

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

## Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(377)(i)(A)(*5*), (c)(378)(i)(C)(*2*), and (c)(389)(i)(B) to read as follows:

**§ 52.220 Identification of plan.**

* * * * *

(c) * * *

(377) * * *

(i) * * *

(A) * * *

(*5*) Rule 464, ''Organic Chemical Manufacturing Operations,'' adopted on September 25, 2008.

* * * * *

(378) * * *

(i) * * *

(C) * * *

(*2*) Rule74.29, ''Soil Decontamination Operations,'' adopted on April 8, 2008.

* * * * *

(389) * * *

(i) * * *

(B) Placer County Air Pollution Control.

(*1*) Rule 243, ''Polyester Resin Operations,'' adopted on April 10, 2003.

* * * * *

[FR Doc. 2011–25284 Filed 9–30–11; 8:45 am]

BILLING CODE 6560–50–P

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 50 CFR Part 648

**[Docket No. 0907301205–0289–02]**

**RIN 0648–XA413**

## Fisheries of the Northeastern United States; Atlantic Herring Fishery; Sub-ACL (Annual Catch Limit) Harvested for Management Area 1B

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

**ACTION:** Temporary rule; closure.

**SUMMARY:** NMFS announces that, effective 0001 hr, October 1, 2011, federally permitted vessels may not fish for, catch, possess, transfer, or land more than 2,000 lb (907.2 kg) of Atlantic herring (herring) in or from Management Area 1B (Area 1B) per calendar day until January 1, 2012, when the 2012 sub-ACL for Area 1B becomes available, except when transiting as described in this notice. This action is based on the determination that 95 percent of the Atlantic herring sub-ACL allocated to Area 1B for 2011 is projected to be harvested by October 1, 2011.

**DATES:** Effective 0001 hr local time, October 1, 2011, through December 31, 2011.

**FOR FURTHER INFORMATION CONTACT:** Lindsey Feldman, Fishery Management Specialist, (978) 675–2179.

**SUPPLEMENTARY INFORMATION:** Regulations governing the Atlantic herring fishery are found at 50 CFR part 648. The regulations require annual specification of the overfishing limit, acceptable biological catch, ACL, optimum yield, domestic harvest and processing, U.S. at-sea processing, border transfer and sub-ACLs for each management area. The 2011 Domestic Annual Harvest is 91,200 metric tons (mt); the 2011 sub-ACL allocated to Area 1B is 4,362 mt and 0 mt of the sub-ACL is set aside for research (75 FR 48874, August 12, 2010).

The regulations at § 648.201 require the Administrator, Northeast Region, NMFS (Regional Administrator), to monitor the Atlantic herring fishery in each of the four management areas designated in the Fishery Management Plan (FMP) for the Atlantic herring fishery and, based upon dealer reports, state data, and other available information, to determine when the harvest of Atlantic herring is projected to reach 95 percent of the management area sub-ACL. When such a determination is made, NMFS is required to publish notification in the **Federal Register** and prohibit Atlantic herring vessel permit holders from fishing for, catching, possessing, transferring, or landing more than 2,000 lb (907.2 kg) of herring per calendar day in or from the specified management area for the remainder of the closure period. Transiting of Area 1B with more than 2,000 lb (907.2 kg) of herring on board is allowed under the conditions specified below.

The Regional Administrator has determined, based upon dealer reports and other available information that 95 percent of the total Atlantic herring sub-ACL allocated to Area 1B for FY 2011 is projected to be harvested. Therefore, effective 0001 hr local time, October 1, 2011, federally permitted vessels may not fish for, catch, possess, transfer, or land more than 2,000 lb (907.2 kg) of Atlantic herring in or from Area 1B per calendar day through December 31, 2011. Vessels transiting Area 1B with more than 2,000 lb (907.2 kg) of herring on board may land this amount, provided such herring was not caught in Area 1B and provided all fishing gear aboard is stowed and not available for immediate use as required by § 648.23(b). Effective October 1, 2011, federally permitted dealers are also advised that they may not purchase Atlantic herring from federally permitted Atlantic herring vessels that harvest more than 2,000 lb (907.2 kg) of Atlantic herring from Area 1B through 2400 hr local time, December 31, 2011.

**Classification**

This action is required by 50 CFR part 648 and is exempt from review under Executive Order 12866.

The Assistant Administrator for Fisheries, NOAA (AA), finds good cause pursuant to 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment because it would be contrary to the public interest. This action closes the Atlantic herring fishery for Management Area 1B until January 1, 2012, under current regulations. The regulations at § 648.201(a) require such action to ensure that Atlantic herring

vessels do not exceed the 2011 sub-ACL allocated to Area 1B. The Atlantic herring fishery opened for the 2011 fishing year on January 1, 2011. Data indicating the Atlantic herring fleet will have landed at least 95 percent of the 2011 sub-ACL allocated to Area 1B have only recently become available. If implementation of this closure is delayed to solicit prior public comment, the sub-ACL for Area 1B for this fishing year will be exceeded, thereby undermining the conservation objectives of the FMP. The AA further finds, pursuant to 5 U.S.C 553(d)(3), good cause to waive the 30 day delayed effectiveness period for the reasons stated above.

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

Dated: September 28, 2011.

**Steven Thur,**

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

[FR Doc. 2011–25423 Filed 9–29–11; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 50 CFR Part 648

**[Docket No. 0910051338–0151–02]**

**RIN 0648–XA732**

## Fisheries of the Northeastern United States; Northeast Multispecies Fishery; Correction to Cod Landing Limit for Handgear B Vessels in the Common Pool Fishery

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

**ACTION:** Temporary rule; inseason adjustment of landing limit.

**SUMMARY:** NMFS is decreasing the Gulf of Maine and Georges Bank cod landing limit to 50 lb (22.7 kg) and 25 lb (11.3 kg) per trip for Northeast multispecies open access Handgear B permitted vessels fishing in the common pool fishery for the remainder of the 2011 fishing year (through April 30, 2012). This action is authorized under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), and is required by the regulations implementing the Northeast Multispecies Fishery Management Plan.

**DATES:** *Effective* October 3, 2011, through April 30, 2012.

**FOR FURTHER INFORMATION CONTACT:** Brett Alger, Fisheries Management Specialist, (978) 675–2153, fax (978) 281–9135.

**SUPPLEMENTARY INFORMATION:**

Regulations governing possession and landing limits for Handgear B (HB) vessels fishing under common pool regulations at § 648.88(a)(1) state that the HB cod trip limit for the Gulf of Maine (GOM) and Georges Bank (GB) shall be adjusted proportionally (rounded up to the nearest 25 lb (11.3 kg)) ''if either the GOM or GB cod trip limit applicable to a vessel fishing under a Northeast (NE) multispecies day-at-sea (DAS) permit, as specified in § 648.86(b)(1) and (2), respectively, is adjusted by NMFS.'' The initial GOM and GB cod trip limits for NE multispecies common pool vessels fishing under a day-at-sea (DAS) are set at 800 lb (362.9 kg) per DAS and 2,000 lb (907.2 kg) per DAS respectively. However, for fishing year (FY) 2011, Framework Adjustment 45 (FW 45) reduced the initial GOM cod trip limit to 500 lb (226.8 kg) per DAS from 800 lb (362.9 kg) per DAS (76 FR 23042; April 25, 2011). An inseason adjustment on May 24, 2011, increased the GB cod trip limit to 3,000 lb (1,360.8 kg) per DAS from 2,000 lb (907.2 kg) per DAS (76 FR 30035; May 24, 2011). A second inseason adjustment, on August 30, 2011, decreased the GOM cod trip limit to 350 lb (158.8 kg) per DAS and the GB cod trip limit to 300 lb (136.1 kg) per DAS (76 FR 53832, August 30, 2011). Due to an oversight, the HB trip limits for GOM and GB cod were not adjusted at the beginning of FY 2011 through the FW 45 final rule, at the time of the first inseason adjustment, or the most recent inseason adjustment.

In the GOM, the current 350 lb (158.8 kg) per DAS landing limit represents a 56.3-percent reduction from the initial 800 lb (362.9 kg) per DAS limit. Therefore, the landing limit for HB vessels for GOM cod is reduced to 50 lb (22.7 kg) per trip (75 lb (34.0 kg) per trip reduced by 56.3 percent = 32.8 lb (14.9 kg) per trip, rounded up to 50 lb (22.7 kg) per trip). On GB, the current 300 lb (136.1 kg) per DAS landing limit represents an 85-percent reduction from the initial 2,000 lb (907.2 kg) per DAS limit. Therefore, the landing limit for HB vessels for GB cod is reduced to 25 lb (11.3 kg) per trip (75 lb (34.0 kg) per trip reduced by 85.0 percent = 11.3 lb (5.1 kg) per trip, rounded up to 25 lb (11.3 kg) per trip). To correct the oversights in the previous actions, NMFS is reducing the trip limit for GOM cod to 50 lb (22.7 kg) per trip and GB cod to 25 lb (11.3 kg) per trip for NE multispecies HB permitted vessels in the common pool fishery for the remainder of FY 2011 (through April 30, 2012).

Catch will be closely monitored through dealer-reported landings, vessel monitoring system (VMS) catch reports, and other available information. NMFS may consider future inseason adjustments to decrease the trip limit, or to increase differential DAS measures, based on updated catch data and projections. Conversely, if the common pool sub-annual catch limit (ACL) is projected to be under-harvested by the end of FY 2011, NMFS will consider in-season adjustments, such as increasing the trip limit for the remainder of FY 2011.

### Classification

This action is authorized by 50 CFR part 648 and is exempt from review under Executive Order 12866.

The Assistant Administrator for Fisheries, NOAA (AA) finds good cause pursuant to 5 U.S.C. 553(b)(3)(B) to waive prior notice and the opportunity for public comment for this inseason adjustment because notice and comment would be impracticable and contrary to the public interest. The regulations at § 648.86(o) grant the RA authority to adjust the NE multispecies trip limits for common pool vessels in order to prevent the overharvest or underharvest of the pertinent common pool sub-ACLs. This action decreases the trip limits for GOM and GB cod to reduce their harvest in order to prevent the common pool sub-ACLs from being exceeded. The time necessary to provide for prior notice and comment would prevent NMFS from implementing the necessary trip limit adjustments in a timely manner. A resulting delay in the reduction of trip limits would allow for continued higher catch rates and potentially allow the pertinent common pool sub-ACLs to be exceeded. This is contrary to NMFS's obligation under the Magnuson-Stevens Act to prevent overfishing. Further, if the sub-ACLs are exceeded, this would trigger the implementation of accountability measures that would have negative economic impacts on the participants in the common pool. Giving effect to this rule as soon as possible will prevent these unnecessary impacts.

Further, the AA finds good cause pursuant to 5 U.S.C. 553(d)(3) to waive the 30-day delay in effectiveness for this action. This action decreases the trip limits for GOM and GB cod to reduce their harvest in order to prevent the common pool sub-ACLs from being exceeded. A delay in the reduction of trip limits would allow for continued higher catch rates and potentially allow the pertinent common pool sub-ACLs to

be exceeded. This is contrary to NMFS's obligation under the Magnuson-Stevens Act to prevent overfishing. Further, if the sub-ACLs are exceeded, this would trigger the implementation of accountability measures that will have negative economic impacts on the participants in the common pool. Giving effect to this rule as soon as possible will prevent these unnecessary impacts

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

Dated: September 28, 2011.

**Steven Thur,**

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

[FR Doc. 2011–25431 Filed 9–30–11; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 50 CFR Part 648

**[Docket No. 0907301205–0289–02]**

**RIN 0648–XA649**

## Fisheries of the Northeastern United States; Atlantic Herring Fishery; Sub-ACL (Annual Catch Limit) Harvested for Management Area 3

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

**ACTION:** Temporary rule; closure.

**SUMMARY:** NMFS announces that, effective 0001 hr, October 3, 2011, federally permitted vessels may not fish for, catch, possess, transfer, or land more than 2,000 lb (907.2 kg) of Atlantic herring (herring) in or from Management Area 3 (Area 3) per calendar day until January 1, 2012, when the 2012 sub-ACL (annual catch limit) for Area 3 becomes available, except when transiting as described in this notice. This action is based on the determination that 95 percent of the herring sub-ACL allocated to Area 3 for 2011 is projected to be harvested by October 3, 2011.

**DATES:** Effective 0001 hr local time, October 3, 2011, through December 31, 2011.

**FOR FURTHER INFORMATION CONTACT:** Lindsey Feldman, Fishery Management Specialist, (978) 675–2179.

**SUPPLEMENTARY INFORMATION:** Regulations governing the herring fishery are found at 50 CFR part 648. The regulations require annual specification of the overfishing limit, acceptable biological catch, annual catch limit (ACL), optimum yield, domestic harvest and processing, U.S. at-sea processing, border transfer, and sub-ACLs for each management area. The 2011 Domestic Annual Harvest is 91,200 metric tons (mt); the 2011 sub-ACL allocated to Area 3 is 38,146 mt and 0 mt of the sub-ACL is set aside for research (75 FR 48874, August 12, 2010).

The regulations at § 648.201 require the Administrator, Northeast Region, NMFS (Regional Administrator), to monitor the herring fishery in each of the four management areas designated in the Fishery Management Plan for the herring fishery and, based upon dealer reports, state data, and other available information, to determine when the harvest of herring is projected to reach 95 percent of the management area sub-ACL. When such a determination is made, NMFS is required to publish notification in the **Federal Register** and prohibit herring vessel permit holders from fishing for, catching, possessing, transferring, or landing more than 2,000 lb (907.2 kg) of herring per calendar day in or from the specified management area for the remainder of the closure period. Transiting of Area 3 with more than 2,000 lb (907.2 kg) of herring on board is allowed under the conditions specified below.

The Regional Administrator has determined, based upon dealer reports and other available information that 95 percent of the total herring sub-ACL allocated to Area 3 for 2011 is projected to be harvested. Therefore, effective 0001 hr local time, October 3, 2011, federally permitted vessels may not fish for, catch, possess, transfer, or land more than 2,000 lb (907.2 kg) of herring in or from Area 3 per calendar day through December 31, 2011. Vessels may transit through Area 3 with more than 2,000 lb (907.2 kg) of herring on board, provided such herring was not caught in Area 3 and provided all fishing gear aboard is stowed and not available for immediate use as required by § 648.23(b). Effective October 3, 2011, federally permitted dealers are also advised that they may not purchase herring from federally permitted herring vessels that harvest more than 2,000 lb (907.2 kg) of herring from Area 3 through 2400 hr local time, December 31, 2011.

### Classification

This action is required by 50 CFR part 648 and is exempt from review under Executive Order 12866.

NMFS finds good cause pursuant to 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment because it would be contrary to the public interest. This action closes the herring fishery for Management Area 3 until January 1, 2012, under current regulations. The regulations at § 648.201(a) require such action to ensure that herring vessels do not exceed the 2011 sub-ACL allocated to Area 3. The herring fishery opened for the 2011 fishing year on January 1, 2011. Data indicating the herring fleet will have landed at least 95 percent of the 2011 sub-ACL allocated to Area 3 have only recently become available. If implementation of this closure is delayed to solicit prior public comment, the sub-ACL for Area 3 for this fishing year can be exceeded, thereby undermining the conservation objectives of the FMP. NMFS further finds, pursuant to 5 U.S.C 553(d)(3), good cause to waive the 30 day delayed effectiveness period for the reasons stated above.

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

Dated: September 28, 2011.

**Steven Thur,**

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

[FR Doc. 2011–25424 Filed 9–29–11; 8:45 am]

**BILLING CODE 3510–22–P**

# Proposed Rules

Federal Register
Vol. 76, No. 191
Monday, October 3, 2011

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

**[EPA–R09–OAR–2010–0717; FRL–9473–7]**

## Approval and Promulgation of Implementation Plans; Arizona; Update to Stage II Gasoline Vapor Recovery Program; Change in the Definition of ''Gasoline'' To Exclude ''E85''

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

**ACTION:** Proposed rule.

**SUMMARY:** Under the Clean Air Act, EPA is proposing to approve certain revisions to the Arizona State Implementation Plan submitted by the Arizona Department of Environmental Quality. These revisions concern amendments to the statutory and regulatory provisions adopted by the State of Arizona to regulate volatile organic compound emissions from the transfer of gasoline from storage tanks to motor vehicle fuel tanks at gasoline dispensing sites, i.e., stage II vapor recovery. The revisions would also amend the definition of ''gasoline'' to explicitly exclude E85 and thereby amend the requirements for fuels available for use in the Phoenix metropolitan area as well as the requirements for vapor recovery. In proposing approval of the revisions, EPA is proposing to waive the statutory stage II vapor recovery requirements at E85 dispensing pumps within the Phoenix area. Lastly, EPA is proposing to correct an EPA rulemaking that approved a previous version of the Arizona rules regulating these sources.

**DATES:** Comments must be received on or before December 2, 2011. Anyone wishing the opportunity for the oral presentation of data, views, or arguments, must submit a request on or before October 18, 2011.

**ADDRESSES:** Submit comments, identified by docket number EPA–R09–OAR–2010–0717, by one of the following methods:

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

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

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

*Instructions:* All comments will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *http://www.regulations.gov* or e-mail. *http://www.regulations.gov* is an ''anonymous access'' system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send e-mail directly to EPA, your e-mail address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

*Docket:* The index to the docket for this action is available electronically at *http://www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (e.g., copyrighted material), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

**FOR FURTHER INFORMATION CONTACT:** For further information on the revisions to the Arizona State Implementation Plan submitted by the Arizona Department of Environmental Quality, contact Mr. Andrew Steckel, EPA Region IX, 75 Hawthorne Street (AIR–4), San Francisco, CA 94105, phone number (415) 947–4115, fax number (415) 947–3579, or by e-mail at *steckel.andrew@epa.gov.*

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

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## I. The State's Submittal

### *A. What did the state submit for EPA action?*

On September 21, 2009, the Arizona Department of Environmental Quality (ADEQ) submitted a revision to the Arizona state implementation plan (SIP) updating the gasoline vapor recovery program that was originally submitted and approved by EPA in 1994 to meet certain applicable requirements of the Clean Air Act, as amended in 1990 (CAA or ''Act'').[1] The specific revisions include statutory provisions and administrative rules regulating the emissions of volatile organic compounds (VOC) due to the transfer of gasoline from storage tanks (typically underground) to motor vehicle fuel tanks at gasoline stations in the Phoenix metropolitan area. The statutory

[1] Gasoline dispensing pump vapor control devices, commonly referred to as ''stage II'' vapor recovery, are systems that control VOC vapor releases during the refueling of motor vehicles. This process takes the vapors normally emitted directly into the atmosphere when pumping gas and recycles them back into the fuel storage tank, preventing them from polluting the air. For more information on Stage II vapor recovery systems, please see EPA's proposed rule, ''Air Quality: Widespread Use for Onboard Refueling Vapor Recovery and Stage II Waiver,'' 76 FR 41731, at 41734 (July 15, 2011).

provisions and administrative rules are contained in enclosures 3 and 4 of ADEQ's September 21, 2009 SIP revision submittal package.[2]

ADEQ's submittal represents an update to the stage II requirements but is comprehensive in that the submitted statutory and regulatory provisions also address general requirements related to stage I vapor recovery.[3] While ADEQ's submittal relates almost entirely to the state's vapor recovery program, it also amends the State's fuels program by amending the definition of the term ''gasoline'' to exclude ''E85,'' a change that affects both the gasoline fuels program established for the Phoenix metropolitan area and the stage II vapor recovery program because both programs now rely on that particular definition. ADEQ's September 21, 2009 SIP revision submittal also contains adequate documentation of public notice, opportunity for comment, and a public hearing on the proposed SIP revision (see enclosure 5 of the submittal). The public participation materials submitted by ADEQ demonstrate compliance with the procedural requirements set forth in section 110(l) of the Clean Air Act (CAA or ''Act''). (The substantive requirements of section 110(l) are discussed in section II.B.4 of this document.)

Table 1 lists the statutory provisions, and table 2 lists the administrative rules, that were submitted by ADEQ on September 21, 2009 and that we are proposing to approve in today's action.

TABLE 1—SUBMITTED STATUTORY PROVISIONS

| Arizona revised statutes | Title | Submitted |
|---|---|---|
| Title 41, chapter 15, article 1, section 41–2051. | Definitions: subsection 6 (''Certification''), subsection 10 (''Department''), subsection 11 (''Diesel fuel''), subsection 12 (''Director''), and subsection 13 (''E85''). | 09/21/09 |
| Title 41, chapter 15, article 6, section 41–2121. | Definitions: subsection 5 (''Gasoline'') | 09/21/09 |
| Title 41, chapter 15, article 7, section 41–2131. | Definitions: subsection 1 (''Annual throughput''), subsection 2 (''Clean air act''), subsection 3 (''Gasoline dispensing site''), subsection 4 (''Stage I vapor collection system''), subsection 5 (''Stage II vapor collection system''), and subsection 6 (''Vapor control system''). | 09/21/09 |
| Title 41, chapter 15, article 7, section 41–2132. | Stage I and stage II vapor recovery systems | 09/21/09 |
| Title 41, chapter 15, article 7, section 41–2133. | Compliance schedules | 09/21/09 |

TABLE 2—SUBMITTED RULES

| Arizona administrative code | Rule title | Effective date (for state purposes) | Submitted |
|---|---|---|---|
| Title 20, chapter 2, article 1, section R20–2–101 | Definitions | 06/05/04 | 09/21/09 |
| Title 20, chapter 2, article 9, section R20–2–901 | Material Incorporated by Reference | 06/05/04 | 09/21/09 |
| Title 20, chapter 2, article 9, section R20–2–902 | Exemptions | 06/05/04 | 09/21/09 |
| Title 20, chapter 2, article 9, section R20–2–903 | Equipment and Installation | 06/05/04 | 09/21/09 |
| Title 20, chapter 2, article 9, section R20–2–904 | Application Requirements and Process for Authority to Construct Plan Approval. | 06/05/04 | 09/21/09 |
| Title 20, chapter 2, article 9, section R20–2–905 | Initial Inspection and Testing | 06/05/04 | 09/21/09 |
| Title 20, chapter 2, article 9, section R20–2–907 | Operation | 10/08/98 | 09/21/09 |
| Title 20, chapter 2, article 9, section R20–2–908 | Training and Public Education | 10/08/98 | 09/21/09 |
| Title 20, chapter 2, article 9, section R20–2–909 | Recordkeeping and Reporting | 10/08/98 | 09/21/09 |
| Title 20, chapter 2, article 9, section R20–2–910 | Annual Inspection and Testing | 06/05/04 | 09/21/09 |
| Title 20, chapter 2, article 9, section R20–2–911 | Compliance Inspections | 06/05/04 | 09/21/09 |
| Title 20, chapter 2, article 9, section R20–2–912 | Enforcement | 06/05/04 | 09/21/09 |

On March 21, 2010, the submittal of these rules for ADEQ was deemed by operation of law to meet the completeness criteria in 40 CFR part 51, appendix V, which must be met before formal EPA review.

*B. Are there other versions of these provisions in the Arizona SIP?*

On November 1, 1994 (59 FR 54521), we approved Arizona's stage II vapor recovery rules that had been adopted by the Arizona Department of Weights and Measures (ADWM) on August 27, 1993 and submitted to us by ADEQ on May 27, 1994. Specifically, we approved the following sections of title 4, chapter 31, article 9 (''Gasoline Vapor Control'') of the Arizona Administrative Code (AAC):

- R4–31–901—Definitions;
- R4–31–902—Material incorporated by reference;
- R4–31–903—Exemptions;
- R4–31–904—Equipment and installation;

[2] By letter dated April 12, 2011, ADEQ substituted the statutes and rules in enclosures 3 and 4 as submitted on September 21, 2009 with official, published versions of the same statutes and rules in keeping with the requirements. ADEQ did so in response to an EPA request for the official, published versions of the statutes and rules to comply with the requirements established by the Office of the Federal Register for incorporating such materials by reference into the Code of Federal Regulations.

[3] ''Stage I'' vapor recovery refers to the collection of VOC emissions expelled from underground storage tanks at gasoline stations when being refilled by tank trucks. The Maricopa County Air Quality Department (MCAQD) implements its own stage I vapor recovery regulation within the Phoenix metropolitan area, Regulation III, Rule 353 (''Transfer of Gasoline into Stationary Storage Dispensing Tanks''). EPA approved MCAQD rule 353 and incorporated it into the Arizona SIP. See 61 FR 3578 (February 1, 1996). MCAQDM's stage I vapor recovery program and related rule are not affected by today's proposed action.

- R4–31–905—Plan review and approval;
- R4–31–906—Operation;
- R4–31–907—Training and public education;
- R4–31–908—Recordkeeping and reporting;
- R4–31–909—Annual tests; and
- R4–31–910—Enforcement.

In our 1994 final rule, we made an error in how we codified the stage II vapor recovery rules into the Arizona SIP, and are proposing to correct that error in today's proposed action (see section II.C of this document).

The Arizona statutory provisions that establish stage II vapor recovery requirements were originally submitted to EPA on November 13, 1992, and later re-submitted on February 16, 1993, but, in approving the amended Stage II vapor recovery rules submitted in 1994, EPA inadvertently neglected to approve the statutory provisions that had been submitted the previous year. Thus, there are no previous versions of the ARS provisions listed in table 1 with the exception of ARS 41–2121, paragraph (5), which defines the term ''gasoline.'' We approved an earlier version of the definition for ''gasoline'' (then codified in paragraph (4) of ARS section 41–2121) in connection with our approval of the carbon monoxide redesignation request and maintenance plan for Tucson area. See 65 FR 36353 (June 8, 2000), as corrected at 65 FR 50651 (August 21, 2000) and 69 FR 12802 (March 18, 2004).

*C. What are the relevant statutory provisions?*

Under CAA section 182(b)(3), Stage II vapor recovery systems are required to be used at larger gasoline dispensing facilities located in Serious, Severe, and Extreme nonattainment areas for ozone.[4] Based on deadlines established in the Act, within 24 months from the effective date of the initial area designation and classification, states must adopt a Stage II program into their SIPs, and the controls must be installed according to specified deadlines following state rule adoption. For existing facilities the installation deadlines depend on the date the facilities were built and the monthly volume of gasoline dispensed. *See* CAA sections 182(b)(3)(A)–(B), and 324(a)–(c).[5]

However, the CAA provides discretionary authority to the EPA Administrator to, by rule, revise or waive the section 182(b)(3) Stage II requirement after the Administrator determines that On-Board Refueling Vapor Recovery (ORVR) is in widespread use throughout the motor vehicle fleet. *See* CAA section 202(a)(6). ORVR consists of an activated carbon canister installed in the vehicle into which vapors being expelled from the vehicle fuel tanks are forced to flow. There the vapors are captured by the activated carbon in the canister. When the engine is started, the vapors are drawn off of the activated carbon and into the engine where they are burned as fuel. EPA promulgated ORVR standards on April 6, 1994, 59 FR 16262.

EPA first began the phase-in of ORVR by requiring that 40 percent of passenger cars manufactured in model year 1998 be equipped with ORVR. The ORVR requirement for passenger cars was increased to 100 percent by model year 2000. Phase-in continued for other vehicle types and ORVR has been a requirement on virtually all new gasoline-powered motor vehicles (passenger cars, light trucks, and complete[6] heavy-duty gasoline powered vehicles under 10,000 lbs gross vehicle weight rating (GVWR)) sold since model year 2006. *See* 40 CFR part 86. Currently, ORVR-equipped vehicles comprise approximately 64 percent of the in-service vehicle fleet nationwide, and account for around 74 percent of the vehicle miles traveled (VMT) in the nationwide fleet. The percentage of non-ORVR vehicles and the percentage of VMT driven by those vehicles declines each year as these older vehicles wear out and are removed from service. Since certain vehicles are not required to have ORVR, including motorcycles and incomplete heavy-duty gasoline powered trucks chassis, under current requirements the nationwide motor vehicle fleet would never be entirely equipped with ORVR.

Recently, EPA proposed criteria for determining whether ORVR is in ''widespread use'' for purposes of controlling motor vehicle refueling emissions throughout the motor vehicle fleet. See 76 FR 41731 (July 15, 2011). In EPA's July 15, 2011 action, EPA also proposed, based on the proposed criteria, to establish June 30, 2013 as the date on which ''widespread use'' will occur nationally, and to establish June 30, 2013 as the date on which a nationwide waiver of Stage II gasoline vapor recovery systems will be effective. While, if finalized as proposed, our July 15, 2011 proposal would establish a nationwide date for determining when ORVR is in ''widespread use'' and for waiving the Stage II requirement, it also proposes to allow individual states to submit SIP revisions that demonstrate that ORVR widespread use has occurred (or will occur) on a date earlier than June 30, 2013 for areas in their states, and to request that the EPA revise or waive the section 182(b)(3) requirement as it applies to only those areas. See 76 FR at 41733. Consistent with EPA's July 15, 2011 proposal to allow States to submit such SIP revisions, EPA is today proposing to approve an area-specific revision to the Arizona SIP and to approve a waiver for a specific portion of the motor vehicle fleet in the Phoenix metropolitan area.

*D. What is the purpose of the submitted SIP revision?*

Under the Clean Air Act, as amended in 1990, the ''Phoenix area,'' defined by the Maricopa Association of Governments' (MAGs') urban planning area boundary (but later revised to exclude the Gila River Indian Community at 70 FR 68339 (November 10, 2005)), was classified as a ''moderate'' nonattainment area for the 1-hour ozone national ambient air quality standard (NAAQS). See 56 FR 56694, at 56717 (November 6, 1991). Later, the Phoenix area was reclassified as ''serious'' for the 1-hour ozone standard (62 FR 60001, November 6, 1997).

As noted above, section 182(b)(3) of the Act required States with ozone nonattainment areas such as the Phoenix area to adopt and submit a SIP revision requiring gasoline dispensing facilities to install and operate stage II vapor recovery equipment. In response, in 1993, ADEQ submitted the statutory provisions and rules establishing stage II vapor recovery requirements in the Phoenix area, the only area in Arizona subject to section 182(b)(3) of the Act. In May 1994, ADEQ submitted amended

[4] *See* CAA section 182(b)(3), 42 U.S.C. 7511a(b)(3). Originally, the section 182(b)(3) Stage II requirement also applied in all Moderate ozone nonattainment areas. However, under section 202(a)(6) of the CAA, 42 U.S.C. 7521(a)(6), the requirements of section 182(b)(3) no longer apply in Moderate ozone nonattainment areas after EPA promulgated ORVR standards on April 6, 1994, 59 FR 16262, codified at 40 CFR parts 86 (including 86.098–8), 88 and 600. Under implementation rules issued in 2004 for the 1997 8-hour ozone standard, EPA retained the Stage II-related requirements under section 182(b)(3) as they applied for the 1-hour ozone standard. 40 CFR 51.900(f)(5).

[5] Section 182(b)(3)(B) has the following effective date requirements for implementation of Stage II after the adoption date by a state of a Stage II rule: 6 months after adoption of the state rule, for gas stations built after the enactment date (which for newly designated areas would be the designation date); 1 year after adoption date, for gas stations pumping at least 100,000 gal/month based on average monthly sales over 2-year period before adoption date; 2 years after adoption, for all others.

[6] For purposes of ORVR applicability, a ''complete'' vehicle means a vehicle that leaves the primary manufacturer's control with its primary load carrying device or container attached.

stage II vapor recovery rules, which EPA then approved later that year. See 59 FR 54521 (November 1, 1994).

More recently, the Arizona Legislature has amended the relevant statutes (1) to require ADWM to adopt rules to enhance compliance with the stage II vapor recovery requirements, (2) to explicitly exclude ''E85'' from the definition of ''gasoline,'' and (3) to extend the geographic area to which stage II vapor recovery requirements apply to ''area A.'' [7] Since our approval of the stage II vapor recovery rules in 1994, ADWM has renumbered and recodified its gasoline vapor recovery rules and amended them to enhance compliance with the requirements. The purpose of ADEQ's September 21, 2009 SIP revision is to incorporate the statutory and regulatory changes described above into the Arizona SIP.

EPA's ''Technical Support Document for EPA's Notice of Proposed Rulemaking on Revisions to the Arizona State Implementation Plan'' (August 2011) (TSD) has more information about the statutory provisions and rules and our evaluation, and can be found in the docket for this action.

## II. EPA's Evaluation and Action

### *A. How is EPA evaluating the statutes and rules?*

Since 1994, when EPA last approved Arizona's stage II vapor recovery rules, EPA has designated a larger area referred to the ''Phoenix-Mesa'' area as nonattainment for the 1997 8-hour ozone standard (69 23858, April 30, 2004),[8] approved the State's 1-hour ozone redesignation request and maintenance plan for the Phoenix area (70 FR 34362, June 14, 2005), and revoked the 1-hour ozone standard (replaced by the 1997 8-hour ozone standard) effective June 15, 2005 (69 FR 23951, April 30, 2004). Notwithstanding the redesignation of the Phoenix area and the revocation of the 1-hour ozone standard, the Phoenix area remains subject to the CAA section 182(b)(3) stage II requirement by virtue of its classification as ''serious'' for the 1-hour ozone standard on the effective date of the area's designation as ''nonattainment'' for the 8-hour ozone standard (i.e., on June 15, 2004) under the anti-backsliding provisions of EPA's rules governing the transition from the 1-hour to the 8-hour ozone standard. See 40 CFR 51.905(a). Thus, we have evaluated the submitted statutory provisions and rules to ensure Arizona's stage II program complies with section 182(b)(3) of the Act. In addition, we have evaluated the submitted statutory provisions and rules for enforceability (see CAA section 110(a)(2)), and for non-interference with reasonable further progress or attainment of the NAAQS (see CAA section 110(l)).

Guidance and policy documents that we used to evaluate the submitted statutory provisions and rules for enforceability and compliance with CAA section 182(b)(3) stage II vapor requirement requirements include the following:

1. ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations,'' EPA, May 25, 1988 (the Bluebook).

2. ''Guidance Document for Correcting Common VOC & Other Rule Deficiencies,'' EPA Region 9, August 21, 2001 (the Little Bluebook).

3. ''Draft Model Rule, Gasoline Dispensing Facility—Stage II Vapor Recovery,'' EPA (August 17, 1992).

4. ''Gasoline Vapor Recovery Guidelines,'' EPA Region IX (April 24, 2000).

5. ''Removal of Stage II Vapor Recovery in Situations Where Widespread Use of Onboard Vapor Recovery is Demonstrated,'' memorandum from Stephen D. Page, Director, EPA Office of Air Quality Planning and Standards, and Margo Tsirigotis Oge, Director, EPA Office of Transportation and Air Quality, to Regional Air Division Directors, dated December 12, 2006 (''2006 Page/Oge Memorandum'').[9]

6. ''Removal of Stage II Vapor Recovery from Refueling of Corporate Fleets,'' memorandum from Stephen D. Page, Director, EPA Office of Air Quality Planning and Standards, and Margo Tsirigotis Oge, Director, EPA Office of Transportation and Air Quality, to Regional Air Division Directors, dated November 28, 2007 (''2007 Page/Oge Memorandum'').

All of the above documents can be found in the docket for this rulemaking.

### *B. Do the statutes and rules meet the evaluation criteria?*

1. Clean Air Act Requirements

As discussed in section I.C. of this document, CAA section 182(b)(3) requires States with ozone nonattainment areas classified as ''moderate'' or worse to adopt regulations requiring owners or operators of gasoline dispensing systems to install and operate stage II vapor recovery equipment at their facilities. The Act specifies that these State rules must apply to any facility that dispenses more than 10,000 gallons of gasoline per month, or, in the case of an independent small business marketer (as defined in CAA section 324), any facility that dispenses more than 50,000 gallons of gasoline per month.

Section 202(a)(6) of the Act required EPA to promulgate standards requiring that new light-duty vehicles be equipped with onboard refueling vapor recovery (ORVR) systems. ORVR regulations were promulgated by EPA on April 6, 1994 (see 59 FR 16262, 40 CFR 86.001 and 40 CFR 86.098). Upon promulgation of the ORVR rules, under CAA section 202(a)(6) the stage II requirement of section 182(b)(3) no longer applied to moderate areas, but only to serious and worse areas. Since model year 2000, all passenger cars have been required to have ORVR, and since 2006, virtually all new gasoline powered motor vehicles (passenger cars, light trucks, and complete heavy-duty gasoline powered vehicles) have been required to be equipped with ORVR.

The CAA anticipates that, over the long-term, ORVR will reduce the benefit from, and the need for, stage II vapor recovery systems at gasoline dispensing sites in ozone nonattainment areas. Section 202(a)(6) of the CAA allows EPA to revise or waive the application of stage II vapor recovery requirements for areas classified as serious, severe, or extreme for ozone, as appropriate, after such time as EPA determines that ORVR systems are in widespread use throughout the motor vehicle fleet. CAA section 202(a)(6) does not specify which motor vehicle fleet must be the subject of a widespread use determination before EPA may revise or waive the section 182(b)(3) stage II requirement. Nor does the CAA identify what level of ORVR use in the motor vehicle fleet must be reached before it is ''widespread.'' To date, EPA has issued two memoranda addressing when ORVR

[7] EPA most recently approved the definition of ''area A'' as part of the Arizona SIP in 2004. See 69 FR 10161 (March 4, 2004).

[8] In 2009, EPA proposed to classify the Phoenix-Mesa nonattainment area as ''marginal'' for the 1997 8-hour ozone standard. See 74 FR 2936 (January 16, 2009). EPA has not taken final action on the January 2009 proposed rule.

[9] In EPA's recent national rulemaking regarding waiver of Stage II requirements, we indicate that the Agency continues to believe the 2006 Page/Oge Memorandum is sound guidance in areas where Stage II is currently being implemented, and is unaffected by the proposed national widespread use determination. See 76 FR 41731, at 41737 (July 15, 2011). In today's action, we rely primarily on the principles and rationale set forth in the 2006 Page/Oge Memorandum rather than those set forth in EPA's July 15, 2011 proposed rule.

widespread use might be found for particular fleets.[10]

EPA expects the possibility of different rates of implementation of ORVR across different geographic regions and among different types of motor vehicle fleets within any region. Given this, EPA does not believe the CAA section 202(a)(6) must be read narrowly to allow a widespread use determination and waiver of the stage II requirement for a given area or area's fleet only if ORVR use has become widespread through the entire United States, or only if ORVR use has reached a definite level in each area. Rather, EPA believes that section 202(a)(6) allows the Agency to apply the widespread use criterion to either the entire motor vehicle fleet in a State or nonattainment area, or to special segments of the overall fleet for which ORVR use is shown to be sufficiently high, and to base widespread use determinations on differing levels of ORVR use, as appropriate. EPA also believes that the Act allows the Agency to use an area-specific rulemaking approving a SIP revision to issue the section 202(a)(6) waiver for a relevant fleet in a nonattainment area.

One metric that EPA has recommended in determining whether ORVR use is widespread within a given motor vehicle fleet considers when VOC emissions resulting from the application of ORVR controls alone equal the VOC emissions when both stage II vapor recovery systems and ORVR controls are used, after accounting for incompatibility excess emissions. The incompatibility excess emissions factor relates to losses in control efficiency when certain types of stage II and ORVR are used together. EPA believes that one reasonable widespread use metric based on comparable VOC emissions will likely have been reached when the percentage of motor vehicles in service with ORVR, the vehicle miles traveled (VMT) by ORVR-equipped vehicles, or the gasoline dispensed to ORVR-equipped vehicles reaches 95 percent. See the 2006 Page/Oge Memorandum, page 2. Application of the 95 percent criterion could lead, for example, to waiver of stage II vapor recovery requirements at gasoline dispensing sites that exclusively fuel new automobiles at assembly plants and rental cars at rental car facilities given the high percentage (essentially 100%) of ORVR-equipped vehicles associated with such facilities.

[10] ''Removal of Stage II Vapor Recovery in Situations Where Widespread Use of Onboard Vapor Recovery is Demonstrated,'' memorandum from Stephen D. Page, Director, EPA Office of Air Quality Planning and Standards, and Margo Tsirigotis Oge, Director, EPA Office of Transportation and Air Quality, to Regional Air Division Directors, dated December 12, 2006; and ''Removal of Stage II Vapor Recovery from Refueling of Corporate Fleets,'' memorandum from Stephen D. Page, Director, EPA Office of Air Quality Planning and Standards, and Margo Tsirigotis Oge, Director, EPA Office of Transportation and Air Quality, to Regional Air Division Directors, dated November 28, 2007.

2. Arizona's Stage II Vapor Recovery Requirements

Arizona's stage II vapor recovery requirements are set forth in state law (codified in the Arizona Revised Statutes) and administrative rules adopted by ADWM (codified in the Arizona Administrative Code). Arizona Revised Statutes (ARS) section 41–2132 (''Stage I and stage II vapor recovery systems'') requires gasoline dispensing sites to be equipped with a stage II vapor collection system. The requirement applies within ''an ozone nonattainment area designated as moderate, serious, severe or extreme by the United States environmental protection agency under § 107(d) of the clean air act, area A or other geographical area * * *.'' ARS section 41–2132(C). ''Area A'' is defined in ARS section 49–541 and it includes all of the metropolitan Phoenix former 1-hour ozone nonattainment area plus additional areas in Maricopa County to the north, east, and west, as well as small portions of Yavapai County and Pinal County. ADEQ did not submit ARS section 49–541 to EPA as part of the stage II vapor recovery SIP update revision on September 21, 2009, but EPA has previously approved the current definition of ''area A'' from ARS section 49–541 into the SIP. See 69 FR 10161 (March 4, 2004).

ARS 41–2132 also provides an exemption for gasoline dispensing sites with a throughput of less than 10,000 gallons per month or less than 50,000 gallons per month in the case of an independent small business marketer as defined in section 324 of the Clean Air Act, and for gasoline dispensing sites that are located on a manufacturer's proving ground. ARS 41–2133 sets forth certain compliance schedules related to the stage II vapor recovery requirements in ARS 41–2132.

The stage II vapor recovery requirements in ARS 41–2132 rely upon the definitions of certain terms, such as ''gasoline,'' ''stage II vapor collection system,'' and ''E85,'' among others, which are codified in ARS sections 41–2015, 41–2121, and 41–2131, and ADEQ included the relevant definitions, along with ARS sections 41–2132 and 41–2133, in the SIP revision submittal dated September 21, 2009. See table 1 of this document. The definition of ''gasoline,'' which is codified in paragraph (5) of ARS 41–2121, specifically excludes ''diesel fuel'' and ''E85.''

ARS section 41–2132(G) directs ADWM to adopt by rule standards for the installation and operation of stage I and stage II vapor recovery systems. ADWM's rules for such systems are codified at title 20, chapter 2, article 9 (''Gasoline Vapor Recovery''), of the Arizona Administrative Code (AAC). These rules rely upon certain definitions in AAC, title 20, chapter 2, article 1 (''Administration and Procedures''), section R20–2–101 (''Definitions''). ADEQ submitted these rules and definition to EPA as part of the stage II SIP revision dated September 21, 2009—see table 2 of this document.

We previously approved ADWM's stage II vapor recovery rules (59 FR 54521, November 1, 1994), and in so doing, found them to comply with CAA section 182(b)(3), to be consistent with EPA guidance on stage II vapor recovery regulations, and to be enforceable. Thus, our action today is based on an evaluation of the changes in ADWM's rules as submitted on September 21, 2009 relative to those that were approved in 1994 and that are incorporated into the existing Arizona SIP.

In addition to renumbering and recodification, ADWM's vapor recovery rules have been amended to delete, modify, and add certain definitions; to approve use of certain CARB test procedures not previously approved; to include general requirements for stage I vapor recovery systems; to add exemptions for motor raceways, motor vehicle proving grounds, and marine and aircraft refueling facilities; to clarify and expand application requirements; and to enhance compliance-related provisions.

3. Compliance With CAA Section 182(b)(3) Stage II Requirements

As explained in this subsection, based on our review of Arizona's stage II requirements set forth in certain statutes and administrative rules, we conclude that the state meets the CAA section 182(b)(3) stage II requirements. First, the state is requiring stage II vapor recovery controls in an area that encompasses all of the 1-hour ozone ''serious'' nonattainment area consistent with compliance schedules set forth in the Act. The state also provides low-volume throughput exemptions that are consistent with those allowed for in CAA section 182(b)(3). State law, however, also provides an exemption for a ''gasoline dispensing site that is

located on a manufacturer's proving ground.'' See ARS 41–2132(C). This exemption is not specifically allowed under CAA section 182(b)(3); however, ADWM indicates that the one facility to which the exemption had applied has closed at its location within the nonattainment area, and the equipment has been removed to a new location outside of the nonattainment area.[11] Furthermore, ADWM reports that, at the facility's new location, the fuel throughput is less than the low-throughput (i.e., 10,000-gallon per month) threshold exemption authorized in section 182(b)(3). Assuming that the fuel usage rate at the relocated facility is representative of the throughput at gasoline dispensing sites that would be covered by the State's exemption for manufacturer's proving ground in the event that such an exempt facility would locate once again within the nonattainment area, the exemption is acceptable under section 182(b)(3).

Because the state submitted the definition of ''gasoline'' in ARS 41–2121 for our approval as part of the September 21, 2009 SIP revision, we must consider whether the exclusion in ARS 41–2121 of ''E85'' from the definition of gasoline comports with section 182(b)(3) vapor recovery requirements. By excluding ''E85'' from the definition of gasoline, Arizona's stage II vapor recovery law (ARS 41–2132) would not apply to E85 dispensing pumps within the ozone nonattainment area.

E85 is a motor vehicle fuel that is a blend of as little as 15 percent gasoline and up to 85 percent ethanol. (In wintertime applications, the ratio may be 30 percent gasoline and 70 percent ethanol.) E85 can only be used in specially designed flexible fuel vehicles (FFVs), which have mostly been manufactured since 1998. Since these are newer vehicles, most of them are equipped with ORVR, and every FFV built today has ORVR. Thus, most vehicles refueling at E85 dispensing pumps are already having their evaporative emissions captured, as in the cases of late model rental cars refueling at rental car facilities and newly manufactured cars being fueled for the first time at automobile assembly plants. At the time EPA released the 2006 Page/Oge Memorandum, EPA estimated that 59 percent of FFVs in use nationwide were equipped with ORVR, and we noted that the percentage of FFVs with ORVR will continue to climb as older vehicles are taken out of service and new models join the fleet. We also noted that the percentage of FFVs equipped with ORVR varies across different ozone nonattainment areas. In the Phoenix metropolitan area, ADWM estimates, based on a vehicle database for 2008 provided by the Arizona Department of Transportation's Motor Vehicle Division, that approximately 87 percent of FFVs in the Phoenix metropolitan area are equipped with ORVR.[12] Given how close the ORVR-equipped percentage for FFVs in the Phoenix metropolitan area (87 percent in 2008 and climbing) is to the ORVR widespread use threshold based on comparable VOC emissions (95 percent), discussed above, we conclude that ORVR is in widespread use in the FFV vehicle fleet in the Phoenix metropolitan area for the purposes of CAA section 202(a)(6) so long as the change in emissions due to use of E85 does not interfere with attainment and RFP of any of the NAAQS. As discussed in section II.B.4 of this document, we conclude that allowing for greater use of ethanol (by amending the definition of ''gasoline'' to exclude E85) in the Phoenix metropolitan area would not interfere with attainment and RFP of any of the NAAQS, and thus, under CAA section 202(a)(6), we propose to waive the stage II vapor recovery requirements for E85 dispensing pumps in the Phoenix metropolitan area.

As noted above, in general, ADWM's revisions clarify and improve the existing stage II vapor recovery rules that we previously approved. The only significant changes potentially affecting approvability with respect to CAA section 182(b)(3) are the new exemptions for motor raceways, and for marine and aircraft refueling facilities.

ADWM has provided us information concerning the dispensing of gasoline at the one motor raceway, the Phoenix International Raceway, to which the exemption applies.[13] At the Phoenix International Raceway, two types of fuel activities occur: the first is the fueling for service vehicles, and the second is the fueling for race cars during the racing event. According to the information provided ADWM by the facility, approximately 8,000 gallons of gasoline per year are dispensed at this facility for service vehicles, which is far below the 10,000-gallon per month low-throughput threshold exemption in CAA section 182(b)(3). Thus, as applied to service vehicles, the exemption for gasoline dispensing sites at motor raceways is acceptable.

The facility's fixed gasoline dispensers, which are used to fuel service vehicles, are not used for race car fueling. Instead, for race events, the fuels are special blends that are trucked into the facility by the supplier and dispensed from a mobile truck into gas cans to be used during the racing event. We believe it is reasonable to interpret CAA section 182(b)(3) as applying to ''motor vehicles'' as defined in CAA section 216(2) (''As used in this part, * * * (2) The term ''motor vehicle'' means any self-propelled vehicle designed for transporting persons or property on a street or highway''), and as such, the motor raceway exemption as it applies to refueling of race cars, which are not designed for street or highway use, is acceptable under section 182(b)(3). The same is also true for the exemption for marine and aircraft refueling facilities, which refuel mobile sources that clearly are not motor vehicles as defined in CAA section 216(2). In sum, for the reasons stated above, the new exemptions in ADWM's Stage II vapor recovery rules for motor raceways, and for marine and aircraft refueling facilities are acceptable.

4. Compliance With CAA Section 110(l)

Under CAA section 110(l), EPA must not approve a SIP revision if the revision would interfere with any applicable requirement concerning reasonable further progress (RFP) and attainment of any of the NAAQS or any other applicable requirement under the Act. With respect to this SIP revision, we find that the only potentially significant adverse effect on emissions and, thus, potential for interference stems from the exclusion of E85 from the definition of ''gasoline'' in ARS 41–2121, which would allow for increased use of E85 (by FFVs) as a motor fuel in the Phoenix metropolitan area, and the relative difference in emissions from FFVs using E85 relative to the same vehicles using the specially formulated gasoline (referred to as ''Arizona Cleaner Burning Gasoline,'' or ''Arizona CBG'')

[11] The information concerning the application of the exemption for gasoline dispensing sites located on a manufacturers' proving ground is contained in a letter from Duane M. Yantorno, Director, Transportation Fuels and Air Quality Program, Arizona Department of Weights and Measures, to Andrew Steckel, Chief, Rules Office, Air Division, EPA Region IX, dated August 1, 2011.

[12] The information on the percentage of FFVs in the Phoenix metropolitan area that are ORVR-equipped is from a report titled ''Widespread Use Analysis for E85 Stage II Waiver Request,'' sent to EPA by Duane M. Yantorno, Director, Transportation Fuels and Air Quality Programs, ADWM, via email on October 25, 2010.

[13] The information concerning the application of the exemption for motor raceways in the Phoenix metropolitan area is contained in a letter from Duane M. Yantorno, Director, Transportation Fuels and Air Quality Program, Arizona Department of Weights and Measures, to Andrew Steckel, Chief, Rules Office, Air Division, EPA Region IX, dated August 1, 2011.

otherwise required.[14] (Arizona CBG is a boutique fuel established to reduce vehicle emissions in the Phoenix metropolitan area and to help meet CAA air quality planning requirements.) The gasoline portion of E85 must continue to meet the specifications for Arizona CBG pursuant to AAC R20–2–718(B).

We would normally look to EPA's motor vehicle emissions model (the most recent of which is ''MOVES2010'') to estimate changes in vehicle emissions resulting from combustion of different fuel types, but MOVES2010 is only designed to estimate the effects of ethanol in gasoline up to 10% by volume, and thus is not capable of estimating vehicle emissions using E85. (EPA is planning on evaluating recently completed and ongoing studies using E85 this year in order to add an E85 option to the next version of MOVES.) However, we did review a recently published study in the Journal of the Air & Waste Management Association titled ''Effect of E85 on Tailpipe Emissions from Light-Duty Vehicles [15]'' (herein, the ''E85 Vehicle Emissions Study''), which provides us with insight into the potential emissions effects.

The E85 Vehicle Emissions Study compiled the results from previous published studies but also analyzed a significantly larger database compiled by EPA for vehicle certification purposes. Though the results vary by pollutant and between ''tier 1'' (i.e., model year (MY) 1994–2003) and ''tier 2'' (MY 2004–2008) vehicles, in general, the study suggests that FFVs emit fewer oxides of nitrogen ($NO_X$), carbon monoxide, and particulate matter (PM) relative to the same FFVs using gasoline. However, with respect to VOCs, FFVs may well emit greater VOCs than the same FFVs using gasoline [based on the measurement results for non-methane organic gases (NMOGs)].[16]

Thus, with respect to nitrogen dioxide, carbon monoxide and particulate matter, because emissions using E85 would be lower than those using CBG, the incremental substitution of CBG with E85 would not interfere with RFP or attainment of the ambient standards for those pollutants.

We also believe that the net effect on ozone conditions in the Phoenix 8-hour ozone nonattainment area would be beneficial despite the potential higher VOC emission rate by E85-fueled FFVs (relative to CBG-fueled FFVs) because of the offsetting effect of $NO_X$ emissions reductions (from use of E85 relative to Arizona CBG) and because of the extension of Stage II vapor recovery requirements to ''Area A,'' an area that is larger than the area formerly designated as nonattainment for the 1-hour ozone standard and that includes the fast-growing region west of the City of Phoenix.[17]

Therefore, we have determined that this SIP revision, including the change in the definition of ''gasoline'' to exclude ''E85,'' would not interfere with RFP and attainment for any of the NAAQS.

*C. Correction of Previous Rulemaking*

On November 1, 1994, we took direct final action to approve the administrative rules adopted by the Arizona Department of Weights and Measures providing for the installation and operation of stage II vapor recovery systems. 59 FR 54521, November 1, 1994. We incorporated the approved rules into the Arizona SIP by adding a new paragraph (69) to 40 CFR 52.120(c), which reads: ''Maricopa County Bureau of Air Pollution Control stage II vapor recovery program, adopted on August 27, 1993.'' The descriptive reference in paragraph (69) was erroneous in that administrative rules governing the vapor recovery program in the Phoenix metropolitan area in Maricopa County, and adopted on August 27, 1993, were adopted by the Arizona Department of Weights and Measures, not the Maricopa County Bureau of Air Pollution Control (since renamed the Maricopa County Air Quality Department). Moreover, the descriptive reference to the vapor recovery program alone does not inform the public and regulated community that our approval relates to specific rules, and thus is potentially confusing to the public and regulated community as to the contents of the SIP.

We are therefore, under section 110(k)(6) and 301(a) of the Clean Air Act,[18] proposing to correct our previous codification of our approval of the stage II vapor recovery rules adopted by ADWM on August 27, 1993, and submitted by ADEQ on May 27, 1994, to identify the appropriate regulatory agency and to identify the specific rules that were approved.

## III. Proposed Action and Request for Public Comment

As authorized in section 110(k)(3) of the Act, EPA is proposing to approve the statutory provisions and updated administrative rules establishing certain vapor recovery requirements in the Phoenix metropolitan area as a revision to the Arizona SIP. Specifically, we are proposing to approve Arizona Revised Statutes (ARS) sections listed in table 1

[14] EPA's guidance for States in developing their Stage II SIPs in the early 1990s suggested that States use the same definition of ''gasoline'' as the one found in EPA's Standard of Performance for Bulk Gasoline Terminals at 40 CFR 60.501, which includes ''any petroleum distillate or petroleum distillate/alcohol blend having a Reid vapor pressure of 27.6 kilopascals or greater which is used as a fuel for internal combustion engines.'' EPA recommended using this definition to most broadly reach situations in which refueling of motor vehicles results in evaporative VOC emissions that contribute to ozone nonattainment concentrations, and to avoid a narrow interpretation of what is ''gasoline'' that would allow significant VOC emissions from motor vehicle refueling activities in nonattainment areas to go uncontrolled.

In the existing SIP, Arizona includes a definition of ''gasoline,'' AAC R4–31–901(5), that is consistent with the NSPS definition. The SIP revision for which we are proposing approval in today's action would replace the existing SIP definition of ''gasoline'' from Arizona's rules for gasoline vapor recovery (AAC title 20, chapter 2, article 9) with the definition of ''gasoline'' from Arizona's statutes governing motor fuel (ARS section 41–2121(5)). The definition of ''gasoline'' in ARS section 41–2121(5) is as inclusive as the existing SIP definition in AAC R4–31–901(5), except for the explicit exclusion of E85. Given that E85 can only be used by FFVs, and based on our proposed ''widespread use'' determination with respect to the FFV fleet in the Phoenix area that would be fueled at E85 dispensing pumps, we find the exception for E85 from the definition of ''gasoline'' acceptable under section 182(b)(3). Moreover, to allow for the distribution and sale of E85 in the Phoenix area, a change in the term of ''gasoline'' (to exclude E85) for stage II vapor recovery purposes alone would not have sufficed. Because of the boutique fuel requirements of Arizona CBG that have been approved into the Arizona SIP, a change in the definition of ''gasoline'' as a motor fuel (to exclude E85) was also necessary.

[15] Janet Yanowitz and Robert L. McCormick, ''Effect of E85 on Tailpipe Emissions from Light-Duty Vehicles,'' Journal of the Air & Waste Management Association, Volume 59, February 2009, pages 172–182.

[16] Ethanol itself contains no lead (Pb) or sulfur, but the ethanol portion of E85 does contain some Pb and sulfur due to the addition of a denaturant, which can comprise up to 5% of the ethanol portion of E85. The denaturant used by ethanol producers is typically gasoline (either RFG or conventional gasoline, depending on where the ethanol plant is located), which has sulfur and Pb specifications similar to those for CBG. Therefore, a gallon of E85 would have less sulfur and Pb than a gallon of CBG (due to the dilution provided by the ethanol), and thus the emissions of sulfur dioxide and Pb from use of E85 in FFVs would be less than the corresponding emissions from use of CBG in those vehicles. Therefore, there would be no interference with RFP or attainment of the Pb and sulfur dioxide NAAQS.

[17] As submitted in 1993, ARS section 41–2132(C) established the stage II vapor recovery requirement within the ozone nonattainment area, but the current version of this statute, which is included in today's proposed approval, extends the requirement to ''Area A.''

[18] Section 110(k)(6) of the CAA provides that, whenever EPA determines that the Agency's action approving, disapproving, or promulgating any plan or plan revision, area designation, redesignation, classification, or reclassification was in error, EPA may in the same manner as the approval, disapproval, or promulgation revise such action as appropriate without requiring any further submission from the State. Section 301(a) of the CAA authorizes EPA to prescribe such regulations as are necessary to carry out the Agency's functions under the CAA.

of this document and the Arizona Administrative Code (AAC) sections listed in table 2 of this document.[19] Second, as authorized under CAA section 202(a)(6), we are proposing to waive the stage II vapor recovery requirements at E85 dispensing pumps in the Phoenix area under CAA section 202(a)(6) based on our conclusion that ORVR is in widespread use among the FFVs that use such facilities.

In so doing, we propose to conclude that the submitted statutory provisions and updated administrative rules meet the related requirements for stage II vapor recovery under CAA section 182(b)(3) and would not interfere with attainment and RFP of any of the NAAQS or any other CAA applicable requirement, consistent with the requirements of CAA section 110(l). Final EPA approval of the updated statutory provisions and rules and incorporation of them into the Arizona SIP would make them federally enforceable.

Lastly, under section 110(k)(6) and 301(a) of the CAA, we are proposing to correct and clarify the incorporation of the previous version of these administrative rules into the Arizona SIP.

We will accept comments from the public on this proposed approval for the next 30 days.

## IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve State choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely proposes to approve State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State 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) given the limited nature of this SIP revision (as to geographic scope and vehicle applicability);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

## List of Subjects in 40 CFR Part 52

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

Dated: September 19, 2011.

**Keith Takata,**

*Acting Regional Administrator, Region IX.*

[FR Doc. 2011–25397 Filed 9–30–11; 8:45 am]

**BILLING CODE 6560–50–P**

[19] Our proposed approval of the statutory provisions and administrative rules would supersede the previously-approved versions of the administrative rules in the Arizona SIP (i.e., AAC Article 9 (''Gasoline Vapor Control''), Rules R4–31–901 through R4–31–910, adopted by the Arizona Department of Weights and Measures on August 27, 1993, submitted on May 27, 1994, and approved on November 1, 1994 (59 FR 54521).

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

**[EPA–R09–OAR–2011–0580; FRL–9468–1]**

### Revisions to the California State Implementation Plan, Sacramento Metropolitan Air Quality Management District, Ventura County Air Pollution Control District, and Placer County Air Pollution Control District

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

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to approve revisions to the Sacramento Metropolitan Air Quality Management District (SMAQMD), Ventura County Air Pollution Control District (VCAPCD), and Placer County Air Pollution Control District (PCAPCD) portion of the California State Implementation Plan (SIP). These revisions concern volatile organic compound (VOC) emissions from organic chemical manufacturing, soil decontamination, and polyester resin operations. We are proposing to approve local rules to regulate these emission sources under the Clean Air Act as amended in 1990 (CAA or the Act).

**DATES:** Any comments on this proposal must arrive by November 2, 2011.

**ADDRESSES:** Submit comments, identified by docket number EPA–R09–OAR–2011–0580, by one of the following methods:

1. *Federal eRulemaking Portal: www.regulations.gov.* Follow the on-line instructions.
2. *E-mail: steckel.andrew@epa.gov.*
3. *Mail or deliver:* Andrew Steckel (Air-4), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

*Instructions:* All comments will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *http://www.regulations.gov* or e-mail. *http://www.regulations.gov* is an ''anonymous access'' system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send e-mail directly to EPA, your e-mail address will be automatically captured and

included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

*Docket:* Generally, documents in the docket for this action are available electronically at *http://www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed at *http://www.regulations.gov,* some information may be publicly available only at the hard copy location (e.g., copyrighted material, large maps), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

**FOR FURTHER INFORMATION CONTACT:** David Grounds, EPA Region IX, (415) 972–3019, *grounds.david@epa.gov.*

**SUPPLEMENTARY INFORMATION:** This proposal addresses the following local rules: SMAQMD Rule 464 (Organic Chemical Manufacturing Operations), VCAPCD Rule 74.29 (Soil Decontamination), and PCAPCD Rule 243 (Polyester Resin Operations). In the Rules and Regulations section of this **Federal Register**, we are approving these local rules in a direct final action without prior proposal because we believe these SIP revisions are not controversial. If we receive adverse comments, however, we will publish a timely withdrawal of the direct final rule and address the comments in subsequent action based on this proposed rule. Please note that if we receive adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of an adverse comment.

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

Dated: August 16, 2011.

**Jared Blumenfeld,**

*Regional Administrator, Region IX.*

[FR Doc. 2011–25283 Filed 9–30–11; 8:45 am]

**BILLING CODE 6560–50–P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

### 44 CFR Part 67

**[Docket ID FEMA–2010–0003; Internal Agency Docket No. FEMA–B–1169]**

### Proposed Flood Elevation Determinations

*Correction*

In proposed rule document 2010–31549 appearing on pages 78664–78666 in the issue of December 16, 2010, make the following correction:

**§ 67.4 [Corrected]**

On page 78665, in the fifth row from the bottom, immediately beneath the sentence ''Maps are available for inspection at the Meeker County Courthouse, 325 Sibley Avenue North, Litchfield, MN 55355.'', the heading which was inadvertently omitted from the table, is added to read ''Carroll County, Missouri, and Incorporated Areas''.

[FR Doc. C1–2010–31549 Filed 9–30–11; 8:45 am]

**BILLING CODE 1505–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

### 44 CFR Part 206

**[Docket ID FEMA–2011–0004]**

**RIN 1660–AA02;Formerly 3067–AC69**

### Disaster Assistance; Hazard Mitigation Grant Program

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Proposed rule; withdrawal.

**SUMMARY:** On May 1, 1998, the Federal Emergency Management Agency (FEMA) published a Notice of Proposed Rulemaking (NPRM) to revise the categories of projects eligible for funding under the Hazard Mitigation Grant Program (HMGP). The NPRM proposed to define eligible mitigation activities under the HMGP to include minor flood control projects that do not duplicate the efforts and authorities of other Federal agencies. It proposed to include vegetation management programs for wildfire hazard mitigation and erosion hazard mitigation in the list of eligible activities; it proposed to remove development or improvement of warning systems from the list of eligible project types; and modified language relating to general, allowable open space, recreational, and wetlands management uses. FEMA is withdrawing the NPRM so that relevant issues involved in the NPRM may be further considered and because portions of it are redundant or outdated.

**DATES:** The Notice of Proposed Rulemaking published on May 1, 1998 (63 FR 24143), is withdrawn as of October 3, 2011.

**ADDRESSES:** The Notice of Proposed Rulemaking and this withdrawal notice may be found under Docket ID: FEMA–2011–0004 and are available online by going to *http://www.regulations.gov,* inserting FEMA–2011–0004 in the ''Keyword'' box, and then clicking ''Search.'' The Docket is also available for inspection or copying at FEMA, 500 C Street, SW., Room 840, Washington, DC 20472.

**FOR FURTHER INFORMATION CONTACT:** Cecelia Rosenberg, Federal Insurance and Mitigation, DHS/FEMA, 1800 South Bell Street, Arlington, VA 20598–3015. *Phone:* (202) 646–3321. *Facsimile:* (202) 646–2880. *E-mail: Cecelia.Rosenberg@dhs.gov.*

**SUPPLEMENTARY INFORMATION:**

#### I. Background

Authorized by section 404 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act), 42 U.S.C. 5170c, the Hazard Mitigation Grant Program (HMGP) provides States, Tribes, and local governments financial assistance to implement measures that permanently reduce or eliminate future damages and losses from natural hazards.

The HMGP regulations at 44 CFR part 206, subpart N, address the eligibility of multi-hazard mitigation projects through a list of general eligibility criteria: a project must be cost-effective, be environmentally sound, must address a repetitive problem, and must contribute to a long-term solution. Further, HMGP funds cannot be used to fund projects that are available under other Federal authorities. The regulations also provide a list of eligible types of projects. The project-type listing is not all-inclusive. FEMA published a Notice of Proposed Rulemaking (NPRM) (63 FR 24143, May 1, 1998) proposing the following revisions to the HMGP regulations.

*Minor Flood Control Projects*

Under the NPRM, minor flood control projects that do not duplicate the flood prevention activities of other Federal agencies would be eligible for HMGP

funding. Major flood control projects, such as dikes, levees, dams, channelization, channel widening, stream realignment, seawalls, groins, and jetties, would be distinguished from minor flood control activities. Typically, funding for major flood control projects would fall under the water resources design and construction authorities of the U.S. Army Corps of Engineers and the Natural Resources Conservation Service of the U.S. Department of Agriculture.

*Wildfire and Erosion*

Under the NPRM, vegetation management related to wildfire and erosion hazard mitigation measures would be eligible for HMGP funding. This would reflect FEMA's multi-hazard HMGP objectives and priorities authorized by section 404 of the Stafford Act.

*Warning Systems*

The NPRM sought to minimize an emphasis on warning systems by removing them from the list of eligible projects. This was due to benefit/cost considerations. The benefits of some hazard mitigation project types can be difficult to show using FEMA's conventional benefit/cost calculation methodology. Because of this in certain circumstances FEMA will allow applicants to demonstrate project cost-effectiveness using means other than the conventional benefit/cost methodology. The NPRM proposed to remove warning systems from the example list of eligible project types because the project type does not lend itself to use of the conventional benefit/cost methodology.

*Allowable Open Space Uses*

The NPRM proposed a revision to the list of allowable open space uses for previously funded and acquired open space land by replacing the word ''previous'' (which was actually a typo in the regulation that should have been ''pervious'') with the more widely familiar term of permeable.

## II. Summary of Comments

FEMA received 12 comments on the NPRM from State and local governments. Several commenters had reservations about the NPRM's possible effects on the eligibility of certain flood control projects because these projects were viewed as good hazard mitigation activities that should be funded by FEMA. Some commenters expressed concern regarding the term ''minor flood control'' and the criteria used to define it. Two commenters were concerned that major flood control projects may become ineligible due to concerns of duplicating other Federal assistance, and were concerned about the applicability of this rationale to the practice of partnering with other Federal agencies. One commenter urged FEMA to recognize the importance of allowing HMGP funding to be used for mitigation activities related to facilities that would be regarded as major structural flood control facilities.

One commenter expressed support for the wildfire and erosion vegetation management provisions in the NPRM, and was concerned that vegetation management activities were not extended to other project types. Another commenter expressed concern that wildfire and erosion vegetation provisions may conflict with other pre-existing regulatory requirements.

Two commenters expressed dissatisfaction with the NPRM's removal of warning systems from the list of ''traditionally'' eligible HMGP activities.

One commenter requested consideration of allowable open space activities beyond the scope of the NPRM.

## III. Reason for Withdrawal

FEMA is withdrawing the NPRM so that relevant issues involved in the NPRM may be further considered and because portions of it are redundant. The definition of minor flood control projects is being examined in greater detail relative to the HMGP eligibility criteria of the regulations at 44 CFR 206.434(c). Further, the distinction that minor flood control projects not duplicate the activities of other Federal agencies is redundant because the existing program regulations, at 44 CFR 206.434(f), clearly state that HMGP funds cannot be used as a substitute or replacement to fund projects or programs that are available under other Federal authorities. Therefore, to state the requirement again is redundant, and to highlight it for minor flood control projects over other project types may lead to some confusion regarding its applicability to all project types.

FEMA considers the other provisions of the NPRM to be outdated. Eligibility considerations of vegetation management are addressed through FEMA's existing HMGP regulations identifying general eligibility considerations, and there is no significant benefit derived from listing them specifically. Removing warning systems from the list of eligible projects could create the impression that they are not eligible for funding.

The remaining proposed revision, to replace the word ''previous'' (a typo for ''pervious'') with ''permeable'' is not sufficient reason for continuing the NPRM as the original word and the word proposed to replace it mean essentially the same thing.

## IV. Conclusion

FEMA is withdrawing the May 1, 1998 NPRM for the reasons stated in this notice.

**W. Craig Fugate,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. 2011–25102 Filed 9–30–11; 8:45 am]

**BILLING CODE 9111–23–P**

# Notices

Federal Register
Vol. 76, No. 191
Monday, October 3, 2011

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

## ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

### Committees on Administration and Management, Collaborative Governance, Judicial Review, and Regulation

**ACTION:** Notice of public meetings.

**SUMMARY:** Notice is hereby given of public meetings of four committees of the Assembly of the Administrative Conference of the United States (ACUS). Each committee will meet to discuss recommendations for consideration by the full Conference. Complete details regarding each committee's meeting, related research reports, how to attend (including information about remote access and obtaining special accommodations for persons with disabilities), and how to submit comments to the committee can be found in the ''Research'' section of the ACUS Web site. Go to *http://www.acus.gov* and click on Research -> Committee Meetings. Additional project information may also be found by clicking on Research -> Conference Projects.

Comments may be submitted by e-mail to *Comments@acus.gov,* with the name of the relevant committee in the subject line, or by postal mail to ''[Name of Committee] Comments'' at the address given below. To be guaranteed consideration, comments must be received five calendar days before the meeting to which they are related.

**ADDRESSES:** The meetings will be held at 1120 20th Street, NW., Suite 706 South, Washington, DC 20036.

**FOR FURTHER INFORMATION CONTACT:** The Designated Federal Officer for the individual committee (see listings below), ACUS, 1120 20th Street, NW., Suite 706 South, Washington, DC 20036; Telephone 202–480–2080.

**SUPPLEMENTARY INFORMATION:**

**Committee on Administration and Management**

The Committee on Administration and Management will meet to consider issues arising when agencies use ''incorporation by reference'' in regulations; i.e., when an agency regulation incorporates by reference material available elsewhere. Among other things, the committee will discuss procedural and drafting issues that arise when agencies use incorporation by reference, challenges agencies face in updating such references, and ways to ensure the reasonable availability of incorporated materials, which may be subject to copyright.

*Date:* Friday, October 28, 2011, from 9:30 a.m. to 12:30 p.m.

*Designated Federal Officer:* Scott Rafferty.

**Committee on Collaborative Governance**

The Committee on Collaborative Governance will consider recommending improvements to the *Federal Advisory Committee Act* (FACA) and the implementation of the Act. Potential issues for discussion include the chartering requirements for advisory committees; improving access to committee meetings and materials; virtual committee meetings; and other improvements that might reduce the burdens imposed by FACA or improve the transparency of FACA committees.

The Committee on Collaborative Governance may also discuss a project regarding the use of third-party certification in government inspections.

*Date:* Tuesday, October 18, 2011, from 1:30 p.m. to 4:30 p.m.

*Designated Federal Officer:* David Pritzker.

**Committee on Judicial Review**

The Committee on Judicial Review will discuss potential changes to 28 U.S.C. 1500, which regulates the jurisdiction of the Court of Federal Claims (CFC). The statute currently deprives the CFC of jurisdiction over a claim if the plaintiff has a claim based on the same facts pending in another court. The committee will consider whether this statute should be repealed or revised.

The committee may also consider the Congressional Review Act and agency practices under the Act.

*Date:* Thursday, October 27, 2011, from 1:30 p.m. to 4:30 p.m.

*Designated Federal Officer:* Reeve Bull.

**Committee on Regulation**

The Committee on Regulation will meet to consider a project concerning international regulatory cooperation. This project will examine how the Conference might update its Recommendation 91–1, ''Federal Agency Cooperation with Foreign Government Regulators,'' in light of developments in United States government structure, trade agreements, and technology since the recommendation was adopted 20 years ago.

*Date:* Tuesday, October 25, 2011, from 2 p.m. to 5 p.m.

*Designated Federal Officer:* Reeve Bull.

Dated: September 28, 2011.

**Jonathan R. Siegel,**

*Director of Research and Policy.*

[FR Doc. 2011–25393 Filed 9–30–11; 8:45 am]

**BILLING CODE 6110–01–P**

## DEPARTMENT OF AGRICULTURE

### Submission for OMB Review; Comment Request

September 27, 2011.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB),

*OIRA_Submission@OMB.EOP.gov* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

**Animal Plant and Health Inspection Service**

*Title:* Swine Health Protection.

*OMB Control Number:* 0579–0065.

*Summary of Collection:* The Animal Health Protection Act (AHPA) of 2002 is the primary Federal law governing the protection of animal health. The law gives the Secretary of Agriculture broad authority to detect, control, or eradicate pests or diseases of livestock or poultry. The AHPA is contained in Title X, Subtitle E, Sections 10401–18 of P.O. 107–171, May 13, 2002, the Farm Security and Rural Investment Act of 2002. Veterinary Services, a program with the Animal and Plant Health Inspection Service (APHIS), is responsible for administering regulations intended to prevent the dissemination of animal diseases within the United States. Garbage is one of the primary media through which numerous infections or communicable diseases of swine are transmitted. Because of the serious threat to the U.S. swine industry, Congress passed Public Law 96–468 ''Swine Health Protection Act'' on October 17, 1980. This law requires USDA to ensure that all garbage is treated prior to its being fed to swine that are intended for interstate or foreign commerce or that substantially affect such commerce. The Act and the regulations will allow only operators of garbage treatment facilities, which meet certain specification to utilize garbage for swine feeding. APHIS will use various forms to collect information.

*Need and Use of the Information:* APHIS collects information from persons desiring to obtain a permit (license) to operate a facility to treat garbage. Prior to issuance of a license, an inspection will be made of the facility by an authorized representative to determine if it meets all requirements of the regulations. Periodic inspections will be made to determine if licenses are meeting the standards for operation of their approved facilities. Upon receipt of the information from the Public Health Officials, the information is used by Federal or State animal health personnel to determine whether the waste collector is feeding garbage to swine, whether it is being treated, and whether the feeder is licensed or needs to be licensed.

*Description of Respondents:* Business or other for profit; State, Local or Tribal Government.

*Number of Respondents:* 2,105.

*Frequency of Responses:* Recordkeeping; Reporting: On occasion.

*Total Burden Hours:* 11,324.

**Animal and Plant Health Inspection Service**

*Title:* CWD in Cervids; Payment of Indemnity.

*OMB Control Number:* 0579–0189.

*Summary of Collection:* The Animal Health Protection Act (AHPA) of 2002 is the primary Federal law governing the protection of animal health. The law gives the Secretary of Agriculture broad authority to detect, control and eradicate pests or diseases of livestock or poultry, and to pay claims arising from destruction of animals. Disease prevention is the most effective method for maintaining a healthy animal population and enhancing the Animal and Plant Health Inspection Service (APHIS) ability to compete in exporting animals and animal products. Chronic wasting disease (CWD) is a transmissible spongiform encephalopathy (TSE) of elk, deer and moose typified by chronic weight loss leading to death.

The presence of CWD disease in cervids causes significant economic and market losses to U.S. producers. APHIS will collect information using VS Form 1–23, Appraisal & Indemnity Claim form.

*Need and Use of the Information:* APHIS will collect the owner's name and address, the number of animals for which the owner is seeking payment, and the appraised value of each animal. The owner must also certify as to whether the animals are subject to a mortgage. If there is a mortgage the form must be signed by the owner and each person holding a mortgage. As a condition of receiving indemnity, herd owners must review and sign a written agreement with APHIS stating that the farm has been effectively cleaned and disinfected. Failure to collect this information would cripple APHIS' ability to effectively sustain its CWD control program.

*Description of Respondents:* Business or other for-profit; State, Local or Tribal Government.

*Number of Respondents:* 4.

*Frequency of Responses:* Reporting: On occasion .

*Total Burden Hours:* 62.

**Animal and Plant Health Inspection Service**

*Title:* Trichinae Certification Program.

*OMB Control Number:* 0579–0323.

*Summary of Collection:* The Animal Health Protection Act (AHPA) of 2002 is the primary Federal law governing the protection of animal health. The law gives the Secretary of Agriculture broad authority to detect, control and eradicate pests or diseases of livestock or poultry. The AHPA is contained in Title X, Subtitle E, Sections 10401–18 of Public Law 107–171, May 13, 2002, the Farm Security and Rural Investment Act of 2002. *Trichinelia spiralis* is a contagious nematode affecting animals and people. The disease, trichinellosis is transmitted by consuming the meat of an infected animal. The Animal Plant and Health Inspection Service (APHIS) will collect information using certificate site audit, program audit form, request for information during a spot audit, animal disposal plan and recordkeeping, animal movement record and recordkeeping, rodent control logbook and recordkeeping, trichinae herd certification feed mill quality assurance affidavit and recordkeeping, and records for slaughter testing and recordkeeping.

*Need and Use of the Information:* APHIS will collect information to certify swine are raised using practices that will reduce or eliminate *T. spiralis* exposure. If this information is not collected, it will compromise APHIS' ability to determine the trichinae infection status of pork produced in the United States.

*Description of Respondents:* Business or other for-profit; State, Local or Tribal Government.

*Number of Respondents:* 1,250.

*Frequency of Responses:* Recordkeeping; Reporting: On occasion.

*Total Burden Hours:* 7,494.

**Ruth Brown,**

*Departmental Information Collection Clearance Officer.*

[FR Doc. 2011–25330 Filed 9–30–11; 8:45 am]

**BILLING CODE 3410–34–P**

## DEPARTMENT OF AGRICULTURE

### Office of the Secretary

### USDA Increases the Fiscal Year 2011 Tariff-Rate Quota for Refined Sugar

**AGENCY:** Office of the Secretary, USDA.

**ACTION:** Notice.

**SUMMARY:** The Secretary of Agriculture today announced an increase in the fiscal year (FY) 2011 refined sugar tariff-rate quota (TRQ) of 136,078 metric tons raw value (MTRV).

**DATES:** *Effective:* October 3, 2011.

**FOR FURTHER INFORMATION CONTACT:** Angel F. Gonzalez, Import Policies and Export Reporting Division, Foreign Agricultural Service, AgStop 1021, U.S. Department of Agriculture, Washington, DC 20250–1021; or by telephone (202) 720–2916; or by fax to (202) 720–0876; or by e-mail to *angel.f.gonzalez@fas.usda.gov.*

**SUPPLEMENTARY INFORMATION:** A quantity of 22,000 MTRV for sugars, syrups, and molasses (collectively referred to as refined sugar) described in subheadings 1701.12.10, 1701.91.10, 1701.99.10, 1702.90.10, and 2106.90.44 of the U.S. Harmonized Tariff Schedule (HTS) is the minimum level necessary to comply with U.S. World Trade Organization Uruguay Round Agreements, of which 1,656 MTRV is the minimum quantity to be reserved for specialty sugar. On August 5, 2010, USDA established the FY 2011 (October 1, 2010—September 30, 2011) refined sugar TRQ at an aggregate quantity of 99,111 MTRV, of which 20,344 MTRV, was refined sugar other than specialty sugar. On August 17, 2010, the Office of the U.S. Trade Representative (USTR) allocated this refined sugar as follows: 10,300 MTRV to Canada; 2,954 MTRV to Mexico; and 7,090 MTRV to be administered on a first-come, first-served basis. On August 2, 2011, the Secretary of Agriculture (the Secretary) increased the FY 2011 specialty sugar TRQ by 9,072 MTRV, resulting in an FY 2011 specialty sugar TRQ to 87,839 MTRV, and an FY 2011 refined sugar TRQ to 108,183 MTRV.

The Secretary today announced an increase in the FY 2011 refined sugar TRQ of 136,078 MTRV, to a total of 244,261 MTRV. The authority to increase the refined sugar TRQ is found in the HTS, Chapter 17, Additional U.S. Note 5(a)(ii). The Secretary also announced that sugar entering under the FY 2011 refined sugar TRQ would be permitted to enter until November 30, 2011. Authority for the Secretary to permit entry of sugar in a subsequent quota period is found in the HTS, Chapter 17, Additional U.S. Note 5(a)(iv).

USTR will allocate this increase among supplying countries and customs areas. This action is being taken after a determination that additional supplies of refined sugar are necessary to reduce risks associated with adverse weather and other supply disruptions. Harvest of the FY 2012 sugar beet crop is significantly slower to date than during several of the previous fiscal years. USDA will closely monitor stocks, consumption, imports and all sugar market and program variables on an ongoing basis.

* Conversion factor: 1 metric ton = 1.10231125 short tons.

Dated: September 27, 2011.

**Darci L. Vetter,**

*Acting Under Secretary, Farm and Foreign Agricultural Service.*

[FR Doc. 2011–25329 Filed 9–30–11; 8:45 am]

**BILLING CODE 3410–10–P**

## DEPARTMENT OF AGRICULTURE

### Forest Service

### Lake Tahoe Basin Federal Advisory Committee (LTFAC)

**AGENCY:** Forest Service, USDA.

**ACTION:** Notice of meeting.

**SUMMARY:** The Lake Tahoe Federal Advisory Committee will hold a meeting on October 21 or 24, 2011 at the Lake Tahoe Basin Management Unit, 35 College Drive, South Lake Tahoe, CA 96150. This Committee, established by the Secretary of Agriculture on December 15, 1998 (64 FR 2876), is chartered to provide advice to the Secretary on implementing the terms of the Federal Interagency Partnership on the Lake Tahoe Region and other matters raised by the Secretary.

**DATES:** The meeting will be held October 21 or 24, 2011, beginning at 9 a.m. and ending at 3 p.m. A final date can be confirmed at *http://www.fs.fed.us/r5/ltbmu/local/ltfac.*

**ADDRESSES:** Lake Tahoe Basin Management Unit, 35 College Drive, South Lake Tahoe, CA 96150.

*For Further Information or to Request an Accommodation (One Week Prior to Meeting Date) Contact:* Arla Hains, Lake Tahoe Basin Management Unit, Forest Service, 35 College Drive, South Lake Tahoe, CA 96150, (530) 543–2773.

**SUPPLEMENTARY INFORMATION:** Items to be covered on the agenda: (1) Facilitated workshop to discuss a strategic workplan for Fiscal Year 2012, and (2) public comment.

All Lake Tahoe Basin Federal Advisory Committee meetings are open to the public. Interested citizens are encouraged to attend at the above address. Issues may be brought to the attention of the Committee during the open public comment period at the meeting or by filing written statements with the secretary for the Committee before or after the meeting. Please refer any written comments to the Lake Tahoe Basin Management Unit at the contact address stated above.

Dated: September 27, 2011.

**Jeff Marsolais,**

*Deputy Forest Supervisor.*

[FR Doc. 2011–25361 Filed 9–30–11; 8:45 am]

**BILLING CODE 3410–11–P**

## UNITED STATES ARCTIC RESEARCH COMMISSION

### Reports and Updates on Arctic Research Programs and Projects; Meetings

Notice is hereby given that the US Arctic Research Commission will hold its 96th meeting in Durham and Hanover, NH, on October 5–7, 2011. The business sessions on October 5 and 7 are open to the public and will convene at 8:00 a.m. each day. On October 6, the Commission will hold a meeting at the US Army Cold Regions Research and Engineering Lab (CRREL), a secure US Army facility with limited and pre-screened access for visitors. The Commission will hold public question and comment sessions on both October 5 and 7 between 5 and 5:30 p.m. where the public is invited to address the Commissioners about topics of interest related to research activities in the Arctic.

*96th Meeting Schedule:*

Wed., Oct. 5, 2011, University of New Hampshire, Durham, NH, Center for Coastal & Ocean Mapping, Joint Hydrographic Center, 24 Colovos Rd., Admiral's Conference Room, 2nd Floor, Room 240, Public comment and question period: Captain's Library, 1st Floor, Room 166.

Thurs., Oct. 6, 2011, CRREL, Hanover, NH.

Fri., Oct. 7, 2011 Dartmouth College, Rockefeller Center, 2 Webster Street, 1930s Room, 1st Flr., *Public Comment and Question Period:* Rockefeller Center, 2 Webster Street, 1930s Room, 1st Floor.

*The Agenda items include:*

(1) Call to order and approval of the agenda.

(2) Approval of the minutes from the 95th meeting.

(3) Commissioner and staff reports.

(4) Discussion and presentations concerning Arctic research activities.

The focus of the meeting will be reports and updates on Arctic research programs and projects.

If you plan to attend this meeting, please notify us via the contact information below. Any person planning to attend who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission of those needs in advance of the meeting.

Contact person for further information: John Farrell, Executive Director, US Arctic Research Commission, 703–525–0111 or TDD 703–306–0090.

Yours truly,

**John Farrell,**

*Executive Director.*

[FR Doc. 2011–25176 Filed 9–29–11; 8:45 am]

**BILLING CODE 7555–01–P**

## DEPARTMENT OF COMMERCE

### Foreign-Trade Zones Board

**[Docket 58–2011]**

### Foreign-Trade Zone 275—Lansing, MI; Application for Reorganization Under Alternative Site Framework

An application has been submitted to the Foreign-Trade Zones (FTZ) Board (the Board) by the Capital Region Airport Authority, grantee of FTZ 275, requesting authority to reorganize the zone under the alternative site framework (ASF) adopted by the Board (74 FR 1170, 1/12/09 (correction 74 FR 3987, 1/22/09); 75 FR 71069–71070, 11/22/10). The ASF is an option for grantees for the establishment or reorganization of general-purpose zones and can permit significantly greater flexibility in the designation of new ''usage-driven'' FTZ sites for operators/users located within a grantee's ''service area'' in the context of the Board's standard 2,000-acre activation limit for a general-purpose zone project. The application was submitted pursuant to the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on September 27, 2011.

FTZ 275 was approved by the Board on August 12, 2009 (Board Order 1633, 74 FR 44822, 8/31/2011).

The current zone project includes the following site: *Site 1* (846 acres)—Capital Region International Airport, 4100 Capital City Boulevard, Lansing (Ingham County).

The grantee's proposed service area under the ASF would be Clinton, Eaton, Gratiot, Ingham, Isabella (portions), Jackson, Livingston and Shiawassee Counties, Michigan, as described in the application. If approved, the grantee would be able to serve sites throughout the service area based on companies' needs for FTZ designation. The proposed service area is adjacent to the user fee airport designated by U.S. Customs and Border Protection at the Capital Regional International Airport, Lansing.

The applicant is requesting authority to reorganize its existing zone project to include the existing site as a ''magnet'' site. The ASF allows for the possible exemption of one magnet site from the ''sunset'' time limits that generally apply to sites under the ASF, and the applicant proposes that Site 1 be so exempted. No usage-driven sites are being requested at this time. Because the ASF only pertains to establishing or reorganizing a general-purpose zone, the application would have no impact on FTZ 275's authorized subzone.

In accordance with the Board's regulations, Elizabeth Whiteman of the FTZ Staff is designated examiner to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the Board.

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is December 2, 2011. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to December 19, 2011.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 2111, U.S. Department of Commerce, 1401 Constitution Avenue, NW., Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's Web site, which is accessible via *http://www.trade.gov/ftz.* For further information, contact Elizabeth Whiteman at *Elizabeth.Whiteman@trade.gov* or (202) 482–0473.

Dated: September 27, 2011.

**Andrew McGilvray,**

*Executive Secretary.*

[FR Doc. 2011–25430 Filed 9–30–11; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### Foreign-Trade Zones Board

**[Docket 57–2011]**

### Foreign-Trade Zone 127—Columbia, SC; Application for Reorganization/Expansion Under Alternative Site Framework

An application has been submitted to the Foreign-Trade Zones (FTZ) Board (the Board) by the Richland-Lexington Airport District, grantee of FTZ 127, requesting authority to reorganize and expand the zone under the alternative site framework (ASF) adopted by the Board (74 FR 1170, 1/12/09 (correction 74 FR 3987, 1/22/09); 75 FR 71069–71070, 11/22/10). The ASF is an option for grantees for the establishment or reorganization of general-purpose zones and can permit significantly greater flexibility in the designation of new ''usage-driven'' FTZ sites for operators/users located within a grantee's ''service area'' in the context of the Board's standard 2,000-acre activation limit for a general-purpose zone project. The application was submitted pursuant to the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on September 23, 2011.

FTZ 127 was approved by the Board on July 2, 1986 (Board Order 333, 51 FR 25075, 7/10/86). The current zone project includes the following sites: *Site 1* (109 acres)—Richland-Lexington Airport District, 125A Summer Lake Drive, West Columbia; and, *Site 2* (44 acres, expires 3/30/13)—Urban Outfitters, Inc., Edgefield Industrial Park, 30 Industrial Park Blvd., Trenton.

The grantee's proposed service area under the ASF would be Aiken, Allendale, Bamberg, Barnwell, Calhoun, Clarendon, Edgefield, Fairfield, Kershaw, Lee, Lexington, McCormick, Newberry, Richland, Saluda, and Sumter Counties, South Carolina, as described in the application. If approved, the grantee would be able to serve sites throughout the service area based on companies' needs for FTZ designation. The proposed service area is within and adjacent to the Columbia Customs and Border Protection port of entry.

The applicant is requesting authority to reorganize and expand its existing zone project to include Site 1 as a ''magnet'' site and temporary Site 2 as a ''usage-driven site''. The ASF allows for the possible exemption of one magnet site from the ''sunset'' time limits that generally apply to sites under the ASF, and the applicant proposes

that Site 1 be so exempted. Because the ASF only pertains to establishing or reorganizing a general-purpose zone, the application would have no impact on FTZ 127's authorized subzones.

In accordance with the Board's regulations, Kathleen Boyce of the FTZ Staff is designated examiner to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the Board.

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is December 2, 2011. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to December 19, 2011.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 2111, U.S. Department of Commerce, 1401 Constitution Avenue, NW., Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's website, which is accessible via *http://www.trade.gov/ftz.* For further information, contact Kathleen Boyce at *Kathleen.Boyce @trade.gov* or (202) 482–1346.

Dated: September 23, 2011.

**Andrew McGilvray,**

*Executive Secretary.*

[FR Doc. 2011–25316 Filed 9–30–11; 8:45 am]

**BILLING CODE;P**

## DEPARTMENT OF COMMERCE

### Foreign-Trade Zones Board

**[Docket 7–2009]**

### Foreign-Trade Zone 57—Mecklenburg County, NC; Termination of Review of Application for Subzone; FMS Enterprises USA, Inc. (Para-Aramid UD Shield); Lincolnton, NC

Notice is hereby given of termination of review of a subzone application submitted by the Charlotte Regional Partnership, grantee of FTZ 57, requesting special-purpose subzone status with manufacturing authority for para-aramid UD shield at the manufacturing facility of FMS Enterprises USA, Inc., located in Lincolnton, North Carolina. The application was filed on February 12, 2009 (74 FR 8904, 2/27/2009).

The termination is the result of changed circumstances, and the case has been closed without prejudice.

Dated: September 27, 2011.

**Andrew McGilvray,**

*Executive Secretary.*

[FR Doc. 2011–25428 Filed 9–30–11; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

### Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocations in Part

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**SUMMARY:** The Department of Commerce (''the Department'') has received requests to conduct administrative reviews of various antidumping and countervailing duty orders and findings with August anniversary dates. In accordance with the Department's regulations, we are initiating those administrative reviews. The Department also received requests to revoke three antidumping duty orders in part.

**DATES:** *Effective Date:* October 3, 2011.

**FOR FURTHER INFORMATION CONTACT:** Brenda Waters, Office of AD/CVD Operations, Customs Unit, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230, *telephone:* (202) 482–4735.

**SUPPLEMENTARY INFORMATION:**

#### Background

The Department has received timely requests, in accordance with 19 CFR 351.213(b), for administrative reviews of various antidumping and countervailing duty orders and findings with August anniversary dates. The Department also received timely requests to revoke in part the antidumping duty orders on Certain Corrosion-Resistant Carbon Steel Flat Products from the Republic of Korea for one exporter, on Light-Walled Rectangular Pipe and Tube from Mexico for one exporter, and on Certain Frozen Fish Fillets from the Socialist Republic of Vietnam with respect to three exporters.

All deadlines for the submission of various types of information, certifications, or comments or actions by the Department discussed below refer to the number of calendar days from the applicable starting time.

#### Notice of No Sales

If a producer or exporter named in this notice of initiation had no exports, sales, or entries during the period of review (''POR''), it must notify the Department within 60 days of publication of this notice in the **Federal Register**. All submissions must be filed electronically at *http://iaaccess.trade.gov* in accordance with 19 CFR 351.303. *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011). Such submissions are subject to verification in accordance with section 782(i) of the Tariff Act of 1930, as amended (''Act''). Further, in accordance with 19 CFR 351.303(f)(3)(ii), a copy of each request must be served on the petitioner and each exporter or producer specified in the request.

#### Respondent Selection

In the event the Department limits the number of respondents for individual examination for administrative reviews, the Department intends to select respondents based on U.S. Customs and Border Protection (''CBP'') data for U.S. imports during the POR. We intend to release the CBP data under Administrative Protective Order (''APO'') to all parties having an APO within seven days of publication of this initiation notice and to make our decision regarding respondent selection within 21 days of publication of this **Federal Register** notice. The Department invites comments regarding the CBP data and respondent selection within five days of placement of the CBP data on the record of the applicable review.

In the event the Department decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act:

In general, the Department has found that determinations concerning whether particular companies should be ''collapsed'' (*i.e.,* treated as a single entity for purposes of calculating antidumping duty rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, the Department will not conduct collapsing analyses at the respondent selection phase of this review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this antidumping proceeding (*i.e.,* investigation, administrative review, new shipper review or changed circumstances review). For any company subject to this review, if the Department determined,

or continued to treat, that company as collapsed with others, the Department will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, the Department will not collapse companies for purposes of respondent selection. Parties are requested to (a) Identify which companies subject to review previously were collapsed, and (b) provide a citation to the proceeding in which they were collapsed. Further, if companies are requested to complete the Quantity and Value Questionnaire for purposes of respondent selection, in general each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of this proceeding where the Department considered collapsing that entity, complete quantity and value data for that collapsed entity must be submitted.

**Deadline for Withdrawal of Request for Administrative Review**

Pursuant to 19 CFR 351.213(d)(1), a party that has requested a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that the Department may extend this time if it is reasonable to do so. In order to provide parties additional certainty with respect to when the Department will exercise its discretion to extend this 90-day deadline, interested parties are advised that, with regard to reviews requested on the basis of anniversary months on or after August 2011, the Department does not intend to extend the 90-day deadline unless the requestor demonstrates that an extraordinary circumstance has prevented it from submitting a timely withdrawal request. Determinations by the Department to extend the 90-day deadline will be made on a case-by-case basis.

**Separate Rates**

In proceedings involving non-market economy (''NME'') countries, the Department begins with a rebuttable presumption that all companies within the country are subject to government control and, thus, should be assigned a single antidumping duty deposit rate. It is the Department's policy to assign all exporters of merchandise subject to an administrative review in an NME country this single rate unless an exporter can demonstrate that it is sufficiently independent so as to be entitled to a separate rate.

To establish whether a firm is sufficiently independent from government control of its export activities to be entitled to a separate rate, the Department analyzes each entity exporting the subject merchandise under a test arising from the *Final Determination of Sales at Less Than Fair Value: Sparklers From the People's Republic of China,* 56 FR 20588 (May 6, 1991), as amplified by *Final Determination of Sales at Less Than Fair Value: Silicon Carbide From the People's Republic of China,* 59 FR 22585 (May 2, 1994). In accordance with the separate-rates criteria, the Department assigns separate rates to companies in NME cases only if respondents can demonstrate the absence of both *de jure* and *de facto* government control over export activities.

All firms listed below that wish to qualify for separate-rate status in the administrative reviews involving NME countries must complete, as appropriate, either a separate-rate application or certification, as described below. For these administrative reviews, in order to demonstrate separate-rate eligibility, the Department requires entities for whom a review was requested, that were assigned a separate rate in the most recent segment of this proceeding in which they participated, to certify that they continue to meet the criteria for obtaining a separate rate. The Separate Rate Certification form will be available on the Department's Web site at *http://www.trade.gov/ia* on the date of publication of this **Federal Register** notice. In responding to the certification, please follow the ''Instructions for Filing the Certification'' in the Separate Rate Certification. Separate Rate Certifications are due to the Department no later than 60 calendar days after publication of this **Federal Register** notice. The deadline and requirement for submitting a Certification applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers who purchase and export subject merchandise to the United States.

Entities that currently do not have a separate rate from a completed segment of the proceeding [1] should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. In addition, companies that received a separate rate in a completed segment of the proceeding that have subsequently made changes, including, but not limited to, changes to corporate structure, acquisitions of new companies or facilities, or changes to their official company name,[2] should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. The Separate Rate Status Application will be available on the Department's Web site at *http://www.trade.gov/ia* on the date of publication of this **Federal Register** notice. In responding to the Separate Rate Status Application, refer to the instructions contained in the application. Separate Rate Status Applications are due to the Department no later than 60 calendar days of publication of this **Federal Register** notice. The deadline and requirement for submitting a Separate Rate Status Application applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers that purchase and export subject merchandise to the United States.

For exporters and producers who submit a separate-rate status application or certification and subsequently are selected as mandatory respondents, these exporters and producers will no longer be eligible for separate rate status unless they respond to all parts of the questionnaire as mandatory respondents.

*Initiation of Reviews:*

In accordance with 19 CFR 351.221(c)(1)(i), we are initiating administrative reviews of the following antidumping and countervailing duty orders and findings. We intend to issue the final results of these reviews not later than August 31, 2012.

[1] Such entities include entities that have not participated in the proceeding, entities that were preliminarily granted a separate rate in any currently incomplete segment of the proceeding (*e.g.,* an ongoing administrative review, new shipper review, *etc.*) and entities that lost their separate rate in the most recently complete segment of the proceeding in which they participated.

[2] Only changes to the official company name, rather than trade names, need to be addressed via a Separate Rate Application. Information regarding new trade names may be submitted via a Separate Rate Certification.

| | Period to be reviewed |
|---|---|
| **Antidumping Duty Proceedings** | |
| Italy: Certain Pasta,[3] A–475–818 | 7/1/10–6/30/11 |
| Industria Alimentare Colavita, S.p.A. | |
| Japan: Tin Mill Products, A–588–854 | 8/1/10–7/31/11 |
| JFE Steel Corporation | |
| Kawasaki Steel Corporation | |
| Nippon Steel Corporation | |
| NKK Corporation | |
| Toyo Kohan Co., Ltd. | |
| Mexico: Light-Walled Rectangular Pipe and Tube, A–201–836 | 8/1/10–7/31/11 |
| Maquilacero S.A. de C.V. | |
| Regiomontana de Perfiles y Tubos S.A. de C.V. | |
| Republic of Korea: Corrosion-Resistant Carbon Steel Flat Products, A–580–816 | 8/1/10–7/31/11 |
| Dongbu Steel Co., Ltd. | |
| Dongkuk Industries Co., Ltd. | |
| Haewon MSC Co., Ltd. | |
| Hyundai HYSCO | |
| LG Hausys, Ltd. | |
| LG Chem, Ltd. | |
| Pohang Iron and Steel Co., Ltd./Pohang Coated Steel Co., Ltd. | |
| Union Steel Manufacturing Co., Ltd. | |
| Romania: Certain Small Diameter Carbon and Alloy Seamless Standard, Line and Pressure Pipe, A–485–805 | 8/1/10–7/31/11 |
| ArcelorMittal Tubular Products Roman S.A. | |
| Socialist Republic of Vietnam: Certain Frozen Fish Fillets,[4] A–552–801 | 8/1/10–7/31/11 |
| An Giang Agriculture and Foods Import-Export Joint Stock Company | |
| An Giang Fisheries Import and Export Joint Stock Company | |
| An Phu Seafood Corporation (also known as ASeafood) | |
| Anvifish Joint Stock Company | |
| Anvifish Co., Ltd. | |
| Asia Commerce Fisheries Joint Stock Company (also known as Anvifish JSC) | |
| Bien Dong Seafood Co., Ltd. | |
| Binh An Seafood Joint Stock Company | |
| Cadovimex II Seafood Import-Export and Processing Joint Stock Company (Cadovimex II) | |
| Cantho Import-Export Seafood Joint Stock Company (CASEAMEX) | |
| CUU Long Fish Joint Stock Company (aka CL-Fish) | |
| DOCIFISH Corporation | |
| East Sea Seafoods Limited Liability Company (formerly known as East Sea Seafoods Joint Venture Co., Ltd.) | |
| East Sea Seafoods Joint Venture Co., Ltd. | |
| East Sea Seafoods LLC | |
| GODACO Seafood Joint Stock Company | |
| Hiep Thanh Seafood Joint Stock Company | |
| Hung Vuong Seafood Joint Stock Company | |
| International Development & Investment Corporation (also known as IDI) | |
| Nam Viet Company Limited (aka NAVICO) | |
| Nam Viet Corporation | |
| NTSF Seafoods Joint Stock Company (also known as NTSF) | |
| QVD Food Company, Ltd. | |
| QVD Dong Thap Food Co., Ltd. | |
| Saigon-Mekong Fishery Co., Ltd. (SAMEFICO) | |
| Southern Fishery Industries Company, Ltd. (also known as South Vina) | |
| Thien Ma Seafood Co., Ltd. (also known as THIMACO) | |
| Thuan An Production Trading & Services Co., Ltd. (also known as TAFISHCO) | |
| Thuan Hung Co., Ltd. (also known as THUFICO) | |
| Vinh Hoan Corporation | |
| Vinh Hoan Company, Ltd. | |
| Vinh Quang Fisheries Corporation | |
| Thailand: Polyethylene Retail Carrier Bags, A–549–821 | 8/1/10–7/31/11 |
| Apple Film Company, Ltd. | |
| First Pack Co. Ltd. | |
| Hi-Pack Company, Ltd. | |
| K International Packaging Co., Ltd. | |
| Landblue (Thailand) Co., Ltd. | |
| Multibax Public Co., Ltd. | |
| Praise Home Industry, Co. Ltd. | |
| Siam Flexible Industries Co., Ltd. | |
| Sombatchai Plastic Industry, Ltd. | |
| Thai Jirun Co., Ltd. | |
| Trinity Pac Co. Ltd. | |
| T.S.T. Plaspack Co., Ltd. | |
| U. Yong Industry Co., Ltd. | |
| The People's Republic of China: Certain Steel Nails,[5] A–570–909 | 8/1/10–7/31/11 |
| ABF Freight System, Inc. | |
| Agritech Products Ltd. | |

| | Period to be reviewed |
|---|---|
| Aihua Holding Group Co., Ltd. | |
| Aironware (Shanghai) Co., Ltd. | |
| Anping County Anning Wire Mesh Co. | |
| Anping Fuhua Wire Mesh Making Co. | |
| APM Global Logistics O/B Hasbro Toy | |
| Beijing Daruixing Global Trading Co., Ltd. | |
| Beijing Daruixing Nail Products Co., Ltd. | |
| Beijing Hong Sheng Metal Products Co., Ltd. | |
| Beijing Hongsheng Metal Products Co., Ltd. | |
| Beijing Jinheuang Co., Ltd. | |
| Beijing Kang Jie Kong Cargo Agent | |
| Beijing KJK Intl Cargo Agent Co., Ltd. | |
| Beijing Long Time Rich Tech Develop | |
| Beijing Tri-Metal Co., Ltd. | |
| Beijing Yonghongsheng Metal Products Co., Ltd. | |
| Besco Machinery Industry (Zhejiang) Co., Ltd. | |
| Brighten International, Inc. | |
| Cana (Tianjin) Hardware Ind., Co., Ltd. | |
| Century Shenzhen Xiamen Branch | |
| Certified Products International Inc. | |
| Changzhou MC I/E Co., Ltd. | |
| Changzhou Quyuan Machinery Co., Ltd. | |
| Changzhou Refine Flag & Crafts Co., Ltd. | |
| Chao Jinqiao Welding Material Co., Ltd. | |
| Chaohu Bridge Nail Industry Co., Ltd. | |
| Chaohu Jinqiao Welding Material Co. | |
| Chewink Corp. | |
| Chiieh Yung Metal Ind. Corp. | |
| China Container Line (Shanghai) Ltd. | |
| China Silk Trading & Logistics Co., Ltd. | |
| China Staple Enterprise (Tianjin) Co., Ltd. | |
| Chongqing Hybest Nailery Co., Ltd. | |
| Chongqing Hybest Tools Group Co., Ltd. | |
| Cintee Steel Products Co., Ltd. | |
| Cyber Express Corporation | |
| CYM (Nanjing) Ningquan Nail Manufacture Co., Ltd. (a.k.a. CYM (Nanjing) Nail Manufacture Co., Ltd.) | |
| Dagang Zhitong Metal Products Co., Ltd. | |
| Damco Shenzhen | |
| Daxing Niantan Industrial | |
| Delix International Co., Ltd. | |
| Dezhou Hualude Hardware Products Co., Ltd. | |
| Dingzhou Derunda Material and Trade Co., Ltd. | |
| Dingzhou Ruili Nail Production Co., Ltd. | |
| Dong'e Fuqiang Metal Products Co., Ltd. | |
| Dongguan Five Stone Machinery Products Trading Co., Ltd. | |
| ECO System Corporation | |
| Elite International Logistics Co. | |
| Elite Master International Ltd. | |
| England Rich Group (China) Ltd. | |
| Entech Manufacturing (Shenzhen) Ltd. | |
| Expeditors China Tianjin Branch | |
| Faithful Engineering Products Co., Ltd. | |
| Fedex International Freight Forward Agency Services (Shanghai) Co., Ltd. | |
| Feiyin Co., Ltd. | |
| Fension International Trade Co., Ltd. | |
| Foreign Economic Relations & Trade | |
| Fujiansmartness Imp. & Exp. Co., Ltd. | |
| Fuzhou Builddirect Ltd. | |
| Goal Well Stone Co., Ltd. | |
| Gold Union Group Ltd. | |
| Goldever International Logistics Co. | |
| Goldmax United Ltd. | |
| Grace News Inc. | |
| Guangdong Foreign Trade Import & Export Corporation | |
| Guangzhou Qiwei Imports and Exports Co., Ltd. | |
| Guoxin Group Wang Shun I/E Co., Ltd. | |
| GWP Industries (Tianjin) Co., Ltd. | |
| Haierce Industry Co., Ltd. | |
| Haixing Hongda Hardware Production Co., Ltd. | |
| Haixing Linhai Hardware Products Factory | |
| Haiyan Fefine Import and Export Co. | |
| Handuk Industrial Co., Ltd. | |
| Hangzhou Kelong Electrical Appliance & Tools Co. Ltd. | |

| | Period to be reviewed |
|---|---|
| Hangzhou New Line Co., Ltd. | |
| Hangzhou Zhongding Imp. & Exp. Co., Ltd. | |
| Hebei Cangzhou New Century Foreign Trade Co., Ltd. | |
| Hebei Development Metals Co., Ltd. | |
| Hebei Jinsidun (JSD) Co., Ltd. | |
| Hebei Machinery Import and Export Co., Ltd. | |
| Hebei Minmetals Co., Ltd. | |
| Hebei My Foreign Trade Co., Ltd. | |
| Hebei Super Star Pneumatic Nails Co., Ltd. | |
| Henan Pengu Hardware Manufacturing Co., Ltd. | |
| Hengshui Mingyao Hardware & Mesh Products Co., Ltd. | |
| Heretops (Hong Kong) International Ltd. | |
| Hilti (China) Limited | |
| HK Villatao Sourcing Co., Ltd. | |
| Hong Kong Hailiang Metal Trading Ltd. | |
| Hong Kong Yu Xi Co., Ltd. | |
| Huadu Jin Chuan Manufactory Co., Ltd. | |
| Huanghua Honly Industry Corp. | |
| Huanghua Huarong Hardware Products Co., Ltd. | |
| Huanghua Jinhai Hardware Products Co., Ltd. | |
| Huanghua Jinhai Metal Products Co., Ltd. | |
| Huanghua Shenghua Hardware Manufactory Factory | |
| Huanghua Xinda Nail Production Co., Ltd. | |
| Huanghua Xionghua Hardware Products Co., Ltd. | |
| Huanghua Yufutai Hardware Products Co., Ltd. | |
| Hubei Boshilong Technology Co., Ltd. | |
| Huiyuan Int'l Commerce Exhibition Co., Ltd. | |
| Jiashan Superpower Tools Co., Ltd. | |
| Jiaxing Yaoliang Import & Export Co., Ltd. | |
| Jinding Metal Products Ltd. | |
| Jinhua Kaixin Imp & Exp Ltd. | |
| Jining Huarong Hardware Products Co., Ltd. | |
| Jisco Corporation | |
| Joto Enterprise Co., Ltd. | |
| Karuis Custom Metal Parts Mfg. Ltd. | |
| Kasy Logistics (Tianjin) Co., Ltd. | |
| K.E. Kingstone | |
| Koram Panagene Co., Ltd. | |
| Kuehne & Nagel Ltd. | |
| Kum Kang Trading Co., Ltd. | |
| Kyung Dong Corp. | |
| Le Group Industries Corp. Ltd. | |
| Leang Wey Int. Business Co., Ltd. | |
| Liang's Industrial Corp. | |
| Lijiang Liantai Trading Co., Ltd. | |
| Linhai Chicheng Arts & Crafts Co., Ltd. | |
| Lins Corp. | |
| Linyi Flying Arrow Imp & Exp Co., Ltd. | |
| Maanshan Cintee Steel Products Co., Ltd. | |
| Maanshan Leader Metal Products Co., Ltd. | |
| Maanshan Longer Nail Product Co., Ltd. | |
| Manufacutersinchina (HK) Company Ltd. | |
| Marsh Trading Ltd. | |
| Master International Co., Ltd. | |
| Mingguang Abundant Hardware Products Co., Ltd. | |
| Montana (Taiwan) Int'l Co., Ltd. | |
| Nanjing Dayu Pneumatic Gun Nails Co., Ltd. | |
| Nanjing Yuechang Hardware Co., Ltd. | |
| Nantong Corporation for Internation | |
| Ningbo Bolun Electric Co., Ltd. | |
| Ningbo Dollar King Industrial Co., Ltd. | |
| Ningbo Endless Energy Electronic Co., Ltd. | |
| Ningbo Fension International Trade Center | |
| Ningbo Fortune Garden Tools and Equipment Inc. | |
| Ningbo Haixin Railroad Material Co. | |
| Ningbo Huamao Imp & Exp. Co., Ltd. | |
| Ningbo Hyderon Hardware Co., Ltd. | |
| Ningbo JF Tools Industrial Co., Ltd. | |
| Ningbo KCN Electric Co., Ltd. | |
| Ningbo Meizhi Tools Co., Ltd. | |
| Ningbo Ordam Import & Export Co., Ltd. | |
| OEC Logistics (Qingdao) Co. Ltd. | |
| Omega Products International | |

| | Period to be reviewed |
|---|---|
| OOCL Logistics O B OF Winston Marketing Group | |
| Orisun Electronics HK Co., Ltd. | |
| Pacole International Ltd. | |
| Panagene Inc. | |
| Pavilion Investment Ltd. | |
| Perfect Seller Co., Ltd. | |
| Prominence Cargo Service, Inc. | |
| PT Enterprise Inc. | |
| Qianshan Huafeng Trading Co., Ltd. | |
| Qidong Liang Chyuan Metal Industry Co., Ltd. | |
| Qingdao Bestworld Industry Trading | |
| Qingdao D&L Group Ltd. | |
| Qingdao Denarius Manufacture Co. Limited | |
| Qingdao Golden Sunshine ELE–EAQ Co., Ltd. | |
| Qingdao International Fastening Systems Inc. | |
| Qingdao Jisco Co., Ltd. | |
| Qingdao Koram Steel Co., Ltd. | |
| Qingdao Lutai Industrial Products Manufacturing Co., Ltd. | |
| Qingdao Meijia Metal Products Co. | |
| Qingdao Rohuida International Trading Co., Ltd. | |
| Qingdao Sino-Sun International Trading Company Limited | |
| Qingdao Super United Metals & Wood Prods. Co. Ltd. | |
| Qingdao Tiger Hardware Co., Ltd. | |
| Qingfu Metal Craft Manufacturing Ltd. | |
| Qinghai Wutong (Group) Industry Co. | |
| Qingyuan County Hongyi Hardware Products Factory | |
| Qingyun Hongyi Hardware Factory | |
| Qinhuangdao Kaizheng Industry and Trade Co. Ltd. | |
| Q–Yield Outdoor Great Ltd. | |
| Region International Co., Ltd. | |
| Richard Hung Ent. Co. Ltd. | |
| River Display Ltd. | |
| Rizhao Changxing Nail-Making Co., Ltd. | |
| Rizhao Handuk Fasteners Co., Ltd. | |
| Rizhao Qingdong Electric Appliance Co., Ltd. | |
| Romp (Tianjin) Hardware Co., Ltd. | |
| Saikelong Electric Appliances (Suzhou) Co., Ltd. | |
| Se Jung (China) Shipping Co., Ltd. | |
| SDC International Australia Pty., Ltd. | |
| Senco Products, Inc. | |
| Senco-Xingya Metal Products (Taicang) Co., Ltd. | |
| Shandex Co., Ltd. | |
| Shandex Industrial Inc. | |
| Shandong Dinglong Import & Export Co., Ltd. | |
| Shandong Minmetals Co., Ltd. | |
| Shandong Oriental Cherry Hardware Group Co., Ltd. | |
| Shandong Oriental Cherry Hardware Import and Export Co., Ltd. | |
| Shanghai Chengkai Hardware Product Co., Ltd. | |
| Shanghai Colour Nail Co., Ltd. | |
| Shanghai Curvet Hardware Products Co., Ltd. | |
| Shanghai Ding Ying Printing & Dyeing CLO | |
| Shanghai GBR Group International Co. | |
| Shanghai Holiday Import & Export Co., Ltd. | |
| Shanghai Jade Shuttle Hardware Tools Co., Ltd. | |
| Shanghai Jian Jie International TRA | |
| Shanghai March Import & Export Company Ltd. | |
| Shanghai Mizhu Imp & Exp Corporation | |
| Shanghai Nanhui Jinjun Hardware Factory | |
| Shanghai Pioneer Speakers Co., Ltd. | |
| Shanghai Pudong Int'l Transporation Booking Dep't | |
| Shanghai Seti Enterprise International Co., Ltd. | |
| Shanghai Shengxiang Hardware Co. | |
| Shanghai Suyu Railway Fastener Co. | |
| Shanghai Tengyu Hardware Tools Co., Ltd. | |
| Shanghai Tengyu Hardware Products Co., Ltd. | |
| Shanghai Tymex International Trade Co., Ltd. | |
| Shanghai Yueda Nails Industry Co., Ltd. | |
| Shanghai Yuet Commercial Consulting Co., Ltd. | |
| Shanxi Hairui Trade Co., Ltd. | |
| Shanxi Pioneer Hardware Industrial Co., Ltd. | |
| Shanxi Tianli Enterprise Co., Ltd. | |
| Shanxi Tianli Industries Co., Ltd. | |
| Shanxi Yuci Broad Wire Products Co., Ltd. | |

| | Period to be reviewed |
|---|---|
| Shanxi Yuci Wire Material Factory | |
| Shaoguang International Trade Co. | |
| Shaoxing Chengye Metal Producting Co., Ltd. | |
| Shenyang Yulin International | |
| Shenzhen Changxinghongye Imp. | |
| Shenzhen Erisson Technology Co., Ltd. | |
| Shenzhen Meiyuda Trade Co., Ltd. | |
| Shenzhen Pacific-Net Logistics Inc. | |
| Shenzhen Shangqi Imports-Exports TR | |
| Shijiazhuang Anao Imp & Export Co. Ltd. | |
| Shijiazhuang Glory Way Trading Co. | |
| Shijiazhuang Fangyu Import & Export Corp. | |
| Shijiazhuang Fitex Trading Co., Ltd. | |
| Shijiazhuang Shuangjian Tools Co., Ltd. | |
| Shitong Int'l Holding Limited | |
| Shouguang Meiqing Nail Industry Co., Ltd. | |
| Sinochem Tianjin Imp & Exp Shenzhen Corp. | |
| Sirius Global Logistics Co., Ltd. | |
| S-mart (Tianjin) Technology Development Co., Ltd. | |
| Sunfield Enterprise Corporation | |
| Sunlife Enterprises (Yangjiang) Ltd. | |
| Suntec Industries Co., Ltd. | |
| Sunworld International Logistics | |
| Superior International Australia Pty Ltd. | |
| Suzhou Guoxin Group Wangshun I/E Co. Imp. Exp. Co., Ltd. | |
| Suzhou Xingya Nail Co., Ltd. | |
| Suzhou Yaotian Metal Products Co., Ltd. | |
| Stanley Black & Decker, Inc. | |
| The Stanley Works (Langfang) Fastening Systems Co., Ltd. | |
| Stanley Fastening Systems LP | |
| Shandex Industrial Inc. | |
| Telex Hong Kong Industry Co., Ltd. | |
| The Everest Corp. | |
| Thermwell Products | |
| Tian Jin Sundy Co., Ltd. (a/k/a Tianjin Sunny Co., Ltd.) | |
| Tianjin Baisheng Metal Product Co., Ltd. | |
| Tianjin Bosai Hardware Tools Co., Ltd. | |
| Tianjin Certified Products Inc. | |
| Tianjin Chengyi International Trading Co., Ltd. | |
| Tianjin Chentai International Trading Co., Ltd. | |
| Tianjin City Dagang Area Jinding Metal Products Factory | |
| Tianjin City Daman Port Area Jinding Metal Products Factory | |
| Tianjin City Jinchi Metal Products Co., Ltd. | |
| Tianjin Dagang Dongfu Metallic Products Co., Ltd. | |
| Tianjin Dagang Hewang Nail Factory | |
| Tianjin Dagang Hewang Nails Manufacture Plant | |
| Tianjin Dagang Huasheng Nailery Co., Ltd. | |
| Tianjin Dagang Jingang Nail Factory | |
| Tianjin Dagang Jingang Nails Manufacture Plant | |
| Tianjin Dagang Linda Metallic Products Co., Ltd. | |
| Tianjin Dagang Longhua Metal Products Plant | |
| Tianjin Dagang Shenda Metal Products Co., Ltd. | |
| Tianjin Dagang Yate Nail Co., Ltd. | |
| Tianjin Dery Import and Export Co., Ltd. | |
| Tianjin Everwin Metal Products Co, Ltd. | |
| Tianjin Foreign Trade (Group) Textile & Garment Co., Ltd. | |
| Tianjin Hewang Nail Making Factory | |
| Tianjin Huachang Metal Products Co., Ltd. | |
| Tianjin Huapeng Metal Company | |
| Tianjin Huasheng Nails Production Co., Ltd. | |
| Tianjin Jetcom Manufacturing Co, Ltd. | |
| Tianjin Jieli Hengyuan Metallic Products Co., Ltd. | |
| Tianjin Jietong Hardware Products Co., Ltd. | |
| Tianjin Jietong Metal Products Co., Ltd. | |
| Tianjin Jin Gang Metal Products Co., Ltd. | |
| Tianjin Jinchi Metal Products Co., Ltd. | |
| Tianjin Jinghai County Hongli Industry & Business Co., Ltd. | |
| Tianjin Jinjin Pharmaceutical Factory Co., Ltd. | |
| Tianjin Jishili Hardware Co., Ltd. | |
| Tianjin JLHY Metal Products Co., Ltd. | |
| Tianjin Jurum Metal Products Co., Ltd. | |
| Tianjin Jurun Metal Products Co., Ltd. | |
| Tianjin Kunxin Hardware Co., Ltd. | |

| | Period to be reviewed |
|---|---|
| Tianjin Kunxin Metal Products Co., Ltd. | |
| Tianjin Lianda Group Co., Ltd. | |
| Tianjin Linda Metal Company | |
| Tianjin Longxing (Group) Huanyu Imp. & Exp. Co., Ltd. | |
| Tianjin Master Fastener Co., Ltd. (a/k/a Master Fastener Co., Ltd.) | |
| Tianjin Mei Jia Hua Trade Co., Ltd. | |
| Tianjin Metals and Minerals | |
| Tianjin Port Free Trade Zone Xiangtong Intl. Industry & Trade Corp. | |
| Tianjin Products & Energy Resources Dev. Co., Ltd. | |
| Tianjin Qichuan Metal Products Co., Ltd. | |
| Tianjin Ruiji Metal Products Co., Ltd. | |
| Tianjin Senbohengtong International | |
| Tianjin Senmiao Import and Export Co., Ltd. | |
| Tianjin Shenyuan Steel Producting Group Co., Ltd. | |
| Tianjin Shishun Metal Product Co., Ltd. | |
| Tianjin Shishun Metallic Products Co., Ltd. | |
| Tianjin Universal Machinery Imp & Exp Corporation | |
| Tianjin Xiantong Fucheng Gun Nail Manufacture Co., Ltd. | |
| Tianjin Xiantong Juxiang Metal MFG Co., Ltd. | |
| Tianjin Xiantong Material & Trade Co., Ltd. | |
| Tianjin Xinyuansheng Metal Products Co., Ltd. | |
| Tianjin Yihao Metallic Products Co., Ltd. | |
| Tianjin Yongchang Metal Product Co., Ltd. | |
| Tianjin Yongxu Metal Products Co., Ltd. | |
| Tianjin Yongye Furniture | |
| Tianjin Yongyi Standard Parts Production Co., Ltd. | |
| Tianjin Zhong Jian Wanli Stone Co., Ltd. | |
| Tianjin Zhonglian Metals Ware Co., Ltd. | |
| Tianjin Zhongsheng Garment Co., Ltd. | |
| Tianwoo Logistics Developing Co., Ltd. | |
| Topocean Consolidation Service (CHA) Ltd. | |
| Tradex Group, Inc. | |
| Traser Mexicana, S.A. De C.V. | |
| Treasure Way International Dev. Ltd. | |
| True Value Company (HK) Ltd. | |
| Unicatch Industrial Co., Ltd. | |
| Unigain Trading Co., Ltd. | |
| Union Enterprise (Kunshan) Co., Ltd. (a.k.a. Union Enterprise Co., Ltd.) | |
| Vinin Industries Limited | |
| Wintime Import & Export Corporation Limited of Zhongshan | |
| Wenzhou KLF Medical Plastics Co., Lt. | |
| Wenzhou Ouxin Foreign Trade Co., Ltd. | |
| Wenzhou Yuwei Foreign Trade Co., Ltd. | |
| Winsmart International Shipping Ltd. O/B Zhaoqing Harvest Nails Co., Ltd. | |
| Worldwide Logistics Co., Ltd. (Tianjin Branch) | |
| Wuhan Xinxin Native Produce & Animal By-Products Mfg. Co. Ltd. | |
| Wuhu Sheng Zhi Industrial Co., Ltd. | |
| Wuhu Shijie Hardware Co., Ltd. | |
| Wuhu Xin Lan De Industrial Co., Ltd. | |
| Wuqiao County Huifeng Hardware Products Factory | |
| Wuqiao County Xinchuang Hardware Products Factory | |
| Wuqiao Huifeng Hardware Production Co., Ltd. | |
| Wuxi Baolin Nail Enterprises | |
| Wuxi Baolin Nail-Making Machinery Co., Ltd. | |
| Wuxi Chengye Metal Products Co., Ltd. | |
| Wuxi Colour Nail Co., Ltd. | |
| Wuxi Qiangye Metalwork Production Co., Ltd. | |
| Wuxi Jinde Assets Management Co., Ltd. | |
| Wuxi Moresky Developing Co., Ltd. | |
| Xiamen New Kunlun Trade Co., Ltd. | |
| Xi'an Metals & Minerals Import and Export Co., Ltd. | |
| Xi'an Steel | |
| XL Metal Works Co., Ltd. | |
| XM International, Inc. | |
| Xuzhou CIP International Group Co., Ltd. | |
| Yeswin Corporation | |
| Yitian Nanjing Hardware Co., Ltd. | |
| Yiwu Dongshun Toys Manufacture | |
| Yiwu Excellent Import & Export Co., Ltd. | |
| Yiwu Jiehang Import & Export Co., Ltd. | |
| Yiwu Qiaoli Import & Export Co., Ltd. | |
| Yiwu Richway Imp & Exp Co., Ltd. | |
| Yiwu Zhongai Toys Co., Ltd. | |

| | Period to be reviewed |
|---|---|
| Yongcheng Foreign Trade Corp.<br>Yu Chi Hardware Co., Ltd.<br>Yue Sang Plastic Factory<br>Yuhuan Yazheng Importing<br>Zhangjiagang Lianfeng Metals Products Co., Ltd.<br>Zhangjiagang Longxiang Packing Materials Co., Ltd.<br>Zhaoqing Harvest Nails Co., Ltd.<br>Zhejiang Gem-Chun Hardware Accessory Co., Ltd.<br>Zhejiang Hungyan Xingzhou Industria<br>Zhejiang Jinhua Nail Factory<br>Zhejiang Minmetals Sanhe Imp & Exp Co.<br>Zhejiang Qifeng Hardware Make Co., Ltd.<br>Zhejiang Taizhou Eagle Machinery Co.<br>Zhejiang Yiwu Huishun Import/Export Co., Ltd.<br>Zhongshan Junlong Nail Manufactures Co., Ltd.<br>ZJG Lianfeng Metals Product Ltd. | |
| The People's Republic of China: Floor-Standing Metal-Top Ironing Tables,[6] A–570–888 | 8/1/10–7/31/11 |
| Foshan Shunde Yongjian Housewares & Hardware Co., Ltd. | |
| The People's Republic of China: Polyethylene Retail Carrier Bags,[7] A–570–886 | 8/1/10–7/31/11 |
| Dongguan Nozawa Plastics Products Co., Ltd. and United Power Packaging, Ltd. (collectively Nozawa) | |
| **Countervailing Duty Proceedings** | |
| Republic of Korea: Corrosion-Resistant Carbon Steel Flat Products, C–580–818 | 1/1/10–12/31/10 |
| Dongbu Steel Co., Ltd.<br>Hyandai HYSCO<br>Pohang Iron & Steel Co., Ltd./Pohang Coated Steel Co., Ltd. (POSCO) | |
| **Suspension Agreements** | |
| None. | |

During any administrative review covering all or part of a period falling between the first and second or third and fourth anniversary of the publication of an antidumping duty order under 19 CFR 351.211 or a determination under 19 CFR 351.218(f)(4) to continue an order or suspended investigation (after sunset review), the Secretary, if requested by a domestic interested party within 30 days of the date of publication of the notice of initiation of the review, will determine, consistent with *FAG Italia* v. *United States,* 291 F.3d 806 (Fed Cir. 2002), as appropriate, whether antidumping duties have been absorbed by an exporter or producer subject to the review if the subject merchandise is sold in the United States through an importer that is affiliated with such exporter or producer. The request must include the name(s) of the exporter or producer for which the inquiry is requested.

[3] The company listed was inadvertently omitted from the initiation notice that published on August 26, 2011 (76 FR 53404).

[4] If one of the above named companies does not qualify for a separate rate, all other exporters of frozen fish fillets from the Socialist Republic of Vietnam who have not qualified for a separate rate are deemed to be covered by this review as part of the single Vietnam entity of which the named exporters are a part.

[5] If one of the above named companies does not qualify for a separate rate, all other exporters of Certain Steel Nails from the People's Republic of China (''PRC'') who have not qualified for a separate rate are deemed to be covered by this review as part of the single PRC entity of which the named exporters are a part.

[6] If the above named company does not qualify for a separate rate, all other exporters of Floor-Standing Metal-Top Ironing Tables from the PRC who have not qualified for a separate rate are deemed to be covered by this review as part of the single PRC entity of which the named exporters are a part.

[7] If the above named company does not qualify for a separate rate, all other exporters of Polyethylene Retail Carrier Bags from the PRC who have not qualified for a separate rate are deemed to be covered by this review as part of the single PRC entity of which the named exporters are a part.

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant provisional-measures ''gap'' period, of the order, if such a gap period is applicable to the period of review.

Interested parties must submit applications for disclosure under administrative protective orders in accordance with 19 CFR 351.305. On January 22, 2008, the Department published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures,* 73 FR 3634 (January 22, 2008). Those procedures apply to administrative reviews included in this notice of initiation. Parties wishing to participate in any of these administrative reviews should ensure that the meet the requirements of these procedures (*e.g.,* the filing of separate letters of appearance as discussed at 19 CFR 351.103(d)).

Any party submitting factual information in an antidumping duty or countervailing duty proceeding must certify to the accuracy and completeness of that information. *See* section 782(b) of the Act. Parties are hereby reminded that revised certification requirements are in effect for company/government officials as well as their representatives in all segments of any antidumping duty or countervailing duty proceedings initiated on or after March 14, 2011. *See Certification of Factual Information to Import Administration During Antidumping and Countervailing Duty Proceedings: Interim Final Rule,* 76 FR 7491 (February 10, 2011) (''*Interim Final Rule*''), amending 19 CFR 351.303(g)(1) and (2). The formats for the revised certifications are provided at the end of the *Interim Final Rule.* The Department intends to reject factual submissions in any proceeding segments initiated on or after March 14, 2011 if the submitting party does not comply with the revised certification requirements.

These initiations and this notice are in accordance with section 751(a) of the Tariff Act of 1930, as amended (19 U.S.C. 1675(a)) and 19 CFR 351.221(c)(1)(i).

Dated: September 26, 2011.

**Christian Marsh,**

*Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.*

[FR Doc. 2011–25432 Filed 9–30–11; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–570–924]**

### Polyethylene Terephthalate Film, Sheet, and Strip From the People's Republic of China: Extension of Preliminary Results of Antidumping Duty Administrative Review

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**SUMMARY:** The Department of Commerce (''the Department'') is extending the time limits for the preliminary results of the administrative review of polyethylene terephthalate film, sheet, and strip (''PET film'') from the People's Republic of China (''PRC''). This review covers the period November 1, 2009, through October 31, 2010.

**DATES:** *Effective Date:* October 3, 2011.

**FOR FURTHER INFORMATION CONTACT:** Thomas Martin or Jonathan Hill, AD/CVD Operations, Office 4, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–3936 or (202) 482–3518, respectively.

**Background**

On December 28, 2010, the Department published in the **Federal Register** a notice of initiation of the second administrative review of the antidumping duty order on PET film from the PRC. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocation in Part,* 75 FR 81565 (December 28, 2010). On July 18, 2011, the Department extended the time period for completing the preliminary results of the review by 60 days. *See Polyethylene Terephthalate Film, Sheet, and Strip From the People's Republic of China: Extension of Preliminary Results of Antidumping Duty Administrative Review,* 76 FR 42113 (July 18, 2011). The preliminary results of this review are currently due no later than October 3, 2011.

**Statutory Time Limits**

In antidumping duty administrative reviews, section 751(a)(3)(A) of the Tariff Act of 1930, as amended (''the Act''), requires the Department to issue its preliminary results within 245 days after the last day of the anniversary month of an order for which a review is requested and to issue its final results within 120 days after the date on which the preliminary results are published. However, if it is not practicable to complete the review within these time periods, section 751(a)(3)(A) of the Act allows the Department to extend the time limit for the preliminary results to a maximum of 365 days after the last day of the anniversary month.

**Extension of Time Limit for Preliminary Results of Review**

The Department has determined that it is not practicable to complete the instant administrative review within the original time limits established by section 751(a)(3)(A) of the Act because we require additional time to evaluate the respondents' reporting methodology for the consumption of direct raw material factors of production. Therefore, in accordance with section 751(a)(3)(A) of the Act, the Department is extending the time period for completing the preliminary results of the instant administrative review by an additional 30 days. The new deadline is October 31, 2011.[1] The deadline for the final results of this review continues to be 120 days after the publication of the preliminary results.

We are issuing and publishing this notice in accordance with sections 751(a)(3)(A) and 777(i) of the Act.

Dated: September 27, 2011.

**Christian Marsh,**

*Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.*

[FR Doc. 2011–25417 Filed 9–30–11; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

### Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**FOR FURTHER INFORMATION CONTACT:** Brenda E. Waters, Office of AD/CVD Operations, Customs Unit, Import Administration, International Trade Administration, U.S. Department of

[1] The initial 60 day extension in this administrative review fell on October 1, 2011 which is a Saturday. Per the Department's practice, the Department set the deadline for completion of the preliminary results to be the next business day, October 3, 2011. *See Notice of Clarification: Application of ''Next Business Day'' Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, as Amended,* 70 FR 24533 (May 10, 2005). The Department will extend the deadline for this second extension of the preliminary results of review based upon the original deadline date of October 1, 2011.

Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230, *telephone:* (202) 482–4735.

**Background**

Each year during the anniversary month of the publication of an antidumping or countervailing duty order, finding, or suspended investigation, an interested party, as defined in section 771(9) of the Tariff Act of 1930, as amended (''the Act''), may request, in accordance with 19 CFR 351.213 of the Department of Commerce (''the Department'') regulations, that the Department conduct an administrative review of that antidumping or countervailing duty order, finding, or suspended investigation.

All deadlines for the submission of comments or actions by the Department discussed below refer to the number of calendar days from the applicable starting date.

**Respondent Selection**

In the event the Department limits the number of respondents for individual examination for administrative reviews initiated pursuant to requests made for the orders identified below, the Department intends to select respondents based on U.S. Customs and Border Protection (''CBP'') data for U.S. imports during the period of review. We intend to release the CBP data under Administrative Protective Order (''APO'') to all parties having an APO within five days of publication of the initiation notice and to make our decision regarding respondent selection within 21 days of publication of the initiation **Federal Register** notice. Therefore, we encourage all parties interested in commenting on respondent selection to submit their APO applications on the date of publication of the initiation notice, or as soon thereafter as possible. The Department invites comments regarding the CBP data and respondent selection within five days of placement of the CBP data on the record of the review.

In the event the Department decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act:

In general, the Department has found that determinations concerning whether particular companies should be ''collapsed'' (*i.e.,* treated as a single entity for purposes of calculating antidumping duty rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, the Department will not conduct collapsing analyses at the respondent selection phase of this review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this antidumping proceeding (*i.e.,* investigation, administrative review, new shipper review or changed circumstances review). For any company subject to this review, if the Department determined, or continued to treat, that company as collapsed with others, the Department will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, the Department will not collapse companies for purposes of respondent selection. Parties are requested to (a) Identify which companies subject to review previously were collapsed, and (b) provide a citation to the proceeding in which they were collapsed. Further, if companies are requested to complete the Quantity and Value Questionnaire for purposes of respondent selection, in general each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of this proceeding where the Department considered collapsing that entity, complete quantity and value data for that collapsed entity must be submitted.

**Deadline for Withdrawal of Request for Administrative Review**

Pursuant to 19 CFR 351.213(d)(1), a party that has requested a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that the Department may extend this time if it is reasonable to do so. In order to provide parties additional certainty with respect to when the Department will exercise its discretion to extend this 90-day deadline, interested parties are advised that, with regard to reviews requested on the basis of anniversary months on or after October 2011, the Department does not intend to extend the 90-day deadline unless the requestor demonstrates that an extraordinary circumstance has prevented it from submitting a timely withdrawal request. Determinations by the Department to extend the 90-day deadline will be made on a case-by-case basis.

The Department is providing this notice on its website, as well as in its ''Opportunity to Request Administrative Review'' notices, so that interested parties will be aware of the manner in which the Department intends to exercise its discretion in the future.

*Opportunity to Request a Review:* Not later than the last day of October 2011,[1] interested parties may request administrative review of the following orders, findings, or suspended investigations, with anniversary dates in October for the following periods:

| | Period of review |
|---|---|
| **Antidumping Duty Proceedings** | |
| Australia: Electrolytic Manganese Dioxide A–602–806 | 10/1/10–9/30/11 |
| Brazil: Carbon and Certain Alloy Steel Wire Rod A–351–832 | 10/1/10–9/30/11 |
| Indonesia: Carbon and Certain Alloy Steel Wire Rod A–560–815 | 10/1/10–9/30/11 |
| Italy: Pressure Sensitive Plastic Tape A–475–059 | 10/1/10–9/30/11 |
| Mexico: Carbon and Certain Alloy Steel Wire Rod A–201–830 | 10/1/10–9/30/11 |
| Moldova: Carbon and Certain Alloy Steel Wire Rod A–841–805 | 10/1/10–9/30/11 |
| Republic of Korea: Polyvinyl Alcohol A–580–850 | 10/1/10–9/30/11 |
| The People's Republic of China: | |
| Barium Carbonate A–570–880 | 10/1/10–9/30/11 |
| Barium Chloride A–570–007 | 10/1/10–9/30/11 |
| Electrolytic Manganese Dioxide A–570–919 | 10/1/10–9/30/11 |
| Helical Spring Lock Washers A–570–822 | 10/1/10–9/30/11 |

[1] Or the next business day, if the deadline falls on a weekend, federal holiday or any other day when the Department is closed.

| | Period of review |
|---|---|
| Polyvinyl Alcohol A–570–879 | 10/1/10–9/30/11 |
| Steel Wire Garment Hangers A–570–918 | 10/1/10–9/30/11 |
| Trinidad and Tobago: Carbon and Certain Alloy Steel Wire Rod A–274–804 | 10/1/10–9/30/11 |
| Ukraine: Carbon and Certain Alloy Steel Wire Rod A–823–812 | 10/1/10–9/30/11 |
| **Countervailing Duty Proceedings** | |
| Brazil: Carbon and Certain Alloy Steel Wire Rod C–351–833 | 1/1/10–12/31/10 |
| Iran: Roasted In-Shell Pistachios C–507–601 | 1/1/10–12/31/10 |
| **Suspension Agreements** | |
| Russia: Uranium A–821–802 | 10/1/10–9/30/11 |

In accordance with 19 CFR 351.213(b), an interested party as defined by section 771(9) of the Act may request in writing that the Secretary conduct an administrative review. For both antidumping and countervailing duty reviews, the interested party must specify the individual producers or exporters covered by an antidumping finding or an antidumping or countervailing duty order or suspension agreement for which it is requesting a review. In addition, a domestic interested party or an interested party described in section 771(9)(B) of the Act must state why it desires the Secretary to review those particular producers or exporters.[2] If the interested party intends for the Secretary to review sales of merchandise by an exporter (or a producer if that producer also exports merchandise from other suppliers) which were produced in more than one country of origin and each country of origin is subject to a separate order, then the interested party must state specifically, on an order-by-order basis, which exporter(s) the request is intended to cover.

Please note that, for any party the Department was unable to locate in prior segments, the Department will not accept a request for an administrative review of that party absent new information as to the party's location. Moreover, if the interested party who files a request for review is unable to locate the producer or exporter for which it requested the review, the interested party must provide an explanation of the attempts it made to locate the producer or exporter at the same time it files its request for review, in order for the Secretary to determine if the interested party's attempts were reasonable, pursuant to 19 CFR 351.303(f)(3)(ii).

As explained in *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003), the Department has clarified its practice with respect to the collection of final antidumping duties on imports of merchandise where intermediate firms are involved. The public should be aware of this clarification in determining whether to request an administrative review of merchandise subject to antidumping findings and orders. *See also* the Import Administration Web site at *http://ia.ita.doc.gov.*

All requests must be filed electronically in Import Administration's Antidumping and Countervailing Duty Centralized Electronic Service System (''IA ACCESS'') on the IA ACCESS Web site at *http://iaaccess.trade.gov. See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011). Further, in accordance with 19 CFR 351.303(f)(l)(i), a copy of each request must be served on the petitioner and each exporter or producer specified in the request.

The Department will publish in the **Federal Register** a notice of ''Initiation of Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation'' for requests received by the last day of October 2011. If the Department does not receive, by the last day of October 2011, a request for review of entries covered by an order, finding, or suspended investigation listed in this notice and for the period identified above, the Department will instruct the CBP to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of (or bond for) estimated antidumping or countervailing duties required on those entries at the time of entry, or withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant provisional-measures ''gap'' period, of the order, if such a gap period is applicable to the period of review.

This notice is not required by statute but is published as a service to the international trading community.

Dated: September 26, 2011.

**Christian Marsh,**

*Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.*

[FR Doc. 2011–25422 Filed 9–30–11; 8:45 am]

**BILLING CODE 3510–DS–P**

[2] If the review request involves a non-market economy and the parties subject to the review request do not qualify for separate rates, all other exporters of subject merchandise from the non-market economy country who do not have a separate rate will be covered by the review as part of the single entity of which the named firms are a part.

## DEPARTMENT OF COMMERCE

### International Trade Administration

### Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Advance Notification of Sunset Reviews

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

#### Background

Every five years, pursuant to section 751(c) of the Tariff Act of 1930, as amended (''the Act''), the Department of Commerce (''the Department'') and the International Trade Commission automatically initiate and conduct a review to determine whether revocation of a countervailing or antidumping duty order or termination of an investigation suspended under section 704 or 734 of the Act would be likely to lead to continuation or recurrence of dumping or a countervailable subsidy (as the case may be) and of material injury.

#### Upcoming Sunset Reviews for November 2011

The following Sunset Reviews are scheduled for initiation in November 2011 and will appear in that month's

Notice of Initiation of Five-Year Sunset Reviews.

| Antidumping duty proceedings | Department contact |
|---|---|
| Silicon Metal from the People's Republic of China (A–570–806) (3rd Review) | Julia Hancock, (202) 482–1394. |
| Stainless Steel Butt-Weld Pipe Fittings from Italy (A–475–828) (2nd Review) | Dana Mermelstein, (202) 482–1391. |
| Stainless Steel Butt-Weld Pipe Fittings from Malaysia (A–557–809) (2nd Review) | Dana Mermelstein, (202) 482–1391 |
| Stainless Steel Butt-Weld Pipe Fittings from the Philippines (A–565–801) (2nd Review) | Dana Mermelstein, (202) 482–1391. |

**Countervailing Duty Proceedings**

No Sunset Review of countervailing duty orders is scheduled from initiation in November 2011.

**Suspended Investigations**

No Sunset Review of suspended investigations is scheduled from initiation in November 2011.

The Department's procedures for the conduct of Sunset Reviews are set forth in 19 CFR 351.218. Guidance on methodological or analytical issues relevant to the Department's conduct of Sunset Reviews is set forth in the Department's Policy Bulletin 98.3—*Policies Regarding the Conduct of Five-year (''Sunset'') Reviews of Antidumping and Countervailing Duty Orders; Policy Bulletin,* 63 FR 18871 (April 16, 1998) . The Notice of Initiation of Five-Year (''Sunset'') Reviews provides further information regarding what is required of all parties to participate in Sunset Reviews.

Pursuant to 19 CFR 351.103(c), the Department will maintain and make available a service list for these proceedings. To facilitate the timely preparation of the service list(s), it is requested that those seeking recognition as interested parties to a proceeding contact the Department in writing within 10 days of the publication of the Notice of Initiation.

Please note that if the Department receives a Notice of Intent to Participate from a member of the domestic industry within 15 days of the date of initiation, the review will continue. Thereafter, any interested party wishing to participate in the Sunset Review must provide substantive comments in response to the notice of initiation no later than 30 days after the date of initiation.

This notice is not required by statute but is published as a service to the international trading community.

Dated: September 20, 2011.

**Christian Marsh,**

*Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.*

[FR Doc. 2011–25420 Filed 9–30–11; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–552–801]**

### Certain Frozen Fish Fillets From the Socialist Republic of Vietnam: Initiation of New Shipper Reviews

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**DATES:** *Effective Date:* October 3, 2011.

**SUMMARY:** The Department of Commerce (''Department'') has determined that the three requests for new shipper reviews of the antidumping duty order on certain frozen fish fillets from the Socialist Republic of Vietnam, received between August 3, 2011 and August 16, 2011 meet the statutory and regulatory requirements for initiation. The period of review (''POR'') of these new shipper reviews is August 1, 2010–July 31, 2011.

**FOR FURTHER INFORMATION CONTACT:** Jamie Blair-Walker, AD/CVD Operations, Office 9, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–2615.

**SUPPLEMENTARY INFORMATION:**

**Background**

The antidumping duty order on certain frozen fish fillets from the Socialist Republic of Vietnam was published in the **Federal Register** on August 12, 2003. *See Notice of Antidumping Duty Order: Certain Frozen Fish Fillets From the Socialist Republic of Vietnam,* 68 FR 47909 (August 12, 2003). On August 3, 4, and 16, 2011, respectively, we received a timely request for a new shipper review from An Phu Seafood Corporation (''An Phu''), GODACO Seafood Joint Stock Company (''GODACO''), and DOCIFISH Corporation (''DOCIFISH''). All three new shipper requests were filed in accordance with 19 CFR 351.214(c) and 351.214(d)(1). On August 25, 2011, An Phu responded to the Department's August 19, 2011, supplemental questionnaire. The questionnaire and corresponding response concerned the need for clarification regarding certain information observed in data obtained by the Department from U.S. Customs and Border Protection (''CBP''). The Department found no issue with the response given by An Phu. An Phu, GODACO, and DOCIFISH have certified that they are both the producers and exporters of the subject merchandise upon which the requests for the new shipper review are based.

**Initiation of New Shipper Reviews**

Pursuant to section 751(a)(2)(B)(i)(I) of the Tariff Act of 1930, as amended (''Act''), and 19 CFR 351.214(b)(2), An Phu, GODACO, and DOCIFISH certified that they did not export certain frozen fish fillets to the United States during the period of investigation (''POI''). Pursuant to section 751(a)(2)(B)(i)(II) of the Act and 19 CFR 351.214(b)(2)(iii)(A), An Phu, GODACO, and DOCIFISH certified that, since the initiation of the less-than-fair-value investigation, they have never been affiliated with any exporter or producer who exported certain frozen fish fillets to the United States during the POI, including those not individually examined during the less-than-fair-value investigation. As required by 19 CFR 351.214(b)(2)(iii)(B), An Phu, GODACO, and DOCIFISH have also certified that their export activities are not controlled by the central government of Vietnam.

In addition to the certifications described above, An Phu, GODACO, and DOCIFISH submitted documentation establishing the following: (1) The date on which the company first shipped certain frozen fish fillets for export to the United States and the date on which the certain frozen fish fillets first entered, or withdrawn from warehouse, for consumption; (2) the volume of the company's first shipment; and (3) the date of the company's first sales to an unaffiliated customer in the United States.

Pursuant to section 751(a)(2)(B) of the Act and 19 CFR 351.214(d)(1), we are initiating these new shipper reviews for shipments of certain frozen fish fillets from Vietnam produced and exported by An Phu, GODACO, and DOCIFISH.

We intend to issue preliminary results of this review no later than 180 days from the date of initiation, and final results of these reviews no later than 270 days from the date of initiation. *See* section 751(a)(2)(B)(iv) of the Act.

We will instruct CBP to allow, at the option of the importer, the posting, until the completion of the review, of a bond or security in lieu of a cash deposit for each entry of the subject merchandise from An Phu, GODACO, or DOCIFISH in accordance with section 751(a)(2)(B)(iii) of the Act and 19 CFR 351.214(e). Because An Phu, GODACO, and DOCIFISH certified that they have both produced and exported the subject merchandise, the sales of which are the bases for these new shipper review requests, we will apply the bonding privilege to these three companies only for subject merchandise which the respondents both produced and exported.

This initiation notice serves as notification to the three companies that upon initiation of this new shipper review, the Department will require An Phu, GODACO, and DOCIFISH to submit on an ongoing basis complete transaction information concerning any sales of subject merchandise to the United States that were made subsequent to the period of review in order to assist in its analysis of the *bona fides* of the sales of the three companies.

Interested parties requiring access to proprietary information in these new shipper reviews should submit applications for disclosure under administrative protective order in accordance with 19 CFR 351.305 and 351.306. This initiation and notice are in accordance with section 751(a)(2)(B) of the Act and 19 CFR 351.214 and 351.221(c)(1)(i).

Dated: September 26, 2011.

**Gary Taverman,**

*Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.*

[FR Doc. 2011–25426 Filed 9–30–11; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### Indirect Cost Rates for the Damage Assessment, Remediation, and Restoration Program for Fiscal Years 2009 and 2010

**AGENCY:** National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Notice of Indirect Cost Rates for the Damage Assessment, Remediation, and Restoration Program for Fiscal Years 2009 and 2010.

**SUMMARY:** The National Oceanic and Atmospheric Administration's (NOAA's) Damage Assessment, Remediation, and Restoration Program (DARRP) is announcing new indirect cost rates on the recovery of indirect costs for its component organizations involved in natural resource damage assessment and restoration activities for fiscal years (FY) 2009 and 2010. The indirect cost rates for these fiscal years and dates of implementation are provided in this notice. More information on these rates and the DARRP policy can be found at the DARRP web site at www.darrp.noaa.gov.

**FOR FURTHER INFORMATION CONTACT:** For further information, contact LaTonya Burgess at 301–713–4248, ext. 211, by fax at 301–713–4389, or e-mail at *LaTonya.Burgess@noaa.gov.*

**SUPPLEMENTARY INFORMATION:** The mission of the DARRP is to restore natural resource injuries caused by releases of hazardous substances or oil under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) (42 U.S.C. 9601 *et seq.*), the Oil Pollution Act of 1990 (OPA) (33 U.S.C. 2701 *et seq.*), and support restoration of physical injuries to National Marine Sanctuary resources under the National Marine Sanctuaries Act (NMSA) (16 U.S.C. 1431 *et seq.*). The DARRP consists of three component organizations: the Office of Response and Restoration (ORR) within the National Ocean Service; the Restoration Center within the National Marine Fisheries Service; and the Office of the General Counsel for Natural Resources (GCNR). The DARRP conducts Natural Resource Damage Assessments (NRDAs) as a basis for recovering damages from responsible parties, and uses the funds recovered to restore injured natural resources.

Consistent with Federal accounting requirements, the DARRP is required to account for and report the full costs of its programs and activities. Further, the DARRP is authorized by law to recover reasonable costs of damage assessment and restoration activities under CERCLA, OPA, and the NMSA. Within the constraints of these legal provisions and their regulatory applications, the DARRP has the discretion to develop indirect cost rates for its component organizations and formulate policies on the recovery of indirect cost rates subject to its requirements.

**The DARRP's Indirect Cost Effort**

In December 1998, the DARRP hired the public accounting firm Rubino & McGeehin, Chartered (R&M) to: evaluate the DARRP cost accounting system and allocation practices; recommend the appropriate indirect cost allocation methodology; and determine the indirect cost rates for the three organizations that comprise the DARRP. A **Federal Register** notice on R&M's effort, their assessment of the DARRP's cost accounting system and practice, and their determination regarding the most appropriate indirect cost methodology and rates for FYs 1993 through 1999 was published on December 7, 2000 (65 FR 76611). The notice and report by R&M can also be found on the DARRP Web site at *http://www.darrp.noaa.gov.*

R&M continued its assessment of DARRP's indirect cost rate system and structure for FYs 2000 and 2001. A second federal notice specifying the DARRP indirect rates for FYs 2000 and 2001 was published on December 2, 2002 (67 FR 71537).

In October 2002, DARRP hired the accounting firm of Cotton and Company LLP (Cotton) to review and certify DARRP costs incurred on cases for purposes of cost recovery and to develop indirect rates for FY 2002 and subsequent years. As in the prior years, Cotton concluded that the cost accounting system and allocation practices of the DARRP component organizations are consistent with Federal accounting requirements. Consistent with R&M's previous analyses, Cotton also determined that the most appropriate indirect allocation method continues to be the Direct Labor Cost Base for all three DARRP component organizations. The Direct Labor Cost Base is computed by allocating total indirect cost over the sum of direct labor dollars, plus the application of NOAA's leave surcharge and benefits rates to direct labor. Direct labor costs for contractors from I.M. Systems Group (IMSG) were included in the direct labor base because Cotton determined that these costs have the same relationship to the indirect cost pool as NOAA direct labor costs. IMSG provided on-site support to the DARRP in the areas of injury assessment, natural resource economics, restoration planning and implementation, and policy analysis. IMSG continues to provide on-site support to the DARRP. Starting in FY 2010, contractors from Genwest provide on-site support for cost documentation. A third federal notice

specifying the DARRP indirect rates for FY 2002 was published on October 6, 2003 (68 FR 57672), a fourth notice for the FY 2003 indirect cost rates appeared on May 20, 2005 (70 FR 29280), and a fifth notice for the FY 2004 indirect cost rates was published on March 16, 2006 (71 FR 13356). The notice for the FY 2005 indirect cost rates was published on February 9, 2007 (72 FR 6221). The notice for the FY 2006 rates was published on June 3, 2008 (73 FR 31679). Finally, the notice for the FY 2007 and FY 2008 rates was published on November 16, 2009 (74 FR 58948). Cotton's reports on these indirect rates can also be found on the DARRP Web site at *http://www.darrp.noaa.gov.*

Cotton reaffirmed that the Direct Labor Cost Base is the most appropriate indirect allocation method for the development of the FY 2009 and FY 2010 indirect cost rates.

The DARRP's Indirect Cost Rates and Policies

The DARRP will apply the indirect cost rates for FY 2009 and FY 2010 as recommended by Cotton for each of the DARRP component organizations as provided in the following table:

| DARRP Component organization | FY2007 Indirect rate (percent) | FY2008 Indirect rate (percent) |
|---|---|---|
| Office of Response and Restoration (ORR) | 197.44 | 125.88 |
| Restoration Center (RC) | 142.07 | 90.42 |
| General Counsel for Natural Resources (GCNR) | 83.93 | 49.49 |

These rates are based on the Direct Labor Cost Base allocation methodology.

The FY 2009 rates will be applied to all damage assessment and restoration case costs incurred between October 1, 2008 and September 30, 2009. The FY 2010 rates will be applied to all damage assessment and restoration case costs incurred between October 1, 2009 and September 30, 2010. DARRP will use the FY 2010 indirect cost rates for future fiscal years, beginning with FY 2011, until subsequent year-specific rates can be developed.

For cases that have settled and for cost claims paid prior to the effective date of the fiscal year in question, the DARRP will not re-open any resolved matters for the purpose of applying the revised rates in this policy for these fiscal years. For cases not settled and cost claims not paid prior to the effective date of the fiscal year in question, costs will be recalculated using the revised rates in this policy for these fiscal years. Where a responsible party has agreed to pay costs using previous year's indirect rates, but has not yet made the payment because the settlement documents are not finalized, the costs will not be recalculated.

The DARRP indirect cost rate policies and procedures published in the Federal Register on December 7, 2000 (65 FR 76611), on December 2, 2002 (67 FR 71537), October 6, 2003 (68 FR 57672), May 20, 2005 (70 FR 29280), March 16, 2006 (71 FR 13356), February 9, 2007 (72 FR 6221), June 3, 2008 (73 FR 31679), and November 16, 2009 (74 FR 58948) remain in effect except as updated by this notice.

Dated: September 15, 2011.

**David Westerholm,**

*Director, Office of Response and Restoration.*

[FR Doc. 2011–25373 Filed 9–30–11; 8:45 am]

**BILLING CODE 3510–JE–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648–XA725**

### Endangered and Threatened Species; Counterpart Regulations

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce; Fish and Wildlife Service (USFWS), Interior.

**ACTION:** Notice of availability.

**SUMMARY:** The U.S. Forest Service and Bureau of Land Management (together, action agencies) in coordination with the USFWS and NMFS, have agreed to revoke the March 4, 2004, National Fire Plan Counterpart Regulation Alternative Consultation Agreements (ACAs).

**DATES:** This is effective on October 1, 2011.

**ADDRESSES:** The final decision of revocation is available on the internet at *http://www.nmfs.noaa.gov/pr/laws/esa/policies.htm#consultation* and *http://www.fws.gov/endangered/esa-library/index.html.* Action Agency documents, as well as supporting documentation used in the preparation of this decision, will be available for public inspection, by appointment, during normal business hours at: NMFS Office of Protected Resources, 1315 East-West Highway, Room 13535, Silver Spring, MD 20910 or USFWS, 4401 N. Fairfax Drive, Arlington, VA 22203.

**FOR FURTHER INFORMATION CONTACT:** Angela Somma, NMFS, at 301–427–8474 or by fax at 301–713–0376; or Rick Sayers, USFWS at 703–358–2171 or by fax at 703–358–1735.

**SUPPLEMENTARY INFORMATION:** Section 7(a)(2) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.;* hereafter ESA) requires federal agencies, in consultation with, and with the assistance of, the Secretaries of Commerce and Interior, to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of endangered or threatened species or destroy or adversely modify designated critical habitat. The principles, practices, and protocols for section 7 consultations are identified in the ESA, and regulations promulgated in 1986 for implementing section 7 (50 CFR, part 402), further expound the procedural and substantive requirements for consultation. The counterpart regulations provide an optional alternative to the standard section 7 consultation process, and were developed specifically for agency projects that authorize, fund, or carry out actions that support the National Fire Plan. Upon entering into an ACA with the Services, action agencies may make ''not likely to adversely affect'' determinations for National Fire Plan projects without consulting with the Services. The March 4, 2004, ACAs included specific requirements for reporting and conducting periodic program monitoring of the use of the counterpart regulations.

NMFS and USFWS reviewed the projects carried out during years two through four by the action agencies. Based on results of the review of these projects, the relatively limited use of the counterpart regulations since their inception, the action agencies' cursory assessment of the year five through seven projects, and the action agencies' request to revoke the ACAs; NMFS and USFWS agree to terminate the ACAs with the action agencies.

Dated: September 20, 2011.

**Angela Somma,**

*Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 2011–25425 Filed 9–30–11; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648–XA744**

### Fisheries of the South Atlantic; South Atlantic Fishery Management Council; Public Meetings

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

**ACTION:** Notice of conference call meetings of the South Atlantic Fishery Management Council and the LEAP.

**SUMMARY:** The Law Enforcement Advisory Panel (LEAP) will meet via conference call on October 20, 2011 to select nominees for a Law Enforcement Office of the Year (LEOY) Award. The Council will meet via conference call on November 2, 2011 to review the LEAP's recommendations and select a deserving law enforcement officer to receive the award. See **SUPPLEMENTARY INFORMATION.**

**DATES:** The LEAP conference call will take place on October 20, 2011 from 10 a.m. to 11 a.m. The Council conference call will take place on November 2, 2011 from 10 a.m. to 11 a.m. See **SUPPLEMENTARY INFORMATION.**

**ADDRESSES:** The meetings will take place via conference call. For more information contact Kim Iverson (see **FOR FURTHER INFORMATION CONTACT**).

**FOR FURTHER INFORMATION CONTACT:** Kim Iverson, Public Information Officer, South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC, 29405; telephone: (843) 571–4366 or toll free (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net.*

**SUPPLEMENTARY INFORMATION:** Members of the Law Enforcement Advisory Panel will meet via conference call from 10 a.m. until 11 a.m. on October 20, 2011. The LEAP will review nominations for a Law Enforcement of the Year (LEOY) Award. The distinction is awarded by the Council to recognize an exceptional individual who has demonstrated a distinct pattern of service to enforcing fisheries regulations in the South Atlantic region. Nominees have been provided to the LEAP for their review. During the conference call, the LEAP will select and rank three nominees to recommend to the Council.

Members of the Council will meet via conference call from 10 a.m. to 11 a.m. on November 2, 2011. The Council will review the three nominees provided by the LEAP and select a deserving officer to receive the award. Presentation of the LEOY Award will take place at the December 12–16, 2011 Council meeting in Raleigh, NC.

**Special Accommodations**

The LEAP conference call is physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 3 days prior to the conference call.

**Note:** The specific end time for each conference call is subject to change.

Dated: September 28, 2011.

**Tracey L. Thompson,**

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

[FR Doc. 2011–25418 Filed 9–30–11; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### Hydrographic Services Review Panel Meeting

**AGENCY:** National Ocean Service, National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

**ACTION:** Notice of open meeting.

**SUMMARY:** The Hydrographic Services Review Panel (HSRP) is a Federal Advisory Committee established to advise the Under Secretary of Commerce for Oceans and Atmosphere on matters related to the responsibilities and authorities set forth in section 303 of the Hydrographic Services Improvement Act of 1998, its amendments, and such other appropriate matters that the Under Secretary refers to the Panel for review and advice.

*Date and Time:* The public meeting will be held on October 26–27, 2011. October 26th from 8:30 a.m. to 5:30 p.m.; October 27th from 8:30 a.m. to 4:30 p.m.

*Location:* Half Moone Cruise and Celebration Center, One Waterside Drive, Norfolk, Virginia 23510, tel: (757) 664–1074. Refer to the HSRP Web site listed below for the most current meeting agenda. Times and agenda topics are subject to change.

**FOR FURTHER INFORMATION CONTACT:** Kathy Watson, HSRP Program Coordinator, National Ocean Service (NOS), Office of Coast Survey, NOAA (N/CS), 1315 East West Highway, Silver Spring, Maryland 20910; Telephone: 301–713–2770 ext. 158; Fax: 301–713–4019; E-mail: *Hydroservices.panel@noaa.gov* or visit the NOAA HSRP Web site at *http://nauticalcharts.noaa.gov/ocs/hsrp/hsrp.htm.*

**SUPPLEMENTARY INFORMATION:** The meeting will be open to the public and public comment periods (on-site) will be scheduled at various times throughout the meeting. These comment periods will be included in the final agenda published before verbal presentation will be limited to a total time of five (5) minutes. Comments will be recorded. Written comments should be submitted to *Hydroservices.panel@noaa.gov* by October 21, 2011. Written comments received after Oct 21, 2011, will be distributed to the HSRP, but may not be reviewed until the meeting. Approximately 30 seats will be available for the public, on a first-come, first-served basis.

*Special Accommodations:* HSRP public meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Watson, HSRP Program Coordinator, National Ocean Service (NOS), Office of Coast Survey, NOAA (N/CS), 1315 East West Highway, Silver Spring, Maryland 20910; Telephone: 301–713–2770 ext. 158, or E-mail: *Kathy.Watson@noaa.gov* by October 17, 2011.

*Matters to be Considered:* Presentations from local and regional key stakeholders to the HSRP Panel will address issues such as: (1) Expanded requirements for navigation data in Virginia; (2) the Port Access Route Study and shipping routes for the Port of Virginia; (3) offshore wind energy development, and impacts to marine transportation; (4) planning for sea level rise; and (5) the roles of the Federal government, the ocean shipping industry, and other traditional maritime users in coastal and marine spatial planning. The HSRP will also engage in a strategic planning session to develop and produce an outline of priority issues for the Panel to focus on over the next two to three years.

Dated: September 23, 2011.

**John E. Lowell, Jr.,**

*Director, Office of Coast Survey, National Ocean Service, National Oceanic and Atmospheric Administration.*

[FR Doc. 2011–25371 Filed 9–30–11; 8:45 am]

**BILLING CODE 3510–JE–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648–XA662**

### Stock Assessment Reports for Dusky, Sandbar, and Blacknose Sharks in the U.S. Atlantic and Gulf of Mexico

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

**ACTION:** Notice of availability.

**SUMMARY:** NMFS announces the availability of final stock assessment reports for dusky, sandbar, and blacknose sharks in the Atlantic and Gulf of Mexico. The reports summarize the consensus of an independent Review Panel, describe methodologies used to determine stock statuses, and detail relevant working documents, including copies of Data and Assessment workshop reports.

**ADDRESSES:** Electronic copies of the stock assessments and all supporting documents may also be obtained on the internet at: *http://www.sefsc.noaa.gov/sedar/.* A limited number of hard copies are available. Requests for these hard copies of the final stock assessment reports for dusky, sandbar, and blacknose sharks should be sent to Peter Cooper, Highly Migratory Species Management Division (F/SF1), National Marine Fisheries Service (NMFS), 1315 East-West Highway, Silver Spring, MD 20910, or may be sent via facsimile (fax) to (301) 713–1917 or phone (301) 427–8503.

**FOR FURTHER INFORMATION CONTACT:** For information on the stock assessments, contact Peter Cooper by phone at (301) 427–8503 or by fax at (301) 713–1917.

**SUPPLEMENTARY INFORMATION:** The assessments for dusky, sandbar, and blacknose sharks were conducted as part of the Southeast Data, Assessment, and Review (SEDAR) process to ensure the best available data and techniques were used. SEDAR is a cooperative process initiated in 2002 to improve the quality and reliability of fishery stock assessments in the South Atlantic, Gulf of Mexico, and U.S. Caribbean. The SEDAR process emphasizes constituent and stakeholder participation in assessment development, transparency in the assessment process, and a rigorous and independent scientific review of completed stock assessments.

SEDAR 21, which conducted the stock assessments for dusky, sandbar, and blacknose sharks, was organized around a series of face-to-face workshops and webinars. The first Data Workshop was held in Charleston, SC, June 21–25, 2010 (May 4, 2010, 75 FR 23676), and participants evaluated all available data and selected appropriate sources for providing information on life history characteristics, catch statistics, discard estimates, length and age composition, and fishery dependent and fishery independent measures of stock abundance.

The Assessment Process was conducted via a series of webinars between September 2010 and January 2011 (August 26, 2010, 75 FR 52510; October 12, 2010, 75 FR 62506; November 17, 2010, 75 FR 70216; December 16, 2010, 75 FR 78679). During the assessment process, the assessment models were developed and population parameters were estimated using the information provided from the Data Workshop.

The Review Workshop was the final workshop, in which a panel of independent experts met in Annapolis, MD, April 18–22, 2011 (March 15, 2011, 76 FR 13985), and reviewed the data and assessments developed during the Data Workshop and Assessment Webinars. All workshops and webinars were open to the public. More information on the SEDAR process can be found at *http://www.sefsc.noaa.gov/sedar/.* Additionally, the final stock assessment reports and all supporting documents can be found at that Web site under the heading ''SEDAR 21—HMS Sandbar, Dusky, and Blacknose Sharks.''

Sandbar and dusky sharks were each assessed as one stock whereas, for the first time, blacknose sharks were assessed as two separate stocks: an Atlantic and Gulf of Mexico stock. The stock assessments provide information on the status of the stocks and project their future abundance under a variety of catch levels in the U.S. Atlantic Ocean, Gulf of Mexico, and Caribbean Sea. The 2010 assessments include updated catch estimates, new biological data, and a number of fishery-independent and fishery-dependent catch rate series for each species.

The Review Panel for the Review Workshop of SEDAR 21 found that the data and methods used were appropriate and the best available for the dusky, sandbar, and Atlantic blacknose shark assessments. However, because the assessment model for the Gulf of Mexico blacknose stock was unable to fit the apparent trends in some of the abundance indices, and because there was a fundamental lack of fit of the model to some of the input data, the Review Panel did not accept the stock assessment for the Gulf of Mexico blacknose stock. Based on these assessments, NMFS will be making stock status determinations in an upcoming **Federal Register** notice for four separate stocks: (1) Dusky Sharks, (2) sandbar sharks, (3) Gulf of Mexico blacknose sharks, and (4) Atlantic blacknose sharks. NMFS is also considering amending the 2006 Consolidated Highly Migratory Species Fishery Management Plan, as necessary.

**Authority:** 16 U.S.C. 971 *et seq.,* and 1801 *et seq.*

Dated: September 28, 2011.

**Steven Thur,**

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

[FR Doc. 2011–25429 Filed 9–30–11; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF DEFENSE

### Department of the Navy

### Notice of Intent To Prepare a Supplement to the Draft Environmental Impact Statement for the TRIDENT Support Facilities Explosives Handling Wharf, Naval Base Kitsap at Bangor, Silverdale, Kitsap County, WA

**AGENCY:** Department of the Navy, DoD.

**ACTION:** Notice.

**SUMMARY:** Pursuant to section 102 of the National Environmental Policy Act of 1969, and the regulations implemented by the Council on Environmental Quality (40 CFR parts 1500–1508), the Department of the Navy (DoN) announces its intent to prepare a Supplement to the Draft Environmental Impact Statement (DEIS) for the proposed second Explosives Handling Wharf (EHW–2) at Naval Base Kitsap at Bangor, Silverdale, WA. The Supplement to the DEIS will focus on the methodology used to assess the potential for injurious impacts to the marbled murrelet from impact pile driving, the construction and operation of new facilities and associated infrastructure, and compensatory mitigation options under consideration.

*Dates and Addresses:* Written comments must be submitted within 45 days of the **Federal Register** publication date for the U.S. Environmental Protection Agency (EPA) Notice of Availability (NOA) of this Supplement to the DEIS, and should be addressed to: Naval Facilities Engineering Command Northwest, 1101 Tautog Circle, Silverdale, WA 98315–1101, Attn: Christine Stevenson, EHW–2 EIS Project Manager. Written comments may also be submitted online at *http://ehw.nbkeis.com* during the comment period.

**FOR FURTHER INFORMATION CONTACT:** Naval Facilities Engineering Command Northwest, 1101 Tautog Circle, Silverdale, WA 98315–1101, Attn: Christine Stevenson, EHW–2 EIS Project Manager, 360–396–0080; or *http://ehw.nbkeis.com.*

**SUPPLEMENTARY INFORMATION:** On May 15, 2009, the DoN provided notice in the **Federal Register** (74 FR 22900) of its intent to prepare an EIS for TRIDENT Support Facilities EHW–2, Naval Base Kitsap at Bangor, Silverdale, Kitsap County, WA and to announce public scoping meetings. The DoN held public scoping meetings in Poulsbo, Port Ludlow, and Seattle, WA during June 2009. The DoN prepared and filed a DEIS with the EPA to evaluate the potential environmental effects of constructing and operating an EHW–2 at Naval Base Kitsap Bangor. A NOA was published in the **Federal Register** by the EPA on March 18, 2011 (76 FR 14968) for the DoN's DEIS, announcing availability of the DEIS and commencing the 45 day public comment period. The DoN extended the public comment period to 60 days and published a notice of extension of the comment period for the DEIS in the **Federal Register** on May 3, 2011 (76 FR 24868). The EPA published a NOA revision on May 13, 2011 (76 FR 28029) announcing the comment period extension. The DoN's Notice of Public Hearing for the DEIS was published in the **Federal Register** on March 21, 2011 (76 FR 15302). Public hearings were held in Poulsbo, Chimacum, and Seattle, WA to receive oral and written comments on the Draft EIS.

This Supplement to the DEIS will include analysis of new information that has become available since release of the DEIS. The DEIS analysis of noise impacts to the marbled murrelet, a species listed as federally threatened under the Endangered Species Act, was based on an underwater physical injury threshold of 180 dBpeak re: 1µPa for any single impact hammer strike. Concurrent with publication of the DEIS, the U.S. Fish and Wildlife Service (USFWS) proposed an interim criterion of 183 dB Sound Exposure Level (SEL) re: 1µPa$^2$-sec. The USFWS and the DoN collaborated to form the Marbled Murrelet Science Panel to assist in development of a scientifically-based injury criterion. The USFWS accepted the panel's recommendation and notified the DoN on August 5, 2011 that the Endangered Species Act section 7 consultation on EHW–2 would be based on this new criterion. This Supplement analyzes the impacts to the marbled murrelet for all alternatives, based on the new underwater noise injury criterion of 202 dB SEL re: 1µPa$^2$-sec cumulative of all impact hammer strikes in a 24-hour period.

The DEIS analyzed the impacts of modifying or demolishing approximately 20 existing facilities and/or structures in proximity to the EHW–2 to comply with Department of Defense Explosives Safety Board and Naval Ordnance Safety and Security Activity requirements to protect buildings located in the vicinity of explosives handling operations. Since release of the DEIS, the DoN has determined that four new buildings and associated infrastructure would be constructed to replace the functions of five buildings to be demolished. This Supplement will analyze the impacts from construction and operation of the four new buildings and associated infrastructure. Three buildings would be constructed on a 2.6 acre upland site located northwest of Service Pier and 2.2 miles south of the existing EHW. These buildings would house the functions of an Administrative/Construction Field Office, an Inert Storage building, a Rigging Shop, and a Refit Support Facility and would include paved and fenced storage areas, associated roads, parking, and sidewalks. The fourth building, a pure water facility, would be constructed along the Bangor waterfront at the end of Delta Pier on a 0.5 acre site located approximately 1.0 miles south of the existing EHW. This facility would house the function of the existing Pure Water Facility to be demolished and would consist of a treatment building, an auxiliary water storage tank, liquid nitrogen storage tank, sewage tank and pump, loading aprons, parking areas, and new water lines between the facility and Delta Pier.

The DEIS presented compensatory mitigation the DoN is considering and identified the In Lieu Fee (ILF) Program as the preferred compensatory mitigation for the unavoidable impacts to aquatic resources from the proposed action as described in the Mitigation Action Plan in the DEIS. Since the public release of the DEIS, further development of the ILF Program has occurred. In addition to the preferred ILF compensatory mitigation strategy, the DoN is also considering other compensatory mitigation alternatives. The DoN continues to review the feasibility, habitat values, and potential benefits of all mitigation alternatives. This Supplement discusses compensatory mitigation alternatives in regard to Dabob Bay Conservation and Washington State Parks Mitigation.

The DoN is soliciting comments on the Supplement to the DEIS. Federal, state, and local agencies, American Indian tribes, and interested persons are encouraged to provide written comments. All written comments will become part of the public record and will be responded to in the Final EIS. Written comments must be postmarked within 45 days of the **Federal Register** publication date for the EPA's NOA of this Supplement to the DEIS. Written comments should be submitted to: Naval Facilities Engineering Command Northwest, 1101 Tautog Circle, Silverdale, WA 98315–1101, Attn: Christine Stevenson, EHW–2 EIS Project Manager. Written Comments may also be submitted online at *http://ehw.nbkeis.com* during the comment period.

All public comments previously received during the March through May 2011 DEIS public comment period are still valid and will be considered and addressed in the Final EIS for this action. Previously submitted comments need not be resubmitted. A NOA of the Supplement to the DEIS will be published by the EPA in the **Federal Register**. No decision will be made to implement the proposed action until the EIS process is completed and a Record of Decision is signed by the DoN.

Dated: September 28, 2011.

**J. M. Beal,**

*Lieutenant Commander, Office of the Judge Advocate General, U.S. Navy, Federal Register Liaison Officer.*

[FR Doc. 2011–25421 Filed 9–30–11; 8:45 am]

**BILLING CODE 3810–FF–P**

## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

### Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

*Docket Numbers:* ER11–4595–000.

*Applicants:* Palmco Power OH, LLC.

*Description:* Palmco Power OH, LLC submits tariff filing per 35.1: Palmco Power OH FERC Electric Tariff to be effective 9/22/2011.

*Filed Date:* 09/22/2011.

*Accession Number:* 20110922–5030.

*Comment Date:* 5 p.m. Eastern Time on Thursday, October 13, 2011.

*Docket Numbers:* ER11–4596–000.

*Applicants:* South Carolina Electric & Gas Company.

*Description:* South Carolina Electric & Gas Company submits tariff filing per 35.13(a)(2)(iii: Attachment C—Revision for Clarification to be effective 9/22/2011.

*Filed Date:* 09/22/2011.
*Accession Number:* 20110922–5032.
*Comment Date:* 5 p.m. Eastern Time on Thursday, October 13, 2011.

*Docket Numbers:* ER11–4597–000.
*Applicants:* KeyTex Energy, LLC.
*Description:* KeyTex Energy, LLC submits tariff filing per 35.1: KeyTex Energy, LLC MBR Re-Filing to be effective 9/22/2011.
*Filed Date:* 09/22/2011.
*Accession Number:* 20110922–5034.
*Comment Date:* 5 p.m. Eastern Time on Thursday, October 13, 2011.

*Docket Numbers:* ER11–4598–000.
*Applicants:* PJM Interconnection, LLC.
*Description:* PJM Interconnection, LLC submits tariff filing per 35.13(a)(2)(iii: Queue No. W3–126; Original Service Agreement No. 3066 to be effective 8/24/2011.
*Filed Date:* 09/22/2011.
*Accession Number:* 20110922–5051.
*Comment Date:* 5 p.m. Eastern Time on Thursday, October 13, 2011.

*Docket Numbers:* ER11–4599–000.
*Applicants:* PJM Interconnection, LLC.
*Description:* PJM Interconnection, LLC submits tariff filing per 35.13(a)(2)(iii: Queue No. W3–032; Original Service Agreement No. 3062 to be effective 8/30/2011.
*Filed Date:* 09/22/2011.
*Accession Number:* 20110922–5053.
*Comment Date:* 5 p.m. Eastern Time on Thursday, October 13, 2011.

*Docket Numbers:* ER11–4600–000.
*Applicants:* Moguai Energy LLC.
*Description:* Moguai Energy LLC submits tariff filing per 35.1: Baseline 714 compliance to be effective 9/22/2011.
*Filed Date:* 09/22/2011
*Accession Number:* 20110922–5055.
*Comment Date:* 5 p.m. Eastern Time on Thursday, October 13, 2011.

*Docket Numbers:* ER11–4601–000.
*Applicants:* Avista Corporation.
*Description:* Avista Corporation submits tariff filing per 35.12: Avista Corp Rate Schedule FERC No. 528 to be effective 10/1/2011.
*Filed Date:* 09/22/2011.
*Accession Number:* 20110922–5061.
*Comment Date:* 5 p.m. Eastern Time on Thursday, October 13, 2011.

*Docket Numbers:* ER11–4602–000.
*Applicants:* IDT Energy, Inc.
*Description:* IDT Energy, Inc. submits tariff filing per 35.1: Market-Based Rate Tariff Baseline to be effective 9/22/2011.
*Filed Date:* 09/22/2011.
*Accession Number:* 20110922–5085.
*Comment Date:* 5 p.m. Eastern Time on Thursday, October 13, 2011.

*Docket Numbers:* ER11–4603–000.
*Applicants:* Monterey Consulting Associates, Inc.
*Description:* Monterey Consulting Associates, Inc. submits tariff filing per 35.1: Market Based Rates Re-file to be effective 9/22/2011.
*Filed Date:* 09/22/2011.
*Accession Number:* 20110922–5086.
*Comment Date:* 5 p.m. Eastern Time on Thursday, October 13, 2011.

*Docket Numbers:* ER11–4604–000.
*Applicants:* Thicksten Grimm Burgum, Inc.
*Description:* Thicksten Grimm Burgum, Inc. submits tariff filing per 35.1: Market Based Rates Re-file to be effective 9/22/2011.
*Filed Date:* 09/22/2011.
*Accession Number:* 20110922–5087.
*Comment Date:* 5 p.m. Eastern Time on Thursday, October 13, 2011.

*Docket Numbers:* ER11–4605–000.
*Applicants:* Forest Investment Group, LLC..
*Description:* Forest Investment Group, LLC submits tariff filing per 35.1: Forest Investment Group Baseline Filing to be effective 9/22/2011.
*Filed Date:* 09/22/2011.
*Accession Number:* 20110922–5089
*Comment Date:* 5 p.m. Eastern Time on Thursday, October 13, 2011.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: September 22, 2011.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2011–25335 Filed 9–30–11; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

*Docket Numbers:* ER11–3616–001.
*Applicants:* California Independent System Operator Corporation.
*Description:* California Independent System Operator Corporation submits tariff filing per 35.17(b): 2011–09–21 CAISO Deficiency Filing for RDRR Amendment to be effective 4/1/2012.
*Filed Date:* 09/21/2011.
*Accession Number:* 20110921–5105.
*Comment Date:* 5 p.m. Eastern Time on Wednesday, October 12, 2011.

*Docket Numbers:* ER11–3912–002.
*Applicants:* Arizona Public Service Company.
*Description:* Arizona Public Service Company submits tariff filing per 35: Compliance Filing, Service Agreement No. 311 to be effective 8/29/2011.
*Filed Date:* 09/21/2011.
*Accession Number:* 20110921–5075.
*Comment Date:* 5 p.m. Eastern Time on Wednesday, October 12, 2011.

*Docket Numbers:* ER11–4103–001.
*Applicants:* Arizona Public Service Company.
*Description:* Arizona Public Service Company submits tariff filing per 35: Compliance Filing, Rate Schedule No. 253 to be effective 9/9/2011.
*Filed Date:* 09/21/2011.
*Accession Number:* 20110921–5074.
*Comment Date:* 5 p.m. Eastern Time on Wednesday, October 12, 2011.

*Docket Numbers:* ER11–4567–001.
*Applicants:* Pypha Energy LLC.
*Description:* Pypha Energy LLC submits tariff filing per 35: Baseline MBR Tariff Filing to be effective 9/20/2011.
*Filed Date:* 09/21/2011.
*Accession Number:* 20110921–5099.
*Comment Date:* 5 p.m. Eastern Time on Wednesday, October 12, 2011.

*Docket Numbers:* ER11–4582–000.
*Applicants:* 511 Plaza Energy, LLC.
*Description:* 511 Plaza Energy, LLC submits tariff filing per 35.1: Baseline Filing of Tariff to be effective 9/21/2011.
*Filed Date:* 09/21/2011.
*Accession Number:* 20110921–5039.
*Comment Date:* 5 p.m. Eastern Time on Wednesday, October 12, 2011.

*Docket Numbers:* ER11–4583–000.
*Applicants:* PacifiCorp.
*Description:* PacifiCorp submits tariff filing per 35.13(a)(2)(iii: BPA AC Intertie Agreement 5th Revised to be effective 9/22/2011.

*Filed Date:* 09/21/2011.
*Accession Number:* 20110921–5066.
*Comment Date:* 5 p.m. Eastern Time on Wednesday, October 12, 2011.

*Docket Numbers:* ER11–4584–000.
*Applicants:* Burgess Capital LLC.
*Description:* Burgess Capital LLC submits tariff filing per 35.1: Baseline 714 compliance to be effective 9/21/2011.
*Filed Date:* 09/21/2011.
*Accession Number:* 20110921–5068.
*Comment Date:* 5 p.m. Eastern Time on Wednesday, October 12, 2011.

*Docket Numbers:* ER11–4585–000.
*Applicants:* New York Independent System Operator, Inc.
*Description:* New York Independent System Operator, Inc. submits tariff filing per 35: NYISO filing of tariff revisions per NYISO PJM settlement agreement to be effective 9/16/2010.
*Filed Date:* 09/21/2011.
*Accession Number:* 20110921–5084.
*Comment Date:* 5 p.m. Eastern Time on Wednesday, October 12, 2011.

*Docket Numbers:* ER11–4586–000.
*Applicants:* Florida Power & Light Company.
*Description:* Florida Power & Light Company submits tariff filing per 35.13(a)(2)(iii: FPL and FMPA Third Revised Service Agreement No. 80 to be effective 10/1/2011.
*Filed Date:* 09/21/2011.
*Accession Number:* 20110921–5096.
*Comment Date:* 5 p.m. Eastern Time on Wednesday, October 12, 2011.

*Docket Numbers:* ER11–4587–000.
*Applicants:* Glenwood Energy Partners, Ltd.
*Description:* Glenwood Energy Partners, Ltd. submits tariff filing per 35.1: Glenwood FERC Rate Schedule No. 1 Baseline to be effective 9/21/2011.
*Filed Date:* 09/21/2011.
*Accession Number:* 20110921–5097.
*Comment Date:* 5 p.m. Eastern Time on Wednesday, October 12, 2011.

*Docket Numbers:* ER11–4588–000.
*Applicants:* LoneStar Energy Partners LLC.
*Description:* LoneStar Energy Partners LLC submits tariff filing per 35.1: Lonestar FERC Rate Schedule No. 1 Baseline to be effective 9/21/2011.
*Filed Date:* 09/21/2011.
*Accession Number:* 20110921–5098.
*Comment Date:* 5 p.m. Eastern Time on Wednesday, October 12, 2011.

*Docket Numbers:* ER11–4589–000.
*Applicants:* EcoGrove Wind, LLC.
*Description:* EcoGrove Wind, LLC submits tariff filing per 35.1: EcoGrove Wind LLC Baseline Tariff Filing to be effective 9/21/2011.
*Filed Date:* 09/21/2011.
*Accession Number:* 20110921–5100.
*Comment Date:* 5 p.m. Eastern Time on Wednesday, October 12, 2011.

*Docket Numbers:* ER11–4590–000.
*Applicants:* Westar Energy, Inc.
*Description:* Westar Energy, Inc. submits tariff filing per 35.13(a)(2)(iii: Revisions to Schedule 3A, Balancing Area Services Agreement to be effective 12/1/2011.
*Filed Date:* 09/21/2011.
*Accession Number:* 20110921–5101.
*Comment Date:* 5 p.m. Eastern Time on Wednesday, October 12, 2011.

*Docket Numbers:* ER11–4591–000.
*Applicants:* Red Hills Wind Project, LLC.
*Description:* Red Hills Wind Project, LLC submits tariff filing per 35.1: Red Hills Wind Project, LLC Baseline Tariff to be effective 9/21/2011.
*Filed Date:* 09/21/2011.
*Accession Number:* 20110921–5102.
*Comment Date:* 5 p.m. Eastern Time on Wednesday, October 12, 2011.

*Docket Numbers:* ER11–4592–000.
*Applicants:* Tatanka Wind Power, LLC.
*Description:* Tatanka Wind Power, LLC submits tariff filing per 35.1: Tatanka Wind Power, LLC Baseline Tariff Filing to be effective 9/21/2011.
*Filed Date:* 09/21/2011.
*Accession Number:* 20110921–5103.
*Comment Date:* 5 p.m. Eastern Time on Wednesday, October 12, 2011.

*Docket Numbers:* ER11–4593–000.
*Applicants:* Nevada Solar One, LLC.
*Description:* Nevada Solar One, LLC submits tariff filing per 35.1: Nevada Solar One, LLC Baseline Tariff Filing to be effective 9/21/2011.
*Filed Date:* 09/21/2011.
*Accession Number:* 20110921–5104.
*Comment Date:* 5 p.m. Eastern Time on Wednesday, October 12, 2011.

*Docket Numbers:* ER11–4594–000.
*Applicants:* Niagara Mohawk Power Corporation.
*Description:* Notice of Termination of Service Agreement No. 121 of Niagara Mohawk Power Corporation.
*Filed Date:* 09/21/2011.
*Accession Number:* 20110921–5133.
*Comment Date:* 5 p.m. Eastern Time on Wednesday, October 12, 2011.

Take notice that the Commission received the following electric securities filings:

*Docket Numbers:* ES11–48–000.
*Applicants:* Kentucky Utilities Company.
*Description:* Kentucky Utilities Company submits its Application under Section 204 of the Federal Power Act.
*Filed Date:* 09/21/2011.
*Accession Number:* 20110921–5131.
*Comment Date:* 5 p.m. Eastern Time on Wednesday, October 12, 2011.

*Docket Numbers:* ES11–49–000.
*Applicants:* Louisville Gas & Electric Company.
*Description:* Louisville Gas and Electric Company's Application under Section 204 of the Federal Power Act.
*Filed Date:* 09/21/2011.
*Accession Number:* 20110921–5132.
*Comment Date:* 5 p.m. Eastern Time on Wednesday, October 12, 2011.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: September 22, 2011.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2011–25334 Filed 9–30–11; 8:45 am]

**BILLING CODE 6717–01–P**

## ENVIRONMENTAL PROTECTION AGENCY

**[FRL–9474–5]**

## California State Motor Vehicle Pollution Control Standards; Within the Scope Determination and Waiver of Preemption Decision for Amendments to California's Zero-Emission Vehicle (ZEV) Standards

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

**ACTION:** Notice of Decision.

**SUMMARY:** By this decision the Environmental Protection Agency (EPA) has determined that provisions of the California Air Resources Board's (CARB's) 2008 amendments to the California Zero-Emission Vehicle (ZEV) regulations as they affect 2011 and prior model years (MYs) are within the scope of previous waivers of preemption granted to California for its ZEV regulations. In the alternative, EPA is

also granting a waiver of preemption for the 2008 ZEV amendments at they affect 2011 and prior MYs. EPA is also granting California's request for a waiver of preemption to enforce the 2008 ZEV amendments as they affect 2012 and later MYs.

**DATES:** Under section 307(b)(1) of the Clean Air Act, judicial review of this final action may be sought only in the United States Court of Appeals for the District of Columbia Circuit. Petitions for review must be filed December 2, 2011. Under section 307(b)(2) of the Act, judicial review of this final action may not be obtained in subsequent enforcement proceedings.

**ADDRESSES:** The Agency's Decision Document, containing an explanation of this decision, as well as all documents relied upon in making that decision, including those submitted to EPA by CARB, are available at EPA's Air and Radiation Docket (Air Docket). Materials relevant to this decision are contained in Docket No. EPA–HQ–OAR–2009–0780. The docket is located in the EPA Headquarters Library, EPA West Building, Room 3334, located at 1301 Constitution Avenue, NW., Washington, DC 20460, and may be viewed between 8:30 a.m. and 4:30 p.m., Monday through Friday. The telephone is (202) 566–1742. A reasonable fee may be charged by EPA for copying docket material.

Additionally, an electronic version of the public docket is available through the Federal government's electronic public docket and comment system. You may access EPA dockets at *http://www.regulations.gov.* After opening the *http://www.regulations.gov* web site, select ''Environmental Protection Agency'' from the pull-down Agency list, then scroll to ''Keyword or ID'' and enter EPA–HQ–OAR–2009–0780 to view documents in the record of this California request. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

EPA's Office of Transportation and Air Quality (OTAQ) maintains a Web page that contains today's decision along with the Decision Document; this page is accessible at *http://www.epa.gov/otaq/climate/ca-waiver.htm.* OTAQ also maintains a Web page that contains general information on its review of California waiver requests. Included on that page are links to prior waiver decisions and can be accessed at *http://www.epa.gove/otaq/cafr.htm.*

**FOR FURTHER INFORMATION CONTACT:** David Dickinson, Compliance and Innovative Strategies Division, U.S. Environmental Protection Agency, Ariel Rios Building (6405J), 1200 Pennsylvania Avenue, NW., Washington, DC 20460. *Telephone:* (202) 343–9256. *E-Mail Address: Dickinson.David@EPA.GOV*

**SUPPLEMENTARY INFORMATION:**

## I. Chronology

California's initial ZEV program was included as part of its first low-emission vehicle program known as LEV I. The ZEV component of this program had a ZEV sales requirement that phased-in starting with the 1998 MY with a 10 percent sales requirement by the 2003 MY. EPA issued a waiver of preemption for these regulations on January 13, 1993.[1] CARB subsequently amended its ZEV regulations in March, 1996, by eliminating the ZEV sales requirement for the 1998–2002 MYs and retaining the 10 percent sales requirement for the 2003 and later MYs. EPA issued a within-the-scope determination for these amendments on January 25, 2001.[2]

On December 21, 2006, EPA waived preemption for CARB's 1999, 2001, and 2003 ZEV rulemaking amendments through the 2011 MY.[3] EPA determined that certain provisions of the 1999–2003 amendments to the ZEV regulations as they affect 2006 and prior MYs were within-the-scope of previous waivers of preemption granted to California for its ZEV regulations pursuant to section 209(b) of the Clean Air Act (the Act). EPA also granted California's request for a waiver of preemption to enforce certain provisions of the ZEV regulations as they affected 2007 through 2011 MY vehicles. EPA also stated that that although we believed it appropriate to grant a full waiver of preemption for the 2007 MY, we also believed it appropriate to consider the 2007 MY regulations (with one exception noted) as within the scope of previous waivers of preemption, as they applied to certain vehicles that were already subject to the pre-existing ZEV regulations. In its December 21, 2006 decision EPA did not making any findings or determinations with regard to CARB's ZEV regulations as they pertained to the 2012 and later MYs.

On September 17, 2009 CARB submitted a request to EPA (Waiver Request) seeking confirmation that amendments to its ZEV regulations adopted in 2008 (2008 ZEV amendments) as they relate to the 2011 and earlier MYs are within the scope of EPA's prior ZEV waivers.[4] In addition, CARB sought confirmation that its 2008 ZEV amendments as they relate to 2012 and later MYs are within the scope of EPA's prior ZEV waivers or, in the alternative, meet the criteria for a full waiver of preemption.[5] EPA issued a **Federal Register** notice that announced a tentative hearing (a hearing only if one was requested by a commenter; in this case no hearing was requested or held) and opportunity for public comment and held the written comment period open until May 17, 2010.[6] EPA received a comment written jointly by the Alliance of Automobile Manufacturers and the Association of International Automobile Manufacturers (Manufacturers' Comments) and subsequent comment from CARB (CARB's Supplemental Comments).[7]

## II. CARB's Zero-Emission Vehicle Amendments

The 2008 ZEV amendments maintain the ZEV obligation or percentage ZEV requirements, but give manufacturers increased flexibility to comply with the ZEV requirements by giving credit to plug-in hybrid electric vehicles (PHEV), and establishing additional ZEV categories in recognition of new developments in fuel cell vehicles (FCV) and battery electric vehicles (BEV). As discussed below, a large-volume manufacturer is no longer expected to produce fuel-cell vehicles to meet part of its gold vehicle credit requirements for 2012 and later MYs. The 2008 ZEV amendments maintain the current options for large volume manufacturers to select either the Primary Compliance Path or the Alternative Compliance Path through MY 2011. For MYs 2012 through 2017, the 2008 ZEV amendments establish a ''New Path,'' a single compliance strategy or set of requirements that all large volume manufacturers are required to follow. CARB's requirements for the 2018 and later MYs were not amended by the 2008 ZEV amendments apart from allowing additional flexibility in the technologies that meet the ZEV requirements.[8]

[1] 58 FR 4166.

[2] 66 FR 7751.

[3] 71 FR 78190 (December 28, 2006).

[4] EPA–HQ–OAR–2009–0780–0001.

[5] CARB's 2008 ZEV Amendments were adopted by Executive Order R–08–015 on December 17, 2008, and were approved by the California Office of Administrative Law on March 18, 2009.

[6] 75 FR 11878 (March 12, 2010).

[7] EPA–HQ–OAR–2009–0780–0003 and EPA–HQ–OAR–2009–0780–0004, respectively.

[8] CARB's 2008 ZEV amendments were adopted by Executive Order R–08–015 on December 17, 2008 and approved by the California Office of Administrative Law on March 18, 2009. The 2008 ZEV amendments place the ZEV requirements in two sections of title 13 of the California Code of Regulations—sections 1962 and 1962.1.

## III. Clean Air Act Waivers of Preemption and Within the Scope Decisions

Section 209(a) of the Act provides:

> No State or any political subdivision thereof shall adopt or attempt to enforce any standard relating to the control of emissions from new motor vehicles or new motor vehicle engines subject to this part. No State shall require certification, inspection or any other approval relating to the control of emissions from any new motor vehicle or new motor vehicle engine as condition precedent to the initial retail sale, titling (if any), or registration of such motor vehicle, motor vehicle engine, or equipment.

Section 209(b)(1) of the Act requires the Administrator, after an opportunity for public hearing, to waive application of the prohibitions of section 209(a) for any State that has adopted standards (other than crankcase emission standards) for the control of emissions from new motor vehicles or new motor engines prior to March 30, 1966,[9] if the State determines that standards will be, in the aggregate, at least as protective of public health and welfare as applicable Federal standards. The Administrator must grant a waiver unless she finds that: (A) The protectiveness determination of the State is arbitrary and capricious; (B) the State does not need the State standards to meet compelling and extraordinary conditions; or (C) the State standards and accompanying enforcement procedures are not consistent with section 202(a) of the Act.

Previous waiver decisions have stated that State standards are inconsistent with section 202(a) if there is inadequate lead time to permit the development of the necessary technology, given the cost of compliance within that time, or if the Federal and State test procedures impose inconsistent certification requirements.[10]

With regard to enforcement procedures accompanying standards, the Administrator must grant the waiver unless she finds that these procedures may cause the California standards, in the aggregate, to be less protective of public health and welfare than the applicable Federal standards promulgated pursuant to section 202(a), or unless the Federal and California certification and test procedures are inconsistent.[11]

Once California has received a waiver for its standards and enforcement procedures for a certain group or class of vehicles, it may adopt other conditions precedent to the initial retail sale, titling or registration of these vehicles without the necessity of receiving an additional waiver.

If California acts to amend a previously waived standard or accompanying enforcement procedure, the amendment may be considered within the scope of a previously granted waiver provided that it does not undermine California's determination that its standards, in the aggregate, are as protective of public health and welfare as applicable Federal standards, does not affect its consistency with section 202(a) of the Act, and raises no new issues affecting EPA's previous waiver decisions.[12]

## IV. Analysis

As explained in the Agency's Decision Document EPA examined CARB's 2008 ZEV amendments, as they affect 2011 and earlier MYs, under the within the scope criteria. EPA in the alternative also applied the full waiver criteria to the 2011 and earlier MYs. Although CARB requested that EPA confirm that the 2008 ZEV amendments, as they affect 2012 and later MYs, are within the scope of previous waivers of preemption, EPA instead applied the full waiver criteria to the regulations affecting those MYs.

### *A. California's Protectiveness Determination*

In its Waiver Request to EPA, CARB stated that the amendments to its ZEV requirements will not cause the California standards, in the aggregate, to be less protective of public health and welfare than the applicable Federal standards nor undermine CARB's previous protectiveness determination. Because EPA has not received adverse public comment challenging CARB's protectiveness determination, I cannot find that CARB was arbitrary and capricious in its protectiveness determination and cannot deny the within the scope determination nor the waiver based on this criterion.

### *B. California's Need for State Standards To Meet Compelling and Extraordinary Conditions*

CARB also demonstrated continuing existence of compelling and extraordinary conditions, justifying the state's need for its own motor vehicle pollution control program. Because EPA has not received adverse public comment challenging the need for CARB's own motor vehicle pollution control program, I cannot deny the waiver based on a lack of compelling and extraordinary conditions.

### *C. Consistency With Section 202(a) of the Clean Air Act*

CARB stated in its Waiver Request that the 2008 ZEV amendments provide manufacturers with additional compliance options and do not raise any concerns with regard to the technological feasibility of its regulations when giving due consideration to lead time and costs. In addition, CARB notes that the 2008 ZEV amendments do not create an issue of test procedure inconsistency.

The Manufacturers' suggested that the 2008 ZEV amendments were not consistent with section 202(a). However, as explained in EPA's Decision Document, EPA finds that the manufacturer groups opposing the within the scope confirmation and the waiver of preemption have not met their burden of proof that the 2008 ZEV amendments are inconsistent with section 202(a) of the Act. I cannot find that CARB's ZEV regulations, as noted, would cause the California motor vehicle emission standards to be inconsistent with section 202(a).

### *D. New Issues*

As explained in the Decision Document, EPA finds that the 2008 ZEV amendments raise no new issues for 2011 and earlier MYs.

### *E. Decision*

Therefore, I confirm that CARB's 2008 ZEV amendments as they affect the 2011 and earlier MYs, as noted above, are within the scope of existing waivers of preemption. I also find that the 2008 ZEV amendments as they affect the 2011 and earlier MYs meet the criteria for a full waiver and thus I alternatively grant a waiver of preemption for the regulations as they affect these MYs. I also grant a waiver of preemption of CARB's 2008 ZEV amendments as they affect 2012 and later MYs. A full explanation of EPA's decision, including our review of comments received in opposition to CARB's request, is contained in a Decision

[9] California is the only State which meets section 209(b)(1) eligibility criteria for obtaining waivers. *See e.g.,* S. Rep. No. 90–403, at 632 (1967).

[10] *See, e.g.,* 43 FR 32,182 (July 25, 1978).

[11] *See Motor and Equip. Mfr. Assoc., Inc.* v. *EPA,* 627 F.2d 1095, 1111–14 (DC Cir. 1979), *cert. denied,* 446 U.S. 952 (1980); 43 FR 25,729 (Jun. 14, 1978). To be consistent, the California procedures need not be identical to the Federal procedures. California procedures would be inconsistent, however, if manufacturers would be unable to meet both the state and the Federal requirements with the same vehicle. *See, e.g.,* 43 FR 36679–680 (Aug. 18, 1978).

[12] Decision Documents accompanying within the scope of waiver determination in 66 FR 7751 (January 25, 2001) at p. 5, and 51 FR 12391 (April 10, 1986) at p. 2; see also, e.g., 46 FR 36742 (July 15, 1981).

Document which may be obtained as explained above.

**V. Statutory and Executive Order Reviews**

My decision will affect not only persons in California but also the manufacturers outside the State who must comply with California's requirements in order to produce new motor vehicles for sale in California. For this reason, I hereby determine and find that this is a final action of national applicability.

This action is not a rule as defined by Executive Order 12866. Therefore, it is exempt from review by the Office of Management and Budget as required for rules and regulations by Executive Order 12866.

In addition, this action is not a rule as defined in the Regulatory Flexibility Act, 5 U.S.C. 601(2). Therefore, EPA has not prepared a supporting regulatory flexibility analysis addressing the impact of this action on small business entities.

Further, the Congressional Review Act, 5 U.S.C. 801, *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, does not apply because this action is not a rule for purposes of 5 U.S.C. 804(3).

Finally, the Administrator has delegated the authority to make determinations regarding waivers under § 209(b) of the Act to the Assistant Administrator for Air and Radiation.

Dated: September 26, 2011.

**Gina McCarthy,**

*Assistant Administrator for Air and Radiation.*

[FR Doc. 2011–25399 Filed 9–30–11; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

**[FRL–9474–2]**

## Exposure Factors Handbook: 2011 Edition; Release of Final Report

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

**ACTION:** Notice of Availability.

**SUMMARY:** On September 30, 2011, the EPA publically released the final report entitled *Exposure Factors Handbook: 2011 Edition.* The document was prepared by the National Center for Environmental Assessment (NCEA) within EPA's Office of Research and Development. The *Exposure Factors Handbook: 2011 Edition* provides information on various physiological and behavioral factors commonly used in assessing exposure to environmental chemicals. The handbook was first published in 1989 and was updated in 1997. This edition incorporates information made available from 1997 up until July 2011. It also reflects the revisions made to the *Child-Specific Exposure Factors Handbook,* which was last updated and published in 2008. Each chapter in the *Exposure Factors Handbook: 2011 Edition* presents recommended values for the exposure factors covered in that particular chapter's exposure route as well as a discussion of the underlying data used in developing the recommendations.

The *Exposure Factors Handbook: 2011 Edition* (EPA/600/R–09/052F) is available via the Internet at *http://www.epa.gov/ncea.*

**DATES:** This report was posted publically on September 30, 2011.

**ADDRESSES:** The report is available primarily via the Internet on the National Center for Environmental Assessment's home page under the Recent Additions and Publications menus at *http://www.epa.gov/ncea.* Paper copies of the report are not available. A limited number of CD–ROMs will be available from the Information Management Team, NCEA; telephone: 703–347–8561; facsimile: 703–347–8691. If you are requesting a CD–ROM, please provide your name, your mailing address, and the document title.

**FOR FURTHER INFORMATION CONTACT:** For additional information, contact the National Center for Environmental Assessment; Jacqueline Moya; telephone: 703–347–8539; or e-mail: *moya.jacqueline@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

**I. Information About the Project/ Document**

The *Exposure Factors Handbook: 2011 Edition* provides a summary of the available statistical data on various factors used in assessing human exposure. These factors include: drinking water consumption; mouthing behavior; soil ingestion rates; inhalation rates; dermal factors, including skin area and soil adherence factors; consumption of fruits and vegetables, fish, meats, dairy products, and homegrown foods; human milk intake; human activity factors; consumer product use; and building characteristics. This handbook is intended for use by exposure assessors, within the Agency as well as those outside, as a reference tool and primary source of exposure factor information. It may be used by scientists, economists, and other interested parties as a source of data and/or U.S. EPA recommendations on numeric estimates for behavioral and physiological characteristics needed to estimate exposure to environmental agents. Recommended values are available for the general population and, for most of the exposure factors, are also available by age, sex, as well as for other populations that may have characteristics different from the general population.

Dated: September 23, 2011.

**Darrell A. Winner,**

*Acting Director, National Center for Environmental Assessment.*

[FR Doc. 2011–25412 Filed 9–30–11; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

**[EPA–HQ–OAR–2010–1059; FRL–9471–8]**

## Guidance for 1-Hour $SO_2$ NAAQS SIP Submissions

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

**ACTION:** Notice of availability and public comment period.

**SUMMARY:** Notice is hereby given that the EPA has posted its draft non-binding guidance titled, ''Guidance for 1–Hour $SO_2$ NAAQS SIP Submissions'' on its Web site. The EPA invites public comments on this guidance document during the comment period specified below, and plans to issue an updated version of the guidance after reviewing timely submitted comments.

**DATES:** Comments should be submitted on or before November 2, 2011. Please refer to **SUPPLEMENTARY INFORMATION** for additional information on the comment period.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2010–1059, by one of the following methods:

- *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *E-mail: a-and-r-docket@epa.gov.* Attention Docket ID No. EPA–HQ–OAR–2010–1059.
- *Fax:* 202–566–9744. Attention Docket ID No. EPA–HQ–OAR–2010–1059.
- *Mail:* Air Docket, Attention Docket ID No. EPA–HQ–OAR–2010–1059, Environmental Protection Agency, Mail Code: 6102T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.
- *Hand Delivery:* EPA Docket Center, 1301 Constitution Avenue, NW., Room 3334, Washington, DC. Such deliveries are only accepted during the Docket

Center's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

*Instructions:* Direct your comments to Docket ID No. EPA–HQ–OAR–2010–1059. The 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 *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 is unable to read your comment and contact you for clarification due to technical difficulties, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.* For additional instructions on submitting comments, go to Section II of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *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 the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Avenue, NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742.

**FOR FURTHER INFORMATION CONTACT:** For questions concerning this action, please contact Larry D. Wallace, Ph.D., U.S. EPA, Office of Air Quality Planning and Standards, Air Quality Policy Division, C504–03, Research Triangle Park, NC 27711, telephone (919) 541–0906, e-mail at *wallace.larry@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. General Information

A. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *http://www.regulations.gov* or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. Send or deliver information identified as CBI only to the following address: Roberto Morales, U.S. EPA, Office of Air Quality Planning and Standards, Mail Code C404–02, Research Triangle Park, NC 27711, telephone (919) 541–0880, e-mail at *morales.roberto@epa.gov,* Attention Docket ID No. OAR–2010–1059.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

- Identify the docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions. The agency may ask you to respond to specific questions or organize comments by referencing a part or section number in the guidance.
- Explain why you agree or disagree with EPA's guidance; and suggest alternatives and substitute language that would help to clarify or better explain the points made and positions taken in EPA's guidance document.

## II. Background

The purpose of this notice is to solicit public comments on EPA's recently posted draft non-binding guidance titled, ''Guidance for 1–Hour $SO_2$ NAAQS SIP Submissions.'' This document is available online at *http://www.epa.gov/airquality/sulfurdioxide/implement.html* or within the associated docket, EPA–HQ–OAR–2010–1059.

The draft guidance document is intended to assist state and tribal governments in preparing State Implementation Plan (SIP) submittals under section 110(a)(1) of the Clean Air Act (CAA) to address implementation, maintenance, and enforcement of the 1-hour primary sulfur dioxide ($SO_2$) National Ambient Quality Standards (NAAQS). The CAA directs states to submit these SIPs to EPA by no later than June 3, 2013, which is 3 years after promulgation of the primary $SO_2$ NAAQS. To be approved, the EPA would expect the SIP submittals to demonstrate through the use of refined air quality dispersion modeling that the affected areas will attain the standard as expeditiously as practicable. This draft guidance provides the basic information that states, tribes and emission sources would need to address the section 110(a)(1) SIP submittal for the 1-hour $SO_2$ NAAQS including modeling guidance. After receiving timely submitted public comments on the draft guidance, the EPA plans to issue updated non-binding guidance. In addition, the EPA will continue to work closely with states and tribes to address issues arising under the section 110(a)(1) SIP submittals.

EPA invites public comment on all aspects of this draft guidance during the 30-day comment period. The draft guidance is not a regulation or any other kind of final action and does not establish binding requirements on the EPA or any state, local, or tribal agency or any emissions source. While the EPA has established a docket and is requesting public comment on the draft guidance, this procedure does not alter the nature or effect of the draft guidance and does not constitute a formal rulemaking process or require the EPA to respond to public comments in the updated guidance before the EPA or other agencies may use the guidance in reaching decisions related to SIPs submitted under section 110(a)(1). The EPA retains the discretion to revise its guidance, issue additional guidance, propose regulations as appropriate, and to utilize information submitted in public comments to inform future decisions. Because this draft guidance does not constitute a formal rulemaking action, the EPA is not required to respond to comments, but intends to take significant comments under consideration in amending or updating

the non-binding guidance. To the extent that the EPA determines that comments received during the 30-day comment period justify corrections or clarifications to the guidance, the EPA may revise and reissue the guidance and post the revised document at: *http://www.epa.gov/airquality/sulfurdioxide/implement.html.*

Please refer to the **ADDRESSES** section above in this document for specific instructions on submitting comments.

### III. Internet Web Site for Guidance Information

The guidance titled, ''Guidance for 1–Hour $SO_2$ NAAQS SIP Submissions'' can be found at: *http://www.epa.gov/airquality/sulfurdioxide/implement.html.*

Dated: September 21, 2011.

**Mary Henigin,**

*Acting Director, Office of Air Quality Planning and Standards.*

[FR Doc. 2011–25400 Filed 9–30–11; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

**[FRL–9474–3]**

### National and Governmental Advisory Committees to the U.S. Representative to the Commission for Environmental Cooperation

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

**ACTION:** Notice of meeting.

**SUMMARY:** Under the Federal Advisory Committee Act, Public Law 92–463, EPA gives notice of a meeting of the National Advisory Committee (NAC) and Governmental Advisory Committee (GAC) to the U.S. Representative to the North American Commission for Environmental Cooperation (CEC). The National and Governmental Advisory Committees advise the EPA Administrator in her capacity as the U.S. Representative to the CEC Council. The Committees are authorized under Articles 17 and 18 of the North American Agreement on Environmental Cooperation (NAAEC), North American Free Trade Agreement Implementation Act,Public Law 103–182, and as directed by Executive Order 12915, entitled ''*Federal Implementation of the North American Agreement on Environmental Cooperation.*'' The NAC is composed of 13 members representing academia, environmental non-governmental organizations, and private industry. The GAC consists of 12 members representing state, local, and Tribal governments. The Committees are responsible for providing advice to the U.S. Representative on a wide range of strategic, scientific, technological, regulatory, and economic issues related to implementation and further elaboration of the NAAEC.

The purpose of the meeting is to provide advice on the CEC's Draft Communication Strategy, and discuss regional trans-boundary environmental issues. The meeting will also include a public comment session. A copy of the agenda will be posted at *http://www.epa.gov/ocem/nacgac-page.htm.*

**DATES:** The National and Governmental Advisory Committees will hold an open meeting on Thursday, October 20, 2011, from 8:30 a.m. to 5 p.m., and Friday, October 21, from 8:30 a.m. until 2 p.m.

**ADDRESSES:** The meeting will be held at the DoubleTree Hotel, 1617 IH–35 North, Austin, Texas 78702. Telephone: 512–479–4000. The meeting is open to the public, with limited seating on a first-come, first-served basis.

**FOR FURTHER INFORMATION CONTACT:** Oscar Carrillo, Designated Federal Officer, *carrillo.oscar@epa.gov*, 202–564–0347, U.S. EPA, Office of Federal Advisory Committee Management and Outreach (1601–M), 1200 Pennsylvania Avenue NW, Washington, DC 20460.

**SUPPLEMENTARY INFORMATION:** Requests to make oral comments, or provide written comments to the Committees, should be sent to Oscar Carrillo, Designated Federal Officer, at the contact information above.

*Meeting Access:* For information on access or services for individuals with disabilities, please contact Oscar Carrillo at 202–564–0347 or *carrillo.oscar@epa.gov*. To request accommodation of a disability, please contact Oscar Carrillo, preferably at least 10 days prior to the meeting, to give EPA as much time as possible to process your request.

Dated: September 22, 2011.

**Oscar Carrillo,**

*Designated Federal Officer.*

[FR Doc. 2011–25398 Filed 9–30–11; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

**[FRL–9474–6]**

### Notification of a Public Meeting of the Science Advisory Board Biogenic Carbon Emissions Panel

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

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA or Agency) Science Advisory Board (SAB) Staff Office announces a public face-to-face meeting of the SAB Biogenic Carbon Emissions Panel to review EPA's draft *Accounting Framework for Biogenic $CO_2$ Emissions from Stationary Sources (September 2011).*

**DATES:** The meeting will be held on October 25, 2011 from 8:30 a.m. to 5 p.m., October 26, 2011 from 8:30 a.m. to 5 p.m. and on October 27, 2011 from 8:30 a.m. to 12:30 p.m. (Eastern Time).

**ADDRESSES:** The meeting will be held at the Hyatt Regency at 400 New Jersey Avenue, NW., Washington, DC 20001.

**FOR FURTHER INFORMATION CONTACT:** Any member of the public wishing further information regarding this meeting may contact Dr. Holly Stallworth, Designated Federal Officer (DFO), SAB Staff Office, by telephone/voice mail at (202) 564–2073 or via e-mail at *stallworth.holly@epa.gov.* General information concerning the EPA Science Advisory Board can be found at the EPA SAB Web site at *http://www.epa.gov/sab.*

**SUPPLEMENTARY INFORMATION:**

*Background:* The SAB was established pursuant to the Environmental Research, Development, and Demonstration Authorization Act (ERDAA) codified at 42 U.S.C. 4365, to provide independent scientific and technical peer review, advice, consultation, and recommendations to the EPA Administrator on the technical basis for EPA actions. As a Federal Advisory Committee, the SAB conducts business in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2) and related regulations. Pursuant to FACA and EPA policy, notice is hereby given that the SAB Biogenic Carbon Emissions Panel will hold a public meeting to review EPA's draft *Accounting Framework for Biogenic $CO_2$ Emissions from Stationary Sources (September 2011).* The SAB will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

EPA's Office of Atmospheric Programs (OAP) in EPA's Office of Air and Radiation has requested SAB review of the draft report and accounting framework. The SAB Staff Office requested public nominations of experts to serve on a review panel to advise the Agency on April 27, 2011 (76 FR 23587–23588). The SAB Staff Office sought nominations of nationally and internationally recognized scientists and experts with demonstrated expertise in forestry, agriculture, measurement and carbon accounting methodologies, land use economics, climate change,

engineering and monitoring and accounting approaches for agriculture, land use, land-use change and forestry. On June 23, 2011, the SAB Staff Office posted a notice on the SAB website inviting public comments on candidates for the panel by July 15, 2011. Information about formation of the panel can be found at *http://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr_activites/Accounting%20for%20biogenic%20CO2?OpenDocument.* The purpose of the October 25–27, 2011, meeting is for the Panel to review and provide advice on EPA's draft *Accounting Framework for Biogenic $CO_2$ Emissions from Stationary Sources (September 2011).*

*Availability of the review materials:* EPA's review document and charge to the Panel Agenda and other meeting materials will be made available at the URL above. For questions concerning EPA's draft *Accounting Framework for Biogenic $CO_2$ Emissions from Stationary Sources (September 2011),* please contact Dr. Jennifer Jenkins, Climate Change Division, at *jenkins.jennifer@epa.gov* or 202–343–9361 or Sara Ohrel at *ohrel.sara@epa.gov* or 202–343–9712.

*Procedures for Providing Public Input:* Public comment for consideration by EPA's federal advisory committees and panels has a different purpose from public comment provided to EPA program offices. Therefore, the process for submitting comments to a federal advisory committee is different from the process used to submit comments to an EPA program office. Federal advisory committees and panels, including scientific advisory committees, provide independent advice to EPA. Members of the public can submit relevant comments for a federal advisory committee to consider pertaining to EPA's charge to the panel. Input from the public to the SAB will have the most impact if it consists of comments that provide specific scientific or technical information or analysis for the SAB panel to consider or if it relates to the clarity or accuracy of the technical information.

Members of the public wishing to provide comment should contact the Designated Federal Officer for the relevant advisory committee directly. *Oral Statements:* In general, individuals or groups requesting an oral presentation at this public meeting will be limited to five minutes per speaker. Interested parties should contact Dr. Holly Stallworth, DFO, in writing (preferably via e-mail), at the contact information noted above, by October 18, 2011 to be placed on the list of public speakers for the meeting.

*Written Statements:* Written statements should be received in the SAB Staff Office by October 18, 2011 so that the information may be made available to the SAB Panel for their consideration. Written statements should be supplied to the DFO in electronic format via e-mail (acceptable file formats: Adobe Acrobat PDF, WordPerfect, MS Word, MS PowerPoint, or Rich Text files in IBM–PC/Windows 98/2000/XP format). It is the SAB Staff Office general policy to post written comments on the Web page for the advisory meeting or teleconference. Submitters are requested to provide an unsigned version of each document because the SAB Staff Office does not publish documents with signatures on its Web sites. Members of the public should be aware that their personal contact information, if included in any written comments, may be posted to the SAB Web site. Copyrighted material will not be posted without explicit permission of the copyright holder.

*Accessibility:* For information on access or services for individuals with disabilities, please contact Dr. Holly Stallworth at the phone number or e-mail address noted above, preferably at least ten days prior to the meeting, to give EPA as much time as possible to process your request.

Dated: September 27, 2011.

**Vanessa T. Vu,**

*Director, EPA Science Advisory Board Staff Office.*

[FR Doc. 2011–25406 Filed 9–30–11; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

**[FRL–9474–7]**

### Reschedule—Meeting of the Local Government Advisory Committee

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice.

**SUMMARY:** The Local Government Advisory Committee will meet via teleconference on Monday, October 24, 2011, 2:30–4 p.m. (ET). The Committee will discuss the recommendations of the Gulf Coast Restoration Workgroup on ways EPA can engage local government officials in the Gulf Coast Ecosystem restoration efforts and other issues of environmental concern to locally elected officials. This is an open meeting and all interested persons are invited to participate. The Committee will hear comments from the public between 2:45 p.m.–3 p.m. on Monday, October 24, 2011. Individuals or organizations wishing to address the Committee will be allowed a maximum of five minutes to present their point of view. Also, written comments should be submitted electronically to *eargle.frances@epa.gov.* Please contact the Designated Federal Officer (DFO) at the number listed below to schedule a time on the agenda. Time will be allotted on a first come first serve basis, and the total period for comments may be extended if the number of requests for appearances requires it.

*Dates and Addresses:* The Local Government Advisory Committee meeting will be held by teleconference on Monday, October 24, 2011, at 2:30 p.m.–4 p.m. (ET). The Committee's meeting summary will be available after the meeting online at *http://www.epa.gov/ocir/scas* and can be obtained by written request to the DFO.

**FOR FURTHER INFORMATION CONTACT:** Frances Eargle, the Designated Federal Officer for the Local Government Advisory Committee (LGAC) at (202) 564–3115 or e-mail at *eargle.frances@epa.gov.*

*Information on Services for Those With Disabilities:* For information on access or services for individuals with disabilities, please contact Frances Eargle at (202) 564–3115 or *eargle.frances@epa.gov.* To request accommodation of a disability, please request it 10 days prior to the meeting, to give EPA as much time as possible to process your request.

Dated: September 27, 2011.

**Frances Eargle,**

*Designated Federal Officer, Local Government Advisory Committee.*

[FR Doc. 2011–25407 Filed 9–30–11; 8:45 am]

**BILLING CODE 6560–50–P**

## FEDERAL ELECTION COMMISSION

### Sunshine Act Notice

**AGENCY:** Federal Election Commission,

**DATE & TIME:** Thursday, October 6, 2011 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:**

Correction and Approval of the Minutes for the Meetings of September 1 and 22, 2011.

Agency Procedure Following the Submission of Probable Cause Briefs by the Office of General Counsel.

Draft Advance Notice of Proposed Rulemaking for Internet Communication Disclaimers.

Draft Advisory Opinion 2011–18: Western Representation PAC Management and Administrative Matters.

Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Shawn Woodhead Werth, 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. 2011–25592 Filed 9–29–11; 4:15 pm]

**BILLING CODE 6715–01–P**

## FEDERAL RESERVE SYSTEM

### Change in Bank Control Notices; Acquisitions of Shares of a Savings and Loan Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and the Board's Regulation LL (12 CFR part 238) to acquire shares of a savings and loan holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than October 18, 2011.

**A. Federal Reserve Bank of Cleveland** (Nadine Wallman, Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101–2566:

*1. Timothy O'Dell Investor Group,* New Albany, Ohio; to acquire no more than 24.99 percent of the voting shares of Central Federal Corporation, and thereby indirectly acquire voting share of CF Bank, both in Fairlawn, Ohio.

Board of Governors of the Federal Reserve System.

Dated: September 28, 2011.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. 2011–25403 Filed 9–30–11; 8:45 am]

**BILLING CODE 6210–01–P**

## FEDERAL RESERVE SYSTEM

### Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than October 28, 2011.

A. Federal Reserve Bank of Atlanta (Chapelle Davis, Assistant Vice President) 1000 Peachtree Street, NE., Atlanta, Georgia 30309:

1. Platinum Bank Holding Company, to become a bank holding company by acquiring 100 percent of the voting shares of Platinum Bank, both in Brandon, Florida.

Board of Governors of the Federal Reserve System.

Dated: September 28, 2011.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. 2011–25405 Filed 9–30–11; 8:45 am]

**BILLING CODE 6210–01–P**

## FEDERAL RESERVE SYSTEM

### Formations of, Acquisitions by, and Mergers of Savings and Loan Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Home Owners' Loan Act (12 U.S.C. 1461 *et seq.*) (HOLA), Regulation LL (12 CFR part 238), and Regulation MM (12 CFR part 239), and all other applicable statutes and regulations to become a savings and loan holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a savings association and nonbanking companies owned by the savings and loan holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the HOLA (12 U.S.C. 1467a(e)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 10(c)(4)(B) of the HOLA (12 U.S.C. 1467a(c)(4)(B)). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than October 18, 2011.

A. Federal Reserve Bank of San Francisco (Kenneth Binning, Vice President, Applications and Enforcement) 101 Market Street, San Francisco, California 94105–1579:

1. *Opus Bank,* Redondo Beach, California, to become a savings and loan holding company by acquiring shares of RMG Capital Corporation, and thereby indirectly acquire Fullerton Community Bank, both in Fullerton, California. In connection with this application, Fullerton Community Bank will merge into Opus Bank.

In connection with this application, Applicant also has applied to acquire RMG Development Corporation, Fullerton, California, and thereby engage in real estate development joint venture activities, pursuant to section 238.53(b)(4) and (5) of Regulation LL.

Board of Governors of the Federal Reserve System, September 28, 2011.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. 2011–25404 Filed 9–30–11; 8:45 am]

**BILLING CODE 6210–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[CMS–5508–N]**

### Medicare Program; Comprehensive Primary Care Initiative

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces a solicitation for health care payer organizations to participate in the Comprehensive Primary Care initiative (CPC), a multipayer model designed to improve primary care.

**DATES:** *Letter of Intent Submission Deadlines:* Interested organizations must submit a nonbinding letter of intent (LOI), which includes an Excel document identifying preliminary markets of interest by November 15, 2011 using the LOI template provided on the Innovation Center Web site at *http://www.innovation.cms.gov/*.

*Application Submission Deadline:* Applications must be received through an online portal, on or before 5 p.m., Eastern Standard Time (E.S.T) on January 17, 2012. We reserve the right to request additional information from applicants in order to assess their applications.

**ADDRESSES:** Letters of Intent should be submitted electronically in PDF format via encrypted e-mail to the following e-mail address by the applicable date specified in the **DATES** section of this notice: *CPCi@cms.hhs.gov.* Letters of Intent will only be accepted via e-mail. Applications will only be accepted via the online application portal.

**FOR FURTHER INFORMATION CONTACT:** *CPCi@cms.hhs.gov* for questions regarding the aspects of the Comprehensive Primary Care initiative or the application process.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

The Centers for Medicare & Medicaid Services (CMS) are committed to the three-part aim of better health, better health care, and lower per-capita costs for Medicare, Medicaid and Children's Health Insurance Program (CHIP) beneficiaries. One potential mechanism for achieving this goal is to support practice redesign in primary care through payment reform.

The Center for Medicare & Medicaid Innovation (Innovation Center) is seeking to strengthen free-standing primary care capacity by testing a model of comprehensive, accountable primary care supported by multiple payers. We are seeking to collaborate with other payers in select markets and with approximately 75 primary care practices in each market over the course of this 4-year initiative. This solicitation is directed to public and private health care payers who will respond individually to the Innovation Center. Once payers and markets have been selected, primary care practices will be recruited and selected in those markets.

#### II. Provisions of the Notice

Consistent with its authority under section 1115A of the Social Security Act (the Act) as added by section 3021 of the Affordable Care Act, to test innovative payment and service delivery models that reduce spending under Medicare, Medicaid or CHIP, while preserving or enhancing the quality of care, the Innovation Center aims to achieve the following goals through the implementation of the Comprehensive Primary Care (CPC) initiative:

- To collaborate with other payers on aligned strategies to support the delivery of comprehensive primary care services provided by practices participating in the initiative (as described in Section D of the solicitation).
- To test whether a set of comprehensive primary care functions, coupled with payment reform, use of data to guide improvement, and meaningful use of health information technology can achieve the three-part aim of better care, improved health and reduced costs that could ultimately be adopted by Medicare and Medicaid programs.

We will pay a per-beneficiary-per-month care management payment to each participating primary care practices for comprehensive primary care services that the practice provides to its Medicare fee-for-service beneficiaries We will offer an opportunity for participating practices to share in savings in years 2 through 4 of the program if the market in which the practice participates experiences reductions in its reductions in its total health system costs (a described in Section F of the solicitation). Each payer applying for this initiative will propose a strategy that is aligned with the Innovation Center's approach to supporting comprehensive primary care. Learning systems will support participating practices throughout the initiative. Payer selection criteria are described in section II of the Solicitation.

To the extent that States apply, the Innovation Center will also pay a per-beneficiary-per-month care management payment to primary care on behalf of Medicaid fee-forservice beneficiaries; shared savings will not be a part of the payment methodology for Medicaid fee-for–service.

#### III. Collection of Information Requirements

Section 1115A(d)(3)of the Act specifies that the requirements of the Paperwork Reduction Act of 1995 do not apply with respect to the testing and evaluation of payment and service delivery models or the expansion of these models under section 1115A of the Act.

**Authority:** Section 1115A of the Social Security Act.

Dated: September 27, 2011.

**Donald M. Berwick,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2011–25356 Filed 9–28–11; 11:15 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–D–0689]**

### Draft Guidance for Industry and Food and Drug Administration Staff; De Novo Classification Process (Evaluation of Automatic Class III Designation); Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''*De Novo* Classification Process (Evaluation of Automatic Class III Designation).'' The purpose of this document is to provide guidance to FDA staff and industry on the process for the submission and review of petitions submitted under the Federal Food, Drug, and Cosmetic Act (FD&C Act), also known as the de novo classification process. FDA is issuing this draft guidance to provide updated recommendations for efficient interaction with FDA, including what information to submit, when seeking a path to market for a novel device via the de novo process. This draft guidance is not final nor is it in effect at this time.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the

final version of the guidance, submit either electronic or written comments on the draft guidance by December 2, 2011. Submit either electronic or written comments concerning proposed collection of information by December 2, 2011.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled ''*De Novo* Classification Process (Evaluation of Automatic Class III Designation)'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002 or to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Melissa Burns, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1646, Silver Spring, MD 20993–0002, 301–796–5616; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

## I. Background

A medical device that is of a new type that FDA has not yet classified based on risk, and therefore cannot be found to be substantially equivalent to a legally marketed predicate device, may remain in class III even if the risks it presents are relatively low. This is the scenario targeted by Congress when it enacted section 513(f)(2) of the FD&C Act (21 U.S.C. 360c(f)(2)) as part of the Food and Drug Administration Modernization Act of 1997 (FDAMA). The process created by this provision is referred to in FDAMA as the Evaluation of Automatic Class III Designation (e.g., the de novo process). Congress included this section to limit unnecessary expenditure of FDA and industry resources that could occur if lower risk devices were subject to premarket approval under section 515 of the FD&C Act (21 U.S.C. 360e).

FDA issued a guidance document to explain the procedures involved with the de novo program, which has been in place since 1998. Over the past 13 years, even though a number of new medical devices have been evaluated by FDA under the de novo process, FDA believes that the program has been under-utilized, and has evaluated what improvements could be made to enhance the utility and productivity of the program. FDA evaluated its extensive experience gained with respect to the evidence necessary to conduct comprehensive reviews of de novo applications. Accordingly, FDA is issuing this draft guidance to provide updated recommendations designed to foster efficient interaction with FDA, including what information to submit, when seeking a path to market via the de novo process. This guidance describes a mechanism to provide greater clarity about the suitability of a device for de novo review, and timely input on the type of data necessary to support de novo classification of an eligible device.

## II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the de novo classification process. 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 statute and regulations.

## III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at http://www.regulations.gov or from CBER at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* To receive ''*De Novo* Classification Process (Evaluation of Automatic Class III Designation),'' from CDRH you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1769 to identify the guidance you are requesting.

## IV. Paperwork Reduction Act of 1995

Under the PRA (44 U.S.C. 3501–3502), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

*Draft Guidance for Industry and Food and Drug Administration Staff: De Novo Classification Process (Evaluation of Automatic Class III Designation)*

This draft guidance describes how FDA's Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) intend to implement this provision of the law. When final, this document will supersede ''New Section 513(f)(2)—Evaluation of Automatic Class III Designation, Guidance for Industry and CDRH Staff'' dated February 19, 1998.

The proposed collections of information are necessary to satisfy the previously mentioned statutory requirements for implementing this voluntary submission program.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Submission of information for de novo petition program | Number of respondents | Number of responses per respondent per year | Total annual responses | Average burden per respondent (in hours) | Total hours |
|---|---|---|---|---|---|
| CDRH | 25 | 1 | 25 | 100 | 2,500 |
| CBER | 1 | 1 | 1 | 100 | 100 |
| Total | | | | | 2,600 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents are medical device manufacturers seeking to market medical device products that have been classified into class III under section 513(f)(2) of the FD&C Act. Based on FDA's experience with the de novo petition program, FDA expects the program to continue to be utilized as a viable program in the future. It is expected that the number of petitions will increase over its current rate and reach a steady rate of approximately 26 submissions per year

FDA estimates from past experience with the de novo petition program that the complete process involved with the program takes approximately 100 hours. This average is based upon estimates by FDA administrative and technical staff who are familiar with the requirements for submission of a de novo petition (and related materials), have consulted and advised manufacturers on these requirements, and have reviewed the documentation submitted.

Therefore, the total reporting burden hours is estimated to be 2,600 hours.

TABLE 2

| Number of respondents | Total burden hours annualized | Hourly wage rate | Total cost annualized |
|---|---|---|---|
| 26 | 100 | $150 | $390,000 |

The average to industry per hour for this type of work is $150, resulting in a cost of $15,000 per respondent. The estimated submission cost of $15,000 multiplied by 26 submissions per year equals $390,000, which is the aggregated industry reporting cost annualized.

This draft guidance also refers to currently approved information collections found in FDA regulations. The collections of information in 21 CFR part 807, subpart E, are approved under OMB control number 0910–0120.

**V. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 27, 2011.

**Nancy K. Stade,**

*Deputy Director for Policy, Center for Devices and Radiological Health.*

[FR Doc. 2011–25367 Filed 9–30–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Agency Information Collection Activities: Submission for OMB Review: Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office at (301) 443–1129. The following request has been submitted to OMB for review under the Paperwork Reduction Act of 1995:

**Proposed Project: ADAP Data Report—[New]**

HRSA's AIDS Drug Assistance Program (ADAP) is funded through the Ryan White HIV/AIDS Program, Part B, of Title XXVI of the Public Health Service Act, which provides grants to states and territories. Each of the 50 states, the District of Columbia, Puerto Rico, and several territories receive ADAP grants. The ADAP provides medications for the treatment of HIV/AIDS. Program funds may also be used to purchase health insurance for eligible clients or for services that enhance access, adherence, and monitoring of drug treatments.

The Ryan White HIV/AIDS Program specifies HRSA's responsibilities in the administration of grant funds, the allocation of funds, the evaluation of programs for the population served, and the improvement of quality of care. Accurate records of the grantees receiving Ryan White HIV/AIDS Program funding, the services provided, and the clients served, continue to be critical issues for the implementation of the legislation and are necessary for HRSA to fulfill its responsibilities.

The ADAP Data Report (ADR) provides data on the characteristics of ADAP grantees and the clients being served with program funds. The ADR is

intended to support clinical quality management, performance measurement, service delivery, and client monitoring at the system and client levels. The reporting system consists of an online data form—the Grantee Report—and a data file containing the client-level data elements. Data will be submitted every six months. The Grantee Report includes information about program administration, funding, and expenditures, in addition to the medication formulary. The client-level data include demographic, clinical, enrollment, and service data for each patient who is determined eligible and enrolled in the ADAP.

The legislation specifies grantee accountability and links budget to performance. The ADR will be used to ensure compliance with the requirements of the legislation, to evaluate the progress of programs, to monitor grantee performance, to measure the Government Performance and Results Act (GPRA) and the Performance Assessment Rating Tool (PART) goals, and to meet reporting responsibilities to the Department, Congress, and OMB.

In addition to meeting the goal of accountability to Congress, clients, advocacy groups, and the general public, information collected through the ADR is critical to HRSA and grantees for assessing the status of existing HIV-related service delivery systems, investigating trends in service utilization, and identifying the areas of greatest need.

Discussions were held with nine volunteer grantee agencies representing a variety of ADAP models, as a basis for the burden estimates for the ADR that follows. These burden estimates are presented in two tables. The first table represents the estimated burden for the first year, including the estimated time to adjust existing or develop new data collection systems to collect the elements that HRSA is requesting. This is a one-time burden for grantees and will not be a factor after the first year. The second table represents the estimated burden for subsequent years. The Grantee Report burden remains unchanged across the three years of the information collection, as the submission is consistent with current reporting requirements. The Client Report burden is expected to decrease slightly in subsequent years as grantees become more proficient with reporting client-level data, based on feedback and technical assistance resources that HRSA will provide.

The annual estimate of burden for the first year of the information collection is as follows:

| Instrument | Number of respondents | Responses per respondent | Total responses | Hours per response | Total burden hours |
|---|---|---|---|---|---|
| Grantee Report | 57 | 2 | 114 | 12.50 | 1,425.00 |
| Client Report | 57 | 2 | 114 | 34.19 | 3,897.66 |
| Data Collection System | 57 | 1 | 57 | 826.00 | 47,082.00 |
| Total: | | | | | 52,404.66 |

The annual estimate of burden for subsequent years is as follows:

| Instrument | Number of respondents | Responses per respondent | Total responses | Hours per response | Total burden hours |
|---|---|---|---|---|---|
| Grantee Report | 57 | 2 | 114 | 12.50 | 1,425.00 |
| Client Report | 57 | 2 | 114 | 24.00 | 2,736.00 |
| Total: | | | | | 4,161.00 |

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to *OIRA—submission@omb.eop.gov* or by fax to 202–395–6974. Please direct all correspondence to the ''attention of the desk officer for HRSA.''

Dated: September 26, 2011.

**Wendy Ponton,**

*Director, Office of Management.*

[FR Doc. 2011–25339 Filed 9–30–11; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Notice of Intent To Prepare an Environmental Impact Statement

*Summary:* In accordance with the National Environmental Policy Act, the National Institutes of Health (NIH), an agency of the Department of Health and Human Services (HHS), is issuing this notice to advise the public that an environmental impact statement will be prepared for the NIH Animal Center at Poolesville Master Plan, Poolesville, Montgomery County, Maryland.

*For Further Information Contact:* Valerie Nottingham, Chief, Environmental Quality Branch, Division of Environmental Protection, Office of Research Facilities, NIH, B13/2S11, 9000 Rockville Pike, Bethesda, Maryland 20892, telephone 301–496–7775; fax 301–480–8056; or e-mail *nihnepa@mail.nih.gov*.

*Supplementary Information:* The NIH Animal Center is located on 513 acres 4 miles southwest of the City of Poolesville, a small agricultural community located in western Maryland. The campus is a component of the National Institutes of Health (NIH), one of the world's largest biomedical research facilities and the Federal government's focal point for medical and behavioral research. The NIH Animal Center at Poolesville is a major extension of animal holding and production facilities at Bethesda and consists of a number of buildings used to house, quarantine, and study the

behavior and immunological conduct of a variety of animal models. The NIH Animal Center at Poolesville conducts and supports research protocols for various Institutes and Centers, which includes the studies of animal behavior, conduct of immunologic procedures and sampling, and surgical investigation. Total building space on the campus amounts to approximately 364,507 gsf. Approximately 199 people work at the NIH Animal Center site.

A Master Plan is an integrated series of documents that present in graphic, narrative, and tabular form the current composition of NIH campuses and the plan for their orderly and comprehensive development over a 20-year period. The plan provides guidance in coordinating the physical development of NIH campuses, including building locations, utility capacities, road alignments, parking facilities, and the treatment of open spaces. General design guidelines are also used to provide detailed guidance for the placement and design of physical improvements.

The proposed action is to develop a long-range physical master plan for the NIH Animal Center. The plan will cover a 20-year planning period and address the future development of the NIH Animal Center site, including placement of future construction; vehicular and pedestrian circulation on- and off-campus; parking within the property boundaries; open space in and around the campus; required setbacks; historic properties; natural and scenic resources; noise; and lighting. The plan will examine potential growth in the NIH Animal Center personnel, and consequent construction of space over the planning period. Future construction on the site could include such facilities as: new animal holding, research laboratories, and support facilities.

In accordance with 40 CFR 1500–1508 and DHHS environmental procedures, NIH will prepare an Environmental Impact Statement (EIS) for the proposed master plan. The EIS will evaluate the impacts of the master plan should development occur as proposed. Among the items the EIS will examine are the implications of the master plan on community infrastructure, including, but not limited to, utilities, storm water management, traffic and transportation, and other public services.

To ensure that the public is afforded the greatest opportunity to participate in the planning and environmental review process, the NIH is inviting oral and written comments on the master plan and related environmental issues.

The NIH will be sponsoring a public Scoping Meeting to provide individuals an opportunity to share their ideas on the master planning effort, including recommended alternatives and environmental issues the EIS should consider. The meeting is planned for 6:30 p.m. to 9 p.m. on October 25, 2011 at the Town Hall Building at 19721 Beall Street, Poolesville, Maryland 20837. All interested parties are encouraged to attend. The NIH has established a 30-day public comment period for the scoping process. Scoping comments must be postmarked *no later than* November 18, 2011 to ensure they are considered. All comments and questions on the EIS should be directed to Valerie Nottingham at the address listed above, telephone 301–496–7775; fax 301–480–8056; or e-mail *nihnepa@mail.nih.gov.*

Dated: September 23, 2011.

**Daniel G. Wheeland,**

*Director, Office of Research Facilities Development and Operations, National Institutes of Health.*

[FR Doc. 2011–25385 Filed 9–30–11; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

**Project: Networking Suicide Prevention Hotlines—Evaluation of the Lifeline Policies for Helping Callers at Imminent Risk (NEW)**

This proposed project is a new data collection that builds on previously approved data collection activities [Evaluation of Networking Suicide Prevention Hotlines Follow–Up Assessment (OMB No. 0930–0274) and Call Monitoring of National Suicide Prevention Lifeline Form (OMB No. 0930–0275)]. This new data collection is an effort to advance the understanding of crisis hotline utilization and its impact. The Substance Abuse and Mental Health Services Administration's (SAMHSA), Center for Mental Health Services (CMHS) funds a National Suicide Prevention Lifeline Network (''Lifeline''), consisting of a toll-free telephone number that routes calls from anywhere in the United States to a network of local crisis centers. In turn, the local centers link callers to local emergency, mental health, and social service resources.

The overarching purpose of the proposed Evaluation of the Lifeline Policies for Helping Callers at Imminent Risk is to implement data collection to evaluate hotline counselors' management of imminent risk callers and third party callers concerned about persons at imminent risk, and counselor adherence to *Lifeline Policies and Guidelines for Helping Callers at Imminent Risk of Suicide.* Specifically, the Evaluation of the Lifeline Policies for Helping Callers at Imminent Risk will collect data, using an imminent risk form, to inform the network's knowledge of the extent to which counselors are aware of and being guided by the Lifeline's imminent risk guidelines; counselors' definitions of imminent risk; the rates of active rescue of imminent risk callers; types of rescue; barriers to intervention; and the circumstances in which active rescue is initiated, including the caller's agreement to receive the intervention.

Clearance is being requested for one activity to assess the knowledge, actions, and practices of counselors to aid callers who are determined to be at imminent risk for suicide and who may require active rescue. This evaluation will allow researchers to examine and understand the actions taken by counselors to aid imminent risk callers, the need for active rescue, and, ultimately, to improve the delivery of crisis hotline services to imminent risk callers. A total of eight centers will participate in this evaluation. Thus, SAMHSA is requesting OMB review and approval of the National Suicide Prevention Lifeline—Imminent Risk Form. This activity is distinct from the Crisis Center Survey data collection, which targets the entire network of crisis centers and focuses on a different domain of questions (specifically, the makeup, strengths, and needs of crisis centers.) The information gathered from the Crisis Center Survey cannot provide a profile of imminent risk callers or details about interventions with imminent risk or third party callers.

Crisis counselors at eight participating centers will record information discussed with imminent risk callers on the Imminent Risk Form, which does not require direct data collection from callers. As with previously approved evaluations, callers will maintain

anonymity. Counselors will be asked to complete the form for 100% of imminent risk callers to the eight centers participating in the evaluation. This form requests information in 14 content areas, each with multiple sub-items and response options. Response options include open-ended, yes/no, Likert-type ratings, and multiple choice/check all that apply. The form also requests demographic information on the caller, the identification of the center and counselor submitting the form, and the date of the call. Specifically, the form is divided into the following sections: (1) Call type, (2) gender, (3) age, (4) suicidal desire, (5) suicidal intent, (6) suicidal capability, (7) buffers to suicide, (8) interventions agreed to by caller or implemented by counselor without consent, (9) whether imminent risk was reduced enough such that active rescue was not needed, (10) interventions for third party callers calling about a person at imminent risk, (11) if supervisory consultation occurred, (12) barriers to getting needed help to the person at imminent risk, (13) steps taken to confirm emergency contact was made with person at risk, and (14) steps taken when emergency contact was NOT made with person at risk. The form will take approximately 15 minutes to complete and may be completed by the counselor during or after the call. It is expected that a total of 1,440 forms will be completed by 360 counselors over the two-year data collection period.

The estimated response burden to collect this information is annualized over the requested two-year clearance period and is presented below:

TOTAL AND ANNUALIZED AVERAGES: RESPONDENTS, RESPONSES AND HOURS

| Instrument | Number of respondents | Responses/ respondent | Total responses | Hours per response | Total hour burden |
|---|---|---|---|---|---|
| National Suicide Prevention Lifeline—Imminent Risk Form | 360 | 2 | 720 | .25 | 180 |

Written comments and recommendations concerning the proposed information collection should be sent by November 2, 2011 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via e-mail to: *OIRA_Submission@omb.eop.gov.* Although commenters are encouraged to send their comments via e-mail, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

**Rose Shannon,**

*Director, Division of Executive Correspondence.*

[FR Doc. 2011–25375 Filed 9–30–11; 8:45 am]

**BILLING CODE 4162–20–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

**Project: Cross-Site Evaluation of the Minority Substance Abuse/HIV Prevention Program—(OMB No. 0930–0298)—Revision**

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Prevention (CSAP) is requesting from the Office of Management and Budget (OMB) approval for the revision of data collection activities for the cross-site study of the Minority HIV/AIDS Initiative (MAI), which includes both youth and adult questionnaires. This revision includes the addition of 4 cohorts, changes to the data collection procedures based on intervention duration, and the addition of two questions on binge drinking behavior. The current approval is under OMB No. 0930–0298, which expires on 4/30/12.

This cross-site evaluation supports two of SAMHSA's 8 Strategic Initiatives: Prevention of Substance Abuse and Mental Illness and Data, Outcomes, and Quality. It builds on six previous grant programs funded by SAMHSA's CSAP to provide substance abuse and HIV prevention services for minority populations. The first two were planning grant programs and the last four were service grant programs. The goals for the Cohort 3–6 grants were to add, increase, or enhance integrated substance abuse (SA) and HIV prevention services by providing supportive services and strengthening linkages between service providers for at-risk minority populations. The HIV Cohort 1–3 previously received clearance under OMB No. 0930–0208 and Cohort 6 grants previously received clearance under OMB No. 0930–0298. Since neither the HIV Cohort 4 nor the Cohort 5 Programs were cross-site studies, they did not require OMB clearance. The current HIV Minority SA/HIV Prevention Program funded:

- Cohorts 7 and 8 Prevention of Substance Abuse (SA) and HIV for At-Risk Racial/Ethnic Minority Subpopulations Cooperative Agreements—60 grants for 5 years,
- Cohort 9 Ready-To-Respond Initiative—35 grants for 5 years and,
- Cohort 10 Capacity Building Initiative—27 grants for 5 years.

Grantees are community based organizations that are required to address the SAMHSA Strategic Prevention Framework (SPF) and participate in this cross-site evaluation. The grantees are expected to provide leadership and coordination on the planning and implementation of the SPF that targets minority populations, the minority reentry population, as well as other high risk groups residing in communities of color with high prevalence of SA and HIV/AIDS. The primary objectives of the cross-site study are to: (1) Determine the success of the MAI in preventing, delaying, and/or reducing the use of alcohol, tobacco, and other drugs (ATOD) among the target populations. The results of this cross-site study will assist SAMHSA/CSAP in promoting and disseminating optimally effective prevention programs; (2) Measure the effectiveness of evidence-based programs and infrastructure development activities such as: outreach and training, mobilization of key stakeholders, substance abuse and HIV/AIDS

counseling and education, referrals to appropriate medical treatment and/or other intervention strategies (i.e., cultural enrichment activities, educational and vocational resources, and computer-based curricula); and (3) Assess the process of adopting and implementing the Strategic Prevention Framework (SPF) with the target populations.

The grantees are expected to provide an effective prevention process, direction, and a common set of goals, expectations, and accountabilities to be adapted and integrated at the community level. While the grantees have substantial flexibility in choosing their individual evidence-based programs, they are all required to base them on the five steps of the SPF to build service capacity specific to SA and HIV prevention services. Conducting this cross-site evaluation will assist SAMHSA/CSAP in promoting and disseminating optimally effective prevention programs.

Grantees must also conduct ongoing monitoring and evaluation of their projects to assess program effectiveness including Federal reporting of the Government Performance and Results Act (GPRA) of 1993, SAMHSA/CSAP National Outcome Measures (NOMs), and HIV Counseling and Testing. All of this information will be collected through self-report questionnaires administered to program participants. All grantees will use two instruments, one for youth aged between 12 and 17 and one for adults aged 18 and older. Participants in interventions lasting 30 days or longer will complete questionnaires three times, taking an average of 50 minutes for baseline, exit, and follow-up questionnaires. Participants in interventions lasting 2–29 days will complete questionnaires two times taking an average of 30 minutes to complete. Single-session intervention participants will complete one questionnaire at exit only. The GPRA and NOMs measures on the instruments have already been approved by OMB (OMB No. 0930–0230), and the remaining HIV-related questions have been approved under OMB No. 0930–0298.The youth questionnaire contains 125 questions, of which 28 relate to HIV/AIDS and the adult questionnaire contains 118 items, 47 of which relate to HIV/AIDS. Two additional questions have been added to address SAMHSA's need to collect information on binge drinking behavior.

These questions are:

1. Females only: During the past 30 days, on how many days did you have 4 or more drinks on the same occasion?

2. Males only: During the past 30 days, on how many days did you have 5 or more drinks on the same occasion?

Sample size, respondent burden, and intrusiveness have been minimized to be consistent with the cross-site objectives. Procedures are employed to safeguard the privacy and confidentiality of participants. Every effort has been made to coordinate cross-site data collection with local data collection efforts in an attempt to minimize respondent burden.

The cross-site evaluation results will have significant implications for the substance abuse and HIV/AIDS prevention fields, the allocation of grant funds, and other evaluation activities conducted by multiple Federal, State, and local government agencies. They will be used to develop Federal policy in support of SAMHSA/CSAP program initiatives, inform the public of lessons learned and findings, improve existing programs, and promote replication and dissemination of effective prevention strategies.

**Total Estimates of Annualized Hour Burden**

The following table shows the estimated annualized burden for data collection.

TABLE 1A—ESTIMATES OF ANNUALIZED HOUR BURDEN BY INTERVENTION LENGTH

| Intervention length | Number of respondents | Responses per respondent | Total responses | Hours per response | Total hour burden |
|---|---|---|---|---|---|
| 30-Days or More Intervention: | | | | | |
| Base line | 7,937 | 1 | 7,937 | 0.83 | 6,588 |
| Exit | 4,887 | 1 | 4,887 | 0.83 | 4,056 |
| Follow-up | 2,942 | 1 | 2,942 | 0.83 | 2442 |
| Subtotal | 7,937 | ..... | 15,766 | ..... | 13,086 |
| 2 to 29 Day Intervention: | | | | | |
| Base line | 1,416 | 1 | 1,416 | 0.5 | 708 |
| Exit | 872 | 1 | 872 | 0.5 | 436 |
| Subtotal | 1,416 | ..... | 2,288 | ..... | 1,144 |
| Single Day Intervention: | | | | | |
| Exit | 2,458 | 1 | 2,458 | 0.25 | 614 |
| Annualized Total | 11,811 | ..... | 20,512 | ..... | 14,844 |

TABLE 1B—ESTIMATES OF ANNUALIZED HOUR BURDEN BY SURVEY TYPE

| Questionnaire | Number of respondents | Total responses | Total hour burden |
|---|---|---|---|
| Annualized Total Adult | 9,682 | 16,899 | 12,234 |
| Annualized Total Youth | 2,128 | 3,612 | 2,610 |
| Annualized Total | 11,811 | 20,512 | 14,844 |

Written comments and recommendations concerning the proposed information collection should be sent by November 2, 2011 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via e-mail to: *OIRA_Submission@omb.eop.gov.* Although commenters are encouraged to send their comments via e-mail, commenters may also fax their comments to: 202–395–7285.

Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

**Rose Shannon,**

*Director, Division of Executive Correspondence.*

[FR Doc. 2011–25374 Filed 9–30–11; 8:45 am]

**BILLING CODE 4162–20–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

### Current List of Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

**AGENCY:** Substance Abuse and Mental Health Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Department of Health and Human Services (HHS) notifies Federal agencies of the Laboratories and Instrumented Initial Testing Facilities (IITF) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); and on April 30, 2010 (75 FR 22809).

A notice listing all currently certified Laboratories and Instrumented Initial Testing Facilities (IITF) is published in the **Federal Register** during the first week of each month. If any Laboratory/IITF's certification is suspended or revoked, the Laboratory/IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any Laboratory/IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at *http://www.workplace.samhsa.gov* and *http://www.drugfreeworkplace.gov.*

**FOR FURTHER INFORMATION CONTACT:** Mrs. Giselle Hersh, Division of Workplace Programs, SAMHSA/CSAP, Room 2–1042, One Choke Cherry Road, Rockville, Maryland 20857; 240–276–2600 (voice), 240–276–2610 (fax).

**SUPPLEMENTARY INFORMATION:** The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71. The ''Mandatory Guidelines for Federal Workplace Drug Testing Programs,'' as amended in the revisions listed above, requires {or set} strict standards that Laboratories and Instrumented Initial Testing Facilities (IITF) must meet in order to conduct drug and specimen validity tests on urine specimens for Federal agencies.

To become certified, an applicant Laboratory/IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a Laboratory/IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and Instrumented Initial Testing Facilities (IITF) in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A Laboratory/IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with the Mandatory Guidelines dated November 25, 2008 (73 FR 71858), the following Laboratories and Instrumented Initial Testing Facilities (IITF) meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

**Instrumented Initial Testing Facilities (IITF)**

None.

**Laboratories**

ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227, 414–328–7840/800–877–7016. (Formerly: Bayshore Clinical Laboratory).

ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 585–429–2264.

Advanced Toxicology Network, 3560 Air Center Cove, Suite 101, Memphis, TN 38118, 901–794–5770/888–290–1150.

Aegis Analytical Laboratories, 345 Hill Ave., Nashville, TN 37210, 615–255–2400. (Formerly: Aegis Sciences Corporation, Aegis Analytical Laboratories, Inc.)

Alere Toxicology Services, 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433 –3823. (Formerly: Kroll Laboratory Specialists, Inc., Laboratory Specialists, Inc.)

Alere Toxicology Services, 450 Southlake Blvd., Richmond, VA 23236, 804–378–9130. (Formerly: Kroll Laboratory Specialists, Inc., Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.)

Baptist Medical Center-Toxicology Laboratory, 11401 I–30, Little Rock, AR 72209–7056, 501–202–2783. (Formerly: Forensic Toxicology Laboratory Baptist Medical Center.)

Clinical Reference Lab, 8433 Quivira Road, Lenexa, KS 66215–2802, 800–445–6917.

Doctors Laboratory, Inc., 2906 Julia Drive, Valdosta, GA 31602, 229–671–2281.

DrugScan, Inc., P.O. Box 2969, 1119 Mearns Road, Warminster, PA 18974, 215–674–9310.

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662–236–2609.

Gamma-Dynacare Medical Laboratories,* A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519–679–1630.

Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713–856–8288/800–800–2387.

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908–526–2400/800–437–4986. (Formerly: Roche Biomedical Laboratories, Inc.)

Laboratory Corporation of America Holdings, 1904 Alexander Drive, Research Triangle Park, NC 27709, 919–572–6900/800–833–3984. (Formerly: LabCorp Occupational Testing Service Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group.)

Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866–827–8042/800–233–6339. (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center.)

LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927/800–873–8845. (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.)

Maxxam Analytics,* 6740 Campobello Road, Mississauga, ON, Canada L5N 2L8, 905–817–5700. (Formerly: Maxxam Analytics Inc., NOVAMANN (Ontario), Inc.)

MedTox Laboratories, Inc., 402 W. County Road D, St. Paul, MN 55112, 651–636–7466/800–832–3244.
MetroLab-Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295.
Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612–725–2088.
National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661–322–4250/800–350–3515.
One Source Toxicology Laboratory, Inc., 1213 Genoa-Red Bluff, Pasadena, TX 77504, 888–747–3774. (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory.)
Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–328–6942. (Formerly: Centinela Hospital Airport Toxicology Laboratory.)
Pathology Associates Medical Laboratories, 110 West Cliff Dr., Spokane, WA 99204, 509–755–8991/800–541–7891 x7.
Phamatech, Inc., 10151 Barnes Canyon Road, San Diego, CA 92121, 858–643–5555.
Quest Diagnostics Incorporated, 1777 Montreal Circle, Tucker, GA 30084, 800–729–6432. (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories.)
Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610–631–4600/877–642–2216. (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories.)
Quest Diagnostics Incorporated, 8401 Fallbrook Ave., West Hills, CA 91304, 800–877–2520. (Formerly: SmithKline Beecham Clinical Laboratories.)
S.E.D. Medical Laboratories, 5601 Office Blvd., Albuquerque, NM 87109, 505–727–6300/800–999–5227.
South Bend Medical Foundation, Inc., 530 N. Lafayette Blvd., South Bend, IN 46601, 574–234–4176 x1276.
Southwest Laboratories, 4625 E. Cotton Center Boulevard, Suite 177, Phoenix, AZ 85040, 602–438–8507/800–279–0027.
St. Anthony Hospital Toxicology Laboratory, 1000 N. Lee St., Oklahoma City, OK 73101, 405–272–7052.
STERLING Reference Laboratories, 2617 East L Street, Tacoma, Washington 98421, 800–442–0438.
Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics, 301 Business Loop 70 West, Suite 208, Columbia, MO 65203, 573–882–1273.
Toxicology Testing Service, Inc., 5426 N.W. 79th Ave., Miami, FL 33166, 305–593–2260.
U.S. Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755–5235, 301–677–7085.

* The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register**, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on April 30, 2010 (75 FR 22809). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

Dated: September 21, 2011.

**Elaine Parry,**

*Director, Office of Management, Technology, and Operations, SAMHSA.*

[FR Doc. 2011–25225 Filed 9–30–11; 8:45 am]

**BILLING CODE 4160–20–P**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–5481–N–13]**

### Notice of Proposed Information Collection: Comment Request Self-Help Homeownership Opportunity Program (SHOP)

**AGENCY:** Office of the Assistant Secretary for Community Planning and Development, HUD.

**ACTION:** Notice of proposed information collection.

**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:** *Comment Due Date:* December 2, 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: Rudene Thomas, Reports Liaison Officer, U.S. Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7233, Washington, DC 20410–4500.

**FOR FURTHER INFORMATION CONTACT:** Ginger Macomber, SHOP Program Manager, Office of Affordable Housing Programs, U.S. Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7162, Washington, DC 20410–4500; telephone 202–402–4605 (this is not a toll-free number) or by e-mail at *ginger.macomber@hud.gov.*

**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 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.

The Self-Help Homeownership Opportunity Program (SHOP) is authorized by the Housing Opportunity Program Extension Act of 1996, Section 11. The purpose of SHOP is to provide grant funds to facilitate and encourage innovative homeownership opportunities on a national, geographically diverse basis through the provision of self-help homeownership housing programs. SHOP funds are appropriated by Congress, generally annually. HUD publishes a SHOP Notice of Funding Availability (NOFA) that announces the amount of SHOP grant funds and the application criteria, including the rating and ranking system HUD will use to select grantees.

SHOP grant funds may be used for land acquisition, the installation or

improvement of infrastructure, and for reasonable and necessary planning, administration and management costs. The average SHOP expenditure for the combined costs of land and infrastructure must not exceed $15,000 per dwelling unit. SHOP homeowners must contribute a significant amount of sweat equity towards the purchase of their units. Donated volunteer labor is also required. Assisted units must be decent, safe, and sanitary non-luxury dwellings that comply with local building and safety codes and standards. These units must be sold to eligible low-income homebuyers at prices below the prevailing market price. The homebuyer's sweat equity contribution must not be mortgaged or otherwise restricted upon future sale of the SHOP unit. SHOP grantees may award SHOP funds to affiliates to carry out the grantee's SHOP program.

This Notice also lists the following information:

*Title of Proposal:* Self-Help Homeownership Opportunity Program (SHOP).

*OMB Control Number:* 2506–0157. Expiration Date: July 31, 2011.

*Description of the Need for the Information and Proposed Use:* This is a proposed information collection for submission requirements under the SHOP Notice of Funding Availability (NOFA). HUD requires information in order to ensure the eligibility of SHOP applicants and SHOP proposals, to rate and rank SHOP applications, and to select applicants for grant awards. Information is collected on an annual basis from each applicant that responds to the SHOP NOFA. The SHOP NOFA requires applicants to submit specific forms and narrative responses.

*Agency Form Numbers:* HUD–424, HUD–424B, HUD–424CB, HUD–2880, HUD–2990, HUD–2993, HUD–2995, HUD–9601, HUD–96011.

*Members of Affected Public:* National and regional non-profit self-help housing organizations (including consortia) that apply for funds in response to the SHOP NOFA.

*Estimation of the total number of hours needed to prepare the information collection including number of respondents, hours per response, frequency of response, and total hours of response for all respondents.*

The estimates of the average hours needed to prepare the information collection are based on information provided by previous applicants. Actual hours will vary depending on the proposed scope of the applicant's program, the applicant's geographic service area and the number of affiliate organizations. The information burden is generally greater for national organizations with numerous affiliates.

| Paperwork requirement | Number of respondents | Frequency | Hours per response | Total annual hours |
|---|---|---|---|---|
| HUD–424 | 10 | 1 | 1 | 10 |
| HUD–424B | 10 | 1 | .5 | 5 |
| HUD–424CB | 10 | 1 | 10 | 10 |
| HUD–424 CBW | 10 | 1 | 30 | 300 |
| SF–LLL | 10 | 1 | .5 | 5 |
| HUD–2880 | 10 | 1 | .5 | 5 |
| HUD–2990 | 10 | 1 | 1.5 | 15 |
| HUD–2993 | 10 | 1 | .5 | 5 |
| HUD–2995 | 10 | 1 | .5 | 5 |
| HUD–96010 | 10 | 1 | 20 | 200 |
| HUD–96011 | 10 | 1 | .5 | 5 |
| Applicant Eligibility | 10 | 1 | 10 | 100 |
| SHOP Program Design and Scope of Work | 10 | 1 | 30 | 300 |
| Rating Factor 1 | 10 | 1 | 25 | 250 |
| Rating Factor 2 | 10 | 1 | 25 | 250 |
| Rating Factor 3 | 10 | 1 | 55 | 550 |
| Rating Factor 4 | 10 | 1 | 30 | 300 |
| Rating Factor 5 | 10 | 1 | 25 | 250 |
| Total Annual Hour Burden | ..... | ..... | 265.5 | 2,655 |

*Frequency of Submission:* Annually in response to the issuance of a SHOP NOFA.

*Status of the proposed information collection:* Extension of a currently approved collection.

**Authority:** Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35, as amended.

Dated: September 27, 2011.

**Clifford Taffet,**

*General Deputy Assistant Secretary for Community Planning and Development.*

[FR Doc. 2011–25410 Filed 9–30–11; 8:45 am]

**BILLING CODE 4210–67–P**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR 5481–N–16]**

## Notice of Proposed Information Collection: Comment Request; Annual Progress Reports for Empowerment Zones

**AGENCY:** Office of Community Planning and Development, 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:* December 2, 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: Colette Pollard, Departmental Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 4160, Washington, DC 20410; telephone: 202–708–0306, (this is not a toll-free number) or e-mail Ms. Pollard at *Colette.Pollard@Hud.Gov* for a copy of the proposed form and other available information.

**FOR FURTHER INFORMATION CONTACT:** Judith Mize, Office of Community Renewal, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; telephone (202) 402–4167 (this is not a toll-free number).

**SUPPLEMENTARY INFORMATION:** The Department will submit 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 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:* Annual Progress Reports for Empowerment Zones.

*OMB Control Number:* 2506–0148.

*Description of the need for the information and proposed use:* This is an information collection for reporting requirements of 30 Urban Empowerment Zones (EZs). HUD will regularly evaluate the progress of implementation of the strategic plan in each designated Empowerment Zone (Rounds I, II and III) as required by HUD's regulations (24 CFR 597.400 and 24 CFR 598.415). The information submitted will enable HUD to assess performance of designees and the effectiveness of the Empowerment Zone Initiative.

*Agency form numbers, if applicable:*

*Members of affected public:* State or local governments.

*Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response:*

| Paperwork requirement | Number of respondents | Frequency of response | Annual responses | Hours per response | Burden hours |
|---|---|---|---|---|---|
| Annual Reports: | | | | | |
| Round I EZs | 7 | 2 | 7 | 10 | 70 |
| Round II EZs | 15 | 15 | 15 | 10 | 150 |
| Round III EZs | 8 | 2 | 8 | 10 | 80 |
| Response to a letter of warning | 0 | 2 | ..... | 4 | 8 |
| Total | 30 | ..... | 30 | ..... | 308 |

*Frequency of submission:* Periodically and annually.

*Status of the proposed information collection:* Extension of a currently approved collection.

**Authority:** section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: September 22, 2011.

**Clifford Taffet,**

*General Deputy Assistant Secretary for Community Planning and Development.*

[FR Doc. 2011–25411 Filed 9–30–11; 8:45 am]

**BILLING CODE 4210–67–P**

## DEPARTMENT OF THE INTERIOR

### U.S. Geological Survey

### Scientific Earthquake Studies Advisory Committee

**AGENCY:** U.S. Geological Survey, Interior.

**ACTION:** Notice of meeting.

**SUMMARY:** Pursuant to Public Law 106–503, the Scientific Earthquake Studies Advisory Committee (SESAC) will hold its next meeting at the Incorporated Research Institutions for Seismology, 1200 New York Avenue, Suite 800, Washington, DC 20005. The Committee is comprised of members from academia, industry, and State government. The Committee shall advise the Director of the U.S. Geological Survey (USGS) on matters relating to the USGS's participation in the National Earthquake Hazards Reduction Program.

The Committee will receive updates and provide guidance on Earthquake Hazards Program activities and the status of teams supported by the Program.

Meetings of the Scientific Earthquake Studies Advisory Committee are open to the public.

**DATES:** November 2–3, 2011, commencing at 8:30 a.m. on the first day and adjourning at Noon on November 3, 2011.

Contact: Dr. William Leith, U.S. Geological Survey, MS 905, 12201 Sunrise Valley Drive, Reston, Virginia 20192, (703) 648–6786, *wleith@usgs.gov.*

Dated: September 21, 2011.

**David Applegate,**

*Associate Director for Natural Hazards.*

[FR Doc. 2011–25401 Filed 9–30–11; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[LLNV952000 L14200000.BJ0000 241A; 11–08807; MO#4500025674; TAS: 14X1109]**

### Filing of Plats of Survey; Nevada

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice.

**SUMMARY:** The purpose of this notice is to inform the public and interested state and local government officials of the filing of plats of survey in Nevada.

**DATES:** *Effective Dates:* Filing is effective at 10:00 a.m. on the dates indicated below.

**FOR FURTHER INFORMATION CONTACT:** David D. Morlan, Chief, Branch of Geographic Sciences, Bureau of Land Management (BLM), Nevada State Office, 1340 Financial Blvd., Reno, NV 89502, phone: 775–861–6541. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

**SUPPLEMENTARY INFORMATION:** 1. The plat of survey of the following described land will be officially filed at the BLM Nevada State Office in Reno on the first business day after 30 days from the publication of this notice:

This plat represents the survey of a portion of the sub-divisional lines of Township 12 North, Range 30 East, Mount Diablo Meridian, Nevada, under Group No. 898, and was accepted on September 1, 2011. This survey was executed to meet certain administrative needs of the Bureau of Indian Affairs and the BLM.

2. The plat of survey of the following described lands will be officially filed at the BLM Nevada State Office in Reno on the first business day after 30 days from the publication of this notice:

This plat represents the survey of a portion of the sub-divisional lines of Township 13 North, Range 31 East, Mount Diablo Meridian, Nevada, under Group No. 899, and was accepted on September 1, 2011. This survey was executed to meet certain administrative needs of the Bureau of Indian Affairs and the BLM.

Subject to valid existing rights, the provisions of existing withdrawals and classifications, the requirement of applicable laws, and other segregations of record, these lands are open to application, petition, and disposal, including application under the mineral leasing laws. All such valid applications received on or before the official filing of the plats of survey described above, shall be considered as simultaneously filed at that time. Applications received thereafter shall be considered in order of filing.

The above-listed surveys are now the basic record for describing the lands for all authorized purposes. These surveys have been placed in the open files at the BLM Nevada State Office and are available to the public as a matter of information. Copies of the surveys and related field notes may be furnished to the public upon payment of the appropriate fees.

Dated: September 16, 2011.

**David D. Morlan,**

*Chief Cadastral Surveyor, Nevada.*

[FR Doc. 2011–25362 Filed 9–30–11; 8:45 am]

**BILLING CODE 4310–HC–P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[LLOR957000–L63100000–HD0000: HAG11–0349]**

### Filing of Plats of Survey: Oregon/Washington

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice.

**SUMMARY:** The plats of survey of the following described lands are scheduled to be officially filed in the Bureau of Land Management Oregon/Washington State Office, Portland, Oregon, 30 days from the date of this publication.

**Willamette Meridian**

*Oregon*

T. 25 S., R. 8 W., accepted September 6, 2011
T. 30 S., R. 8 W., accepted September 6, 2011
T. 30 S., R. 7 W., accepted September 6, 2011
T. 17 S., R. 1 W., accepted September 7, 2011
T. 15 S., R. 2 W., accepted September 7, 2011
T. 13 S., R. 42 E., accepted September 7, 2011
T. 33 S., R. 3 W., accepted September 7, 2011
T. 27 S., R. 3 W., accepted September 7, 2011
T. 18 S., R. 1 W., accepted September 7, 2011

**ADDRESSES:** A copy of the plats may be obtained from the Land Office at the Bureau of Land Management, Oregon/Washington State Office, 333 S.W. 1st Avenue, Portland, Oregon 97204, upon required payment. A person or party who wishes to protest against a survey must file a notice that they wish to protest (at the above address) with the Oregon/Washington State Director, Bureau of Land Management, Portland, Oregon.

**FOR FURTHER INFORMATION CONTACT:** Kyle Hensley, (503) 808–6124, Branch of Geographic Sciences, Bureau of Land Management, 333 S.W. 1st Avenue, Portland, Oregon 97204. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

**SUPPLEMENTARY INFORMATION:** Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

**Fred O'Ferrall,**

*Chief, Branch of Land, Mineral, and Energy Resources.*

[FR Doc. 2011–25363 Filed 9–30–11; 8:45 am]

**BILLING CODE 4310–33–P**

## DEPARTMENT OF JUSTICE

**[OMB Number 1103–0098]**

### Agency Information Collection Activities: Revision of a Previously Approved Collection, With Change; Comments Requested COPS Application Package

**ACTION:** 60-Day Notice of Information Collection Under Review.

The Department of Justice (DOJ) Office of Community Oriented Policing Services (COPS), 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 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 December 2, 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 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 4,200 respondents annually will complete the form within 9.4 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 39 total annual burden hours associated with this collection.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street, NE., Room 2E–508, Washington, DC 20530.

**Jerri Murray,**

*Department Clearance Officer, PRA, U.S. Department of Justice.*

[FR Doc. 2011–25337 Filed 9–30–11; 8:45 am]

**BILLING CODE 4410–AT–P**

## DEPARTMENT OF LABOR

### Office of the Secretary

### Bureau of International Labor Affairs

### Notice of Publication of 2011 Update to The Department of Labor's List of Goods From Countries Produced by Child Labor or Forced Labor

**AGENCY:** Bureau of International Labor Affairs, Department of Labor.

**ACTION:** Announcement of public availability of updated list of goods.

**SUMMARY:** This notice announces the publication of an updated list of goods—along with countries of origin—that the Bureau of International Labor Affairs (ILAB) has reason to believe are produced by child labor or forced labor in violation of international standards. ILAB is required to develop and make available to the public the List pursuant to the Trafficking Victims Protection Reauthorization Act (TVPRA) of 2005.

**FOR FURTHER INFORMATION CONTACT:** Director, Office of Child Labor, Forced Labor, and Human Trafficking, Bureau of International Labor Affairs, U.S. Department of Labor at (202) 693–4843 (this is not a toll-free number).

**SUPPLEMENTARY INFORMATION:** The Bureau of International Labor Affairs announces the publication of a second update to the *List of Goods Produced by Child Labor or Forced Labor* (List), pursuant to the TVPRA of 2005. The TVPRA mandated that ILAB develop and publish a list of goods from countries that ILAB ''has reason to believe are produced with child labor or forced labor in violation of international standards.'' ILAB published the initial List on September 10, 2009, and published its first update on December 15, 2010. This update adds 2 new goods and 1 new country to the List and adds additional products from countries already on the list. With this update, the List has a total of 130 goods from 71 countries.

The primary purposes of the List are to raise public awareness about the incidence of child labor and forced labor in the production of goods in the countries listed and to promote efforts to eliminate such practices. A full report, including the updated List and a discussion of the List's context, scope, methodology, and limitations, as well as Frequently Asked Questions and a bibliography of sources, are available on the DOL Web site at: *http://www.dol.gov/ilab/programs/ocft/tvpra.htm.*

ILAB's Office of Child Labor, Forced Labor, and Human Trafficking (OCFT) carries out the mandates of section 105(b)(1) of the TVPRA, Public Law 109–164. For complete information on OCFT's TVPRA activities, please visit the Web site listed above.

Previous **Federal Register** notices issued on this subject include: *Notice of Proposed Procedural Guidelines for the Development and Maintenance of the List of Goods From Countries Pursuant to the Trafficking Victims Protection Reauthorization Act of 2005* (72 Fed. Reg. 55808, Oct. 1, 2007); *Notice of Procedural Guidelines for the Development and Maintenance of the List of Goods From Countries Produced by Child Labor or Forced Labor; Request for Information* (72 FR 73374, Dec. 27, 2007); *Notice of Public Hearing To Collect Information To Assist in the Development of the List of Goods From Countries Produced by Child Labor or Forced Labor* (73 FR 21985, Apr. 23, 2008); and *Notice of Publication of The Department of Labor's List of Goods From Countries Produced by Child Labor or Forced Labor* (74 FR 46620, Sept. 10, 2009).

Signed at Washington, DC, this 20th day of September, 2011.

**Carol Pier,**

*Associate Deputy Undersecretary for International Affairs.*

[FR Doc. 2011–24625 Filed 9–30–11; 8:45 am]

**BILLING CODE 4510–28–P**

## DEPARTMENT OF LABOR

### Employment and Training Administration

### Migrant and Seasonal Farmworkers (MSFWs) Monitoring Report and One-Stop Career Center Complaint/Referral Record: Comments

**AGENCY:** Employment and Training Administration, Labor.

**ACTION:** Notice.

**SUMMARY:** The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be

properly assessed. Currently, the Employment and Training Administration (ETA) is soliciting comments concerning the proposed extension of the expiration date without revision for ETA Form 5148, Services to Migrant and Seasonal Farm Workers Report, and an extension with revision for ETA Form 8429, One-Stop Career Center Complaint/Referral Record, to March 1, 2015. The changes incorporated to ETA Form 8429 include the following: (1) In Part I, of item 8, increased the space provided for description of complaint, (2) in Part II, of items 2 and 3, added the word ''Job Service,'' and (3) Part II, item 9 at the bottom added ''Complaint resolved? □ Yes □ No—If ''No,'' explain.''

The current Office of Management and Budget (OMB) Information Collection Request (ICR) authorization number 1205–0039 expires on February 29, 2012. A copy of the proposed ICR can be obtained by contacting the office listed below in the addressee section of this notice or by accessing: *http://www.doleta.gov/OMBCN/OMBControlNumber.cfm.*

**DATES:** Submit comments on or before December 2, 2011.

**ADDRESSES:** Send comments to: Kimberly Vitelli, U.S. Department of Labor, Employment and Training Administration, Office of Workforce Investment, 200 Constitution Avenue, NW., Room C–4510, Washington, DC 20210, *telephone number:* 202–693–3045, *fax:* 202–693–3015, and *e-mail address: vitelli.kimberly@dol.gov.*

**FOR FURTHER INFORMATION CONTACT:** Juan Regalado, U.S. Department of Labor, Employment and Training Administration, Office of Workforce Investment, Division of National Programs, Tools and Technical Assistance, Migrant and Seasonal Farmworkers Monitor Advocate, Room S–4209, 200 Constitution Avenue, NW., Washington, DC 20210, telephone number 202–693–2661, *fax:* 202–693–3945, and *e-mail address: regalado.juan@dol.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

Wagner-Peyser regulations at 20 CFR 651, 653, and 658 set forth requirements to ensure that Migrant and Seasonal Farmworkers (MSFWs) receive services that are qualitatively equivalent and quantitatively proportionate to the services provided to non-MSFWs. In compliance with 20 CFR 653.109, the Department of Labor established record keeping requirements to allow for the efficient and effective monitoring of State Workforce Agencies' (SWA) regulatory compliance. The ETA Form 5148, Services to Migrant and Seasonal Farmworkers Report, is used to collect data which are primarily used to monitor and measure the extent and effectiveness of SWA service delivery to MSFWs. The ETA Form 8429, One-Stop Career Center Complaint/Referral Record, is used to collect and document complaints filed by MSFWs and non-MSFWs pursuant to the regulatory framework established at 20 CFR 658.400.

## II. Desired Focus of Comments

Currently, ETA is soliciting comments concerning the proposed extension of the Services to Migrant and Seasonal Farm Workers Report, ETA Form 5148, and the One-Stop Career Center Complaint/Referral Record, ETA Form 8429 to March 1, 2015, which:

- 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 by including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

A copy of the proposed Information Collection Request (ICR) can be obtained by contacting the office listed above in the *addressee section* of this notice.

## III. Current Actions

*Type of Review:* Extension with revision of a currently approved collection.

*Agency:* Employment and Training Administration.

*Title:* Migrant and Seasonal Farmworker (MSFW) Monitoring Report and One-Stop Career Center Complaint/Referral Record.

*OMB Number:* 1205–0039.

*Affected Public:* State.

*Type of Response:* Mandatory.

*Number of Respondents:* (See Below).

*Annual Responses:* (See Below).

*Breakdown of Burden Hours:* (See Below).

*Complaint Form 8429*

1. Recordkeeping

*Number of record keepers:* 50 states.

*Annual number of records:* 3,000 (60 reports per state, 50 states × ports).

*Annual hours per record keeper:* .13 (8 minutes per report).

*Total record-keeper hours:* 400 (3,000 reports × 8 min. per report).

2. Processing

*Annual average number of forms:* 3,000.

*Minutes per form:* 120 (2 hrs.).

*Total processing hours:* 6,000 (3,000 reports at 2 hours each).

*Estimated Total Burden Hours for ETA 8429:* 6,400 − (400 + 6,000).

*Comments:* Not all complaints that are logged utilize the Employment Service Complaint/Referral Record, ETA Form 8429. The SWA's are only required to utilize this form for MSFW complaints and ES related complaints from non-MSFWs. Based upon contacts with those states with the highest level of reported complaint activity, we believe that approximately 3,000 complaints were captured on the ETA Forms 8429 in the previous program year.

*5148 Report*

1. Recordkeeping

*Number of record-keepers:* 50 states.

*Annual number of records:* 200 (record keepers = 50 × reports = 4 = 200).

*Estimated hours per record-keeper:* 1.16 (70 minutes per report).

*Total Record-keeping hours:* 233.3.

2. Compilation and Reporting

*Number of Respondents:* 50.

*Annual number of reports:* 4.

*Total number of reports:* 200.

*Estimated minutes per report:* 90 (1.5 hrs.).

*Total Record-keeping hours:* 300 (200 reports × 90 minutes = 18,000/60).

*Estimated Total Burden Hours for ETA 5148:* 533 (233 + 300).

*Estimated Total Burden Cost:* $172,211:

| | Total annual hours | One FTE | FTE | Annual salary | Total burden cost |
|---|---|---|---|---|---|
| SMA—5148 | 533 | 1,920 | 0.28 | $65,000 | $18,044 |

| | Total annual hours | One FTE | FTE | Annual salary | Total burden cost |
|---|---|---|---|---|---|
| Local OSC—8429 | 6,000 | 1,920 | 3.13 | 45,000 | 140,625 |
| SMA—8429 | 400 | 1,920 | 0.21 | 65,000 | 13,542 |
| Total Burden Cost for 8429 & 5148 | | | | | 172,211 |

A local One-Stop Center Record Keeper average annual salary is $45,000 and for the State Monitor Advocate (SMA) is $65,000 for Record Keeping, Processing, Compilation and Reporting on ETA 8429 and ETA 5148 respectively.

| Hours per day | Working days | Monthly hours | Months in year | Hours per year |
|---|---|---|---|---|
| 8 | 20 | 160 | 12 | 1,920 |

*Comments:* The calculations are based on a normal work week for most jobs are 8 hours a day for 5 days.

There are 52 weeks in a year but most workers get a two week vacation. So, 8 × 5 × 50 = 2000 hours worked in a year.

Many companies also give 10 holidays, which brings it down to: 8 × 5 × 48 = 1920.

Also the calculations are based on the average median salary of one local one-stop center record keeper's of $45,000 per year and the average median salary of a State Monitor Advocate of $65,000 per year, and the estimated hours expended in record keeping and processing on ETA Form 8429 and ETA Form 5148 respectively, providing the grand total of burden cost reflected above.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: Washington, DC, this 21st day of September, 2011.

**Jane Oates,**

*Assistant Secretary, Employment and Training Administration.*

[FR Doc. 2011–25388 Filed 9–30–11; 8:45 am]

**BILLING CODE 4510–FN–P**

## NATIONAL SCIENCE FOUNDATION

### Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978 (Pub. L. 95–541)

**AGENCY:** National Science Foundation.

**ACTION:** Notice of Permit Applications Received under the Antarctic Conservation Act of 1978, Public Law 95–541.

**SUMMARY:** The National Science Foundation (NSF) is required to publish a notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act at Title 45 part 670 of the Code of Federal Regulations. This is the required notice of permit applications received.

**DATES:** Interested parties are invited to submit written data, comments, or views with respect to this permit application by November 2, 2011. This application may be inspected by interested parties at the Permit Office, address below.

**ADDRESSES:** Comments should be addressed to Permit Office, Room 755, Office of Polar Programs, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230.

**FOR FURTHER INFORMATION CONTACT:** Polly A. Penhale at the above address or (703) 292–7420.

**SUPPLEMENTARY INFORMATION:** The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas as requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

The applications received are as follows:

**Permit Application: 2012–010**

1. *Applicant:* Mahlon C. Kennicutt, II, Professor of Oceanography, Department of Oceanography, Eller Oceanography & Meteorology Bldg., Rm. 608, 3146 TAMU, College Station, TX 77843–3146.

**Activity for Which Permit Is Requested**

Enter Antarctic Specially Protected Areas. The applicant plans to enter the Antarctic Specially Protect Areas of Hut Point, Ross Island (ASPA 158), Arrival Heights, Ross Island (ASPA 122), Backdoor Bay, Cape Royds (ASPA 157), and New College Valley, Cape Bird (ASPA 116). These sites are specifically targeted because of the nature of their geology, climatic influences and topography. Backdoor Bay (ASPA 157) and New College Valley (ASPA 116) are two sampling sites used as reference controls for the study of the temporal and spatial scales of various types of disturbances in and around McMurdo Station. The sampling locations at Backdoor Bay and New College Valley will be situated to avoid disturbance to biota in the area. The other sites, Arrival Heights (ASPA 122) and Hut Point (ASPA 158 have been sampled in previous field seasons and are slated to be sampled as part of the ongoing environmental monitoring program.

**Location**

Hut Point, Ross Island (ASPA 158), Arrival Heights, Ross Island (ASPA 122), Backdoor Bay, Cape Royds (ASPA 157), and New College Valley, Cape Bird (ASPA 116).

**Dates**

November 11, 2011 to December 31, 2011.

**Nadene G. Kennedy,**

*Permit Officer, Office of Polar Programs.*

[FR Doc. 2011–25320 Filed 9–30–11; 8:45 am]

**BILLING CODE 7555–01–P**

## NATIONAL SCIENCE FOUNDATION

### Advisory Committee for Computer and Information Science and Engineering; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

*Name:* Advisory Committee for Computer and Information Science and Engineering (1115).

*Date and Time:* November 1, 2011 from 12 p.m.–5:30 p.m. November 2, 2011 from 8 a.m.–12 p.m.

*Place:* National Science Foundation, 4201 Wilson Blvd., Room 1235, Arlington, VA.

*Type of Meeting:* Open.

*Contact Person:* Carmen Whitson, Directorate for Computer and Information Science and Engineering, National Science Foundation, 4201 Wilson Blvd., Suite 1105, Arlington, VA 22230. *Telephone:* (703) 292–8900.

*Minutes:* May be obtained from the contact person listed above.

*Purpose of Meeting:* To advise NSF on the impact of its policies, programs and activities on the CISE community. To provide advice to the Assistant Director for CISE on issues related to long-range planning, and to form ad hoc subcommittees to carry out needed studies and tasks.

Dated: September 28, 2011.

**Susanne Bolton,**

*Committee Management Officer.*

[FR Doc. 2011–25355 Filed 9–30–11; 8:45 am]

**BILLING CODE 7555–01–P**

## NUCLEAR REGULATORY COMMISSION

### Advisory Committee on Reactor Safeguards (ACRS)

### Meeting of the ACRS Subcommittee on Advanced Boiling Water Reactor; Notice of Meeting

The ACRS Subcommittee on Advanced Boiling Water Reactor (ABWR) will hold a meeting on October 4, 2011, Room T–2B1, 11545 Rockville Pike, Rockville, MD.

The entire meeting will be open to public attendance, with the exception of a portion that may be closed to protect information that is proprietary pursuant to 5 U.S.C. 552b(c)(4).

The agenda for the subject meeting shall be as follows:

*Tuesday, October 4, 2011—8:30 a.m. until 2 p.m.*

The Subcommittee will review proposed resolution of ACRS Action Items related to long term cooling and other issues associated with the Combined License Application (COLA) for the South Texas Project (STP) Units 3 and 4. The Subcommittee will hear presentations by and hold discussions with the NRC staff, South Texas Project Nuclear Operating Company (STPNOC), and other interested persons. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Maitri Banerjee (Telephone 301–415–6973 or E-mail: *Maitri.Banerjee@nrc.gov)* five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be e-mailed to the DFO one day before meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 21, 2010, (75 FR 65038–65039).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, MD. After registering with security, please contact Mr. Theron Brown (240–888–9835) to be escorted to the meeting room.

Dated: September 27, 2011.

**Yoira Diaz-Sanabria,**

*Technical Assistant, Technical Support Branch, Advisory Committee on Reactor Safeguards.*

[FR Doc. 2011–25384 Filed 9–30–11; 8:45 am]

**BILLING CODE 7590–01–P**

## NUCLEAR REGULATORY COMMISSION

### Advisory Committee on Reactor Safeguards; Revised Meeting Notice

The Agenda for the 587th ACRS meeting, scheduled to be held on October 6–8, 2011, has been revised as noted below. Notice of this meeting was previously published in the **Federal Register** on September 26, 2011 (76 FR 59449–59450).

The discussion on the Development of Draft Fire Human Reliability Analysis (HRA) Guidelines—NUREG–1921 scheduled to be held on Friday, October 7, 2011 between 10:15 a.m. and 11:45 a.m. is being postponed to a future meeting. The Preparation of ACRS Reports will now start at 10:15 a.m. on Friday, October 7, 2011.

A revised agenda is posted on the NRC Web site at *http://www.nrc.gov/reading-rm/adams.html* or *http://www.nrc.gov/reading-rm/doc-collections/ACRS/.*

Further information regarding this meeting can be obtained by contacting Ms. Ilka Berrios of the ACRS staff (Telephone: 301–415–3179, E-mail: *Ilka.Berrio@nrc.gov*).

Dated: September 27, 2011.

**Andrew L. Bates,**

*Advisory Committee Management Officer.*

[FR Doc. 2011–25387 Filed 9–30–11; 8:45 am]

**BILLING CODE 7590–01–P**

## NUCLEAR REGULATORY COMMISSION

### Advisory Committee on Reactor Safeguards (ACRS) Meeting of the ACRS Subcommittee on Plant Operations and Fire Protection; Notice of Meeting

The ACRS Subcommittee on Plant Operations and Fire Protection will hold a meeting on October 5, 2011, Room T–2B3, 11545 Rockville Pike, Rockville, MD.

The entire meeting will be open to public attendance, with the exception of a portion that may be closed to protect information that is proprietary pursuant to 5 U.S.C. 552b(c)(4).

The agenda for the subject meeting shall be as follows:

*Wednesday, October 5, 2011—8:30 a.m. thru 5 p.m.*

The Subcommittee will review the supplemental Safety Evaluation Reports (SERs) associated with the staff's review of the Watts Bar Unit 2 Operating License application. The Subcommittee will hear presentations by and hold discussions the NRC staff and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Girija Shukla (Telephone 301–415–6855 or e-mail: *Girija.Shukla@nrc.gov* five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 21, 2010, (75 FR 65038–65039).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs*. Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the website cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, MD. After registering with security, please contact Mr. Theron Brown (240–888–9835) to be escorted to the meeting room.

Dated: 09/27/2011.

**Yoira Diaz-Sanabria,**

*Technical Assistant, Reactor Safety Branch, Advisory Committee on Reactor Safeguards.*

[FR Doc. 2011–25392 Filed 9–30–11; 8:45 am]

**BILLING CODE 7590–01–P**

## NUCLEAR REGULATORY COMMISSION

### Advisory Committee on Reactor Safeguards (ACRS) Meeting of the ACRS Subcommittee on Planning and Procedures; Notice of Meeting

The ACRS Subcommittee on Planning and Procedures will hold a meeting on October 5, 2011, Room T–2B3, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance, with the exception of a portion that may be closed pursuant to 5 U.S.C. 552b (c)(2) and (6) to discuss organizational and personnel matters that relate solely to the internal personnel rules and practices of the ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.

The agenda for the subject meeting shall be as follows:

*Wednesday, October 5, 2011—12 p.m. until 1 p.m.*

The Subcommittee will discuss proposed ACRS activities and related matters. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee. Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Mrs. Ilka Berrios (Telephone 301–415–3179 or E-mail: *Ilka.Berrios@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 21, 2010, (75 FR 65038–65039).

Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the website cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, MD. After registering with security, please contact Mr. Theron Brown (240–888–9835) to be escorted to the meeting room.

Dated: *09/27/2011.*

**Yoira Diaz-Sanabria,**

*Technical Assistant, Reactor Safety Branch, Advisory Committee on Reactor Safeguards.*

[FR Doc. 2011–25390 Filed 9–30–11; 8:45 am]

**BILLING CODE 7590–01–P**

## NUCLEAR REGULATORY COMMISSION

### Advisory Committee on Reactor Safeguards (ACRS) Meeting of the ACRS Subcommittee on Radiation Protection and Nuclear Materials; Notice of Meeting

The ACRS Subcommittee on Radiation Protection and Nuclear Materials will hold a meeting on October 4, 2011, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

*Tuesday, October 4, 2011—2 p.m. until 4:30 p.m.*

The Subcommittee will review the revised Branch Technical Position on Concentration Averaging and Encapsulation regarding the circumstances under which large scale blending of low-level radioactive waste, as described in SECY–10–0043, is acceptable. The Subcommittee will hear presentations by and hold discussions with the NRC staff and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated

Federal Official (DFO), Derek Widmayer (Telephone 301–415–7366 or E-mail: *Derek.Widmayer@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 21, 2010, (75 FR 65038–65039).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the website cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, MD. After registering with security, please contact Mr. Theron Brown (240–888–9835) to be escorted to the meeting room.

Dated: September 21, 2011.

**Yoira Diaz-Sanabria,**

*Technical Assistant, Technical Support Branch, Advisory Committee on Reactor Safeguards.*

[FR Doc. 2011–25386 Filed 9–30–11; 8:45 am]

**BILLING CODE 7590–01–P**

## POSTAL SERVICE

### Notice of Intent To Prepare a Programmatic Environmental Assessment for Proposed Network Optimization, Nationwide; Notice of Public Scoping Period

**AGENCY:** Postal Service.

**ACTION:** Notice of intent to prepare a Programmatic Environmental Assessment; Notice of Public Scoping Period.

**SUMMARY:** To comply with the requirements of the National Environmental Policy Act (NEPA), the Postal Service intends to prepare a Programmatic Environmental Assessment (PEA) to assess the Network Optimization initiative (the ''Proposed Action''), which would create a more streamlined processing and distribution network using fewer facilities to handle reduced mail volume. The proposal also includes revisions to mailing standards. This PEA will evaluate the environmental impacts of the proposed action versus taking no action. Public input is sought on the scope of environmental issues to be addressed in the PEA.

**DATES:** Written scoping comments must be submitted by October 30, 2011. It is estimated that the Programmatic Environmental Assessment will be completed by January 20, 2012.

**ADDRESSES:** Interested parties may submit written scoping comments or direct questions or requests for additional information to: Thomas G. Day, Chief Sustainability Officer, United States Postal Service, 475 L'Enfant Plaza, SW., Room 2737, Washington DC, 20260; (202) 268–7488.

**SUPPLEMENTARY INFORMATION:**

*Purpose.* This notice concerns the Network Optimization initiative and the intent of the Postal Service, pursuant to the requirements of the National Environmental Policy Act (NEPA) of 1969, its implementing procedures at 39 CFR 775, and the President's Council on Environmental Quality Regulations (40 CFR Parts 1500–1508), to prepare a Programmatic Environmental Assessment to evaluate the environmental impacts of the proposed action versus taking ''no action.''

*Proposed Action.* The Postal Service is exploring options to accelerate ongoing network optimization efforts. The recently announced Network Optimization initiative (herein referred to as the ''Proposed Action'') seeks to create a more streamlined processing and distribution network, using fewer facilities to handle the reduced mail volume. This initiative also includes proposals to revise mailing standards to better reflect the capacity of a new, smaller network and may result in numerous mail processing facility closures and network consolidations. The Proposed Action will be addressed programmatically under the National Environmental Policy Act (NEPA).

The proposal under consideration includes studying nearly 250 processing facilities for possible consolidation or closure, reducing mail processing equipment by as much as 50 percent, dramatically decreasing the nationwide transportation network, adjusting the workforce size by as many as 35,000 positions, and revising service standards for mail services, including First-Class Mail from 1–3 days to 2–3 days.

Alternatives that will be evaluated by the Postal Service in the PEA include the above-described Proposed Action and a ''No Action'' alternative. Under the ''No Action'' alternative, the Postal Service would maintain its current processing and distribution network and service standards. The Postal Service may consider other reasonable alternatives identified during the public scoping process.

Additional information about the Network Optimization initiative, including a list of the facilities being studied for closure and consolidation, is located at the following URL: *http://about.usps.com/news/electronic-press-kits/our-future-network/welcome.htm.*

Hard copies of this information are available upon request.

**Stanley F. Mires,**

*Attorney, Legal Policy & Legislative Advice.*

[FR Doc. 2011–25331 Filed 9–30–11; 8:45 am]

**BILLING CODE 7710–12–P**

## SECURITIES AND EXCHANGE COMMISSION

### Submission for OMB Review; Comment Request

*Upon Written Request, Copies Available From:* Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

*Extension*:

Rule 10A–1; SEC File No. 270–425; OMB Control No. 3235–0468.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for extension of the previously approved collection of information discussed below.

Rule 10A–1 (17 CFR 240.10A–1) implements the reporting requirements in Section 10A of the Exchange Act (15 U.S.C. 78j–1), which was enacted by Congress on December 22, 1995 as part of the Private Securities Litigation Reform Act of 1995, Public Law 104–67, 109 Stat 737. Under section 10A and

Rule 10A–1 reporting occurs only if a registrant's board of directors receives a report from its auditor that (1) There is an illegal act material to the registrant's financial statements, (2) senior management and the board have not taken timely and appropriate remedial action, and (3) the failure to take such action is reasonably expected to warrant the auditor's modification of the audit report or resignation from the audit engagement. The board of directors must notify the Commission within one business day of receiving such a report. If the board fails to provide that notice, then the auditor, within the next business day, must provide the Commission with a copy of the report that it gave to the board.

Likely respondents are those registrants filing audited financial statements under the Securities Exchange Act of 1934 (15 U.S.C. 78a, *et seq.*) and the Investment Company Act of 1940 (15 U.S.C. 80a–1, *et seq.*).

It is estimated that Rule 10A–1 results in an aggregate additional reporting burden of 10 hours per year. The estimated average burden hours are solely for purposes of the Paperwork Reduction Act and are not derived from a comprehensive or even a representative survey or study of the costs of SEC rules or forms.

There are no recordkeeping retention periods in Rule 10A–1. Because of the one business day reporting periods, recordkeeping retention periods should not be significant.

Filing the notice or report under Rule 10A–1 is mandatory once the conditions noted above have been satisfied. Because these notices and reports discuss potential illegal acts, they are considered to be investigative records and are kept confidential.

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 public may view the information discussed in this notice at *http://www.reginfo.gov*. Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an e-mail to: *Shagufta_Ahmed@omb.eop.gov*; and (ii) Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, VA 22312 or send an e-mail to: *PRA_Mailbox@sec.gov*. Comments must be submitted to OMB within 30 days of this notice.

Dated: September 26, 2011.

**Elizabeth M. Murphy,**

*Secretary.*

[FR Doc. 2011–25368 Filed 9–30–11; 8:45 am]

**BILLING CODE 8011–01–P**

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–65410; File No. 4–631]**

## Joint Industry Plan; Notice of Designation of a Longer Period for Commission Action on the National Market System Plan To Address Extraordinary Market Volatility by BATS Exchange, Inc., BATS Y–Exchange, Inc., Chicago Board Options Exchange, Incorporated, Chicago Stock Exchange, Inc., EDGA Exchange, Inc., EDGX Exchange, Inc., Financial Industry Regulatory Authority, Inc., NASDAQ OMX BX, Inc., NASDAQ OMX PHLX LLC, The Nasdaq Stock Market LLC, National Stock Exchange, Inc., New York Stock Exchange LLC, NYSE Amex LLC, and NYSE Arca, Inc.

September 27, 2011.

On April 5, 2011, NYSE Euronext, on behalf of New York Stock Exchange LLC (''NYSE''), NYSE Amex LLC (''NYSE Amex''), and NYSE Arca, Inc. (''NYSE Arca''), and the following parties to the proposed National Market System Plan: BATS Exchange, Inc., BATS Y–Exchange, Inc., Chicago Board Options Exchange, Incorporated, Chicago Stock Exchange, Inc., EDGA Exchange, Inc., EDGX Exchange, Inc., Financial Industry Regulatory Authority, Inc., NASDAQ OMX BX, Inc., NASDAQ OMX PHLX LLC, the Nasdaq Stock Market LLC, and National Stock Exchange, Inc. (collectively with NYSE, NYSE Amex, and NYSE Arca, the ''Participants''), filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 11A of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 608 of Regulation NMS (''Rule 608'') thereunder,[2] a proposed Plan to Address Extraordinary Market Volatility (''Plan'').[3] The proposed Plan was published for comment in the **Federal Register** on June 1, 2011.[4] The Commission received 18 comments on the proposed Plan.[5]

Rule 608[6] under Section 11A of the Act[7] provides that within 120 days of the date of publication of notice of filing of a national market system plan or an amendment to an effective national market system plan, or within such longer period as the Commission may designate up to 180 days of such date if it finds such longer period to be appropriate and publishes its reasons

[1] 15 U.S.C. 78k–1.

[2] 17 CFR 242.608.

[3] *See* Letter from Janet M. McGinness, Senior Vice President, Legal and Corporate Secretary, NYSE Euronext, to Elizabeth M. Murphy, Secretary, Commission, dated April 5, 2011.

[4] *See* Securities Exchange Act Release No. 64547 (May 25, 2011), 76 FR 31647.

[5] *See* Letter from Steve Wunsch, Wunsch Auction Associates, LLC, to Elizabeth M. Murphy, Secretary, Commission, dated June 2, 2011; Letter from Peter J. Driscoll, Investment Professional, Chicago, IL, to Elizabeth M. Murphy, Secretary, Commission, dated June 17, 2011; Letter from Stuart J. Kaswell, Executive Vice President & Managing Director, General Counsel, Managed Funds Association, to Elizabeth M. Murphy, Secretary, Commission, dated June 21, 2011; Letter from George U. Sauter, Managing Director and Chief Investment Officer, The Vanguard Group, Inc., to Elizabeth M. Murphy, Secretary, Commission, dated June 22, 2011; Letter from Karrie McMillan, General Counsel, Investment Company Institute, to Elizabeth M. Murphy, Secretary, Commission, dated June 22, 2011; Letter from Manisha Kimmel, Executive Director, Financial Information Forum, to Elizabeth M. Murphy, Secretary, Commission, dated June 22, 2011; Letter from Craig S. Donohue, Chief Executive Officer, CME Group Inc., to Elizabeth M. Murphy, Secretary, Commission, dated June 22, 2011; Letter from Joseph N. Cangemi, Chairman, and Jim Toes, President and Chief Executive Officer, Security Traders Association, to Elizabeth M. Murphy, Secretary, Commission, dated June 22, 2011; Letter from Leonard J. Amoruso, General Counsel, Knight Capital Group, Inc., to Elizabeth M. Murphy, Secretary, Commission, dated June 22, 2011; Letter from Ann L. Vlcek, Managing Director and Associate General Counsel, Securities Industry and Financial Markets Association, to Elizabeth M. Murphy, Secretary, Commission, dated June 22, 2011; Letter from Jamie Selway, Managing Director, and Patrick Chi, Chief Compliance Officer, ITG Inc., to Elizabeth M. Murphy, Secretary, Commission, dated June 23, 2011; Letter from Jose Marques, Managing Director and Global Head of Electronic Equity Trading, Deutsche Bank Securities Inc., to Elizabeth M. Murphy, Secretary, Commission, dated June 23, 2011; Letter from Kimberly Unger, Esq., Executive Director, The Security Traders Association of New York, Inc., to Elizabeth M. Murphy, Secretary, Commission, dated June 23, 2011; Letter from James J. Angel, PhD, CFA, Associate Professor of Finance, Georgetown University, McDonough School of Business, to Commission, dated June 24, 2011; Letter from John A. McCarthy, General Counsel, GETCO, to Elizabeth M. Murphy, Secretary, Commission, dated June 24, 2011; Letter from Andrew C. Small, Executive Director and General Counsel, Scottrade, Inc., to Elizabeth M. Murphy, Secretary, Commission, dated July 5, 2011; Letter from Peter Skopp, President, Molinete Trading Inc., to Elizabeth M. Murphy, Secretary, Commission, dated July 19, 2011; and Letter from Sal Arnuk, Joe Saluzzi, and Paul Zajac, Themis Trading, LLC, to Elizabeth M. Murphy, Secretary, Commission. Copies of all comments received on the proposed Plan are available on the Commission's Web site, located at *http://www.sec.gov/comments/4–631/4–631.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 ET.

[6] 17 CFR 242.608.

[7] 15 U.S.C. 78k–1.

for so finding or as to which the sponsors consent, the Commission shall approve such plan or amendment, with such changes or subject to such conditions as the Commission may deem necessary or appropriate, if it finds that such plan or amendment is necessary or appropriate in the public interest, for the protection of investors and the maintenance of fair and orderly markets, to remove impediments to, and perfect the mechanisms of, a national market system, or otherwise in furtherance of the purposes of the Act. The 120th day for this notice of filing of a national market system plan is September 29, 2011.

The Commission is hereby extending the 120-day time period for Commission action on the proposed rule change. The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change. In particular, the extension of time will ensure that the Commission has sufficient time to consider and take action on the Participants' proposal, in light of, among other things, the comments received on the proposal.

Accordingly, pursuant to Section 11A of the Act [8] and Rule 608 thereunder,[9] the Commission designates November 28, 2011 as the date by which the Commission shall approve the proposed Plan (File Number 4–631), with such changes or subject to such conditions as the Commission may deem necessary or appropriate, if it finds that such plan or amendment is necessary or appropriate in the public interest, for the protection of investors and the maintenance of fair and orderly markets, to remove impediments to, and perfect the mechanisms of, a national market system, or otherwise in furtherance of the purposes of the Act.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

**Elizabeth M. Murphy,**

*Secretary.*

[FR Doc. 2011–25353 Filed 9–30–11; 8:45 am]

**BILLING CODE 8011–01–P**

[8] *Id.*

[9] 17 CFR 242.608.

[10] 17 CFR 200.30–3(a)(42).

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–65405; File No. SR–NASDAQ–2011–105]**

## Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Order Approving Proposed Rule Change To Establish an Acceptable Trade Range for Quotes and Orders Entered on The NASDAQ Options Market

September 27, 2011.

### I. Introduction

On August 2, 2011, The NASDAQ Stock Market LLC (''NASDAQ'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b-4 thereunder,[2] a proposed rule change to establish an Acceptable Trade Range (''ATR'') for quotes and orders entered on The NASDAQ Options Market (''NOM''). The proposed rule change was published for comment in the **Federal Register** on August 18, 2011.[3] The Commission received no comment letters regarding the proposal. This order approves the proposed rule change.

### II. Description of the Proposal

The Exchange proposes to establish an ATR for quotes and orders entered on NOM, which is intended to create a level of protection on NOM that prevents the market from moving beyond set thresholds. These thresholds would consist of a reference price plus or minus set dollar amounts based on the nature and premium of the option. This mechanism is intended to prevent the NOM trading system from experiencing dramatic price swings, which can exist if, for example, a market order or aggressively-priced limit order is entered that is larger than the total volume of contracts quoted at the top-of-book across all U.S. options exchanges.[4] The Exchange believes that, without the ATR, options could execute at prices that have little or no relation to the theoretical price of the option, resulting in potential harm to investors.[5]

#### *A. ATR Operation*

Prior to executing orders received by NOM, an ATR would be calculated to determine the range of prices at which orders may be executed. When an order is initially received, the range would be calculated by adding (for buy orders) or subtracting (for sell orders) a value to the National Best Offer (''NBO'') (for buy orders) or the National Best Bid (''NBB'') (for sell orders) to determine the range of prices that would be valid for execution. A buy (sell) order would be allowed to execute up (down) to and including the maximum (minimum) price within the ATR (''Threshold Price''). If an order could not be executed completely within the ATR, the unexecuted portion of the original order would be posted at the Threshold Price for a brief period, not to exceed one second (''Posting Period''), to allow the market to refresh and determine whether or not more liquidity becomes available on NOM (or any other exchange if the order is designated as routable) within the posted price of the order before moving on to a new Threshold Price. The Threshold Price, at which the order is posted, would then become the new reference price,[6] and a new ATR would be calculated.

Once the Posting Period has expired, if the order has not been fully executed, it would be allowed to execute up to and including the Threshold Price of the new ATR. During the Posting Period, NOM would display the ATR Threshold Price on one side of the market and the best available price on the opposite side of the market using a ''non-firm'' indicator. The order setting the ATR retains price/time priority in the NOM book.[7] The Exchange notes that, if NOM were to display trading interest available on the opposite side of the market, that trading interest would be automatically accessible to later-entered orders during the period when the order triggering the ATR is paused.[8] Following the Posting Period, the Exchange would return to a normal trading state and disseminate its best bid and offer.

The ATR will be neutral with respect to away markets in that NOM will route orders to other destinations to access liquidity priced within the ATR, provided the order is designated as routable.[9] If an order remains unexecuted, the process would repeat until it is executed, cancelled, or posted at its limit price. If an order is routed

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 65125 (August 12, 2011), 76 FR 51453 (August 18, 2011) (''Notice'').

[4] *Id.*

[5] The Exchange provides an example of such executions in the Notice. *Id.*

[6] If a new NBB is received that is greater than a buy order posted at the Threshold Price, or a new NBO is received that is lower than a sell order posted at the Threshold Price, the new NBB (for buy orders) or NBO (for sell orders) would become the new reference price.

[7] *See* Notice, *supra* note 3, 76 FR at 51454.

[8] *Id.*

[9] *Id.*

to the full size of an away exchange and additional size remains available on NOM, the remaining contracts would be posted on NOM at a price that assumes the away market has executed the routed order. The Exchange believes this practice of routing and then posting would be consistent with the national market system plan governing trading and routing of options orders and the NOM policies and procedures that implement that plan.[10]

*B. Setting ATR Values*

The Exchange represents that the options class premium would be the dominant factor in determining the ATR.[11] The Exchange further represents that options with lower premiums tend to be more liquid and have tighter bid/ask spreads, while options with higher premiums have wider spreads and less liquidity.[12] Accordingly, the Exchange proposes to use a table consisting of several steps based on the premium of the option to determine how far the market for a given option would be allowed to move. The table(s) would be listed on the NASDAQTrader.com website, and any periodic updates to the table(s) would be announced via an Options Trader Alert (''OTA'').[13] The Exchange does not anticipate updating the table(s) frequently or intraday.[14] The Exchange will provide sufficient advanced notice of changes to the ATR table(s) to its membership via OTAs.[15]

Other market conditions, such as extreme volatility or historically low liquidity, would also be considered when determining the ATR. The Exchange believes these different market conditions could present the need to adjust the ATRs from time to time to ensure a well-functioning market.[16] Without adjustments, the Exchange believes the market could become too constrained or, conversely, prone to wide price swings.[17]

The Exchange represents that the ATR would be generally the same across all options traded on NOM, but it proposes to maintain flexibility to set them separately based on characteristics of the underlying security.[18] Initially, the Exchange expects to set ATRs for three categories of options: Standard Penny Pilot, Special Penny Pilot (*e.g.,* IWM, QQQQ, SPY), and Non-Penny Pilot.[19]

## III. Discussion

After careful review of the proposal, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[20] In particular, the Commission finds that the proposal is consistent with Section 6(b)(5) of the Act,[21] which requires, among other things, that the rules of an exchange be designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission also finds that the proposed rule change is consistent with the provisions of Section 6(b)(8) of the Act,[22] which requires that the rules of an exchange not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

The ATR is intended to reduce the negative impacts of sudden, unanticipated volatility in individual NOM options, assist in preserving an orderly market in a transparent and uniform manner, enhance the price-discovery process, increase overall market confidence, and promote fair and orderly markets and the protection of investors.[23] The Commission notes that the ATR will be neutral with respect to away markets in that NOM will route orders to other destinations to access liquidity priced within the ATR, provided the order is designated as routable.[24] The Commission believes that the ATR functionality should result in greater continuity in prices as it is designed to prevent immediate or rapid executions at far away prices; thereby protecting investors and the public interest.

The Exchange believes that disseminating a non-firm quotation message during the Posting Period would be consistent with its obligations under the Quote Rule.[25] Specifically, the Exchange believes that volatility strong enough to trigger the ATR on NOM qualifies as an unusual market condition.[26] The Exchange expects such situations to be rare, and the Exchange will set the parameters of the ATR at levels that would ensure that it is triggered infrequently.[27] The Commission believes that the Exchange's dissemination of a non-firm quotation on the opposite side of the market from the Threshold Price of the paused order during the Posting Period is consistent with the Quote Rule's provisions regarding non-firm quotations.[28]

## IV. Conclusion

*It Is Therefore Ordered,* pursuant to Section 19(b)(2) of the Act,[29] that the proposed rule change (SR–NASDAQ–2011–105) be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[30]

**Elizabeth M. Murphy,**

*Secretary.*

[FR Doc. 2011–25351 Filed 9–30–11; 8:45 am]

**BILLING CODE 8011–01–P**

[10] *See* Notice, *supra* note 3, 76 FR at 51455, n.9 and accompanying text. The Exchange provides examples of this process in the Notice. *Id.* at 51455–56.

[11] *Id.* at 51456.

[12] *Id.*

[13] The value added to or subtracted from the reference price would be set by the Exchange and posted on the Exchange Web site: *http://www.nasdasqtrader.com.*

[14] *See* Notice, *supra* note 3, 76 FR at 51455.

[15] *Id.*

[16] *Id.*

[17] *Id.*

[18] The Exchange provides examples of options that could require this flexibility because of the underlying securities. *Id.* The Exchange notes that the Acceptable Range Test in place at NASDAQ OMX PHLX LLC (''Phlx'') currently provides for this flexibility. *See* Phlx Rule 1082(a)(ii)(B)(3)(f).

[19] *See* Notice, *supra* note 3, 76 FR at 51456.

[20] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[21] 15 U.S.C. 78f(b)(5).

[22] 15 U.S.C. 78f(b)(8).

[23] *See* Notice, *supra* note 3, 76 FR at 51456.

[24] *See id.* at 51454.

[25] *Id.*

[26] *Id.*

[27] *Id.* The ATR will cause the market to pause for no more than one second, which the Exchange notes is a briefer pause than occurs in other markets that experience and attempt to dampen volatility. For example, the Posting Period would be briefer than the pause triggered by the Liquidity Replenishment Point (''LRP'') employed by the New York Stock Exchange LLC (''NYSE''). *See* NYSE Rules 1000(a)(iv) and 60(d).

[28] *See* 17 CFR 242.602(a)(3)(i)–(ii). Specifically, Rule 602(a)(3) provides that, if, at any time a national securities exchange is open for trading, the exchange determines, pursuant to rules approved by the Commission, that the level of trading activities or the existence of unusual market conditions is such that the exchange is incapable of collecting, processing, and making available to vendors the data for a subject security required to be made available in a manner that accurately reflects the current state of the market on such exchange, such exchange shall immediately notify all specified persons of that determination and, upon such notification, the exchange is generally relieved of its obligations relating to collecting and disseminating quotations.

[29] 15 U.S.C. 78s(b)(2).

[30] 17 CFR 200.30–3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–65408; File No. SR–FINRA–2011–049]**

## Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Aggregation of Activity of Affiliated Members for Purposes of FINRA/Nasdaq TRF Fees and Credits

September 27, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 13, 2011, 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, II, and III below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as ''constituting a stated policy, practice, or interpretation with respect to the meaning, administration, or enforcement of an existing rule'' under Section 19(b)(3)(A)(i) of the Act[3] and Rule 19b–4(f)(1) thereunder,[4] 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 amend Rule 7630A (Aggregation of Activity of Affiliated Members) relating to the pricing schedule for the FINRA/NASDAQ Trade Reporting Facility (the ''FINRA/NASDAQ TRF'') under the Rule 7600A Series.

The text of the proposed rule change is available on FINRA's Web site at *http:/www.finra.org,* at the principal office of FINRA, 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, 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

Rule 7630A allows affiliated members to aggregate their activity under certain provisions of the fee and credit schedule applicable to the FINRA/NASDAQ TRF that make fees and credits dependent upon the volume of their activity. For example, Rule 7620A caps fees for members with a daily average number of media/executing party trades during the month in excess of 2500. Affiliated members that might not qualify for the cap by themselves may be able to qualify by aggregating their activity.

Under Rule 7630A, a member may request that the FINRA/NASDAQ TRF aggregate its activity with the activity of its affiliates.[5] The rule defines an ''affiliate'' of the member as any wholly owned subsidiary, parent or sister (as those terms are defined under the rule) of the member that is also a member. Thus, the rule requires that one affiliated member own 100% of the voting interests in the other, or that they both be under the common control of a parent that owns 100% of each. A member requesting aggregation of affiliate activity under Rule 7630A is required to certify the affiliate status of entities whose activity it seeks to aggregate and immediately to provide notice of any event that causes an entity to cease to be an affiliate. A review of information regarding the entities is conducted, and the member may be requested to provide additional information to verify the affiliate status of an entity. A request will be approved unless it is determined that the member's certification is not accurate.[6] FINRA is proposing to clarify Rule 7630A by describing the process for review and approval in proposed paragraph (a)(1). However, FINRA is not proposing any changes to this process.

In addition, FINRA is proposing to adopt a stated policy with respect to the timing of recognition of aggregation requests. Because bills for the FINRA/NASDAQ TRF are prepared on a monthly basis, recognizing an affiliation in the middle of a month would require a complex proration of members' bills. Accordingly, it has been the FINRA/NASDAQ TRF's practice to recognize an affiliation request either at the beginning of the month in which the affiliation occurs or at the beginning of the following month. FINRA is proposing to adopt new paragraph (a)(2) of Rule 7630A, which provides that if two or more members become affiliated on or prior to the sixteenth day of a month and submit a request for aggregation on or prior to the twenty-second day of the month, approval of the request shall be deemed effective as of the first day of that month. Thus, for example, if one member acquires another, the acquisition is completed by June 16, and the members file a request for aggregation by June 22, approval of the request would allow the members to aggregate all activity during June. This would be the case regardless of the time required to review and approve the request. However, if members become affiliated after the sixteenth day of the month, or do not submit a request for aggregation until after the twenty-second day of the month, the request would not be recognized until the following month.

FINRA has filed the proposed rule change for immediate effectiveness. The effective date and the implementation date will be the date of filing.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15(b)(6) of the Act,[7] which requires, among other things, that FINRA rules 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, by adopting a clear policy with respect to the meaning, administration and enforcement of Rule 7630A, will promote members' understanding of the parameters of the rule and enhance the efficiency of its administration.

FINRA further believes that the proposed rule change is consistent with Section 15A(b)(5) of the Act,[8] which requires, among other things, that

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(i).

[4] 17 CFR 240.19b–4(f)(1).

[5] The rule is administered by The NASDAQ OMX Group, Inc. (''NASDAQ''), in its capacity as the ''Business Member'' and operator of the FINRA/NASDAQ TRF on behalf of FINRA. FINRA's oversight of this function performed by the Business Member is conducted through an annual assessment and review of TRF operations by an outside independent audit firm.

[6] In the event of an inaccurate certification, FINRA would investigate whether the member had violated FINRA rules and would take appropriate disciplinary action.

[7] 15 U.S.C. 78*o*–3(b)(6).

[8] 15 U.S.C. 78*o*–3(b)(5).

FINRA rules provide for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system that FINRA operates or controls. All similarly situated members are subject to the same fee structure, and access to the FINRA/NASDAQ TRF is offered on fair and non-discriminatory terms. The proposed rule change is reasonable because it establishes a standard for recognition of aggregation requests that is easy to administer and that reflects the need to review and approve aggregation requests while avoiding the complexities associated with proration of the bills of members that affiliate during the course of a month. The proposed rule change is equitable because all members seeking to aggregate their activity are subject to the same parameters, in accordance with a commonsense standard that recognizes an affiliation as of the month's beginning closest in time to when the affiliation occurs, provided the members submit a timely request.

*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**

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [9] and paragraph (f)(1) of Rule 19b–4 thereunder.[10] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

**IV. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

*Electronic Comments*

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–FINRA–2011–049 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–FINRA–2011–049. 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 publicly available. All submissions should refer to File Number SR–FINRA–2011–049 and should be submitted on or before October 24, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

**Elizabeth M. Murphy,**

*Secretary.*

[FR Doc. 2011–25352 Filed 9–30–11; 8:45 am]

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[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(1).

[11] 17 CFR 200.30–3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–65406; File No. SR–BYX–2011–023]**

## Self-Regulatory Organizations; BATS Y-Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Related to Fees for Use of BATS Y-Exchange, Inc.

September 27, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 14, 2011, BATS Y-Exchange, Inc. (the ''Exchange'' or ''BYX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act [3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective upon filing with 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**

The Exchange proposes to amend the fee schedule applicable to Members[5] of the Exchange pursuant to BYX Rules 15.1(a) and (c). While changes to the fee schedule pursuant to this proposal will be effective upon filing, the changes will become operative on September 16, 2011.

The text of the proposed rule change is available at the Exchange's Web site at *http://www.batstrading.com*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] A Member is any registered broker or dealer that has been admitted to membership in the Exchange.

**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 these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

The Exchange proposes to modify its fee schedule applicable to use of the Exchange effective September 16, 2011, in order to adopt a fee for any order subject to price sliding that adds liquidity to the Exchange and receives price improvement over its ranked price when executed. Pursuant to Exchange price sliding, an order that would lock or cross a protected quotation is ranked on the Exchange's order book at the locked price and then displayed at one minimum price level less aggressive than the locking price. For bids, this means that a price slid order is displayed at one minimum price variation less than the current national best offer (''NBO''), and for offers, this means that a price slid order is displayed at one minimum price variation more than the current national best bid (''NBB'').

The Exchange received approval in June of a rule change to allow a non-displayed order or an order subject to the price sliding process that is not executable at its most aggressive price to be executed at one-half minimum price variation less aggressive than the price at which it is ranked.[6] The Exchange immediately implemented the change for non-displayed orders, but delayed the implementation related to orders subject to price sliding in order to complete development of the necessary system functionality. On September 16, 2011, the Exchange plans to implement the systems change to allow an order subject to price sliding to execute at one-half minimum price variation less aggressive than the price at which such order is ranked. Specifically, in the event an order submitted to the Exchange on the side opposite such a price slid order is a market order or a limit order priced more aggressively than the locking price, the Exchange will execute the resting order subject to price sliding at, in the case of a resting bid, one-half minimum price variation less than the locking price, and, in the case of a resting offer, at one-half minimum price variation more than the locking price. Based on the functionality, orders executed as described above will receive price improvement over the price at which such orders are ranked. Because price slid orders subject to the order handling process described above will receive price improvement, the Exchange proposes to execute the orders subject to a fee of $0.0030 per share, which is the same fee imposed for executions of non-displayed orders that receive price improvement when executed. The Exchange believes that price improvement received for executions of orders subject to price sliding will offset the additional fee charged by the Exchange for such orders.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6 of the Act.[7] Specifically, the Exchange believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,[8] in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and other persons using any facility or system which the Exchange operates or controls. The Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. The Exchange believes that the proposed fee applicable to any execution of a price slid order that receives price improvement over its ranked price is competitive, fair and reasonable, and non-discriminatory in that the fee will apply uniformly to all Members and because the proposed fee is the same fee imposed for non-displayed orders that are handled similarly. Finally, the Exchange believes that the additional fee for executions of orders subject to price sliding that receive price improvement is appropriate because the price improvement received will offset the change in the fee structure for such orders.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange does not believe that the proposed rule change imposes any burden on competition.

*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.

**III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

Pursuant to Section 19(b)(3)(A)(ii) of the Act[9] and Rule 19b–4(f)(2) thereunder,[10] the Exchange has designated this proposal as establishing or changing a due, fee, or other charge applicable to the Exchange's Members and non-members, which renders the proposed rule change effective upon filing.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

**IV. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

*Electronic Comments*

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–BYX–2011–023 on the subject line.

*Paper Comments*

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary,

[6] *See* Securities Exchange Act Release No. 64753 (June 27, 2011), 76 FR 38714 (July 1, 2011) (SR–BYX–2011–009) (Order Approving a Proposed Rule Change to Amend BATS Rule 11.9, entitled ''Orders and Modifiers'' and BATS Rule 11.13, entitled ''Order Execution'').

[7] 15 U.S.C. 78f.

[8] 15 U.S.C. 78f(b)(4).

[9] 15 U.S.C. 78s(b)(3)(A)(ii).

[10] 17 CFR 240.19b–4(f)(2).

Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BYX–2011–023. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room on official business days between the hours of 10 a.m. and 3 p.m. Copies of 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–BYX–2011–023 and should be submitted on or before October 24, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

**Elizabeth M. Murphy,**

*Secretary.*

[FR Doc. 2011–25378 Filed 9–30–11; 8:45 am]

**BILLING CODE 8011–01–P**

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–65407; File No. SR–BATS–2011–037]**

## Self-Regulatory Organizations; BATS Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Related to Fees for Use of BATS Exchange, Inc.

September 27, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 19, 2011, BATS Exchange, Inc. (the ''Exchange'' or ''BATS'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective upon filing with 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

The Exchange proposes amend the fee schedule applicable to Members[5] and non-members of the Exchange pursuant to BATS Rules 15.1(a) and (c). While changes to the fee schedule pursuant to this proposal will be effective upon filing, the changes will become operative on September 23, 2011.

The text of the proposed rule change is available at the Exchange's Web site at *http://www.batstrading.com,* at the principal office of the Exchange, 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 these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

The Exchange proposes to modify its fee schedule applicable to use of the Exchange effective September 23, 2011, in order to: (1) Discontinue payment of a liquidity rebate for any order subject to price sliding that adds liquidity to the Exchange and receives price improvement over its ranked price when executed; and (2) modify the ''Options Pricing'' section of its fee schedule to impose a fee for newly available logical ports with bulk-quoting capabilities, as further described below.

Orders Subject to Price Sliding

The Exchange proposes to discontinue payment of a liquidity rebate for any order subject to price sliding that adds liquidity to the Exchange and receives price improvement over its ranked price when executed. Pursuant to Exchange price sliding, an order that would lock or cross a protected quotation is ranked on the Exchange's order book at the locked price and then displayed at one minimum price level less aggressive than the locking price. For bids, this means that a price slid order is displayed at one minimum price variation less than the current national best offer (''NBO''), and for offers, this means that a price slid order is displayed at one minimum price variation more than the current national best bid (''NBB'').

The Exchange received approval in June of a rule change to allow a non-displayed order or an order subject to the price sliding process that is not executable at its most aggressive price to be executed at one-half minimum price variation less aggressive than the price at which it is ranked.[6] The Exchange immediately implemented the change for non-displayed orders, but delayed the implementation related to orders subject to price sliding in order to complete development of the necessary system functionality. On September 23, 2011, the Exchange plans to implement the systems change to allow an order subject to price sliding to execute at one-half minimum price variation less aggressive than the price at which such order is ranked. Specifically, in the event an order submitted to the Exchange on the side opposite such a price slid order is a market order or a limit order priced more aggressively than the locking price, the Exchange will execute the resting order subject to price sliding at, in the case of a resting bid, one-half minimum price variation less than the locking price, and, in the case of a resting offer, at one-half

[11] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] A Member is any registered broker or dealer that has been admitted to membership in the Exchange.

[6] *See* Securities Exchange Act Release No. 64754 (June 27, 2011), 76 FR 38712 (July 1, 2011) (SR–BATS–2011–01 [sic]) (Order Approving a Proposed Rule Change to Amend BATS Rule 11.9, entitled ''Orders and Modifiers'' and BATS Rule 11.13, entitled ''Order Execution'').

minimum price variation more than the locking price. Based on the functionality, orders executed as described above will receive price improvement over the price at which such orders are ranked. Because price slid orders subject to the order handling process described above will receive price improvement, the Exchange proposes to eliminate the payment of a liquidity rebate for such executions, which is the same fee structure applied to executions of non-displayed orders that receive price improvement when executed. The Exchange believes that price improvement received for executions of orders subject to price sliding will offset the change in the fee structure for such orders.

Options Logical Port Fees

The Exchange currently charges a fee of $400.00 per month per logical port used by Members or non-members to access and receive information from the Exchange's cash equities platform. A logical port is also commonly referred to as a TCP/IP port, and represents a port established by the Exchange within the Exchange's system for trading and billing purposes. Each logical port established is specific to a Member or non-member and grants that Member or non-member the ability to operate a specific application, such as FIX order entry or PITCH data receipt.

In contrast to its cash equities platform, the Exchange currently provides logical ports free of charge to Members and non-members that have access to or receive data from the Exchange's equity options platform (''BATS Options''). On August 9, 2011, the Exchange filed an immediately effective rule filing for BATS Options to introduce a bulk-quoting interface for registered BATS Options market makers to allow such market makers to provide liquidity to the market in a broader set of series in a more efficient manner.[7] On September 2, 2011, the Exchange filed an immediately effective rule filing for BATS Options to expand the availability of the bulk-quoting interface to all Users[8] of BATS Options.[9] Due to the development and infrastructure costs associated with bulk-quoting functionality, the Exchange proposes to charge Users $1,000.00 per month for any logical port with bulk-quoting capabilities. The bulk-quoting interface allows Users to provide both a bid and an offer in one message as well as bundle several quote updates into one bulk message. This is a useful feature for Users that provide quotations in many different options. As proposed, the change applies to any User that obtains a port enabled with bulk-quoting functionality to access the Exchange.

In order to differentiate logical port fees from physical connection charges and because the fee described above is applicable only to BATS Options, the Exchange also proposes to modify a sub-heading included in the ''Equities Pricing'' section of the Exchange's fee schedule from ''Port Fees'' to ''Equities Logical Port Fees.'' Although the Exchange is implementing this fee effective September 23, 2011, the Exchange will not charge any User of BATS Options a fee for bulk-quoting ports until October 1, 2011.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6 of the Act.[10] Specifically, the Exchange believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,[11] in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and other persons using any facility or system which the Exchange operates or controls. The Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. With respect to the fee change related to price slid orders, the Exchange believes that the lack of a fee or rebate for any execution of a price slid order that receives price improvement over its ranked price is competitive, fair and reasonable, and non-discriminatory in that this fee structure will apply uniformly to all Members and because the proposed fee structure is the same fee structure imposed for non-displayed orders that are handled similarly. Finally, the Exchange believes that the lack of a rebate for executions of orders subject to price sliding that receive price improvement is appropriate because the price improvement received will offset the change in the fee structure for such orders.

With respect to the proposed charge for ports with bulk-quoting functionality, the Exchange notes that the use of such ports is optional, and that market participants can continue to access BATS Options through other logical ports free of charge. At the same time, the Exchange believes that its fees for bulk-quoting logical ports are reasonable, given the benefits and added efficiencies Users of BATS Options will realize through such ports. In addition, the Exchange believes that its fees are equitably allocated among its constituents as they are uniform in application to all Users of BATS Options. The Exchange believes that fees for each port with bulk-quoting capabilities will enable it to cover the development and infrastructure costs associated with offering and continuing to offer bulk-quoting capabilities to BATS Options Users.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange does not believe that the proposed rule change imposes any burden on competition.

*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.

**III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

Pursuant to Section 19(b)(3)(A)(ii) of the Act[12] and Rule 19b–4(f)(2) thereunder,[13] the Exchange has designated this proposal as establishing or changing a due, fee, or other charge applicable to the Exchange's Members and non-members, which renders the proposed rule change effective upon filing.

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.

[7] *See* Securities Exchange Act Release No. 65133 (August 15, 2011), 76 FR 52032 (August 19, 2011) (SR–BATS–2011–029).

[8] As defined in BATS Rule 16.1(a)(62), a ''User'' on BATS Options is either a member of BATS Options or a sponsored participant who is authorized to obtain access to the Exchange's system pursuant to BATS Rule 11.3.

[9] *See* Securities Exchange Act Release No. 65307 (September 9, 2011), 76 FR 57092 (September 15, 2011) (SR–BATS–2011–034).

[10] 15 U.S.C. 78f.

[11] 15 U.S.C. 78f(b)(4).

[12] 15 U.S.C. 78s(b)(3)(A)(ii).

[13] 17 CFR 240.19b–4(f)(2).

## IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

*Electronic Comments*

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–BATS–2011–037 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–BATS–2011–037. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room on official business days between the hours of 10 a.m. and 3 p.m. Copies of 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–BATS–2011–037 and should be submitted on or before October 24, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

**Elizabeth M. Murphy,**

*Secretary.*

[FR Doc. 2011–25379 Filed 9–30–11; 8:45 am]

**BILLING CODE 8011–01–P**

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–65317; File No. SR–NASDAQ–2011–127]**

## Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify Fees for Members Using the NASDAQ Options Market

September 12, 2011.

*Correction*

In notice document 2010–23721 beginning on page 57778 the issue of Friday, September 16, 2011 make the following correction:

On page 57781, in the first column, in the 8th line from the bottom of the page, ''October 6, 2011'' should read ''October 7, 2011''.

[FR Doc. C1–2011–23721 Filed 9–30–11; 8:45 am]

**BILLING CODE 1505–01–D**

## SECURITIES AND EXCHANGE COMMISSION

**[File No. 500–1]**

## BB Liquidation Inc., Order of Suspension of Trading

September 29, 2011.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of BB Liquidation Inc. because of assertions in third-party press releases to investors concerning, among other things, the company's current financial condition and business prospects.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the company listed above.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the company listed above is suspended for the period from 9:30 a.m. EDT, September 29, 2011, through 11:59 p.m. EDT, on October 12, 2011.

[14] 17 CFR 200.30–3(a)(12).

By the Commission.

**Elizabeth M. Murphy,**

*Secretary.*

[FR Doc. 2011–25506 Filed 9–29–11; 4:15 pm]

**BILLING CODE 8011–01–P**

## SMALL BUSINESS ADMINISTRATION

## Reporting and Recordkeeping Requirements Under OMB Review

**AGENCY:** Small Business Administration.

**ACTION:** Notice of Reporting Requirements Submitted for OMB Review.

**SUMMARY:** Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission.

**DATES:** Submit comments on or before November 2, 2011. If you intend to comment but cannot prepare comments promptly, please advise the OMB Reviewer and the Agency Clearance Officer before the deadline.

*Copies:* Request for clearance (OMB 83–1), supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

**ADDRESSES:** Address all comments concerning this notice to: Agency Clearance Officer, Jacqueline White, Small Business Administration, 409 3rd Street, SW., 5th Floor, Washington, DC 20416; and OMB Reviewer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

**FOR FURTHER INFORMATION CONTACT:** Jacqueline White, Agency Clearance Officer, (202) 205–7044.

**SUPPLEMENTARY INFORMATION:**

*Title:* ''Gulf Opportunity Pilot Loan Program (GO) Loan Pilot''.

*Frequency:* On Occasion.

*SBA Form Number:* 2276 A, B, C 2281 2282.

*Description of Respondents:* Loan Borrowers.

*Responses:* 580.

*Annual Burden:* 362.

**Jacqueline White,**

*Chief, Administrative Information Branch.*

[FR Doc. 2011–25409 Filed 9–30–11; 8:45 am]

**BILLING CODE 8025–01–P**

## SMALL BUSINESS ADMINISTRATION

**[Disaster Declaration #12856 and #12857]**

### Missouri Disaster #MO–00054

**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 the State of Missouri (FEMA–4012–DR), dated 09/09/2011.

*Incident:* Flooding.

*Incident Period:* 06/01/2011 through 08/01/2011.

*Effective Date:* 09/09/2011.

*Physical Loan Application Deadline Date:* 11/08/2011.

*Economic Injury (EIDL) Loan Application Deadline Date:* 06/06/2012.

**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 09/09/2011, 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 Counties:* Andrew, Atchison, Buchanan, Carroll, Cooper, Holt, Howard, Lafayette, Platte, Ray, Saline.

The Interest Rates are:

| | Percent |
|---|---|
| *For Physical Damage:* | |
| Non-Profit Organizations with Credit Available Elsewhere ... | 3.250 |
| Non-Profit Organizations without Credit Available Elsewhere ..... | 3.000 |
| *For Economic Injury:* | |
| Non-Profit Organizations without Credit Available Elsewhere ..... | 3.000 |

The number assigned to this disaster for physical damage is 128566 and for economic injury is 128576.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

**James E. Rivera,**

*Associate Administrator for Disaster Assistance.*

[FR Doc. 2011–25348 Filed 9–30–11; 8:45 am]

**BILLING CODE 8025–01–P**

## SMALL BUSINESS ADMINISTRATION

**[Disaster Declaration #12826 and #12827]**

### Maine Disaster Number ME–00029

**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 Maine (FEMA–4032–DR), dated 09/13/2011.

*Incident:* Tropical Storm Irene.

*Incident Period:* 08/27/2011 through 08/29/2011.

*Effective Date:* 09/23/2011.

*Physical Loan Application Deadline Date:* 11/14/2011.

*Economic Injury (EIDL) Loan Application Deadline Date:* 06/13/2012.

**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 of Maine, dated 09/13/2011, is hereby amended to include the following areas as adversely affected by the disaster.

*Primary Counties:* Lincoln.

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. 2011–25347 Filed 9–30–11; 8:45 am]

**BILLING CODE 8025–01–P**

## SMALL BUSINESS ADMINISTRATION

**[Disaster Declaration #12822 and #12823]**

### Pennsylvania Disaster Number PA–00044

**AGENCY:** U.S. Small Business Administration.

**ACTION:** Amendment 1.

**SUMMARY:** This is an amendment of the Presidential declaration of a major disaster for the Commonwealth of Pennsylvania (FEMA–4030–DR), dated 09/12/2011.

*Incident:* Tropical Storm Lee.

*Incident Period:* 09/03/2011 and continuing.

*Effective Date:* 09/23/2011.

*Physical Loan Application Deadline Date:* 11/14/2011.

*EIDL Loan Application Deadline Date:* 06/12/2012.

**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 Presidential disaster declaration for the Commonwealth of Pennsylvania, dated 09/12/2011 is hereby amended to include the following areas as adversely affected by the disaster:

*Primary Counties:* (*Physical Damage and Economic Injury Loans*): Berks, Bucks, Chester, Delaware, Montgomery, Northampton, Philadelphia.

*Contiguous Counties:* (*Economic Injury Loans Only*):
Delaware: New Castle.
New Jersey: Burlington, Camden, Gloucester, Hunterdon, Mercer, Warren.

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. 2011–25346 Filed 9–30–11; 8:45 am]

**BILLING CODE 8025–01–P**

## SMALL BUSINESS ADMINISTRATION

**[Disaster Declaration #12824 and #12825]**

### New York Disaster Number NY–00110

**AGENCY:** U.S. Small Business Administration.

**ACTION:** Amendment 3.

**SUMMARY:** This is an amendment of the Presidential declaration of a major disaster for the State of New York (FEMA–4031–DR), dated 09/13/2011.

*Incident:* Remnants of Tropical Storm Lee.

*Incident Period:* 09/07/2011 through 09/11/2011.

*Effective Date:* 09/23/2011.

*Physical Loan Application Deadline Date:* 11/14/2011.

*EIDL Loan Application Deadline Date:* 06/13/2012.

**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 the State of New York, dated 09/13/2011 is hereby amended to establish the incident period for this disaster as beginning 09/07/2011 and continuing through 09/11/2011.

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. 2011–25345 Filed 9–30–11; 8:45 am]

**BILLING CODE 8025–01–P**

## SMALL BUSINESS ADMINISTRATION

**[Disaster Declaration #12809 and #12810]**

### New Hampshire Disaster Number NH–00020

**AGENCY:** U.S. Small Business Administration.

**ACTION:** Amendment 3.

**SUMMARY:** This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of New Hampshire (FEMA–4026–DR), dated 09/03/2011.

*Incident:* Tropical Storm Irene.

*Incident Period:* 08/26/2011 through 09/06/2011.

**DATES:** *Effective Date:* 09/23/2011.

*Physical Loan Application Deadline Date:* 11/02/2011.

*Economic Injury (EIDL) Loan Application Deadline Date:* 06/05/2012.

**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 of New Hampshire, dated 09/03/2011, is hereby amended to include the following areas as adversely affected by the disaster.

*Primary Counties:* Belknap.

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. 2011–25357 Filed 9–30–11; 8:45 am]

**BILLING CODE 8025–01–P**

## SMALL BUSINESS ADMINISTRATION

**[Disaster Declaration #12850 and #12851]**

### Rhode Island Disaster #RI–00008

**AGENCY:** U.S. Small Business Administration.

**ACTION:** Notice.

**SUMMARY:** This is a notice of an Administrative declaration of a disaster for the State of Rhode Island dated 09/26/2011.

*Incident:* Hurricane Irene.

*Incident Period:* 08/27/2011 through 08/29/2011.

*Effective Date:* 09/26/2011.

*Physical Loan Application Deadline Date:* 11/25/2011.

*Economic Injury (EIDL) Loan Application Deadline Date:* 06/26/2012.

**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 Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

*Primary Counties:* Providence.

*Contiguous Counties:*

Rhode Island: Bristol, Kent.

Connecticut: Windham.

Massachusetts: Bristol, Norfolk, Worcester.

The Interest Rates are:

| | Percent |
|---|---|
| *For Physical Damage:* | |
| Homeowners with Credit Available Elsewhere | 5.000 |
| Homeowners without Credit Available Elsewhere | 2.500 |
| Businesses with Credit Available Elsewhere | 6.000 |
| Businesses without Credit Available Elsewhere | 4.000 |
| Non-Profit Organizations with Credit Available Elsewhere | 3.250 |
| Non-Profit Organizations without Credit Available Elsewhere | 3.000 |
| *For Economic Injury:* | |
| Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere | 4.000 |
| Non-Profit Organizations without Credit Available Elsewhere | 3.000 |

The number assigned to this disaster for physical damage is 12850 8 and for economic injury is 12851 0.

The States which received an EIDL Declaration # are Rhode Island, Connecticut, Massachusetts.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Dated: September 26, 2011.

**Karen G. Mills,**

*Administrator.*

[FR Doc. 2011–25358 Filed 9–30–11; 8:45 am]

**BILLING CODE 8025–01–P**

## DEPARTMENT OF STATE

**[Public Notice 7617]**

### Determination and Certification Related to Colombian Armed Forces Under Section 7046(b) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2010

Pursuant to the authority vested in the Secretary of State, including under section 7046(b) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2010 (Div. F, Pub. L. 111–117) (''FY 2010 SFOAA''), as carried forward in the Full-Year Continuing Appropriations Act, 2011 (Div. B, Pub. L. 112–10) I hereby determine, certify, and report that the Government of Colombia is meeting the conditions contained in section 7046(b)(1)(B) and section 7046(b)(2) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2009 (Div. H, Pub. L. 111–8) (''FY 2009 SFOAA'').

Pursuant to section 7046(b) of the FY 2010 SFOAA, the Department of State has periodically consulted with

Colombian and internationally recognized human rights organizations regarding the Colombian Armed Forces' progress in meeting the above-mentioned conditions, as provided in section 7046(c) of the FY 2009 SFOAA.

This Determination and Certification shall be published in the **Federal Register**, and copies shall be transmitted to the appropriate committees of Congress.

Dated: September 7, 2011.

**William J. Burns,**

*Deputy Secretary of State.*

[FR Doc. 2011–25448 Filed 9–30–11; 8:45 am]

**BILLING CODE 4710–29–P**

## DEPARTMENT OF STATE

**[Public Notice: 7632]**

## Privacy Act; System of Records: State-77, Country Clearance Records

**SUMMARY:** Notice is hereby given that the Department of State proposes to create a system of records, Country Clearance Records, State-77, pursuant to the provisions of the Privacy Act of 1974, as amended (5 U.S.C. 552a) and Office of Management and Budget Circular No. A–130, Appendix I.

**DATES:** This system of records will become effective on November 14, 2011, unless we receive comments that will result in a contrary determination.

**ADDRESSES:** Any persons interested in commenting on this new system of records may do so by submitting comments in writing to the Director; Office of Information Programs and Services, A/GIS/IPS; Department of State, SA–2; 515 22nd Street, NW.; Washington, DC 20522–8001.

**FOR FURTHER INFORMATION CONTACT:** Director; Office of Information Programs and Services, A/GIS/IPS; Department of State, SA–2; 515 22nd Street, NW.; Washington, DC 20522–8001.

**SUPPLEMENTARY INFORMATION:**

The Department of State proposes the new system of records named ''Country Clearance Records.'' During a review of Department of State operations, this system was identified as being in operation and subject to the provisions of the Privacy Act. This notice is being published to address the requirements of the Privacy Act of 1974, as amended. The proposed system will maintain information required to request permission from the chief of mission for the planned presence in his or her country, post, or mission of an employee or contractor of the Department of State or other Executive Branch agency.

The Department's report was filed with the Office of Management and Budget. The new system description, ''Country Clearance Records, State-77'' will read as set forth below.

Dated: September 8, 2011.

**Keith D. Miller,**

*Director, Office of Operations, Bureau of Administration, U.S. Department of State.*

### STATE–77

**SYSTEM NAME:**

Country Clearance Records.

**SECURITY CLASSIFICATION:**

Unclassified.

**SYSTEM LOCATION:**

Office of Management Policy, Rightsizing and Innovation (M/PRI), Department of State, 2201 C Street NW., Washington, DC 20520–3822; all U.S. posts and missions abroad; and corresponding automated data processing facilities.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Employees and contractors of the Department of State and other Executive Branch agencies of the U.S. Government.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Individual name, email address, phone number, passport country and number, agency, employment type, country of birth, emergency contact information, purpose of visit, lodging information, carrier information, level of security clearance and travel itineraries.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

22 U.S.C. 3927, Chief of Mission.

**PURPOSE:**

To request permission from the chief of mission for the planned presence in his or her country, post, or mission of an employee or contractor of the Department of State or other Executive Branch agency.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:**

The Department shares Country Clearance records with designated administrators of other Executive Branch agencies utilizing the eCountry Clearance system for employees or contractors on official travel to U.S. posts and missions abroad.

The Department of State periodically publishes in the **Federal Register** its standard routine uses which apply to all of its Privacy Act systems of records. These notices appear in the form of a Prefatory Statement. These standard routine uses apply to Country Clearance Records, State-77.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Electronic and paper records.

**RETRIEVABILITY:**

Records are retrieved by the individual's name or itinerary number.

**SAFEGUARDS:**

All users are given cyber security awareness training which covers the procedures for handling Sensitive but Unclassified information, including personally identifiable information (PII). Annual refresher training is mandatory. In addition, all Foreign Service and Civil Service employees and those Locally Engaged Staff who handle PII are required to take the Foreign Service Institute distance learning course instructing employees on privacy and security requirements, including the Rules of Behavior for handling PII and the potential consequences if it is handled improperly. Before being granted access to Country Clearance Records, a user must first be granted access to the Department of State computer system.

Remote access to the Department of State network from non-Department owned systems is authorized only through a Department approved access program. Remote access to the network is configured with the Office of Management and Budget Memorandum M–07–16 security requirements, which include but are not limited to two-factor authentication and time out function.

All Department of State employees and contractors with authorized access have undergone a thorough background security investigation. Access to the Department of State, its annexes, posts, and missions abroad is controlled by security guards and admission is limited to those individuals possessing a valid identification card or individuals under proper escort. All paper records containing personal information are maintained in secured file cabinets in restricted areas, access to which is limited to authorized personnel only. Access to computerized files is password-protected and under the direct supervision of the system manager. The system manager has the capability of printing audit trails of access from the computer media, thereby permitting regular and ad hoc monitoring of computer usage.

When it is determined that a user no longer needs access, the user account is disabled.

**RETENTION AND DISPOSAL:**

Records are disposed of in accordance with published Department of State Records Disposition Schedules as approved by the National Archives and Records Administration (NARA). More specific information may be obtained by writing to the Director, Office of Information Programs and Services, Department of State, SA–2, 515 22nd Street, NW., Washington, DC 20522–8001.

**SYSTEM MANAGER AND ADDRESS:**

Director, Office of Management Policy, Rightsizing and Innovation (M/PRI), 2201 C Street, NW., Washington, DC 20520–3822.

**NOTIFICATION PROCEDURES:**

Individuals who have reason to believe that the Office of Management Policy, Rightsizing and Innovation (M/PRI) may have information pertaining to them may write to the Director, Office of Information Programs and Services, Department of State, SA–2, 515 22nd Street, NW., Washington, DC 20522–8001. The individual must specify that he/she wishes Country Clearance Records to be checked. At a minimum, the individual should include his or her name, current mailing address, zip code, and signature; and a brief description of the circumstances that caused the individual to believe that the system of records contains records pertaining to him or her, including dates and locations of travel episodes for which the individual believes he or she may have caused the creation of country clearance records.

**RECORD ACCESS PROCEDURES:**

Individuals who wish to gain access to or amend records pertaining to them should write to the Director, Office of Information Programs and Services (address above).

**CONTESTING RECORD PROCEDURES:**

(See above).

**RECORD SOURCE CATEGORIES:**

These records contain information obtained directly from the individual who is the subject of these records, from the Executive Branch agency employing the individual, and M/PRI and post or mission staff abroad.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

[FR Doc. 2011–25433 Filed 9–30–11; 8:45 am]

**BILLING CODE 4710–24–P**

## DEPARTMENT OF STATE

**[Public Notice 7631]**

### Waiver of Restriction on Assistance to the Central Government of Niger

Pursuant to Section 7086(c)(2) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2010 (Div. F, Pub. L. 111–117), as carried forward by the Full-Year Continuing Appropriations Act, 2011 (Div. B, Pub. L. 112–10) (''the Act''), and Department of State Delegation of Authority Number 245–1, I hereby determine that it is important to the national interest of the United States to waive the requirements of Section 7086(c)(1) of the Act with respect to Niger and I hereby waive such restriction.

This determination shall be reported to the Congress, and published in the **Federal Register**.

Dated: July 22, 2011.

**Thomas Nides,**

*Deputy Secretary of State for Management and Resources.*

[FR Doc. 2011–25435 Filed 9–30–11; 8:45 am]

**BILLING CODE 4710–26–P**

## DEPARTMENT OF STATE

**[Public Notice: 7626]**

### Waiver of Restriction on Assistance to the Central Government of Guinea-Bissau

Pursuant to Section 7086(c)(2) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2010 (Div. F, Pub. L. 111–117), as carried forward by the Full-Year Continuing Appropriations Act, 2011 (Div. B, Pub. L. 112–10) (''the Act''), and Department of State Delegation of Authority Number 245–1, I hereby determine that it is important to the national interest of the United States to waive the requirements of Section 7086(c)(1) of the Act with respect to Guinea-Bissau and I hereby waive such restriction.

This determination shall be reported to the Congress, and published in the **Federal Register.**

Dated: July 22, 2011.

**Thomas Nides,**

*Deputy Secretary of State for Management and Resources.*

[FR Doc. 2011–25444 Filed 9–30–11; 8:45 am]

**BILLING CODE 4710–26–P**

## DEPARTMENT OF STATE

**[Public Notice: 7629]**

### Waiver of Restriction on Assistance to the Central Government of Guinea

Pursuant to Section 7086(c)(2) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2010 (Div. F, Pub. L. 111–117), as carried forward by the Full-Year Continuing Appropriations Act, 2011 (Div. B, Pub. L. 112–10) (''the Act''), and Department of State Delegation of Authority Number 245–1, I hereby determine that it is important to the national interest of the United States to waive the requirements of Section 7086(c)(1) of the Act with respect to Guinea and I hereby waive such restriction.

This determination shall be reported to the Congress, and published in the **Federal Register**.

Dated: July 22, 2011.

**Thomas Nides,**

*Deputy Secretary of State for Management and Resources.*

[FR Doc. 2011–25447 Filed 9–30–11; 8:45 am]

**BILLING CODE 4710–26–P**

## DEPARTMENT OF STATE

**[Public Notice: 7625]**

### Waiver of Restriction on Assistance to the Central Government of The Gambia

Pursuant to Section 7086(c)(2) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2010 (Division F, Pub. L. 111–117), as carried forward by the Full-Year Continuing Appropriations Act, 2011 (Div. B, Pub. L. 112–10) (''the Act''), and Department of State Delegation of Authority Number 245–1, I hereby determine that it is important to the national interest of the United States to waive the requirements of Section 7086(c)(1) of the Act with respect to The Gambia and I hereby waive such restriction.

This determination shall be reported to the Congress, and published in the **Federal Register**.

Dated: July 28, 2011.

**Thomas Nides,**

*Deputy Secretary of State for Management and Resources.*

[FR Doc. 2011–25451 Filed 9–30–11; 8:45 am]

**BILLING CODE 4710–26–P**

## DEPARTMENT OF STATE

**[Public Notice: 7623]**

### Waiver of Restriction on Assistance to the Central Government of Ethiopia

Pursuant to Section 7086(c)(2) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2010 (Div. F, Pub. L. 111–117) as carried forward by the Full-Year Continuing Appropriations Act, 2011 (Div. B, Pub. L. 112–10) (''the Act''), and Department of State Delegation of Authority Number 245–1, I hereby determine that it is important to the national interest of the United States to waive the requirements of Section 7086(c)(1) of the Act with respect to Ethiopia and I hereby waive such restriction.

This determination shall be reported to the Congress, and published in the **Federal Register**.

Dated: July 11, 2011.

**Thomas Nides,**

*Deputy Secretary of State for Management and Resources.*

[FR Doc. 2011–25453 Filed 9–30–11; 8:45 am]

**BILLING CODE 4710–26–P**

## DEPARTMENT OF STATE

**[Public Notice 7921]**

### Waiver of Restriction on Assistance to the Central Government of Chad

Pursuant to Section 7086(c)(2) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2010 (Div. F, Pub. L.111–117) as carried forward by the Full-Year Continuing Appropriations Act, 2011 (Div. B, Pub. L. 112–10) (''the Act''), and Department of State Delegation of Authority Number 245–1, I hereby determine that it is important to the national interest of the United States to waive the requirements of Section 7086(c)(1) of the Act with respect to Chad and I hereby waive such restriction.

This determination shall be reported to the Congress, and published in the **Federal Register.**

Dated: July 29, 2011.

**Thomas Nides,**

*Deputy Secretary of State for Management and Resources .*

[FR Doc. 2011–25455 Filed 9–30–11; 8:45 am]

**BILLING CODE 4710–26–P**

## DEPARTMENT OF STATE

**[Public Notice: 7618]**

### Waiver of Restriction on Assistance to the Central Government of the Central African Republic

Pursuant to Section 7086(c)(2) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2010 (Div. F, Pub. L. 111–117) as carried forward by the Full-Year Continuing Appropriations Act, 2011 (Div. B, Pub. L. 112–10) (''the Act''), and Department of State Delegation of Authority Number 245–1, I hereby determine that it is important to the national interest of the United States to waive the requirements of Section 7086(c)(1) of the Act with respect to the Central African Republic and I hereby waive such restriction.

This determination shall be reported to the Congress, and published in the **Federal Register**.

Dated: August 1, 2011.

**Thomas Nides,**

*Deputy Secretary of State for Management and Resources.*

[FR Doc. 2011–25446 Filed 9–30–11; 8:45 am]

**BILLING CODE 4710–26–P**

## DEPARTMENT OF STATE

**[Public Notice: 7919]**

### Waiver of Restriction on Assistance to the Central Government of Cameroon

Pursuant to Section 7086(c)(2) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2010 (Div. F, Pub. L. 111–117) as carried forward by the Full-Year Continuing Appropriations Act, 2011 (Div. B, Pub. L. 112–10) (''the Act''), and Department of State Delegation of Authority Number 245–1, I hereby determine that it is important to the national interest of the United States to waive the requirements of Section 7086(c)(1) of the Act with respect to Cameroon and I hereby waive such restriction.

This determination shall be reported to the Congress, and published in the **Federal Register**.

Dated: August 1, 2011.

**Thomas Nides,**

*Deputy Secretary of State for Management and Resources.*

[FR Doc. 2011–25442 Filed 9–30–11; 8:45 am]

**BILLING CODE 4710–26–P**

## DEPARTMENT OF STATE

**[Public Notice: 7920]**

### Waiver of Restriction on Assistance to the Central Government of Angola

Pursuant to Section 7086(c)(2) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2010 (Div. F, Pub. L. 111–117), as carried forward by the Full-Year Continuing Appropriations Act, 2011 (Div. B, Pub. L. 112–10) (''the Act''), and Department of State Delegation of Authority Number 245–1, I hereby determine that it is important to the national interest of the United States to waive the requirements of Section 7086(c)(1) of the Act with respect to Angola and I hereby waive such restriction.

This determination shall be reported to the Congress, and published in the **Federal Register.**

Dated: July 20, 2011.

**Thomas Nides,**

*Deputy Secretary of State for Management and Resources.*

[FR Doc. 2011–25436 Filed 9–30–11; 8:45 am]

**BILLING CODE 4710–26–P**

## DEPARTMENT OF STATE

**[Public Notice 7622]**

### Waiver of Restriction on Assistance to the Central Government of the Democratic Republic of the Congo

Pursuant to Section 7086(c)(2) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2010 (Div. F, Pub. L. 111–117), as carried forward by the Full-Year Continuing Appropriations Act, 2011 (Div. B, Pub. L. 112–10), (''the Act''), and Department of State Delegation of Authority Number 245–1, I hereby determine that it is important to the national interest of the United States to waive the requirements of Section 7086(c)(1) of the Act with respect to the Democratic Republic of the Congo and I hereby waive such restriction.

This determination shall be reported to the Congress, and published in the **Federal Register.**

Dated: July 11, 2011.

**Thomas Nides,**

*Deputy Secretary of State for Management and Resources.*

[FR Doc. 2011–25454 Filed 9–30–11; 8:45 am]

**BILLING CODE 4710–26–P**

## DEPARTMENT OF STATE

**[Public Notice: 7624]**

### Waiver of Restriction on Assistance to the Central Government of Gabon

Pursuant to Section 7086(c)(2) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2010 (Division F, Pub. L. 111–117), as carried forward by the Full-Year Continuing Appropriations Act, 2011 (Div. B, Pub. L. 112–10) (''the Act''), and Department of State Delegation of Authority Number 245–1, I hereby determine that it is important to the national interest of the United States to waive the requirements of Section 7086(c)(1) of the Act with respect to Gabon and I hereby waive such restriction.

This determination shall be reported to the Congress, and published in the **Federal Register**.

Dated: July 28, 2011.

**Thomas Nides,**

*Deputy Secretary of State for Management and Resources.*

[FR Doc. 2011–25452 Filed 9–30–11; 8:45 am]

**BILLING CODE 4710–26–P**

## DEPARTMENT OF STATE

**[Public Notice: 7628]**

### Waiver of Restriction on Assistance to the Central Government of the Kingdom of Swaziland

Pursuant to Section 7086(c)(2) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2010 (Div. F, Pub. L.111–117), as carried forward by the Full-Year Continuing Appropriations Act, 2011 (Div. B, Pub. L. 112–10) (''the Act''), and Department of State Delegation of Authority Number 245–1, I hereby determine that it is important to the national interest of the United States to waive the requirements of Section 7086(c)(1) of the Act with respect to the Kingdom of Swaziland and I hereby waive such restriction.

This determination shall be reported to the Congress, and published in the **Federal Register**.

Dated: June 24, 2011.

**Thomas Nides,**

*Deputy Secretary of State for Management and Resources.*

[FR Doc. 2011–25449 Filed 9–30–11; 8:45 am]

**BILLING CODE 4710–26–P**

## DEPARTMENT OF STATE

**[Public Notice: 7627]**

### Waiver of Restriction on Assistance to the Transitional Federal Government of Somalia

Pursuant to Section 7086(c)(2) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2010 (Div. F, Pub. L. 111–117) as carried forward by the Full-Year Continuing Appropriations Act, 2011 (Div. B, Pub. L. 112–10) (''the Act''), and Department of State Delegation of Authority Number 245–1, I hereby determine that it is important to the national interest of the United States to waive the requirements of Section 7086(c)(1) of the Act with respect to Somalia and I hereby waive such restriction.

This determination shall be reported to the Congress, and published in the **Federal Register**.

Dated: July 28, 2011.

**Thomas Nides,**

*Deputy Secretary of State for Management and Resources.*

[FR Doc. 2011–25445 Filed 9–30–11; 8:45 am]

**BILLING CODE 4710–26–P**

## DEPARTMENT OF STATE

**[Public Notice 7630]**

### Waiver of Restriction on Assistance to the Central Government of Côte d'Ivoire

Pursuant to Section 7086(c)(2) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2010 (Div. F, Pub. L. 111–117) (SFOAA), Section 7086(c)(2) of the SFOAA as carried forward by the Full-Year Continuing Appropriations Act 2011(Div. B, Pub. L. 112–10), and Department of State Delegation of Authority Number 245–1, I hereby determine that it is important to the national interest of the United States to waive the requirements of Section 7086(c)(1) of the SFOAA and Section 7086(c)(1) of the 2011 Full-Year Continuing Appropriations Act with respect to Côte d'Ivoire and I hereby waive such restrictions.

This determination shall be reported to the Congress, and published in the **Federal Register**.

Dated: July 20, 2011.

**Thomas Nides,**

*Deputy Secretary of State for Management and Resources.*

[FR Doc. 2011–25438 Filed 9–30–11; 8:45 am]

**BILLING CODE 4710–26–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### Environmental Impact Statement: Theodore Francis Green Airport, Warwick, RI

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

**ACTION:** Notice of Availability.

**SUMMARY:** The FAA is issuing this notice to advise the public that a Record of Decision (ROD), resulting from an Environmental Impact Statement (EIS) has been prepared for Theodore Francis Green Airport, in Warwick, Rhode Island.

**FOR FURTHER INFORMATION CONTACT:** Richard Doucette, Environmental Program Manager, Federal Aviation Administration New England, 12 New England Executive Park, Burlington, MA. Telephone (781) 238–7613.

**SUPPLEMENTARY INFORMATION:** The FAA is making available a ROD regarding installation of runway safety areas, other safety improvements, a runway extension, and other efficiency improvements at Theodore Francis Green Airport, in Warwick, Rhode Island. The ROD documents the final Agency decisions regarding the proposed projects as described and analyzed in the EIS. The ROD is available for review during normal business hours at the following locations: FAA New England Region, Airports Division, 16 New England Executive Park, Burlington, Massachusetts (781) 238–7613, Theodore Francis Green Airport, 2000 Post Rd, Warwick, Rhode Island, and at public libraries in Warwick and Cranston, Rhode Island.

Issued on: September 23, 2011.

**Bryon H. Rakoff,**

*Acting Manager, Airports Division.*

[FR Doc. 2011–25414 Filed 9–30–11; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

### Environmental Impact Statement: El Paso County, TX

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Rescind Notice of Intent (NOI) to prepare an EIS.

**SUMMARY:** FHWA is issuing this notice to advise the public that the NOI to prepare an environmental impact statement (EIS) for proposed

improvements to Loop 375 Border Highway West, in El Paso County, Texas, is being rescinded.

**FOR FURTHER INFORMATION CONTACT:** Gregory S. Punske, P.E., District Engineer, Federal Highway Administration, Texas Division, 300 East 8th Street, Room 826, Austin, Texas 78701, Telephone (512) 536–5960.

**SUPPLEMENTARY INFORMATION:** In September 2007, the Texas Department of Transportation (TxDOT) and FHWA announced their intent to prepare an EIS pursuant to 40 CFR 1508.22 and 43 TAC Sec. 2.5(e)(2) for the proposed Loop 375 César Chávez Highway (Border Highway West Extension) in El Paso, Texas, to include the Texas, New Mexico, and Ciudad Juárez, Chihuahua México border region. The proposed Border Highway West Extension project limits extended approximately 13.8 miles to provide a continuous route from Interstate 10 (I–10) east of State Highway (SH) 20 (Mesa Street) to Sunland Park Drive and continued on Loop 375 to end at United States Highway (US) 54. The proposed project was part of an alternate route to provide congestion relief for I–10, an east-west facility north of the project. The Loop 375 Border Highway West Extension Project was originally included in the Gateway 2030 Metropolitan Transportation Plan (MTP); and is currently included in the current Mission 2035 MTP, a transportation program adopted by the El Paso Metropolitan Planning Organization (MPO) in August of 2010 and approved for air conformity on January 28, 2011.

The EIS was in the preliminary stages of development. Two scoping meetings were held for cooperating and participating agencies on October 23, 2007 and October 30, 2007 at the El Paso International Airport Board Room, 6701 Convair Road, El Paso, Texas. In addition, two public scoping meetings were held on these same dates at Hilos de Plata Senior Center and the Westside Regional Command Center, El Paso, Texas.

FHWA and TxDOT have decided to rescind the Notice of Intent because the Texas Department of Transportation will be using State funding for the delivery of the project. A project containing no Federal funds or Federal actions is not required to complete NEPA project approvals. Further, the project will be broken into several phases or projects, all to be funded with State funds and all to have logical termini and independent utility. Consequently, the previously proposed project will undergo several environmental evaluations under a State environmental process. Comments or questions concerning the rescission of this proposed action and the EIS should be directed to the FHWA at the address provided above.

**Gregory S. Punske,**

*District Engineer, Austin, Texas.*

[FR Doc. 2011–25364 Filed 9–30–11; 8:45 am]

**BILLING CODE 4910–22–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

**[Docket No. FMCSA–2011–0225]**

### Agency Information Collection Activities; New Information Collection Request: Commercial Driver Individual Differences Study

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

**ACTION:** Notice and request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, FMCSA announces its plan to submit the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for its review and approval and invites public comment. The FMCSA requests approval of a new ICR that is associated with a study that will be conducted by a research contractor to investigate the differences among the characteristics of individual commercial drivers. This information collection will aid FMCSA in developing future safety initiatives by examining a wide array of driver and situational factors to determine if they are associated with increased or decreased crash and incident involvement.

**DATES:** Comments must be submitted on or before December 2, 2011.

**ADDRESSES:** You may submit comments identified by Federal Docket Management System (FDMS) Docket Number FMCSA–2011–0225 using any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building, Ground Floor, Room W12–140, 20590–0001.
- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m. e.t., Monday through Friday, except Federal holidays.

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

*Docket:* For access to the docket to read background documents or comments received, go to *http://www.regulations.gov,* and follow the online instructions for accessing the dockets, or go to the street address listed above.

*Privacy Act:* Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement for the Federal Docket Management System published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdfE8-794.pdf.*

*Public Participation:* The Federal eRulemaking Portal is available 24 hours each day, 365 days each year. You can obtain electronic submission and retrieval help and guidelines under the ''help'' section of the Federal eRulemaking Portal Web site. If you want us to notify you that we received your comments, please include a self-addressed, stamped envelope or postcard, or print the acknowledgement page that appears after submitting comments online. Comments received after the comment closing date will be included in the docket and will be considered to the extent practicable.

**FOR FURTHER INFORMATION CONTACT:** Theresa Hallquist, Federal Motor Carrier Safety Administration, Office of Analysis, Research and Technology, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001. Telephone (202) 366–1064 or e-mail *theresa.hallquist@dot.gov.,* Office hours are from 8 a.m. to 4 p.m., ET, Monday through Friday, except Federal holidays.

**SUPPLEMENTARY INFORMATION:** The purpose of this study is to identify, verify, quantify, and prioritize commercial driver risk factors. Primarily, these are personal factors

such as demographic characteristics, medical conditions, personality traits, and performance capabilities. Risk factors may also include work environmental conditions, such as carrier operations type. The study will identify risk factors by linking the characteristics of individual drivers with their driving records, especially the presence or absence of DOT reportable crashes.

*Title:* Commercial Driver Individual Differences Study.

*OMB Control Number:* 2126–XXXX.

*Type of Request:* New ICR.

*Respondents:* Commercial motor vehicle drivers and fleet managers.

*Estimated Number of Respondents:* 21,020.

*Estimated Time per Response:* The estimated average time per responses are as follow: 1 hour, 5 minutes for paper and 1 hour for electronic Form MCSA–5863, ''Commercial Motor Vehicle Driver Survey,'' submissions; 35 minutes for paper and 30 minutes for electronically Form MCSA–5864, ''Follow-Up Survey of Recent Life Experiences,'' submissions; 75 minutes for paper and 70 minutes for electronic Driver Survey and Job Descriptive Index from the Follow-up Survey submissions; and 10 minutes for the Form MCSA–5865, ''Fleet Managers Survey,'' submissions.

*Expiration Date:* N/A. This is a new information collection request.

*Frequency of Response:* This information collection will be a single, nonrecurring event for 16,000 CMV driver participants and 20 fleet managers. For at least 5,000 CMV driver participants, the information collection will occur twice.

*Estimated Total Annual Burden:* 9,536 hours. 8,822 hours for CMV driver participants: [16,800 CMV drivers completing paper Driver Survey × 65 minutes + 4,200 CMV drivers completing electronic Driver Survey × 1 hour + 4,000 drivers completing paper Follow-Up Survey × 35 minutes per driver / 60 minutes + 1,000 drivers completing electronic Follow-Up Survey × 30 minutes per driver / 60 minutes + 800 CMV drivers completing paper Driver Survey and Job Descriptive Index × 75 minutes per driver / 60 minutes + 200 CMV drivers completing paper Driver Survey and Job Descriptive Inde×× 70 minutes per driver / 60 minutes = 26,466 hours/3 years = 8,822 hours] + 714 hours for Carrier Operations: [20 participating carriers × 2 hours to learn about and agree to participation + 40 carrier managers completing IRB training × 2 hours + 20 Managers recruiting and handling data collection of 20,000 respondents × 83 hours + 20 Managers completing Fleet Manager Survey × 10 minutes + Carrier managers delivering monthly crash reports to VTTI (20 carriers × 36 months) × 30 minutes / 60 minutes = 2,143/3 years = 714 hours]. 8,822 hours for CMV driver participants + 714 hours for Carriers Operations = 9,536 hours.

*Public Comments Invited:* You are asked to comment on any aspect of this revised information collection request, including: (1) The necessity and usefulness of the information collection for FMCSA to meet its goal in reducing truck crashes; (2) the accuracy of the estimated burdens; (3) ways to enhance the quality, usefulness, and clarity of the collected information; and (4) ways to minimize the collection burden without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Issued on: September 23, 2011.

**Kelly Leone,**

*Associate Administrator for Research and Information Technology.*

[FR Doc. 2011–25325 Filed 9–30–11; 8:45 am]

**BILLING CODE 4910–EX–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

**[Docket No. FMCSA–2011–0084]**

### Hours of Service of Drivers: Western Pilot Service Application for Exemption

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

**ACTION:** Notice of application for exemption; request for comments.

**SUMMARY:** FMCSA has received an application from Western Pilot Service (''Western'') requesting an exemption from certain hours-of-service (HOS) provisions of the Federal Motor Carrier Safety Regulations (FMCSRs). The exemption request is for Western's drivers who transport aviation fuel for aircraft used in wild-land firefighting operations. Western specifically requests an exemption for up to 15 drivers from § 395.3(b)(2), the HOS prohibition against driving a commercial motor vehicle (CMV) after the 70th hour of cumulative on-duty time in any 8-day period. FMCSA requests public comment on the Western application for exemption.

**DATES:** Comments must be received on or before November 2, 2011.

**ADDRESSES:** You may submit comments identified by Federal Docket Management System Number [FMCSA–2011–0084] by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., between 9 a.m. and 5 p.m. E.T., Monday through Friday, except Federal holidays.

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

*Docket:* For access to the docket to read background documents or comments received, go to *http://www.regulations.gov,* and follow the online instructions for accessing the dockets, or go to the street address listed above.

*Privacy Act:* Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19476) or you may visit *http://DocketInfo.dot.gov.*

*Public participation:* The Federal eRulemaking Portal is available 24 hours each day, 365 days each year. You can get electronic submission and retrieval help and guidelines under the ''help'' section of the Federal eRulemaking Portal Web site. If you want us to notify you that we received your comments, please include a self-addressed, stamped envelope or postcard, or print the acknowledgement page that appears after submitting comments online. Comments received after the comment closing date will be included in the docket, and we will consider late comments to the extent practicable.

**FOR FURTHER INFORMATION CONTACT:** Mr. Thomas Yager, Chief, FMCSA Driver

and Carrier Operations Division; Office of Bus and Truck Standards and Operations; Telephone: 202–366–4325. E-mail: *MCPSD@dot.gov.*

**SUPPLEMENTARY INFORMATION:**

**Background**

Section 4007 of the Transportation Equity Act for the 21st Century (Pub. L. 105–178, 112 Stat. 107, 401, June 9, 1998) amended 49 U.S.C. 31136(e) and 31315 to provide authority to grant exemptions from the FMCSRs. Under its regulations, FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. The notice must also specify the effective period, and explain the terms and conditions, of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

**Request for Exemption**

The HOS regulations in 49 CFR 395.3(b)(2) prohibit a property-carrying commercial motor vehicle (CMV) driver from driving a CMV after having been on duty for 70 cumulative hours in any period of 8 consecutive days, if the employing motor carrier operates CMVs every day of the week.

Western is a tactical aerial firefighting company that operates in support of wild-land firefighting operations under contract with various government agencies such as the U. S. Forest Service, Bureau of Land Management, and the Bureau of Indian Affairs. Western is based in Phoenix, Arizona. The requested exemption would apply to no more than 15 ground support truck drivers employed by Western. The company operates a total of 12 ground support CMVs.

Each Western firefighting aircraft is teamed with a ground unit, which includes a driver and a CMV that pulls a gooseneck trailer transporting various mixing tanks, motors, and aviation fuel. Western states that its contracts require it to staff its units for a minimum of 9 hours and up to a maximum of 14 hours a day. Western's equipment must be set up at a designated government base and be ready to mix, load, fuel, and service its aircraft at all times during daylight hours and must be capable of going to an alternative base when requested. The ground support vehicles carry aviation fuel for their respective aircraft; the primary role of the driver is to service and re-fuel the aircraft. While the operation of the ground support vehicle is a secondary role, each driver is subject to the FMCSRs including 49 CFR part 395.

Western states that on a typical day its drivers report to work at 9 a.m. and perform a pre-trip inspection. The drivers prepare their daily logs, manifest, load logs, and mileage logs and attend a fire weather outlook briefing. The drivers may relax and sleep if they feel the need after the briefing and completion of any portion of daily duty requirements. If there is no late afternoon fire activity, the drivers are usually released at 6 p.m. (9-hour day).

Western contends that with no fire activity, drivers may perform no more than 4 hours of actual physical and mental work in a given day. While Western's drivers wait for an aircraft to be dispatched or land, they are ''available'' and in ''readiness to work,'' and are therefore considered to be ''on-duty, not driving'' and subject to the 70-hour/8-day rule.

The problem arises because Western's drivers sometimes run out of available hours in 5 days at 14 hours on duty per day, based on the 70-hour/8-day rule. Currently, Western has relief drivers who travel to give regular drivers 2 days off every 7 days to ensure that they stay in compliance with the HOS regulations.

Instead of complying with the 70-hour/8-day rule, Western would like drivers to have 2 consecutive days off in a 14-day period so that they are on the same schedule as the pilots operating the aircraft, who are required by Federal Aviation Administration rules to have 2 consecutive days off daily in a 2-week period. Western states that if its exemption request is granted, the drivers would still be held to the 14-hour driving windows and 11-hour driving limit every day the drivers are on duty. Western reasons that because its regular drivers have access to rest facilities, and permission to rest and relax during the day, they are not becoming fatigued. Western contends that these drivers operate in a relaxing, stress-free environment.

A copy of the Western Pilot Service exemption application is available for review in the docket for this notice.

**Request for Comments**

In accordance with 49 U.S.C. 31136(e) and 31315(b)(4), FMCSA requests public comment on the Western application for an exemption from the ''70-hour/8-day rule'' in 49 CFR part 395. The Agency will consider all comments received by close of business on November 2, 2011. Comments will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. The Agency will consider to the extent practicable comments received in the public docket after the closing date of the comment period.

Issued on: September 16, 2011.

**Larry W. Minor,**

*Associate Administrator for Policy.*

[FR Doc. 2011–25323 Filed 9–30–11; 8:45 am]

**BILLING CODE 4910–EX–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

**[Docket No. FMCSA–2011–0097]**

### Pilot Program on NAFTA Long-Haul Trucking Provisions

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

**ACTION:** Notice of availability.

**SUMMARY:** FMCSA announces the availability of a Final Environmental Assessment (FEA) that evaluates the potential environmental impacts resulting from the implementation of its United States-Mexico cross-border long-haul trucking pilot program. FMCSA received five comments to its draft environmental assessment (DEA) and responds to those comments in the FEA. FMCSA concludes that the potential environmental impacts from the pilot program are not significant and do not warrant additional environmental analysis in the form of an Environmental Impact Statement. FMCSA issues a Finding of No Significant Impact (FONSI) based on the conclusions in the FEA, which is also available in the docket.

*Instructions:* To view the FEA or the FONSI, go to the online docket (Regulations.gov) at *http://www.regulations.gov/* and enter in the docket number (FMCSA–2011–0097) and search for the ''Final Environmental Assessment'' or ''FONSI.''

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

*Privacy Act:* Anyone is able to search the electronic form for all comments received into any of our dockets by the name of the individual submitting the comment. You may review the U.S. Department of Transportation's (DOT) complete Privacy Act Statement in the **Federal Register** published on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8-785.pdf.*

**FOR FURTHER INFORMATION CONTACT:** Michael M. Johnsen, Environmental Protection Specialist, Analysis Division, Federal Motor Carrier Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., Washington, DC 20590, (202) 366–4111.

**SUPPLEMENTARY INFORMATION:**

### Background on the Pilot Project on the U.S.-Mexico Cross-Border Long-Haul Trucking Program

The pilot program is part of FMCSA's implementation of the North American Free Trade Agreement (NAFTA) cross-border long-haul trucking provisions. This pilot program would allow Mexico-domiciled motor carriers to operate throughout the United States for up to 3 years. U.S.-domiciled motor carriers would be granted reciprocal rights to operate in Mexico for the same period. Participating Mexican carriers and drivers would be required to comply with all applicable U.S. laws and regulations, including those concerned with motor carrier safety, customs, immigration, vehicle registration and taxation, and fuel taxation. The safety of the participating carriers would be tracked closely by FMCSA with input from the Motor Carrier Safety Advisory Committee, a Federal advisory committee. For further information regarding this pilot program, including additional background and comments, please see the **Federal Register** notice of the Pilot Program on NAFTA Long Haul Trucking Provisions in docket FMCSA–2011–0097.

### Final Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 (NEPA) (section 102(2)(c)), as implemented by the Council on Environment Quality regulations (40 CFR parts 1500–1508), FMCSA's Order 5610.1, issued March 1, 2004 (69 FR 9680), and other applicable guidance and requirements, FMCSA prepared a DEA for the U.S.-Mexican cross-border long-haul trucking program. FMCSA analyzed the potential impacts to the environment that may result from implementing the pilot project. In the DEA, FMCSA evaluated environmental issues such as emissions from vehicles, air quality impacts, and other pertinent matters, and requested public comments. FMCSA received five comments to the DEA and responded to those comments in the FEA. Additionally, after reviewing those comments, FMCSA has concluded that the potential environmental impacts from the pilot program are not significant and do not warrant additional environmental analysis in the form of an Environmental Impact Statement. Accordingly, FMCSA is issuing a FONSI based on the conclusions in the FEA, which is also available in the docket.

Issued on: September 27, 2011.

**Kenneth M. Leonard,**

*Special Projects Officer, Office of Research and Information Technology, FMCSA.*

[FR Doc. 2011–25389 Filed 9–30–11; 8:45 am]

**BILLING CODE 4910–EX–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

**[FMCSA Docket No. FMCSA–2011–0192]**

### Qualification of Drivers; Exemption Applications; Diabetes Mellitus

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

**ACTION:** Notice of final disposition.

**SUMMARY:** FMCSA announces its decision to exempt thirty-three individuals from its rule prohibiting persons with insulin-treated diabetes mellitus (ITDM) from operating commercial motor vehicles (CMVs) in interstate commerce. The exemptions will enable these individuals to operate CMVs in interstate commerce.

**DATES:** The exemptions are effective October 3, 2011. The exemptions expire on October 3, 2013.

**FOR FURTHER INFORMATION CONTACT:** Elaine M. Papp, Chief, Medical Programs, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Room W64–224, Department of Transportation, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

**SUPPLEMENTARY INFORMATION:**

### Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at: *http://www.regulations.gov.*

*Docket:* For access to the docket to read background documents or comments, go to *http://www.regulations.gov* and/or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

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

### Background

On August 4, 2011, FMCSA published a notice of receipt of Federal diabetes exemption applications from thirty-three individuals and requested comments from the public (76 FR 47291). The public comment period closed on September 6, 2011 and no comments were received.

FMCSA has evaluated the eligibility of the thirty-three applicants and determined that granting the exemptions to these individuals would achieve a level of safety equivalent to or greater than the level that would be achieved by complying with the current regulation 49 CFR 391.41(b)(3).

### Diabetes Mellitus and Driving Experience of the Applicants

The Agency established the current standard for diabetes in 1970 because several risk studies indicated that drivers with diabetes had a higher rate of crash involvement than the general population. The diabetes rule provides that ''A person is physically qualified to drive a commercial motor vehicle if that person has no established medical history or clinical diagnosis of diabetes mellitus currently requiring insulin for control'' (49 CFR 391.41(b)(3)).

FMCSA established its diabetes exemption program, based on the Agency's July 2000 study entitled ''A

Report to Congress on the Feasibility of a Program to Qualify Individuals with Insulin-Treated Diabetes Mellitus to Operate in Interstate Commerce as Directed by the Transportation Act for the 21st Century.'' The report concluded that a safe and practicable protocol to allow some drivers with ITDM to operate CMVs is feasible.

The September 3, 2003 (68 FR 52441) **Federal Register** notice in conjunction with the November 8, 2005 (70 FR 67777) **Federal Register** notice provides the current protocol for allowing such drivers to operate CMVs in interstate commerce.

These thirty-three applicants have had ITDM over a range of 1 to 38 years. These applicants report no severe hypoglycemic reactions resulting in loss of consciousness or seizure, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning symptoms, in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the past 5 years. In each case, an endocrinologist verified that the driver has demonstrated a willingness to properly monitor and manage his/her diabetes mellitus, received education related to diabetes management, and is on a stable insulin regimen. These drivers report no other disqualifying conditions, including diabetes-related complications. Each meets the vision standard at 49 CFR 391.41(b)(10).

The qualifications and medical condition of each applicant were stated and discussed in detail in the August 4, 2011, **Federal Register** notice and they will not be repeated in this notice.

**Discussion of Comment**

FMCSA did not receive any comments in this proceeding.

**Basis for Exemption Determination**

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the diabetes standard in 49 CFR 391.41(b)(3) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. The exemption allows the applicants to operate CMVs in interstate commerce.

To evaluate the effect of these exemptions on safety, FMCSA considered medical reports about the applicants' ITDM and vision, and reviewed the treating endocrinologists' medical opinion related to the ability of the driver to safely operate a CMV while using insulin.

Consequently, FMCSA finds that in each case exempting these applicants from the diabetes standard in 49 CFR 391.41(b)(3) is likely to achieve a level of safety equal to that existing without the exemption.

**Conditions and Requirements**

The terms and conditions of the exemption will be provided to the applicants in the exemption document and they include the following: (1) That each individual submit a quarterly monitoring checklist completed by the treating endocrinologist as well as an annual checklist with a comprehensive medical evaluation; (2) that each individual report within 2 business days of occurrence, all episodes of severe hypoglycemia, significant complications, or inability to manage diabetes; also, any involvement in an accident or any other adverse event in a CMV or personal vehicle, whether or not it is related to an episode of hypoglycemia; (3) that each individual provide a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (4) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the certification when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

**Conclusion**

Based upon its evaluation of the thirty-three exemption applications, FMCSA exempts, Michael J. Alexander, Larry E. Baumgartner, Stanley R. Boots, Carl D. Braddock, Dean A. Chamberlin, Michael E. Conner, Edna R. Contreras, Craig E. Cusick, Ronald D. Fatka, Robert M. Fleming, David W. Hammons, Frank B. Hernandez, Jeffrey D. Horsey, Dale A. Iverson, John H. Krastel, Joshua L. Kroetch, Larry D. Lilley, Edward J. Linhart, Larry D. Matson, Michael L. O'Clair, David W. Payne, Matthew B. Rhodes, Jim B. Robertson, II, Donald M. Rush, Jr., Barry A. Sircy, Andre M. St. Pierre, John S. Starchevich, Michael B. Tortora, Gregory J. Vigil, Charlotte C. Watson, Wayne W. Wenzel, Shaun M. Wheeler and James J. Wolf, Jr. from the ITDM standard in 49 CFR 391.41(b)(3), subject to the conditions listed under ''Conditions and Requirements'' above.

In accordance with 49 U.S.C. 31136(e) and 31315 each exemption will be valid for two years unless revoked earlier by FMCSA. The exemption will be revoked if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315. If the exemption is still effective at the end of the 2-year period, the person may apply to FMCSA for a renewal under procedures in effect at that time.

Issued on: September 26, 2011.

**Larry W. Minor,**

*Associate Administrator for Policy.*

[FR Doc. 2011–25328 Filed 9–30–11; 8:45 am]

**BILLING CODE 4910–EX–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

**[Docket No. FMCSA–2011–0194]**

### Qualification of Drivers; Exemption Applications; Diabetes Mellitus

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

**ACTION:** Notice of applications for exemption from the diabetes mellitus standard; request for comments.

**SUMMARY:** FMCSA announces receipt of applications from 16 individuals for exemption from the prohibition against persons with insulin-treated diabetes mellitus (ITDM) operating commercial motor vehicles (CMVs) in interstate commerce. If granted, the exemptions would enable these individuals with ITDM to operate CMVs in interstate commerce.

**DATES:** Comments must be received on or before November 2, 2011.

**ADDRESSES:** You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA–2011–0194 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* 1–202–493–2251.

*Instructions:* Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be posted without change to *http://*

*www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below for further information.

*Docket:* For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

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

**FOR FURTHER INFORMATION CONTACT:** Elaine M. Papp, Chief, Medical Programs, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue, SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

**SUPPLEMENTARY INFORMATION:**

## Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations for a 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The statute also allows the Agency to renew exemptions at the end of the 2-year period. The 16 individuals listed in this notice have recently requested such an exemption from the diabetes prohibition in 49 CFR 391.41(b)(3), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting the exemption will achieve the required level of safety mandated by the statutes.

## Qualifications of Applicants

*Mark D. Andersen*

Mr. Andersen, age 40, has had ITDM since 2010. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Andersen understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Andersen meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A Commercial Driver's License (CDL) from Iowa.

*David A. Basher*

Mr. Basher, 55, has had ITDM since 2006. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Basher understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Basher meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Massachusetts.

*Brian H. Berthiaume*

Mr. Berthiaume, 44, has had ITDM since 1994. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Berthiaume understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Berthiaume meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Vermont.

*Eric D. Blocker, Sr.*

Mr. Blocker, 56, has had ITDM since before September 2009. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Blocker understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Blocker meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from North Carolina.

*Barry W. Campbell*

Mr. Campbell, 45, has had ITDM since 2009. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Campbell understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Campbell meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class D operator's license from Wisconsin.

*Kevin M. Donohue*

Mr. Donohue, 27, has had ITDM since 2005. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Donohue understands

diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Donohue meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class D operator's license from New Jersey.

*Milton T. Gardiner*

Mr. Gardiner, 43, has had ITDM since 2010. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Gardiner understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Gardiner meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class 10 operator's license from Rhode Island.

*Raymond A. Jack*

Mr. Jack, 52, has had ITDM since 2010. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 3 years. His endocrinologist certifies that Mr. Jack understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Jack meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he has stable proliferative diabetic retinopathy. He holds a Class A CDL from Washington.

*Quency T. Johnson*

Mr. Johnson, 47, has had ITDM since 2004. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Johnson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Johnson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Wisconsin.

*Kenny B. Keels, Jr.*

Mr. Keels, 27, has had ITDM since 1997. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Keels understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Keels meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class D operator's license from South Carolina.

*Gene A. Michaels*

Mr. Michaels, 67, has had ITDM since 1985. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Michaels understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Michaels meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Michigan.

*Jason M. Pritchett*

Mr. Pritchett, 39, has had ITDM since 1990. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Pritchett understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Pritchett meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Michigan.

*Steven R. Sibert*

Mr. Sibert, 42, has had ITDM since 2011. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Sibert understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Sibert meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Minnesota.

*Cassie J. Silbernagel*

Mr. Silbernagel, 33, has had ITDM since 2011. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Silbernagel understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Silbernagel meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from South Dakota.

*Lewis B. Taylor*

Mr. Taylor, 39, has had ITDM since 2011. His endocrinologist examined him

in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Taylor understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Taylor meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Illinois.

*James A. Terilli*

Mr. Terilli, 61, has had ITDM since 2008. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Terilli understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Terilli meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class D operator's license from New York.

**Request for Comments**

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. We will consider all comments received before the close of business on the closing date indicated in the date section of the notice.

FMCSA notes that section 4129 of the Safe, Accountable, Flexible and Efficient Transportation Equity Act: A Legacy for Users requires the Secretary to revise its diabetes exemption program established on September 3, 2003 (68 FR 52441).[1] The revision must provide for individual assessment of drivers with diabetes mellitus, and be consistent with the criteria described in section 4018 of the Transportation Equity Act for the 21st Century (49 U.S.C. 31305).

Section 4129 requires: (1) Elimination of the requirement for 3 years of experience operating CMVs while being treated with insulin; and (2) establishment of a specified minimum period of insulin use to demonstrate stable control of diabetes before being allowed to operate a CMV.

In response to section 4129, FMCSA made immediate revisions to the diabetes exemption program established by the September 3, 2003 notice. FMCSA discontinued use of the 3-year driving experience and fulfilled the requirements of section 4129 while continuing to ensure that operation of CMVs by drivers with ITDM will achieve the requisite level of safety required of all exemptions granted under 49 USC. 31136(e).

Section 4129(d) also directed FMCSA to ensure that drivers of CMVs with ITDM are not held to a higher standard than other drivers, with the exception of limited operating, monitoring and medical requirements that are deemed medically necessary.

The FMCSA concluded that all of the operating, monitoring and medical requirements set out in the September 3, 2003 notice, except as modified, were in compliance with section 4129(d). Therefore, all of the requirements set out in the September 3, 2003 notice, except as modified by the notice in the **Federal Register** on November 8, 2005 (70 FR 67777), remain in effect.

Issued on: September 26, 2011.

**Larry W. Minor,**

*Associate Administrator for Policy.*

[FR Doc. 2011–25327 Filed 9–30–11; 8:45 am]

**BILLING CODE 4910–EX–P**

[1] Section 4129(a) refers to the 2003 notice as a ''final rule.'' However, the 2003 notice did not issue a ''final rule'' but did establish the procedures and standards for issuing exemptions for drivers with ITDM.

## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

**[Docket No. FMCSA–2011–0142]**

### Qualification of Drivers; Exemption Applications; Vision

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

**ACTION:** Notice of final disposition.

**SUMMARY:** FMCSA announces its decision to exempt 17 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs). The exemptions will enable these individuals to operate commercial motor vehicles (CMVs) in interstate commerce without meeting the prescribed vision standard. The Agency has concluded that granting these exemptions will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these CMV drivers.

**DATES:** The exemptions are effective October 3, 2011. The exemptions expire on October 3, 2013.

**FOR FURTHER INFORMATION CONTACT:** Elaine M. Papp, Chief, Medical Programs, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue, SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

**SUPPLEMENTARY INFORMATION:**

**Electronic Access**

You may see all the comments online through the Federal Document Management System (FDMS) at *http://www.regulations.gov.*

*Docket:* For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

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

**Background**

On August 10, 2011, FMCSA published a notice of receipt of exemption applications from certain individuals, and requested comments from the public (76 FR 49528). That notice listed 17 applicants' case histories. The 17 individuals applied for exemptions from the vision requirement in 49 CFR 391.41(b)(10), for drivers who operate CMVs in interstate commerce.

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for a 2-

year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The statute also allows the Agency to renew exemptions at the end of the 2-year period. Accordingly, FMCSA has evaluated the 17 applications on their merits and made a determination to grant exemptions to each of them.

**Vision and Driving Experience of the Applicants**

The vision requirement in the FMCSRs provides:

A person is physically qualified to drive a commercial motor vehicle if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of a least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing standard red, green, and amber (49 CFR 391.41(b)(10)).

FMCSA recognizes that some drivers do not meet the vision standard, but have adapted their driving to accommodate their vision limitation and demonstrated their ability to drive safely. The 17 exemption applicants listed in this notice are in this category. They are unable to meet the vision standard in one eye for various reasons, including amblyopia, glaucoma, macular scar, hyperopia, complete loss of vision, ruptured globe, prosthesis and macular hole. In most cases, their eye conditions were not recently developed. 13 of the applicants were either born with their vision impairments or have had them since childhood. The 4 individuals who sustained their vision conditions as adults have had them for periods ranging from 3 to 17 years.

Although each applicant has one eye which does not meet the vision standard in 49 CFR 391.41(b)(10), each has at least 20/40 corrected vision in the other eye, and in a doctor's opinion, has sufficient vision to perform all the tasks necessary to operate a CMV. Doctors' opinions are supported by the applicants' possession of valid commercial driver's licenses (CDLs) or non-CDLs to operate CMVs. Before issuing CDLs, States subject drivers to knowledge and skills tests designed to evaluate their qualifications to operate a CMV.

All of these applicants satisfied the testing standards for their State of residence. By meeting State licensing requirements, the applicants demonstrated their ability to operate a commercial vehicle, with their limited vision, to the satisfaction of the State. While possessing a valid CDL or non-CDL, these 17 drivers have been authorized to drive a CMV in intrastate commerce, even though their vision disqualified them from driving in interstate commerce. They have driven CMVs with their limited vision for careers ranging from 3 to 42 years. In the past 3 years, one of the drivers was involved in a crash and four were convicted of moving violations in a CMV.

The qualifications, experience, and medical condition of each applicant were stated and discussed in detail in the August 10, 2011 notice (76 FR 49528).

**Basis for Exemption Determination**

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the vision standard in 49 CFR 391.41(b)(10) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. Without the exemption, applicants will continue to be restricted to intrastate driving. With the exemption, applicants can drive in interstate commerce. Thus, our analysis focuses on whether an equal or greater level of safety is likely to be achieved by permitting each of these drivers to drive in interstate commerce as opposed to restricting him or her to driving in intrastate commerce.

To evaluate the effect of these exemptions on safety, FMCSA considered not only the medical reports about the applicants' vision, but also their driving records and experience with the vision deficiency.

To qualify for an exemption from the vision standard, FMCSA requires a person to present verifiable evidence that he/she has driven a commercial vehicle safely with the vision deficiency for the past 3 years. Recent driving performance is especially important in evaluating future safety, according to several research studies designed to correlate past and future driving performance. Results of these studies support the principle that the best predictor of future performance by a driver is his/her past record of crashes and traffic violations. Copies of the studies may be found at Docket Number FMCSA–1998–3637.

We believe we can properly apply the principle to monocular drivers, because data from the Federal Highway Administration's (FHWA) former waiver study program clearly demonstrate the driving performance of experienced monocular drivers in the program is better than that of all CMV drivers collectively (See 61 FR 13338, 13345, March 26, 1996). The fact that experienced monocular drivers demonstrated safe driving records in the waiver program supports a conclusion that other monocular drivers, meeting the same qualifying conditions as those required by the waiver program, are also likely to have adapted to their vision deficiency and will continue to operate safely.

The first major research correlating past and future performance was done in England by Greenwood and Yule in 1920. Subsequent studies, building on that model, concluded that crash rates for the same individual exposed to certain risks for two different time periods vary only slightly (See Bates and Neyman, University of California Publications in Statistics, April 1952). Other studies demonstrated theories of predicting crash proneness from crash history coupled with other factors. These factors—such as age, sex, geographic location, mileage driven and conviction history—are used every day by insurance companies and motor vehicle bureaus to predict the probability of an individual experiencing future crashes (See Weber, Donald C., ''Accident Rate Potential: An Application of Multiple Regression Analysis of a Poisson Process,'' Journal of American Statistical Association, June 1971). A 1964 California Driver Record Study prepared by the California Department of Motor Vehicles concluded that the best overall crash predictor for both concurrent and nonconcurrent events is the number of single convictions. This study used 3 consecutive years of data, comparing the experiences of drivers in the first 2 years with their experiences in the final year.

Applying principles from these studies to the past 3-year record of the 17 applicants, one of the applicants was involved in a crash and four of the applicants were convicted of moving violations in a CMV. All the applicants achieved a record of safety while driving with their vision impairment, demonstrating the likelihood that they have adapted their driving skills to accommodate their condition. As the applicants' ample driving histories with their vision deficiencies are good predictors of future performance, FMCSA concludes their ability to drive safely can be projected into the future.

We believe that the applicants' intrastate driving experience and history provide an adequate basis for predicting their ability to drive safely in interstate commerce. Intrastate driving, like interstate operations, involves

substantial driving on highways on the interstate system and on other roads built to interstate standards. Moreover, driving in congested urban areas exposes the driver to more pedestrian and vehicular traffic than exists on interstate highways. Faster reaction to traffic and traffic signals is generally required because distances between them are more compact. These conditions tax visual capacity and driver response just as intensely as interstate driving conditions. The veteran drivers in this proceeding have operated CMVs safely under those conditions for at least 3 years, most for much longer. Their experience and driving records lead us to believe that each applicant is capable of operating in interstate commerce as safely as he/she has been performing in intrastate commerce. Consequently, FMCSA finds that exempting these applicants from the vision standard in 49 CFR 391.41(b)(10) is likely to achieve a level of safety equal to that existing without the exemption. For this reason, the Agency is granting the exemptions for the 2-year period allowed by 49 U.S.C. 31136(e) and 31315 to the 17 applicants listed in the notice of August 10, 2011 (76 FR 49528).

We recognize that the vision of an applicant may change and affect his/her ability to operate a CMV as safely as in the past. As a condition of the exemption, therefore, FMCSA will impose requirements on the 17 individuals consistent with the grandfathering provisions applied to drivers who participated in the Agency's vision waiver program.

Those requirements are found at 49 CFR 391.64(b) and include the following: (1) That each individual be physically examined every year (a) By an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the standard in 49 CFR 391.41(b)(10), and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provide a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the certification when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

**Discussion of Comments**

FMCSA received one comment in this proceeding. The comment was considered and discussed below.

The Pennsylvania Department of Transportation is in favor of granting a Federal vision exemption to Jason W. Rupp, they indicated that they have reviewed the driving history of the applicant and have no objections to FMCSA granting him a vision exemption.

**Conclusion**

Based upon its evaluation of the 17 exemption applications, FMCSA exempts, Stephan P. Adamczyk, Shaun E. Burnett, Kevin W. Cannon, Daniel W. Eynon, Anton Filic, Mark E. Gessner, Stephen A. Grieser, Michael L. Harrison, Dennis H. Heller, Reginald J. Horner, Eric L. Kinner, Everett H. Logan, Robert E. Morgan, Jr., Jerry R. Orndorff, Gerald A. Pilarski, Jason W. Rupp and John F. Zalar from the vision requirement in 49 CFR 391.41(b)(10), subject to the requirements cited above (49 CFR 391.64(b)).

In accordance with 49 U.S.C. 31136(e) and 31315, each exemption will be valid for 2 years unless revoked earlier by FMCSA. The exemption will be revoked if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315.

If the exemption is still effective at the end of the 2-year period, the person may apply to FMCSA for a renewal under procedures in effect at that time.

Issued on: September 26, 2011.

**Larry W. Minor,**

*Associate Administrator of Policy.*

[FR Doc. 2011–25326 Filed 9–30–11; 8:45 am]

**BILLING CODE 4910–EX–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### Proposed Collection; Comment Request for Form 8899

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8899, Notice of Income Donated Intellectual Property.

**DATES:** Written comments should be received on or before December 2, 2011 to be assured of consideration.

**ADDRESSES:** Direct all written comments to Yvette B. Lawrence, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the form and instructions should be directed to Joel Goldberger at Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 927–9368, or through the Internet at *Joel.P.Goldberger@irs.gov.*

**SUPPLEMENTARY INFORMATION:**

*Title:* Notice of Income Donated Intellectual Property.

*OMB Number:* 1545–1962.

*Form Number:* Form 8899.

*Abstract:* Form 8899 is filed by charitable org. receiving donations of intellectual property if the donor provides timely notice. The initial deduction is limited to the donor's basis; additional deductions are allowed to the extent of income from the property, reducing excessive deductions.

*Current Actions:* There is no change in the paperwork burden previously approved by OMB. This form is being submitted for renewal purposes only.

*Type of Review:* Extension of a currently approved collection.

*Affected Public:* Business or other for-profit, and not-for-profit institutions.

*Estimated Number of Respondents:* 1,000.

*Estimated Time per Respondent:* 3 hrs.

*Estimated Total Annual Burden Hours:* 5,430.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

*Request for Comments:* Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

*Comments are invited on:* (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: September 21, 2011.

**Yvette B. Lawrence,**

*IRS Reports Clearance Officer.*

[FR Doc. 2011–25340 Filed 9–30–11; 8:45 am]

**BILLING CODE 4830–01–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### Proposed Collection; Comment Request for Regulation Project

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). The IRS is soliciting comments concerning cooperative housing corporations.

**DATES:** Written comments should be received on or before December 2, 2011 to be assured of consideration.

**ADDRESSES:** Direct all written comments to Yvette B. Lawrence, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of this regulation should be directed to Joel Goldberger, (202) 927–9368, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224 or through the internet (*Joel.P.Goldberger@irs.gov*).

**SUPPLEMENTARY INFORMATION:**

*Title:* Cooperative Housing Corporations.

*OMB Number:* 1545–1041.

*Regulation Project Number:* T.D. 8316.

*Abstract:* Section 1.216–1(d)(2) of this regulation allows cooperative housing corporations to make an election whereby the amounts of mortgage interest and/or real estate taxes allocated to tenant-stockholders of the corporation will be based on a reasonable estimate of the actual costs attributable to each tenant-stockholder based on the number of shares held in the corporation.

*Current Actions:* There is no change to this existing regulation.

*Type of Review:* Extension of a currently approved collection.

*Affected Public:* Individuals or households, and business or other for-profit organizations.

*Estimated Number of Respondents:* 2,500.

*Estimated Time per Respondent:* 15 minutes.

*Estimated Total Annual Burden Hours:* 625.

The following paragraph applies to all of the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

*Request for Comments:* Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

*Comments are invited on:* (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: September 17, 2011.

**Yvette B. Lawrence,**

*IRS Reports Clearance Officer.*

[FR Doc. 2011–25343 Filed 9–30–11; 8:45 am]

**BILLING CODE 4830–01–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

**[Third-Party Disclosure in IRS Regulations]**

### Proposed Collection; Comment Request for Regulation Project

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). The IRS is soliciting comments concerning third-party disclosure requirements in IRS regulations.

**DATES:** Written comments should be received on or before December 2, 2011 to be assured of consideration.

**ADDRESSES:** Direct all written comments to Yvette B. Lawrence, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the regulations should be directed to Joel Goldberger, at (202) 927–9368, or at Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet, at *Joel.P.Goldberger@irs.gov*.

**SUPPLEMENTARY INFORMATION:**

*Title:* Third-Party Disclosure requirements in IRS Regulations.

*OMB Number:* 1545–1466.

*Abstract:* These existing regulations contain third-party disclosure requirements that are subject to the Paperwork Reduction Act of 1995.

*Current Actions:* There are no changes being made to these regulations at this time.

*Type of Review:* Extension of currently approved collection.

*Affected Public:* Individuals or households, business or other for-profit organizations, and not-for-profit institutions.

*Estimated Number of Responses:* 307,064,630.

*Estimated Time per Respondent:* Varies.

*Estimated Total Annual Burden Hours:* 68,885,183.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

*Request for Comments:* Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: September 21, 2011.

**Yvette B. Lawrence,**

*IRS Reports Clearance Officer.*

[FR Doc. 2011–25341 Filed 9–30–11; 8:45 am]

**BILLING CODE 4830–01–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### Advisory Committee to the Internal Revenue Service; Meeting

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of meeting.

**SUMMARY:** The Information Reporting Program Advisory Committee (IRPAC) will hold a public meeting on Wednesday, October 26, 2011.

**FOR FURTHER INFORMATION CONTACT:** Ms. Caryl Grant, National Public Liaison, CL:NPL:SRM, Rm. 7559, 1111 Constitution Avenue, NW., Washington, DC 20224. Phone: 202–927–3641 (not a toll-free number). E-mail address: **public_liaison@irs.gov.*

**SUPPLEMENTARY INFORMATION:** Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988), that a public meeting of the IRPAC will be held on Wednesday, October 26, 2011 from 9 a.m. to 12 p.m. at the United States Access Board, 1331 F Street, NW., Washington, DC 20004. Report recommendations on issues that may be discussed include: Foreign Account Tax Compliance Act, § 6050W information reporting of payments made in settlement of payment card and third party network transactions and Form 1099–K, information regarding non-resident alien taxation and tax reporting, withholding tax issues, identity theft, tax credit bonds, Affordable Care Act—employer and insurer reporting, tip income reporting compliance and enforcement efforts, employer identification numbers for retirement plans, Form 1099–R reporting and withholding guidance for certain installment payments, Form 1099 instructions, taxpayer identification number masking on payee 1099s, Form 1099–B modifications, business master file address change procedures, program problems encountered by foreign artists when applying for U.S. social security numbers, withholding and reporting on payments for freight, shipping, and other transportation expenses, changes to Publication 3908, gaming tax law and Bank Secrecy Act issues for Indian tribal governments, Form 5500EZ, erroneous claims for itemized deductions for unreimbursed business expenses, and fringe benefit information. Last minute agenda changes may preclude advance notice. Due to limited seating and security requirements, please call or e-mail Caryl Grant to confirm your attendance. Ms. Grant can be reached at 202–927–3641 or **public_liaison@irs.gov.* Should you wish the IRPAC to consider a written statement, please call 202–927–3641, or write to: Internal Revenue Service, Office of National Public Liaison, CL:NPL:SRM, Room 7559, 1111 Constitution Avenue, NW., Washington, DC 20224 or e-mail: **public_liaison@irs.gov.*

Dated: September 23, 2011.

**Candice Cromling,**

*Director, National Public Liaison.*

[FR Doc. 2011–25342 Filed 9–30–11; 8:45 am]

**BILLING CODE 4830–01–P**

## DEPARTMENT OF VETERANS AFFAIRS

**[OMB Control No. 2900–0670]**

### Proposed Information Collection (Fiduciary Statement in Support of Appointment) Activity: Comment Request

**AGENCY:** Veterans Benefits Administration, Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments for information needed to determine a claimant's qualification as a fiduciary.

**DATES:** Written comments and recommendations on the proposed collection of information should be received on or before December 2, 2011.

**ADDRESSES:** Submit written comments on the collection of information through *http://www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0670'' in any correspondence. During the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *http://www.Regulations.gov.*

**FOR FURTHER INFORMATION CONTACT:** Nancy J. Kessinger at (202) 461–9769 or fax (202) 275–5947.

**SUPPLEMENTARY INFORMATION:** Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden 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 through the use of automated collection techniques or the use of other forms of information technology.

*Title:* Fiduciary Statement in Support of Appointment, VA Form 21–0792.

*OMB Control Number:* 2900–0670.

*Type of Review:* Extension of a currently approved collection.

*Abstract:* Individual's seeking appointment as a fiduciary of VA beneficiaries complete VA Form 21–0792. VA uses the data collected to determine the individual's qualification as a fiduciary and to inquire about his or her credit and criminal background.

*Affected Public:* Individuals or households.

*Estimated Annual Burden:* 1,875 hours.

*Estimated Average Burden per Respondent:* 15 minutes.

*Frequency of Response:* One time.

*Estimated Number of Respondents:* 7,500.

Dated: September 28, 2011.

By direction of the Secretary.

**Denise McLamb,**

*Program Analyst, Enterprise Records Service.*

[FR Doc. 2011–25381 Filed 9–30–11; 8:45 am]

**BILLING CODE 8320–01–P**

## DEPARTMENT OF VETERANS AFFAIRS

**[OMB Control No. 2900–0013]**

### Proposed Information Collection (Application for United States Flag for Burial Purposes) Activity: Comment Request

**AGENCY:** Veterans Benefits Administration, Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on the information needed to determine eligibility for issuance of a burial flag for a deceased veteran.

**DATES:** Written comments and recommendations on the proposed collection of information should be received on or before December 2, 2011.

**ADDRESSES:** Submit written comments on the collection of information through *http://www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0013'' in any correspondence. During the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *http://www.Regulations.gov.*

**FOR FURTHER INFORMATION CONTACT:** Nancy J. Kessinger at (202) 461–9769 or FAX (202) 275–5947.

**SUPPLEMENTARY INFORMATION:** Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden 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 through the use of automated collection techniques or the use of other forms of information technology.

*Title:* Application for United States Flag for Burial Purposes, VA Form 21–2008.

*OMB Control Number:* 2900–0013.

*Type of Review:* Extension of a currently approved collection.

*Abstract:* VA Form 21–2008 is used to determine a family member or friend of a deceased veteran eligibility for issuance of a burial flag.

*Affected Public:* Individuals or households.

*Estimated Annual Burden:* 162,500 hours.

*Estimated Average Burden per Respondent:* 15 minutes.

*Frequency of Response:* One time.

*Estimated Number of Respondents:* 650,000.

Dated: September 28, 2011.

By direction of the Secretary.

**Denise McLamb,**

*Program Analyst, Enterprise Records Service.*

[FR Doc. 2011–25383 Filed 9–30–11; 8:45 am]

**BILLING CODE 8320–01–P**

## DEPARTMENT OF VETERANS AFFAIRS

**[OMB Control No. 2900–0049]**

### Proposed Information Collection (Approval of School Attendance) Activity: Comment Request

**AGENCY:** Veterans Benefits Administration, Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments for information necessary to determine entitlement to compensation and pension benefits for a child between the ages of 18 and 23 attending school.

**DATES:** Written comments and recommendations on the proposed collection of information should be received on or before December 2, 2011.

**ADDRESSES:** Submit written comments on the collection of information through *http://www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0049'' in any correspondence. During the comment period, comments may be viewed online through the Federal Docket Management

System (FDMS) at *http://www.Regulations.gov.*

**FOR FURTHER INFORMATION CONTACT:** Nancy J. Kessinger at (202) 461–9769 or fax (202) 275–5947.

**SUPPLEMENTARY INFORMATION:** Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden 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 through the use of automated collection techniques or the use of other forms of information technology.

*Titles:*

a. Request for Approval of School Attendance, VA Form 21–674 and 21–674c.

b. School Attendance Report, VA Form 21–674b.

*OMB Control Number:* 2900–0049.

*Type of Review:* Extension of a currently approved collection.

*Abstract:* Recipients of disability compensation, dependency and indemnity compensation, disability pension, and death pension are entitled to benefits for eligible children between the ages of 18 and 23 who are attending school. VA Forms 21–674, 21–674c and 21–674b are used to confirm school attendance of children for whom VA compensation or pension benefits are being paid and to report any changes in entitlement factors, including marriages, a change in course of instruction and termination of school attendance.

*Affected Public:* Individuals or households.

*Estimated Annual Burden:*

a. VA Forms 21–674 and 674c—34,500 hours.

b. VA Form 21–674b—3,292 hours.

*Estimated Average Burden Per Respondent:*

a. VA Forms 21–674 and 674c—15 minutes.

b. VA Form 21–674b—5 minutes.

*Frequency of Response:* On occasion.

*Estimated Number of Respondents:*

a. VA Forms 21–674 and 674c—138,000 hours.

b. VA Form 21–674b—39,500 hours.

Dated: September 28, 2011.

By direction of the Secretary.

**Denise McLamb,**

*Program Analyst, Enterprise Records Service.*

[FR Doc. 2011–25380 Filed 9–30–11; 8:45 am]

**BILLING CODE 8320–01–P**

## DEPARTMENT OF VETERANS AFFAIRS

**[OMB Control No. 2900–New (DBQs—Group 4)]**

## Agency Information Collection (Disability Benefits Questionnaires—Group 4) Activity Under OMB Review

**AGENCY:** Veterans Benefits Administration, Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

**DATES:** Comments must be submitted on or before November 2, 2011.

**ADDRESSES:** Submit written comments on the collection of information through *http://www.Regulations.gov* or to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316. Please refer to ''OMB Control No. 2900–New (DBQs–Group 4)'' in any correspondence.

**FOR FURTHER INFORMATION CONTACT:** Denise McLamb, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461–7485, fax (202) 461–0966 or e-mail *denise.mclamb@va.gov.* Please refer to ''OMB Control No. 2900–New (DBQs–Group 4).''

**SUPPLEMENTARY INFORMATION:**

*Titles:*

Cranial Nerve Conditions Disability Benefits Questionnaire, VA Form 21–0960C3.

Narcolepsy Disability Benefits Questionnaire, VA Form 21–0960C6.

Fibromyalgia Disability Benefits Questionnaire, VA Form 21–0960C7.

Seizure Disorders (Epilepsy) Disability Benefits Questionnaire, VA Form 21–0960C11.

Dental and Oral Conditions, including Mouth, Lips, and Tongue (Other than Temporomandibular Joint Conditions) Disability Benefits Questionnaire, VA Form 21–0960D1.

Endocrine Diseases (other than Thyroid, Parathyroid or Diabetes Mellitus). Disability Benefits Questionnaire, VA Form 21–0960–E–2.

Thyroid & Parathyroid Conditions Disability Benefits Questionnaire, VA Form 21–0960–E–3.

Hernias (Including Abdominal, Inguinal, and Femoral Hernias) Disability Benefits Questionnaire, VA Form 21–0960–H–1.

HIV-Related Illnesses Disability Benefits Questionnaire, VA Form 21–0960–I–2.

Infectious Diseases (Other Than HIV-Related Illness, Chronic Fatigue Syndrome, or Tuberculosis) Disability Benefits Questionnaire, VA Form 21–0960–I–3.

Systemic Lupus Erythematosus (SLE) and Other Autoimmune Diseases Disability Benefits Questionnaire, VA Form 21–0960–I–4.

Nutritional Deficiencies Disability Benefits Questionnaire, VA Form 21–0960–I–5.

Urinary Tract (including Bladder & Urethra) Conditions (excluding Male Reproductive System) Disability Benefits Questionnaire, VA Form 21–0960–J–4.

Respiratory Conditions (other than Tuberculosis and Sleep Apnea) Disability Benefits Questionnaire, VA Form 21–0960–L–1.

Loss of Sense of Smell and/or Taste Disability Benefits Questionnaire, VA Form 21–0960–N–3.

Sinusitis/Rhinitis and Other Conditions of the Nose, Throat, Larynx, and Pharynx Disability Benefits Questionnaire, VA Form 21–0960–N–4.

Chronic Fatigue Syndrome Disability Benefits Questionnaire, VA Form 21–0960–Q–1.

*OMB Control Number:* 2900–New (DBQs—Group 4).

*Type of Review:* New collection.

*Abstract:* Data collected on VA Form 21–0960 series will be used to obtain information from claimants' treating physician that is necessary to adjudicate a claim for disability benefits.

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 **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on July 27, 2011, at pages 45008–45008.

*Affected Public:* Individuals or households.

*Estimated Annual Burden:*

a. VAF 21–0960–C–3—5,000.
b. VAF 21–0960–C–6—1,250.
c. VAF 21–0960–C–7—1,250.
VAF 21–0960–C–11—1,250.
VAF 21–0960–D–1—1,250.
VAF 21–0960–E–2—2,500.
d. VAF 21–0960–E–3—2,500.
VAF 21–0960–H–1—3,750.
e. VAF 21–0960–I–2—1,250.
f. VAF 21–0960–I–3—2,500.
VAF 21–0960–I–4—2,500.
g. VAF 21–0960–I–5—1,250.
VAF 21–0960–J–4—3,750.
VAF 21–0960–L–1—10,000.
VAF 21–0960–N–3—1,250.
VAF 21–0960–N–4—10,000.
VAF 21–0960–Q–1—2,500.

*Estimated Average Burden per Respondent:*

a. VAF 21–0960–C–3—30 minutes.
b. VAF 21–0960–C–6—15 minutes.
c. VAF 21–0960–C–7—15 minutes.
VAF 21–0960–C–11—15 minutes.
VAF 21–0960–D–1—15 minutes.
VAF 21–0960–E–2—15 minutes.
d. VAF 21–0960–E–3—15 minutes.
VAF 21–0960–H–1—15 minutes.
e. VAF 21–0960–I–2—15 minutes.
f. VAF 21–0960–I–3—15 minutes.
VAF 21–0960–I–4—30 minutes.
g. VAF 21–0960–I–5—15 minutes.
VAF 21–0960–J–4—15 minutes.
VAF 21–0960–L–1—30 minutes.
VAF 21–0960–N–3—15 minutes.
VAF 21–0960–N–4—30 minutes.
VAF 21–0960–Q–1—15 minutes.

*Frequency of Response:* On occasion.

*Estimated Number of Respondents:*

a. VAF 21–0960–C–3—10,000.
b. VAF 21–0960–C–6—5,000.
c. VAF 21–0960–C–7—5,000.
VAF 21–0960–C–11—5,000.
VAF 21–0960–D–1—5,000.
VAF 21–0960–E–2—10,000.
d. VAF 21–0960–E–3—10,000.
VAF 21–0960–H–1—15,000.
e. VAF 21–0960–I–2—5,000.
f. VAF 21–0960–I–3—10,000.
VAF 21–0960–I–4—5,000.
g. VAF 21–0960–I–5—5,000.
VAF 21–0960–J–4—15,000.
VAF 21–0960–L–1—20,000.
VAF 21–0960–N–3—5,000.
VAF 21–0960–N–4—20,000.
VAF 21–0960–Q–1—10,000.

Dated: September 28, 2011.

By direction of the Secretary.

**Denise McLamb,**

*Program Analyst, Enterprise Records Service.*

[FR Doc. 2011–25382 Filed 9–30–11; 8:45 am]

**BILLING CODE 8320–01–P**

## DEPARTMENT OF VETERANS AFFAIRS

### Enhanced-Use Lease (EUL) of Department of Veterans Affairs (VA) Real Property at the VA Connecticut Healthcare System, Newington Campus

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Notice of Intent to Enter into an Enhanced-Use Lease.

**SUMMARY:** The Secretary of VA intends to enter into an EUL on an 11.2-acre parcel of land and improvements to include renovating an existing building at the VA Connecticut Healthcare System, Newington campus. The selected lessee will finance, design, develop, renovate, manage, maintain and operate the EUL development. As consideration for the lease, the lessee will be required to renovate, operate, and maintain a permanent supportive housing facility; provide preference and priority placement for homeless Veterans and Veterans at risk of homelessness; and provide a supportive services program that guides resident Veterans toward attaining long-term self-sufficiency.

**FOR FURTHER INFORMATION CONTACT:** Edward Bradley, Office of Asset Enterprise Management (044C), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461–7778 (this is not a toll-free number).

**SUPPLEMENTARY INFORMATION:** Title 38 U.S.C. 8161 *et seq.* states that the Secretary may enter into an enhanced-use lease if he determines that implementation of a business plan proposed by the Under Secretary for Health for applying the consideration under such a lease for the provision of medical care and services would result in a demonstrable improvement of services to eligible Veterans in the geographic service-delivery area within which the property is located. This project meets this requirement.

Approved: September 26, 2011.

**Eric K. Shinseki,**

*Secretary of Veterans Affairs.*

[FR Doc. 2011–25365 Filed 9–30–11; 8:45 am]

**BILLING CODE 8320–01–P**

## DEPARTMENT OF VETERANS AFFAIRS

### Enhanced-Use Lease (EUL) of Department of Veterans Affairs (VA) Real Property for the Development of a Senior Living Retirement and Affordable Housing Community in Fort Howard, MD

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Notice of Intent to Enter into an Enhanced-Use Lease.

**SUMMARY:** The Secretary of VA intends to enter into an EUL for 94 acres of land and thirty-seven (37) buildings at the Fort Howard VA Campus in Fort Howard, Maryland. The selected lessee will finance, design, renovate, construct, manage, maintain and operate the EUL development. As consideration for the lease, the lessee will be required to provide a new community-based outpatient clinic, profit sharing, and discounted rent to Veterans residing in the senior living retirement and affordable housing community. Fifty units will be set aside to provide transitional housing and supportive services for homeless and at-risk Veterans.

**FOR FURTHER INFORMATION CONTACT:** Edward L. Bradley, III, Office of Asset Enterprise Management (044), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420. Telephone: (202) 461–7778 (this is not a toll-free number).

**SUPPLEMENTARY INFORMATION:** Title 38 U.S.C. 8161 *et seq.* states that the Secretary may enter into an enhanced-use lease if he determines that implementation of a business plan proposed by the Under Secretary for Health for applying the consideration under such a lease for the provision of medical care and services would result in a demonstrable improvement of services to eligible Veterans in the geographic service-delivery area within which the property is located. This project meets this requirement.

Approved: September 26, 2011.

**Eric K. Shinseki,**

*Secretary of Veterans Affairs.*

[FR Doc. 2011–25366 Filed 9–30–11; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF VETERANS AFFAIRS

### Enhanced-Use Lease (EUL) of Department of Veterans Affairs (VA) Real Property for the Development of a Permanent Supportive Housing Facility in Lyons, NJ

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Notice of Intent to Enter into an Enhanced-Use Lease.

**SUMMARY:** The Secretary of VA intends to enter into an EUL on a 16-acre parcel of land at the VA New Jersey Health Care System—Lyons Campus Medical Center in Lyons, New Jersey. The selected lessee will finance, design, develop, construct, manage, maintain and operate the EUL development. As consideration for the lease, the lessee will be required to construct, operate, and maintain a permanent housing facility; provide preference and priority placement for homeless Veterans and Veterans at risk of homelessness and their families; and provide a supportive services program that guides resident Veterans toward attaining long-term self-sufficiency.

**FOR FURTHER INFORMATION CONTACT:** Edward Bradley, Office of Asset Enterprise Management (044), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461–7778 (this is not a toll-free number).

**SUPPLEMENTARY INFORMATION:** Title 38 U.S.C. 8161 *et seq.* states that the Secretary may enter into an enhanced-use lease if he determines that implementation of a business plan proposed by the Under Secretary for Health for applying the consideration under such a lease for the provision of medical care and services would result in a demonstrable improvement of services to eligible Veterans in the geographic service-delivery area within which the property is located. This project meets this requirement.

Approved: September 26, 2011.

**Eric K. Shinseki,**

*Secretary of Veterans Affairs.*

[FR Doc. 2011–25322 Filed 9–30–11; 8:45 am]

BILLING CODE P

# FEDERAL REGISTER

Vol. 76 Monday,
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Part II

## Department of Justice

Drug Enforcement Administration

Robert Raymond Reppy, D.O.; Decision and Order; Notice

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. 09–50]**

### Robert Raymond Reppy, D.O.; Decision and Order

On March 31, 2011, Administrative Law Judge (ALJ) Timothy D. Wing issued the attached recommended decision. Neither party filed exceptions to the decision.

Having reviewed the entire record including the parties' briefs, I have decided to adopt the ALJ's recommended ruling, findings of fact, conclusions of law, and recommended order. Accordingly, I will order that Respondent's DEA Certificate of Registration be revoked and that any pending applications be denied.

As the ALJ found, between 2002 and 2006, Respondent wrote thousands of controlled- substance prescriptions (approximately 5000 each year) to patients who sought such drugs as hydrocodone and alprazolam through the internet, most of whom (at least 90 percent) he never physically examined, let alone met. ALJ at 12, 20–21.[1] Respondent wrote the prescriptions based on medical records which were sent to him not by the patients' doctors, but by the patients themselves, and a telephone consultation with the patients. *Id.* at 20–21. As the ALJ found, ''Respondent rarely contacted a patient's primary care physician whose records he was reviewing'' and had no way of verifying whether the person he prescribed to was the actual person whose record he was reviewing. *Id.* at 21.

Respondent maintains that in 2002, when he agreed to write the prescriptions, the legality of prescribing controlled substances via the internet was ''a gray area'' and that the standards were not the same ''as are agreed upon now.'' Tr. 64. Respondent further claims that he did his ''due diligence,'' which included doing ''a little research on [his] own,'' with the result being that he ''couldn't find anybody saying * * * for definite that you cannot do this'' and that he was even shown a letter from ''DEA giving permission to do it.'' *Id.* at 60. Respondent was shown this letter by an attorney, Mr. Robert Carr, who happened to be the founder and President of United Prescription Services, a Tampa, Florida-based pharmacy which was to fill most of the prescriptions Respondent issued; Respondent knew that Carr had a financial interest in United Prescription Services. *Id.* at 60–61, 151.

As for Respondent's assertion that he was unable to find ''anybody'' definitely saying that it was illegal to prescribe controlled substances over the internet to persons he never examined, this may be consistent with his claim that he did ''*little* research.'' However, it clearly was not the case, as even by 2002, multiple States had enacted statutes, promulgated rules, or published policy statements to the effect that prescribing drugs in this manner was illegal. Moreover, as explained below, it was clearly unreasonable for Respondent to rely on Carr's purported advice.

In 2000, California enacted a provision which prohibits the prescribing or dispensing of a dangerous drug ''on the Internet for delivery to any person in this state, without an appropriate prior examination and medical indication therefore.'' Cal. Bus. & Prof. Code § 2242.1. Moreover, as early as November 2001, the Medical Board of California (MBC) issued a citation order to an out-of-state physician for prescribing over the Internet to California residents. *See* Citation Order, Carlos Gustav Levy (Nov. 30, 2001). The MBC cited *both* the physician's failure to conduct ''a good faith prior examination,'' as well as his lack of ''a valid California Physician and Surgeon's License to practice medicine in California.'' *Id.* at 1. The Board further ordered Doctor Levy ''to cease and desist from Internet prescribing to individuals in California without first performing a good faith prior examination, without having medical indication to prescribe such medication and without having a California Physician and Surgeon's License,'' and fined him $25,000. *Id.* at 1–2. *See also* Citation Order, Martin P. Feldman (Aug. 15, 2003); *see also* Citation Order, Harry Hoff (June 17, 2003); Citation Order, Carlos Gustavo Levy (Jan. 28, 2003).

In addition, in January 2003 (and prior to much of Respondent's prescribing activity which continued until October 2006), the MBC revoked a physician's medical license when he engaged in practices similar to those of Respondent. *See In re Steven Opsahl, M.D.,* Decision and Order, at 3 (Med. Bd. Cal. 2003) (available by query at *http://publicdocs.mbc.ca.gov/pdl/mbc.aspx).*

In *Opsahl,* the MBC held that ''[b]efore prescribing a dangerous drug, a physical examination must be performed'' and that a physician ''cannot do a good faith prior examination based on a history, a review of medical records, responses to a questionnaire, and a telephone consultation with the patient, without a physical examination of the patient.'' *Id.* The MBC also held that a ''medical indication'' is determined only after the taking of a history, the conducting of a physical examination, and an assessment of ''the patient's condition.'' *Id.* The MBC further explained that ''[a] physician cannot determine whether there is a medical indication for prescription of a dangerous drug without performing a physical examination.'' *Id.*

In April 2001, Ohio enacted a statute which defines ''telemedicine'' as ''the practice of medicine in this state through the use of any communication, including oral, written, or electronic communication, by a physician outside th[e] state'' and also requires that a physician obtain a ''telemedicine certificate'' to lawfully prescribe within the State, *id.* § 4731.296 (effective 4–10–01), and a ''special activity certificate.'' *Id.* § 4731.294 (effective 4–10–01). Moreover, in 2002, Ohio adopted a regulation which, except for in circumstances not at issue here, prohibits the dispensing of controlled substances ''to a person who the physician has never personally examined and diagnosed.'' Ohio Admin. Code § 4731–11–09(A).

In 2002, Tennessee law prohibited (as it still does) the practice of medicine within the State without a license issued by the State. Tenn. Code Ann. § 63–6–201(a) (2002); *see also id.* § 63–6–204 (2002) (defining ''a person [who is] regarded as practicing medicine'' as one ''who treats, or professes to diagnose, treat, operate[] on or prescribes for any physical ailment or any physical injury to or deformity of another''). Like Ohio, Tennessee also provides for ''restricted licenses and special licenses based upon licensure to another state for the limited purpose of authorizing the practice of telemedicine.'' *Id.* § 63–6–209(b) (1996). *See also* Tennessee Board of Medical Examiners, *Position Statement: Prerequisites to Prescribing or Dispensing Drugs-In Person, Electronically or Over the Internet* (Sept. 2000) (''[I]t shall be a prima facie violation of [State law] for a physician to prescribe or dispense any drug to any individual, whether in person or by electronic means or over the Internet or over telephone lines, unless the physician has first done and appropriately documents, for the person to whom a prescription is to be issued or drugs dispensed, all of the following: (a) Performed an appropriate history and physical examination * * * '').[2]

[1] All citations to the ALJ's decision are to the slip opinion as originally issued.

[2] This statement likewise recognizes three situations in which a drug may be prescribed

Prior to Respondent's prescribing activity, Tennessee had also promulgated a regulation which provided clear notice that, before issuing a prescription for a controlled substance ''by electronic means or over the Internet or over telephone lines,'' a physician must ''[p]erform[] an appropriate history and medical examination,'' ''[m]a[k]e a diagnosis based upon the examinations and all diagnostic and laboratory tests consistent with good medical care,'' ''[f]ormulate[] a therapeutic plan,'' and ''[i]nsure[] availability of the physician or coverage for the patient for appropriate follow-up care.'' Tenn. Comp. R. & Regs. 0880–2–14.(7)(a) (2002).

In April 2000, the Alabama State Board of Medical Examiners promulgated its ''Contact with Patients before Prescribing'' rule. The rule states the Board's position:

> that prescribing drugs to an individual the prescriber has not personally examined is usually inappropriate. Before prescribing a drug, the physician should make an informed medical judgment based on the circumstances of the situation and on his or her training and experience. Ordinarily, this will require that the physician perform an appropriate history and physical examination, make a diagnosis, and formulate a therapeutic plan, a part of which might be a prescription.

Ala. Admin Code r.540–X–9.11(1). While the Alabama rule also recognizes that in certain situations a prescribing physician is not required to have performed a physical exam of the patient (such as admission orders for a newly admitted patient, where the prescriber is taking call for another physician, and where the prescriber continues medication ''on a short-term basis for a new patient prior to the patient's first appointment''), none of these exceptions applied to Respondent's internet prescribing. *Id.* r.540–X–9.11(2).

In February 2002, the Georgia Composite State Board of Medical Examiners amended its regulation defining ''Unprofessional Conduct'' to include ''[p]roviding treatment and/or consultation recommendations via electronic or other means unless the licensee has performed a history and physical examination of the patient adequate to establish differential diagnoses and identify underlying conditions and/or contra-indications to the treatment recommended.'' Ga. Comp. R. & Regs. 360–3–.02 (2002). While the regulation provided an exception in the case of a licensee who is on call or covering for another doctor, the exception did not apply to Respondent's internet prescribing. *See also* S.C. Code Reg. 81–28(A) (effective May 25, 2001) (requiring prescribing physician to ''[p]ersonally perform an appropriate history and physical examination'').

In addition, prior to Respondent's commencement of internet prescribing, numerous state boards had issued policy statements which made clear that this activity was unprofessional conduct and illegal. For example, in November 1999, the North Carolina Medical Board issued a position statement entitled ''Contact With Patients Before Prescribing'' (available at *http://www.ncmedboard.org/position_statements/detail/contact_with_patients_before_prescribing/*). Therein, the Board stated ''that prescribing drugs to an individual the prescriber has not personally examined is inappropriate'' except in the case of admission orders for newly hospitalized patients, taking call for another physician, and on short-term basis prior to a patient's first appointment. The Board further explained that ''[o]rdinarily, this will require that the physician perform an appropriate history and physical examination, make a diagnosis, and formulate a therapeutic plan, part of which might be a prescription.''

In December 1999, the Texas State Board of Medical Examiners issued its Internet Prescribing Policy. This Policy stated that ''[i]t is unprofessional conduct for a physician to initially prescribe any dangerous drugs or controlled substances without first establishing a proper physician-patient relationship.'' Texas State Board of Medical Examiners, *Internet Prescribing Policy* (available at *http://www.tmb.state.tx.us/rules/guidelines/ipp.php*). The Policy further explained that ''at a minimum,'' this requires, *inter alia,* ''verifying that the person requesting the medication is in fact who they claim to be,'' and ''establishing a diagnosis through the use of accepted medical practices such as a patient history, mental status exam, physical examination and appropriate diagnostic and laboratory testing.'' *Id.*

In May 2000, the Louisiana State Board of Medical Examiners issued a Statement of Position on Internet/Telephonic Prescribing, which stated ''the Board's view, [that] it is unlawful for a physician to prescribe medication, treatment or a plan of care generally if the physician has not examined the patient and established a diagnostic basis for such therapy.'' Louisiana State Board of Medical Examiners, *Statement of Position on Internet/Telephonic Prescribing,* at 2 (available at *http://www.lsbme.la.gov/Statements%20of%20position.html*). The Board further explained that:

A physician establishes a physician-patient relationship by:

- Verifying that the person requesting the medication is in fact who they claim to be;
- Conducting an appropriate examination of the patient;
- Establishing a diagnosis through the use of accepted medical practices, *i.e.,* a patient history, mental status, examination, physical examination and appropriate diagnostic and laboratory testing;
- Discussing with the patient the diagnosis, risks and benefits of various treatment options; and
- Insuring the availability for appropriate follow-up care.

*Id.* at 2. The Louisiana Board further stated that ''[a]s a matter of law, to be valid, effective and lawful, each prescription or order for medication must be issued or given by an authorized practitioner (*i.e.,* a Louisiana licensed physician) with respect to an individually identified patient, based on the practitioner's examination and diagnosis of the patient.'' *Id.* at 3. Finally, the Board explained that:

> because the [State's] Medical Practice Act restricts the practice of medicine to persons possessing a license issued by [it,] [a]n individual who issues a prescription or orders medication for an individual who is a resident of or located in Louisiana, who does not possess a Louisiana medical license or other authorization to practice medicine in this state, is necessarily engaged in the unauthorized practice of medicine in contravention of the Medical Practice Act.

*Id.*

Moreover, in November 2000, the Oklahoma State Board of Medical Licensure and Supervision adopted its Policy on Internet Prescribing. The Oklahoma Board adopted most of the same standards as the Louisiana statement, including that ''at a minimum,'' a physician must verify the identity of a patient requesting medication and ''establish[] a diagnosis through the use of accepted medical practices such as a patient history, mental status exam, physical examinations and appropriate diagnostic and laboratory testing by the prescribing physician.'' Oklahoma State Board of Medical Licensure and Supervision, *Policy on Internet Prescribing* (available at *http://www.*

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without the physician having performed a physical examination of the patient: (1) In admission orders for new admitted hospital patients, (2) when covering for another physician, and (3) on a short-term basis for a new patients prior to the patient's first appointment. None of these applied to Respondent's internet practice.

*okmedicalboard.org/download/308/precribing+on+the+Internet.htm*). The Oklahoma Board also stated that ''[c]omplete management of a patient by Internet, e-mail, or other forms of electronic communications is inappropriate.'' *Id.; see also* Washington Medical Quality Assurance Commission, *Position on Internet Prescribing* (Winter 2001) (available at *http://www.doh.wa.gov/hsqa/mqac/policies.htm*) (''The standard of medical practice in the state of Washington requires a physician, when prescribing medication to [*inter alia,*] verify that the person requesting the medication is in fact who he or she claims to be,'' and ''establish a diagnosis through the use of accepted medical practices such as a patient interview, physical examination, and appropriate ancillary testing.'').

To similar effect, in May 2000, the Mississippi State Board of Medical Licensure issued a policy statement on Internet Prescribing. The Mississippi policy stated that the ''[e]ssential components of proper prescribing and legitimate medical practice require that the physician obtains a thorough medical history and conducts an appropriate physical examination before prescribing any medication for the first time.'' Mississippi State Board of Medical Licensure, *Internet Prescribing* (available at *http://www.msbml.state.ms.us/regulations/2004%20policy%20book.pdf*). While the Mississippi Board recognized exceptions for admission orders for newly hospitalized patients, cross-coverage situations, and for short-term prescribing prior to a new patient's first appointment, as noted previously, none of these situations applied to Respondent's internet prescribing.

In December 2001, the Massachusetts State Board of Registration in Medicine amended its Prescribing Practices Policy and Guidelines to address the subject of Internet Prescriptions. The Board stated that ''a prescription to be legally valid must be issued within the context of a physician-patient relationship under circumstances in which the physician has conformed to certain minimum norms and standards for the care of patients, such as taking an adequate medical history and conducting an appropriate physical examination.'' Massachusetts State Board of Registration in Medicine, *Prescribing Practices Policy and Guidelines, Internet Prescriptions* (available at *http://www.mass.gov/Eeohhs2/docs/borim/policies_guidelines/policy_03_06.pdf*).[3] The Board further advised that ''[p]rescribing over the internet while deviating from these requirements is therefore unlawful.''[4]

At the instant hearing, Respondent did not testify as to any state laws or Board positions (with the exception of Florida) he found which authorized prescribing to patients he would not meet, based on a review of records and a telephone consultation. Instead, he maintained that ''as part of [his] due diligence'' in deciding whether to engage in Internet prescribing, he reviewed the Model Guidelines for the Appropriate Use of the Internet in Medical Practice (RX 9), a policy document issued by the Federation of State Medical Boards of the United States (FSMB). Tr. 76–77. Respondent testified that this document gave him the impression that Attorney Carr's advice that Internet prescribing was legal was accurate ''because it specifically says the physician/patient relationships exists whether or not there has been a personal encounter between the physician and the patient,'' and that this was ''[b]lack and white.''

The fact that a physician-relationship ''is clearly established when a physician agrees to undertake diagnosis and treatment,'' RX 9, at 7, however, does not mean that a physician has established an adequate physician-patient relationship sufficient to support the diagnosis of a patient and the issuance of a prescription. Indeed, the Guidelines further state that ''[t]reatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional (face-to-face) settings.'' *Id.* at 8. At the hearing, Respondent offered no explanation as to what he thought this statement meant.

Just one page later, the Guidelines further state that ''[p]hysicians who treat or prescribe through Internet Web sites are practicing medicine and must possess appropriate licensure in all jurisdictions where patients reside.'' *Id.* at 9. Respondent admitted that during the period of his internet prescribing, he was licensed only in the State of Florida. Respondent thus engaged in the unauthorized practice of medicine in numerous States. As the California Court of Appeals has explained, the ''proscription of the unlicensed practice of medicine is neither an obscure nor an unusual state prohibition of which ignorance can reasonably be claimed, and certainly not by persons * * * who are licensed health care providers. Nor can such persons reasonably claim ignorance of the fact that authorization of a prescription pharmaceutical constitutes the practice of medicine.'' *Hageseth* v. *Superior Court,* 59 Cal. Rptr.3d 385, 403 (Ct. App. 2007).

Respondent's assertion that he relied on the FSMB Guidelines and yet ''couldn't find anybody saying * * * for definite that you cannot do this,'' Tr. 60, is especially remarkable given that the Guidelines included a list of References. RX 9, at 11. Among the authorities cited therein are the position/policy statements of the Boards of Louisiana, New York, North Carolina, Oklahoma, South Carolina, Texas and Washington State, each of which—as discussed above—provided ample notice that each of these Board's considered internet prescribing to violate the accepted standards of professional practice.[5] In

[3] The Board subsequently amended its policy on December 17, 2003; the amended policy did not change the requirement that the prescribing physician must ''conduct[] an appropriate physical'' examination. It further stated that ''[i]ssuance of a prescription, by any means, including the Internet or other electronic process, that does not meet these requirements is therefore unlawful.''

[4] Other States adopted similar statutes, rules and/or policy statements on Internet prescribing within the next several years and well before Respondent ceased his internet prescribing. *See* Colorado Board of Medical Examiners, *Policy 40–9: Guidelines Regarding Prescribing for Unknown Patients* (Nov. 16, 2003) (available at *http://www.dora.state.co.us/medical/policies/40-09.pdf*) ; Ind. Admin Code 5–41 (Oct. 2003) (''Except in institutional settings, on-call situations, cross-coverage situations, and situations involving advanced practice nurses with prescriptive authority * * * a physician shall not prescribe, dispense, or otherwise provide, or cause to be provided, any controlled substance to a person who the physician has never personally physically examined and diagnosed.''); New York State Board for Professional Medical Conduct, *Statements on Telemedicine* (Dec. 24, 2003) (available at *http://www.health.ny.gov/professionals/doctors/conduct/telemedicine.htm.*) (''All the current standards of care regarding the practice of medicine apply. The fact that an electronic medium is utilized for contact between parties or as a substitute for face-to-face consultation does not change the standards of care.''). While these provisions were adopted after Respondent commenced his Internet prescribing, Respondent had a continuing obligation to keep track of the law as it changed.

In addition, as early as June 2001, DEA had revoked the registration of a physician whose state controlled substance registration and medical licenses had been suspended for prescribing over the Internet. See *Rick Joe Nelson,* 66 FR 30752 (2001). This same physician was ultimately indicted for conspiracy to distribute controlled substances outside of the usual course of professional practice, 21 U.S.C. 846, and convicted. *See United States* v. *Nelson,* 383 F.3d 1227 (10th Cir. 2004). Of note, his conviction was affirmed (in a published decision) on September 20, 2004, more than two years before Respondent left the clinic. *See also Mark Wade,* 69 FR 7018, 7021 (Feb. 12, 2004) (revoking registration of Internet prescriber and noting physician had pled guilty to violation of 21 U.S.C. 846).

[5] In April 2001, DEA published a Guidance Document entitled *Dispensing and Purchasing Controlled Substances over the Internet,* 66 FR 21181 (2001). The Guidance explained that ''[o]nly practitioners acting in the usual course of their professional practice may prescribe controlled substances. These practitioners *must be registered*

short, Respondent's assertion that he did ''a little research'' is an accurate statement only to the extent that emphasis is placed on the word ''little.''

Respondent also asserts that a February 27, 2002 letter from the Chief of the DEA's Office of Diversion Control's Liaison and Policy Section to Carr, ''g[ave] permission to do it.'' Tr. 60; *see also* RX 4. According to Respondent, Carr showed him the letter which ''seemed very convincing'' and that the letter ''basically said they [DEA] were okay with it.'' Tr. 90–91.

While the letter stated ''[i]t appears that the submitted policies and procedures meet the federal requirements regarding controlled substances prescriptions,'' it further noted that the pharmacy had represented that under its policies, it ''plans to verify the authenticity and legal authority to prescribe of each prescriber.'' RX 4, at 1. More specifically, the letter noted that ''[m]anagement personnel will verify several elements including, but not limited to * * * [p]rofessional licensure, DEA registration, *[l]egitimate patient/prescriber relationship, [p]rescriptions are issued in the usual course of professional practice, and [p]rescriptions are issued for a legitimate medical purpose.*'' Id. (emphasis added). Continuing, the letter noted ''valid controlled substance prescriptions must be issued for a legitimate medical purpose,'' and that ''this is usually defined and interpreted by the prescriber's respective state professional licensing board.'' [6] *Id.*

Thus, contrary to Respondent's claim, the DEA letter did nothing more than address the lawfulness of the pharmacy's dispensing of prescriptions and did so based on Carr's representation that the underlying prescriptions would be lawfully issued. The letter thus provides no comfort to Respondent.

As for his reliance on Carr's purported legal advice, Respondent stated that he ''assumed the lawyer would give me his honest opinion and expertise and I wouldn't have to go around consulting three or four of them to get the same thing.'' Tr. 60–61. Yet Respondent acknowledged that he knew Carr had a financial interest in the pharmacy. *Id.* at 61. Given Carr's financial interest, and even assuming (without deciding) that Carr and Respondent entered into an attorney-client relationship, Respondent had ample reason to question whether Carr was capable of providing disinterested legal advice. *Id.* at 60–61. Moreover, Carr's advice was fundamentally at odds with various statements contained in the Model Guidelines, a document which Respondent purportedly read, including the statements that: (1) ''[t]reatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional (face-to-face) settings''; and (2) ''[p]hysicians who treat or prescribe through Internet Web sites are practicing medicine and must possess appropriate licensure in all jurisdictions where patients reside.'' RX 9, at 8–9. Thus, because it is clear that Respondent did not reasonably rely on Carr's advice, this is not a mitigating factor.

Finally, Respondent asserts that his cooperation in the proceeding involving *United Prescription Services, Inc.,* 72 FR 50397 (2007), should be considered as a factor in mitigation. Resp. Br. 25. The Government did not dispute that Respondent provided testimony and an affidavit in that matter that was of some benefit to the Government. Tr. 78.

That being said, I conclude that Respondent's cooperation is substantially outweighed by the extensive and egregious misconduct he committed. As the ALJ found, with the exception of a period of several months during which he was on a leave of absence, *see* GX 10, at 85; for more than four years, Respondent wrote thousands of controlled substances prescriptions outside of the usual course of professional practice and which lacked a legitimate medical purpose. ALJ at 54, 60; *see also* 21 CFR 1306.04(a).

While this is reason alone to reject's Respondent cooperation as a mitigating factor, in addition, the ALJ also found that Respondent flagrantly failed to supervise a Physician Assistant, who wrote thousands of controlled substance prescriptions under his registration. ALJ at 65. As the ALJ found, the PA wrote 14,000 prescriptions, many of which were for controlled substances, during the period in which Respondent was on leave of absence. *Id.* Upon his return in March 2004, Respondent discovered that the PA had written some controlled substance prescriptions in his name, Tr. 38, 139; a violation of both state and federal law. *See* Fla. Sta. Ann. § 459.022(4)(e) (prohibiting PAs from prescribing controlled substances); 21 U.S.C. 843(a)(2) (prohibiting dispensing of a controlled substance by use of a registration number ''issued to another person''); *id.* § 822(a)(2) (requiring ''[e]very person who dispenses'' to obtain a registration).

The evidence showed that Respondent was upset that the PA was writing prescriptions under his registration without complying with his instructions and could not be controlled. Tr. 139. Respondent complained to the clinic's owner ''about [the PA's] prescribing patterns using [his] DEA registration,'' RX 12, at 4; and asked him to fire the PA several times; however, the clinic's owner refused to

*with DEA and licensed to prescribe controlled substances by the State(s) in which they operate.*'' Id. at 21181 (emphasis added).

In addition, the Guidance Document specifically stated that ''Federal law requires that '[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.' '' *Id.* at 21182 (quoting 21 CFR 1306.04(a)). The Guidance explained that ''[e]very state separately imposes the same requirement under its laws'' and that ''[u]nder Federal and state law, for a doctor to be acting in the usual course of professional practice, there must be a bona fide doctor/patient relationship.'' *Id.*

Continuing, the Guidance explained that ''[f]or purposes of state law, many state authorities, with the endorsement of medical societies, consider the existence of the following four elements as an indication that a legitimate doctor/patient relationship has been established:

A patient has a medical complaint;

A medical history has been taken;

A physical examination has been performed; and

Some logical connection exists between the medical complaint, the medical history, the physical examination, and the drug prescribed.

*Id.* at 21182–83.

The Guidance further stated that ''[c]ompleting a questionnaire that is then reviewed by a doctor hired by the internet pharmacy could not be considered the basis for a doctor/patient relationship.'' *Id.* at 21183.

While the DEA Guidance Document does not have the force and effect of law, it nonetheless provided an additional source of information as to the potential illegality of Respondent's Internet prescribing.

[6] As explained above, this was not an entirely accurate statement of the law with regards a physician's prescribing to patients who reside in a different State. As the Model Guidelines explained, most (if not all) States deem prescribing to a resident to be practicing medicine within the State, and thus, a physician doing so is subject to both the licensing and medical practice standards of the patient's State and the physician's State. *See* RX 9, at 9; *see also* discussion above.

However, Respondent produced no evidence showing that Carr, in requesting DEA's review of its policies, disclosed to the Agency that the doctors whose prescriptions it filled would be practicing medicine across state lines. *See* RX 3. Moreover, even if Respondent relied on the Florida Telemedicine Regulation, and even conceding that the regulation did not clearly state on its face that the prescriber (as opposed to another doctor) must perform a physical exam, *see* Fla. Admin. Code r.64B15–14.008(2), having claimed to have reviewed the Model Guidelines (and having previously been licensed in other States), Respondent cannot credibly claim ignorance of the fact that the regulation of the practice of medicine is a state function and that each State has its own Board and set of rules with which he was required to comply. *See, e.g., Hageseth,* 59 Cal.Rptr.3d, at 403.

do so.[7] Tr. 37–38; *see* GX 10, at 106. Nonetheless, Respondent continued to work for the clinic and did so for more than another year. Notwithstanding Respondent's professed concern that the PA ''was being pretty arrogant [and] doing a lot of things on his own,'' Tr. 121, and his awareness of the PA's prescribing irregularities, RX 12, at 4; Respondent offered no evidence that he had reported the PA to either law enforcement or regulatory authorities. This provides an additional reason to reject Respondent's cooperation as a ground for mitigating the sanction.

In conclusion, the record here establishes that over the course of more than four years, Respondent was responsible for the issuance of thousands of illegal controlled-substance prescriptions. Respondent's misconduct was egregious, and the Agency's interest in deterring similar misconduct on the part of others provides ample justification to support the ALJ's recommended order. *See Joseph Gaudio,* 74 FR 10083, 10094 (2009); *Southwood Pharmaceuticals, Inc.,* 72 FR 36487, 36504 (2007) (citing *Butz* v. *Glover Livestock Commission Co., Inc.,* 411 U.S. 182, 187–88 (1973)).

Moreover, as the ALJ explained, while at the hearing, Respondent occasionally acknowledged some wrongdoing, most of his testimony was then spent on blaming others or offering absurd or disingenuous justifications for his egregious misconduct. *See* ALJ at 65 (discussing verification of internet customers' identities—''I'm relying on the state that issued their driver's license attesting their identity. If the state did not adequately check their identity before issuing them a driver's license, then * * * I had no way of determining that. * * * I used the same method of checking their identity' as I would if they were present in front of me.''). *See also id.* at 66–67 (finding that ''rather than admit that * * * his telemedicine practices were in clear violation of contemporaneous standards * * * Respondent * * * attempted to cast doubt on the clarity of the rules.''); *id.* at 68 (comparing Respondent's testimony that he was ''sorry'' for the prescriptions but then stating that ''if I thought I was doing anything wrong, I wouldn't have done it''); *id.* (stating that he was remorseful, but adding ''I sincerely wish I had never been duped into being any part of their operation at all'').

In sum, as the ALJ found, Respondent ''fail[ed] to sustain his burden to credibly accept responsibility for his misconduct and demonstrate that he will not engage in future misconduct.'' ALJ at 71. Accordingly, I will adopt the ALJ's recommended sanction.

## Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a)(4), as well as by 28 CFR 0.100(b), I order that DEA Certificate of Registration BR5287342, issued to Robert Raymond Reppy, D.O., be, and it hereby is, revoked. I further order that any application for renewal or modification of such registration be, and it hereby is, denied. This Order is effective November 2, 2011.

Dated: September 19, 2011.

**Michele M. Leonhart,**

*Administrator.*

*D. Linden Barber, Esq.,* for the Government.

*A.S. Weekley, Jr., M.D., Esq.,* for Respondent.

## Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge

### I. Introduction

Timothy D. Wing, Administrative Law Judge. This proceeding is an adjudication pursuant to the Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.,* to determine whether the drug enforcement administration (DEA) should revoke a physician's certificate of registration (COR) as a practitioner and deny any pending applications for renewal or modification of that registration. Without this registration the practitioner Robert Raymond Reppy, D.O. (Respondent or Dr. Reppy), of Tampa, Florida, will be unable to lawfully prescribe, dispense or otherwise handle controlled substances in the course of his practice.

On April 28, 2009, the DEA Deputy Assistant Administrator, Office of Diversion Control, issued an Order to Show Cause (OSC) to Respondent, giving Respondent notice of an opportunity to show cause why the DEA should not revoke Respondent's DEA COR BR5287342 pursuant to 21 U.S.C. 824(a)(4), and deny any pending applications for renewal or modification pursuant to 21 U.S.C. 823(f), on the grounds that Respondent's continued registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 824(a)(4) and 823(f).

In substance, the OSC alleges as follows:

1. Respondent has a DEA COR scheduled to expire by its own terms on April 30, 2009;

2. Respondent issued prescriptions to Internet customers from early 2004 until October 2006;

3. Respondent allowed a physician's assistant (PA) to use Respondent's COR to issue purported prescriptions to Internet customers, in violation of 21 U.S.C. 846 and Fla. Stat. Ann. § 458.347 (2008);

4. The above-referenced prescriptions were issued without a legitimate medical purpose and outside the usual course of professional practice, in violation of 21 CFR 1306.04(a) and 21 U.S.C. 841(a)(1);

5. Respondent issued purported prescriptions of controlled substances to customers throughout the United States even though Respondent is licensed to practice medicine only in Florida;

6. The above-referenced prescriptions violated state laws prohibiting the unauthorized practice of medicine, including unlicensed, out-of-state physicians issuing controlled substance prescriptions to state residents. *See e.g.,* Miss. Code Ann. § 73–25–34; Cal. Bus. & Prof. Code § 2052; Ala. Code § 34–24–51; and

7. Respondent violated Florida law and regulations prohibiting licensed physicians from issuing controlled substance prescriptions in excessive or inappropriate quantities, from issuing prescriptions via the Internet without documented patient evaluation and without discussing treatment options with patients. Fla. Stat. Ann. § 458.331(q); Fla. Admin. Code Ann. r. 64B8–9.014.

On May 26, 2009, Respondent, through counsel, requested a hearing on the allegations in the OSC.[8] Following prehearing procedures,[9] a hearing was held on November 16, 2010, in Bradenton, Florida, with both the Government and Respondent represented by counsel. Both parties called witnesses to testify and introduced documentary evidence. After the hearing, both parties filed proposed findings of fact, conclusions of law and argument. All of the evidence and post-hearing submissions have been considered, and to the extent the parties' proposed findings of fact have

[7] In an affidavit given in the *United Prescription Services* proceeding, Respondent stated that the clinic owner removed the PA from the clinic. RX 12, at 4. However, in both the *united* and instant proceedings, Respondent testified that the clinic owner ''would never fire [the PA], no matter how many times I requested it.'' GX 10, at 106; Tr. 37. Respondent also testified the PA ''was kept away from me,'' TR.101, and that the PA would frequently work from home.

[8] Respondent submitted an application to renew his COR on April 6, 2009. (ALJ Ex. 3 at 1.)

[9] This case was originally assigned to Administrative Law Judge Mary Ellen Bittner. (*See, e.g.,* OPHS May 27, 2009.) On January 15, 2010, Administrative Law Judge Gail A. Randall was assigned to the case. (Mem. Jan. 15, 2010.) Judge Randall reassigned the case to me on July 19, 2010. (Mem. Jul. 19, 2010.)

been adopted, they are substantively incorporated into those set forth below.

**II. Preliminary Evidentiary Issues**

Prior to discussing the evidence and reaching the substantive issues in this case, a threshold evidentiary issue is the weight to be given, if any, to (1) the Deputy Administrator's conclusions of law regarding Dr. Reppy's compliance with state law contained in *United Prescription Services, Inc.,* 72 FR 50,397 (DEA 2007), a separate proceeding in which Dr. Reppy was a witness but not a party; (2) a transcript of Dr. Reppy's sworn testimony in that case, admitted without objection as Government Exhibit 10 in the present proceeding; and (3) affidavits of Respondent's current employees and patients offered as Respondent's Exhibit 19, and an affidavit of Respondent offered as Respondent's Exhibit 13.

*A. The 2007 Final Order in United Prescription Services, Inc.*

On August 23, 2007, the **Federal Register** published a final order in *United Prescription Services, Inc.,* 72 FR 50,397 (DEA 2007). Therein, the then-Deputy Administrator made legal conclusions touching upon the conduct of Dr. Reppy, who testified in that case but was not named as a party. The Deputy Administrator found that ''Dr. Reppy violated the laws of California, Tennessee, Indiana, and Louisiana'' because ''[e]ven if Dr. Reppy's * * * conduct established a valid doctor-patient relationship under Florida law (a dubious proposition at that), [he] violated the laws of other States which clearly require that the prescriber personally perform the physical exam except in limited situations not applicable here.'' *United Prescription Servs.,* 72 FR at 50,408 (internal citations omitted). The Deputy Administrator also concluded that Dr. Reppy's PA, Mr. Protheroe, ''used Dr. Reppy's DEA registration while Reppy was on leave of absence and not supervising him * * *. These prescriptions violated the State of Florida's regulations'' regarding Dr. Reppy's delegation of authority to a PA.[10] *Id.* at 50,409.

In the ''proposed conclusions of law'' section of the Government's post-hearing brief in the present case, the Government cites a number of such conclusions by the Deputy Administrator, apparently arguing that I should give weight to those conclusions here. (*See* Gov't Br. 5–6 (discussing Factors Two and Four of 21 U.S.C. 823(f)).)

At issue, therefore, is whether legal conclusions from a prior proceeding relating to the conduct of a non-party witness should be given weight or controlling effect in a subsequent proceeding against the witness. I note at the outset that Dr. Reppy was not named as a party in *United Prescription Services,* had not yet had any adverse action taken against him by the DEA with respect to his COR (*see* Gov't Ex. 10 at 61), and was apparently unrepresented by counsel at the time.

The APA provides that ''[t]he transcript of testimony and exhibits, together with all papers and requests filed in the proceeding, constitutes the exclusive record for decision'' in this administrative proceeding. 5 U.S.C. 556(e). The APA further defines ''party'' to include a person or agency named or admitted as a party, or properly seeking and entitled as of right to be admitted as a party * * *.'' 5 U.S.C. 551(3), *amended by* Public Law 111–350, Jan. 4, 2011, 124 Stat. 3677 (no relevant changes) (''party[] in an agency proceeding''). In the instant case, the final Agency decision in *United Prescription Services* cannot serve as substantial evidence because it is not part of the ''exclusive record for decision'' to which Dr. Reppy was a party.[11] I therefore find that the APA precludes me from considering the individualized legal conclusions on the ultimate issues[12] regarding Dr. Reppy contained in *United Prescription Services* as a potential basis for imposing a sanction in this case.[13] *See id.* § 556(e).

I further find that the doctrine of *res judicata,* or collateral estoppel, provides no basis for adopting without analysis the Deputy Administrator's findings in *United Prescription Services* that Dr. Reppy violated state law. Under the doctrine of *res judicata,* (1) a final judgment (2) on the merits (3) between the parties is binding on the parties in subsequent litigation. *See, e.g.,* Restatement (Second) of Judgments § 24; Black's Law Dictionary (9th Ed.) (res judicata).[14] Agency precedent has acknowledged the Supreme Court's recognition of the applicability of the *res judicata* doctrine in DEA administrative proceedings. *Christopher Henry Lister, P.A.,* 75 FR 28,068, 28,069 (DEA 2010) (citing *Univ. of Tenn.* v. *Elliot,* 478 U.S. 788, 797–98 (1986) (''When an administrative agency is acting in a judicial capacity and resolves disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply *res judicata* * * *'')).

It is conceded that the Deputy Administrator's conclusions in *United Prescription Services* concerning Dr. Reppy's compliance with state law, including the extent of his supervision of his PA, went to the merits of that decision, and that the decision constituted the Agency's final order. However, Dr. Reppy was not a party to that proceeding. *See* 5 U.S.C. 551(3), *amended by* Public Law 111–350, Jan. 4, 2011, 124 Stat. 3677 (no relevant changes) (the term '''party' includes a person or agency named or admitted as a party, or properly seeking and entitled as of right to be admitted as a party''). Indeed, as the United States Court of Appeals for the Fifth Circuit found before that Circuit split into the Fifth and Eleventh Circuits, ''the offensive use of collateral estoppel calls for the courts to use special care in examining the circumstances to ascertain that the defendant has in fact had a full and fair opportunity to litigate and that preclusion will not lead to unjust results.'' [15] *Johnson* v. *United States,* 576 F.2d 606, 614 (5th Cir. 1978). After carefully examining the circumstances, I conclude that when the Agency issued the final order in *United Prescription Services,* Dr. Reppy had not been afforded a full and fair opportunity to litigate whether he violated the laws of California, Tennessee, Indiana, Louisiana and Florida. *Res judicata* is therefore inapplicable. *See East Main Street Pharmacy,* 75 FR 66,149, 66,154

[10] Specifically, *United Prescription Services* cites Fla. Admin. Code Ann. r. 64B8–30.008(2). *See* 72 FR at 50,409. As discussed below, that rule is inapplicable to Dr. Reppy because he is an osteopathic physician; the applicable rule (which is textually identical) is r. 64B15–6.0038. *Infra* text following note 63.

[11] Although the Government offered the *United Prescription Services* decision as an exhibit in its January 19, 2010 supplemental prehearing statement (Gov't Supp. PHS at 5), it withdrew the exhibit at hearing (*see* Tr. 6–7).

[12] As used herein, ''ultimate issues,'' also called ''mixed questions of law and fact'' and ''deep issues,'' are distinguishable from precedential holdings of general applicability.

[13] I do not suggest that *United Prescription Services* is without binding effect as Agency precedent with respect to its holdings of general applicability. *See, e.g., supra* Section VI(C)(c) (citing *United Prescription Services* for the proposition that state law controls the question of whether a doctor-patient relationship exists).

[14] *Accord, e.g., Ritch* v. *State,* 14 So.3d 1104, 1107 n.5 (Fla. App. 1 Dist. 2009) (''Collateral estoppel bars relitigation of an issue only when (1) an identical issue was presented in the prior proceeding; (2) the issue was a critical and necessary part of the prior determination; (3) there was a full and fair opportunity to litigate that issue; (4) the parties in the two proceedings are identical; and (5) the issue was actually litigated.'').

[15] In *Bonner v. City of Prichard,* 661 F.2d 1206, 1209 (11th Cir. 1981) (en banc), the United States Court of Appeals for the Eleventh Circuit adopted as binding precedent all decisions of the former Fifth Circuit handed down prior to October 1, 1981.

n.24 (DEA 2010) (''While I previously found [in a prior decision that a patient] had died of multiple drug intoxication and had both oxycodone and alprazolam in her system, Respondent was not a party to that proceeding. The Government was thus required to prove this fact anew * * *.'' (internal citations omitted)).

For the foregoing reasons, I find that the Deputy Administrator's finding in a prior case to which Dr. Reppy was not a party that ''Dr. Reppy violated the laws of California, Tennessee, Indiana, Louisiana'' and Florida, 72 FR at 50,408–09 (internal citations omitted), does not constitute substantial evidence in the above-captioned proceeding, and I give that finding no weight in this Recommended Decision.[16]

*B. Respondent's Prior Testimony*

In its January 19, 2010 supplemental prehearing statement (Gov't Supp. PHS at 5), the Government noticed its intention to offer into evidence a transcript of Dr. Reppy's testimony in *United Prescription Services, Inc.,* 72 FR 50,397 (DEA 2007). Dr. Reppy was not a named party in that proceeding, had not yet had any adverse action taken against him by the DEA with respect to his COR (*see* Gov't Ex. 10 at 61) and at the time was apparently unrepresented by counsel. In the present case, on consent of the parties,[17] I admitted the transcript of Dr. Reppy's former testimony. (Tr. 126–27.) A preliminary issue in this Recommended Decision is what weight, if any, to give to that testimony.

The APA provides that final determinations in Agency administrative proceedings must be based upon ''reliable, probative and substantial evidence.'' 5 U.S.C. 556(d). In addition, I may consider ''evidence that is competent, relevant, material and not unduly repetitious.'' 21 CFR 1316.59(a) (2010). Where prior testimony from a previous proceeding is reliable, probative, material and not unduly repetitious, Agency precedent supports the admission of such testimony. *See United Prescription Servs., Inc.,* 72 FR 50,397, 50,403 (DEA 2007) (crediting documentary evidence containing substance of witness's prior testimony ''[i]n another proceeding''); *see also Nestor A. Garcia, M.D.,* 61 FR 30,099, 30,100 (DEA 1996) (giving weight to witness's testimony at hearing that recounted witness's former testimony before state medical board).

Here, the transcript of Respondent's previous testimony in *United Prescription Services* is reliable insomuch as it contains Respondent's sworn testimony at a formal administrative hearing (*see* Tr.127 (referring to what Respondent said ''under oath'')) and Respondent testified at the present proceeding that his former testimony was accurate, true and correct.[18] (Tr. 80.) Moreover, Respondent gave the prior testimony in 2007, closer in time to the events at issue in the present case, presenting an increased chance that his memory accurately reflected the events.[19] The transcript of Respondent's prior testimony is probative and material to the extent it addresses matters at issue in the present proceeding, to include without limitation the state(s) in which Respondent held a medical license from 2004 to 2006 (Gov't Ex. 10 at 69); the relationship between witnesses and between the clinic and pharmacy at which Respondent allegedly worked and had prescriptions filled, respectively (Gov't Ex. 10 at 10, 42, 55, 65, 74–77, 82, 89); the evolving ownership and name of the clinic at which Respondent allegedly worked (Gov't Ex. 10 at 6, 9, 46); the extent of Respondent's supervision of a PA (Gov't Ex. 10 at 84–85, 95–97, 101, 106); the practices of Respondent with respect to patient evaluation and treatment (Gov't Ex. 10 at 12, 25–26, 30, 73–74, 77, 78–80, 93–94); and other topics. Finally, although the transcript of Respondent's prior testimony covers many of the topics he addressed in his testimony at hearing, I find that it is not unduly repetitious and that any repetition is offset by its probative value.

For the foregoing reasons, I find it proper to give weight to relevant portions of the transcript of Respondent's prior testimony in *University Prescription Services.* (*See* Gov't Ex. 10.)

*C. Affidavits of Respondent's Employees, Respondent's Patients and Respondent*

The parties stipulated at hearing to the admission of affidavits of Respondent's employees Adele Durina and Janice Viscio and his patients ''[C.K.]'' [20] and ''[D.C.],'' who did not testify in person. (Tr. 166.) In addition, Respondent testified at hearing that, pursuant to his prior testimony in *United Prescription Services,* he provided an affidavit beneficial to the Government, which he signed. (Tr. 78.) Respondent further testified that Respondent's Exhibit 12 is an unsigned copy of that affidavit. (Tr. 78.) By stipulation of the parties, I admitted Respondent's affidavit. (Tr. 7–9; *see* Resp't Ex. 12.)

An issue is what weight, if any, to give these affidavits.

Because the patient and employee affidavits address Respondent's professional conduct since the conduct alleged in the OSC, they are relevant to the issue of whether Respondent is currently in compliance with state and federal standards for the prescribing and practice of controlled substances. Moreover, the contents of Respondent's affidavit also bear on matters directly relevant to this case, to include his employment and the extent of his supervision of his PA, John Protheroe, among other topics. Finally, the Government stipulates and does not object to the admission of any of the affidavits. I therefore find it proper to give weight to relevant portions of affidavits of Respondent and Respondent's employees and patients. *See* 5 U.S.C. 556(d); 21 CFR 1316.59(a) (2010).

## III. Substantive Issue

Whether a preponderance of the evidence establishes that, pursuant to 21 U.S.C. 824(a)(4), Respondent's DEA COR BR5287342 should be revoked and any pending applications for renewal or modification denied, because Respondent's continued registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(f).

## IV. Evidence and Incorporated Findings of Fact

I find, by a preponderance of the evidence, the following facts:

*A. The Clinic and the Pharmacy*

Significant testimony at hearing related to Respondent's connection with two entities: University Physicians Resources (UPR), a medical clinic, and United Prescription Services (UPS), a pharmacy. (*See, e.g.,* Tr. 23.)

[16] *Compare supra* note 13.

[17] Counsel for Respondent asked Respondent a series of questions regarding whether his former testimony included various topics and was accurate; Respondent answered in the affirmative. (Tr. 78–80.)

[18] I draw a distinction between reliability, on the one hand, and accuracy, on the other. Although I find that Respondent's prior testimony in *United Prescription Services* is reliable, only a balancing of the transcript against other evidence in this case can shed light on whether it is accurate.

[19] As noted throughout this Recommended Decision, I also find that statements contained in the transcript of Respondent's prior testimony are generally consistent with Respondent's testimony at hearing.

[20] To protect the privacy of Respondent's patients, only initials are used.

*B. The Witnesses and Affiants* [21]

Respondent Robert Raymond Reppy, D.O., is licensed as an osteopathic physician in the State of Florida pursuant to license number OS7246. (Tr. 20; Gov't Ex. 15 at 1.) His licensure status is Obligation/Active.[22] (ALJ Ex. 3 at 1.) Although Respondent was previously licensed to practice medicine in Georgia, California and Hawaii, since 2000 he has only been licensed in Florida. (Tr. 20–21; Gov't Ex. 10 at 69.) Respondent is registered with the DEA as a practitioner in Schedules II through V pursuant to DEA COR BR5287342. (ALJ Ex. 3 at 1.) Respondent's COR was scheduled to expire by its terms on April 30, 2009. On April 6, 2009, DEA received Respondent's application for renewal.[23] (ALJ Ex. 3 at 1.)

Respondent's witness Robert Arthur Carr, Esq. (Mr. Carr) is an attorney who has worked in the area of medical malpractice for twenty years. (Tr. 143.) He is not a physician and has no medical training. (Tr. 156–57; *see also* Tr. 61.) Mr. Carr testified that he knew Respondent when he worked at UPS. (Tr. 142.) Mr. Carr stated that he had no ownership interest in UPR, but at one point he did have a financial interest in UPS.[24] (Tr. 151–52; *see* Resp't Ex. 5.) Every prescription filled by UPS represented revenue for Mr. Carr. (Tr. 152.)

Respondent's witness Melissa Messick, also known as Missy Messick (*see* Tr. 67–68) (Ms. Messick), was employed by UPS from 2001 to 2005. (Tr. 129, 132.) She testified that she was in a position to observe Respondent's work. (Tr. 129.) Ms. Messick is not a medical practitioner and lacks legal or medical training. (Tr. 135.) In a prior proceeding, Respondent testified that a ''Ms. Messich'' presently owns UPR. (Gov't Ex. 10 at 10; *see also id.* at 76–77.)

Respondent's affiant Janice Vischio (Ms. Vischio) has been a LPN [25] for twenty years, of which she has spent fifteen years in Florida. Her license is in good standing with the Florida Department of Health. As of July 15, 2010, she had worked with Respondent for at least eighteen months. (*See* Resp't Ex. 19 at 2.) Ms. Vischio handles administrative work for Respondent and does not see patients. (*Id.* at ¶ 3.)

Respondent's affiant Adele Durina (Ms. Durina) has over twenty years of medical office experience and presently works as Respondent's Office Manager and Medical Assistant. (Resp't Ex. 19 at 6 ¶ 2.) As of as late as July 15, 2010, Ms. Durina had worked with Respondent since he began working at Cosmopolitan Clinic. (*Id.* at ¶ 3; *see also* Tr. 167.)

As of July 15, 2010, [C.K.] has been a patient of Respondent since Respondent began practicing in the local area and [D.C.] had been a patient of Respondent for approximately thirteen to fourteen months for the treatment of degenerative spondylosis. (Resp't Ex. 19 at 12 ¶ 2; *id.* at 9 ¶¶ 1–2.)

*C. Respondent, the Clinic and the Pharmacy*

Although he did not remember the precise dates, Respondent testified that he was employed at UPR, a medical clinic, for four years beginning in 2002 until approximately 2006. (Tr. 21–23, 51.) Respondent's salary at UPR was the same as his salary at his previous employer; he was paid by the hour or the day rather than by the number of prescriptions he wrote.[26] (Tr. 61, 79.)

When Respondent was first approached about working at UPR, he understood that customers would interact with UPR via the Internet. (Tr. 59–60.) Respondent testified that he was the only physician who worked at UPR. (Tr. 23.) This statement is somewhat inconsistent with testimony by Mr. Carr that the company worked in the mail-order pharmacy realm and acquired licenses to ship pain relievers to anywhere in the country by working with a number of physicians.[27] (Tr. 143; *see also* Resp't Ex. 5 ¶ 4.)

Before joining UPR, Respondent worked at Home Harbor Urgent Care Center. (Tr. 61.) After leaving UPR, Respondent worked at a clinic called Gulf Shore from 2007–2009; between 2009 and the present, he has worked at Cosmopolitan Clinic in Brooksville, presumably in Florida. (Tr. 56, 68, 107; Resp't Ex. 17.) Gulf Shore was a pain management practice run by an anesthesiologist. (Tr. 57.) Cosmopolitan is a combination family practice and pain management clinic. (Tr. 57.)

In his testimony in a prior proceeding, Respondent testified that UPR changed its name to MediHealth, which evolved into a general family practice. (Gov't Ex. 10 at 6, 9; *see generally* Tr. 107–08.) This testimony is consistent with Respondent's testimony in the present case that from 2007 to 2009 Respondent worked part-time at MediHealth, a clinic owned by Ms. Messick. (Tr. 67–68.)

(a) The Connection between UPR and UPS

Respondent testified that UPS is a pharmacy. (Tr. 23.) UPR, by contrast, is a medical clinic. (Tr. 23.) The two organizations had close connections.

For instance, Respondent learned in 2006 that UPS owned UPR and that a Sam Bollinger [28] (Mr. Bollinger) was the owner of both UPR and UPS.[29] (Tr. 22–23.) Respondent stated, however, that Mr. Bollinger ''had always represented to me that no financial link was there.'' [30] (Tr. 23.) In addition, Mr. Carr testified that he formed UPS in 2001 (Tr. 143; *see* Tr. 61; *see also* Resp't Ex. 5) and that UPS worked in the mail-order pharmacy realm and acquired licenses to ship pain relievers to anywhere in the

[21] In its prehearing statement and supplements thereto, the Government identified Diversion Investigator Peter W. Flagg, Special Agent Daniel A. Forde, Diversion Investigator Deborah Y. Butcher, and Respondent as witnesses. At hearing, however, the Government rested upon the testimony of Respondent alone, along with the exhibits it introduced into evidence. Moreover, Respondent's counsel did not conduct a separate direct examination of Respondent during Respondent's case-in-chief. Instead, I permitted counsel to expand the scope of cross examination.

[22] Respondent's Curriculum Vitae (CV) facially contradicts this stipulation, stating that Respondent's Florida medical license expired on March 31, 2008. The CV, however, appears to be outdated, notwithstanding Respondent's representation in his post-hearing brief that it is ''accurate'' (Resp't Br. at 2) and his argument that I accept evidence that is uncontroverted (Resp't Br. at 26–27). For instance, the CV indicates that Respondent is presently employed at UPR (Resp't Ex. 10 at 4), despite the otherwise uncontroverted testimony at hearing that Respondent stopped working at UPR in 2006. (Tr. 21–23, 51.) In light of this and other evidence concerning the status of Respondent's state medical license, I find that the weight of the evidence contradicts any inference that Respondent lacks state authority to handle controlled substances in Florida.

[23] Pursuant to 5 U.S.C. 558(c), Respondent's COR continues in effect until DEA takes final action on the renewal application. (*See, e.g.,* ALJ Ex. 3.)

[24] In his testimony at a prior proceeding, Respondent testified that a Mr. Jerome Carr and a Mr. Rob Carr were listed as president of UPS in 2003. (Gov't Ex. 10 at 76, 89.) The inconsistency was never explained.

[25] Although the record in this case is silent, various provisions of federal law define the term ''LPN'' as ''licensed practical nurse.'' *See, e.g.,* 32 CFR 199.2; 42 CFR 482.51(a)(2).

[26] Respondent also testified that he did not have any ownership affiliation with UPS. (Gov't Ex. 10 at 46.)

[27] The contradiction is perhaps explained by Respondent's testimony in a prior proceeding that another physician worked at UPR before Respondent began working there. (*See* Gov't Ex. 10 at 65.) Moreover, the record contains no evidence that UPR was the sole clinic with which UPS worked.

[28] The transcript of hearing in the above-captioned case spells the name ''Bollinger,'' (*e.g.,* Tr. 23) and that is the convention adopted here. *But see* Gov't Ex. 10 at 9 (''Ballinger''); Resp't Ex. 12 (same); Resp't Ex. 5 (same).

[29] Mr. Bollinger is not a medical professional. (Tr. 24.)

[30] In his testimony in a prior proceeding, however, Respondent testified that Mr. Bollinger required Respondent to send his patients' prescriptions to UPS, that the vast majority of his prescriptions from 2005 and 2006 were filled at UPS, that most of the clerks and staff at UPR had at one time worked at UPS and that Mr. Bollinger ''pretty much ran the show.'' (Gov't Ex. 10 at 42, 55, 74–76, 82.)

country by ''working with a number of physicians.'' [31] (Tr. 143.)

In addition, Respondent testified that the UPS pharmacy filled the vast majority of the prescriptions Respondent wrote while at UPR. (Tr. 61.) Respondent testified that although he thought he was working for the clinic UPR, he inadvertently was working for UPS. (Tr. 94.) He then contradicted himself, stating that he wasn't working for UPS. (Tr. 94.) Mr. Carr stated that Respondent was not employed by UPS. (Tr. 151–52.) He denied supervising Respondent, and further denied having any say over Respondent's medical practice. (Tr. 152.) Ms. Messick testified that she was employed simultaneously by UPS and UPR from 2001 to 2005. (Tr. 129, 132, 133.) She described it as a ''back and forth,'' and she observed what went on at UPS and UPR. (Tr. 133.) She confirmed that she observed Respondent's work at UPR, and stated that Respondent didn't work at UPS. (Tr. 133.) She had seen Respondent in the pharmacy at UPS only once. (Tr. 134.) She testified that she was in a position to observe Respondent's work, and that Respondent followed guidelines set by Mr. Carr. (Tr. 129.)

(b) Respondent's and Mr. Carr's Telemedicine Research

Respondent stated that when he began prescribing controlled substances to individuals who contacted him at UPR primarily via the Internet, telemedicine was a new practice; ''the legal community was struggling in a gray area to determine what those [legal standards] would be * * *.'' (Tr. 64.) Consequently, Respondent viewed his work at UPR as an experiment involving new ways to use the Internet. (Tr. 31.) He had some concerns about the legitimacy of the practice, ''[s]o I did my due diligence.'' (Tr. 60). He ''did a little research on my own,'' consulted with the attorney Mr. Carr and relied on ''a letter shown me from the DEA giving permission to do it.'' (Tr. 60; *see also* Tr. 89–92.)

The letter to which Respondent referred was preceded by a letter dated January 28, 2002, and signed by ''Robert Carr/President/United Prescription Services, Inc.'' (Resp't Ex. 3.) Addressed to Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, DEA, Mr. Carr's letter describes the ''Community Pharmacy'' UPS and solicits Ms. Good's ''views on whether any requirements or changes are warranted in our policy.'' (Resp't Ex. 3; Tr. 90.) Although the letter recites that a copy of UPS's policies is attached (Resp't Ex. 3), no policy pages are attached to the record copy (*see* Resp't Ex. 3) and Respondent testified that he never saw the policy pages.[32] (Tr. 96.) Mr. Carr confirmed that he contacted the DEA on January 28, 2002, to inquire whether the policies of UPS were in conformity with the law. (Tr. 144–45.)

Slightly less than one month later, Mr. Carr received a response. (Tr. 146.) A February 27, 2002 letter by Ms. Good, addressed to ''Mr. Robert Carr/President/United Prescription Services, Incorporated'' opined that ''the submitted policies and procedures meet the federal requirements regarding controlled substance prescriptions.'' [33] (Resp't Ex. 4 at 1; *see* Tr. 91.) Mr. Carr testified that the DEA advised him that ''there was no further things [sic] we had to be concerned with our physicians that were practicing telemedicine.'' (Tr. 146.) Respondent and Mr. Carr agreed that Mr. Carr advised Respondent that by following Mr. Carr's guidance, Respondent would be in compliance with state and federal law. (*Compare* Tr. 91, *with* Tr. 147.)

Respondent testified that Mr. Carr showed him Ms. Good's February 27, 2002 letter (Tr. 91) and that Respondent believed the letter gave Respondent permission to prescribe to patients in multiple jurisdictions who contacted him via an Internet web site but did not necessarily meet with him face to face. (*See* Tr. 59–60, 110.) Respondent conceded, however, that Mr. Carr's letter asks about the dispensing practices of the pharmacy, not the prescribing practices of physicians. (Tr. 97.) Respondent further conceded that he lacked specific knowledge of what policies Ms. Good approved for the pharmacy. (Tr. 96.) And in any event, the record reflects that Ms. Good's general expression of approval of the pharmacy came with a number of caveats: ''Management personnel will verify several elements including * * * professional licensure[,] DEA registration[, l]egitimate patient/prescriber relationship[, p]rescriptions are issued in the usual course of professional practice, and [p]rescriptions are issued for a legitimate medical purpose.'' (Resp't Ex. 4 at 1.)

Although Respondent now concedes that Mr. Carr's assurances that Respondent was complying with the law were inaccurate (Tr. 110–11), he devoted significant testimony to defending his reliance on Mr. Carr's advice. (*See* Tr. 64, 67, 98, 100–01.)

Mr. Carr also testified as to the legal status of Internet prescribing practices as well as his own role in establishing UPS. Mr. Carr stated that he researched the law regarding telemedicine and related prescribing practices, surveying the laws of all fifty states addressing the regulation of pharmacies, general medicine and pain medication. (Tr. 144.) He said he searched for anything in the telemedicine realm, compiling a file ''well over a foot high of documents that I reviewed extensively from various states, various regulatory authorities.'' (Tr. 150.) He stated that in 2001 the statutes and regulations were very minimal on telemedicine. Mr. Carr testified that the only reference was a statute from an unidentified jurisdiction addressing neural radiology in telemedicine. (Tr. 144.)

Mr. Carr stated that ''California is one of the states that we were prescribing to, or shipping drugs to.'' (Tr. 158.) He could not, however, identify the effective date of the California law requiring that a physician hold a California medical license before prescribing to people in California over the Internet. (Tr. 150, 157.) He moreover could not confirm whether he specifically researched California's law, stating only that ''yes, there would have been a review of all California licenses * * * in 2002 * * *.'' (Tr. 158.)

Mr. Carr also testified regarding the Model Guidelines for the Appropriate Use of the Internet in Medical Practice (Model Guidelines).[34] He did not recall seeing that document in particular during the course of his research of telemedicine. He stated, however, that if it was published in 2002, he would have reviewed it extensively. (Tr. 149–50.) He also stated that he was generally familiar with the document. (Tr. 155.)

Page nine of the Model Guidelines contains the following provision: ''Physicians who treat or prescribe through Internet Web sites are practicing medicine and must possess appropriate licensure in all jurisdictions where patients reside.'' (Resp't Ex. 9 at 9; *See* Tr. 156.) Mr. Carr testified that he did not previously see that sentence.

[31] In light of Respondent's testimony that he was the only physician employed by UPR between 2002 and 2006 (Tr. 21–23, 51), Mr. Carr's statement that UPS worked with ''a number of physicians'' (Tr. 143) may be explained by Respondent's testimony that a Dr. Long and a Dr. Ibanez previously worked at UPR (*See, e.g.,* Gov't Ex. 10 at 80–81). See note 27, *supra.*

[32] Mr. Carr's description of the policies that he sent to DEA for review (*see* Tr. 145–46, 158–59) accordingly have little bearing, if any, on the question of what Respondent believed at the time he read the letter.

[33] Mr. Carr testified that he no longer has a copy of the policy documents he submitted to the DEA with his June 28, 2002 letter, explaining that he left them with UPS when he sold the company. (Tr. 158.)

[34] *See* Resp't Ex. 9.

(Tr. 156.) ''I would not have advised [Respondent] of that'' because ''there wasn't to my knowledge any specific requirement in Florida as to determine the nexus of where physician/patient relationship was in fact occurring and where the medical practice was occurring.'' (Tr. 156.)

Mr. Carr further testified that he relied on statements, such as the one appearing in the Model Guidelines, that ''the [physician-patient] relationship is clearly established when the physician agrees to undertake diagnosis and treatment of the patient * * * whether or not there has been a personal encounter between the physician * * * and patient.'' (Tr. 163; Resp't Ex. 9 at 7.) He did not recall, however, seeing that statement in particular during the course of his research of telemedicine. He could confirm only that ''[s]omething like this was something I'd probably even send down to the doctors to give them * * * assurances.'' (Tr. 163.)

Ms. Messick's testimony in this regard was consistent, if equally vague: Ms. Messick explained that Mr. Carr had provided statutes and regulations on practicing telemedicine and the physician-patient relationship to physicians at UPR.[35] (Tr. 134–35.) Ms. Messick testified that the guidance Mr. Carr provided to Respondent was legal, not medical, and dealt with telemedicine and how to maintain a physician-patient relationship. (Tr. 135.) Ms. Messick elaborated that this question was a controversial subject of much discussion in the office.[36] (Tr. 136.)

Mr. Carr testified that he relied on a **Federal Register** Notice entitled ''Dispensing and Purchasing Controlled Substances Over the Internet.'' (Tr. 153; *see generally* Resp't Ex. 8.) That document provides that ''practitioners must be registered with DEA and licensed to prescribe controlled substances by the state(s) in which they operate.'' (Tr. 154; *see* Resp't Ex. 8 at 3.) Yet, while UPS filled prescriptions written by Respondent and shipped them all over the United States, Respondent was not licensed to practice medicine in any state other than Florida. (Tr. 154.) Many of Respondent's patients did not come to Florida, but interacted with Respondent electronically. (*See* Tr. 25, 154.) Mr. Carr explained that he interpreted Respondent's Internet prescribing practices as operating in the state of Florida. (Tr. 160–61.)

*D. Respondent's Physician's Assistant (PA)*

Significant testimony at hearing concerned actions allegedly taken by John Protheroe (Mr. Protheroe), a PA, and the extent, if any, of Respondent's supervision of Mr. Protheroe.

Mr. Protheroe began working for UPR a few months after Respondent started working there in 2002. (Tr. 37, 38, 120.) Respondent did not hire him, but he worked under Respondent's license. (Tr. 37, 131.) Respondent testified that ''[Mr. Protheroe] was hired because * * * I was not making Mr. Bollinger happy with the amount of restrictions that I was placing on the patients and thus slowing everything down * * * he hired Mr. Protheroe to go behind my back and speed things up. He never discussed with me 'do you need one?' '' (Tr. 120.)

Mr. Protheroe was not often present while Respondent was in the office, and frequently worked from home. (Tr. 37, 38, 41; Gov't Ex. 10 at 85 (''He was purportedly * * * supposed to work under my license, submit himself to my review * * * And yet he was allowed to review patients' charts from his own home, away from the office where no one could see him.'').) Mr. Protheroe was a PA only to Respondent, and not to any other doctor. (Tr. 120.)

Respondent testified to having an antagonistic relationship with Mr. Protheroe (Tr. 37) and developing a number of concerns before November 2003. (Tr. 121.) Respondent accused Mr. Protheroe of exploiting Respondent's license ''behind my back without my permission'' (Tr. 37, 42), and failing to adhere to the criteria by which Respondent rejected patients (Tr. 122).

Mr. Protheroe's compensation was connected to the number of prescriptions Mr. Protheroe wrote, most of which were for controlled substances. (Tr. 79; Gov't Ex. 10 at 96–97; Resp't Ex. 12 at 2.) Ms. Messick testified that Mr. Protheroe was compensated at a rate of fifteen dollars per prescription. (Tr. 132.) According to Respondent, Mr. Protheroe ''wrote so many prescriptions without my authorization using a stamp of my signature'' that Respondent was uncertain whether Respondent had completed the conduct charged in an administrative complaint by the Florida Department of Health,[37] or whether Mr. Protheroe had written the prescriptions in question. (Tr. 41.) Respondent testified that the number of prescriptions that Mr. Protheroe wrote without Respondent's authorization was at least 14,000. (Tr. 80; *see generally* Tr. 132; Gov't Ex. 10 at 84–85.) Respondent did, however, acknowledge occasions in which Respondent approved prescriptions written by Mr. Protheroe. (Tr. 38.) Respondent estimated the quantity as ''only a few a day.'' (Tr. 42.) The vast majority of Mr. Protheroe's prescriptions, however, Respondent was unaware of. (Tr. 38.)

Respondent testified that Mr. Protheroe wrote the majority of the objectionable prescriptions while Respondent was away from the office from November 2004 to March 2005 after his wife was diagnosed with a serious health issue. (Tr. 121–22, 132; Gov't Ex. 10 at 85, 96, 101.) Mr. Protheroe's misconduct continued the entire time Mr. Protheroe worked there, until Mr. Protheroe left in 2005, shortly after Respondent returned from medical leave. (Tr. 138.) It was only after returning that Respondent complained about Mr. Protheroe to Ms. Messick, who recalled Respondent's complaint that Mr. Protheroe wrote prescriptions without accurately reading the diagnoses or medical records. (Tr. 131, 138–39.)

Respondent approached Mr. Bollinger several times and requested that Mr. Protheroe be fired. (Tr. 37; *see also* Tr. 131; Gov't Ex. 10 at 106.) Respondent said he did not need Mr. Protheroe, and that Mr. Protheroe ''was put there by someone else and I had no power to remove him because I did not pay his salary. I could not tell him to leave.'' (Tr. 37; *see* Tr. 122.) In July 2005, Mr. Bollinger removed Mr. Protheroe from UPR. (Resp't Ex. 12 at 4.)

Respondent testified that he was precluded from a full right to supervise Mr. Protheroe, which he now regrets so much that ''it's so soured me on the experience that I've never hired any physician's assistants since and I don't think I ever will.'' (Tr. 108–09.) But Respondent's testimony that he lacked the full authority to supervise Mr. Protheroe, including the right to fire him if necessary, is substantially undercut both by the relationship (Mr. Protheroe was the physician's *assistant* and Respondent was the *physician*), as well as by Respondent's affidavit, affirming that Respondent was medical director of UPR and its sole corporate officer beginning in 2004. (*See* Resp't Ex. 12 at 2.)

[35] He did not provide them to Ms. Messick, however. (Tr. 135.)

[36] For instance, Ms. Messick cited the question of whether ''the patient actually had to be seen by the physician or the physician's office [or] another physician.'' (Tr. 137.)

[37] As detailed below, the Florida Department of Health accused Respondent of prescribing controlled substances to a patient without: conducting a face-to-face meeting, performing an adequate physical exam, taking an adequate medical history, documenting a treatment plan or making referrals, *inter alia.* (Gov't Ex. 14 at 4.)

Negligibly mitigating this contradiction is a statement by Respondent that he did not realize he was UPR's sole corporate officer until 2006, even though as early as 2004, he understood he was medical director:

> In 2004, Mr. Bollinger asked me to sign some corporate documents for [UPR]. I understood that these documents would list me as the medical director of [UPR]. I learned in late 2006, that Mr. Bollinger made me the sole corporate officer and removed himself as a corporate officer of [UPR] by having me sign these documents. When Mr. Bollinger did this, Mr. Bollinger listed my address as 2304 East Fletcher Avenue, Tampa, Florida. That is not the address of [UPR], nor is it the address at which I worked. The address Mr. Bollinger listed for me on the corporate filings is the address for [UPS].

(Resp't Ex. 12 at 2.)

After carefully evaluating Respondent's testimony, other record evidence and Respondent's demeanor while testifying, I find that Respondent's testimony regarding the scope of his authority over Mr. Protheroe is not fully credible. For instance, to the extent that Respondent testified that he lacked the authority to supervise or fire Mr. Protheroe after 2004, this testimony stands in stark contrast with Respondent's own evidence that Respondent understood Respondent was medical director of UPR in 2004. Additionally, the evidence includes Respondent's concession that he had an obligation to properly supervise Mr. Protheroe (Tr. 101; *see* Resp't Ex. 9 at 5 (''physicians should * * * [p]roperly supervise physician extenders'')), and his assertion that he did, in fact supervise Mr. Protheroe ''when he was in the office * * *.'' (Gov't Ex. 10 at 105.) For the foregoing reasons, I find that Respondent possessed both the obligation and the authority to supervise Mr. Protheroe.[38]

*E. Respondent's Prescriptions to Internet Customers, 2004 Through October 2006*

(a) Respondent's Service to Internet Customers at UPR, Generally

Respondent testified as to how he handled prescription requests from customers when he worked at UPR. Respondent conducted a telephonic or in-person consultation with every person to whom he prescribed controlled substances. (Tr. 29.) Respondent would interview most patients over the phone and then determine whether to issue a prescription or order any ''tests on further verifications that were necessary.'' (*See* Tr. 25.) Approximately ninety percent of the consultations occurred exclusively by telephone, without an in-person meeting. (*See* Tr. 26; *see also* Gov't Ex. 10 at 77 (ten percent or ''[m]aybe less than five percent'').) In approximately 2005, Respondent began encouraging more patients to come to the clinic in Florida. (*See, e.g.,* Gov't Ex. 10 at 93–94.)

Before phone consultations took place, patient records ''were compiled by the customer and sent to me.'' [39] (Tr. 34.) Other doctors did not send patient records to Respondent; patients sent them.[40] (Tr. 34, 79–80.) Respondent testified that ''Patients did not make them up on their own.'' (Tr. 34.) Respondent's staff at UPR would initially ''screen'' patients and compile charts containing patients' contact information, diagnoses and medical documentation verifying their conditions. (Tr. 24–25, 37.) The staff would provide a chart ''whenever I requested it.'' [41] (Tr. 70.)

During the four years that Respondent worked at UPR (Tr. 35–36, 51), other doctors referred approximately 300 patients to Respondent. (Tr. 35–36.) As for the rest of Respondent's thousands of patients (*e.g.,* Tr. 43), the physicians whose records Respondent relied on to justify prescribing controlled substances were not affiliated with Respondent and did not provide any medical services, testing or evaluation at Respondent's request. (Tr. 36.)

Respondent testified that to have a valid doctor-patient relationship, a servicing medical professional must have conducted a physical examination of the patient. (Gov't Ex. 10 at 79–80 (''Someone must have done [a physical examination]).'') For follow-up consultations, Respondent did not require ''a new physical exam with every consult. When it became, in my opinion, too dated, then I would demand another physical exam.'' (Gov't Ex. 10 at 79.) But Respondent performed physical examinations on only two percent of his patients in his first year of employment with UPR, a percentage which rose to no more than seven percent of patients in later years. (Tr. 25–26.) Moreover, in a given week, Respondent rarely contacted a patient's primary care physician whose records he was reviewing. (Tr. 32, 34–35, 80; Gov't Ex. 10 at 30, 78.)

Although he sometimes would do so, Respondent did not always find it appropriate to tell customers that online communication cannot take the place of face-to-face communication. (Tr. 102–03.)

(b) Extent of Respondent's Verification of Patient Identities at UPR

Respondent had no face-to-face interactions with as many as ninety percent of his patients. (Tr. 26, 55.) When ascertaining a patient's identity before issuing a controlled substance prescription, therefore, Respondent relied on representations made by the radiologist who read the patient's CAT scan or MRI, or the office notes of the physician who first saw the patient. (Tr. 54.)

As for how he verified the identity of patients with whom he never physically interacted, Respondent testified that ''I used the same method of checking their identity as I would if they were present in front of me.'' (Tr. 54.) Yet Respondent conceded that he never looked at the face of the vast majority of people to whom he issued prescriptions. (Tr. 55.) He conceded that it was possible, therefore, that a family member could take the medical records and identification of a deceased person, and Respondent would have no way of knowing whether the person on the phone was actually the person whose medical records and identification Respondent was reviewing. (Tr. 55–56.)

Respondent explained that ''I was rather good at detecting fraud'' by comparing font and language in different parts of patient medical records. (Tr. 56.) Respondent added: ''If the state did not adequately check their identity before issuing them a driver's license * * * I had no way of determining that.'' (Tr. 54.)

(c) Extent of Respondent's Patient Evaluation and Documentation Practices at UPR

When he worked at UPR, Respondent conducted physical examinations on some of the individuals who contacted him through Internet Web sites. (Tr. 25.) The percentage was very small. (Tr. 25.) ''It went from about two percent in the beginning to six or seven percent towards the end.'' (Tr. 26.) Respondent did not conduct physical examinations on more than ninety percent of his patients. (Tr. 26.) Nor did other physicians perform examinations of those patients at Respondent's

[38] A later section of this Recommended Decision addresses whether Respondent had any legal obligation or authority in this regard, and if so, whether Respondent discharged it.

[39] *See also* Gov't Ex. 10 at 73 (''Usually it was the patient's job to gather the records and forward them to me.'').

[40] There is also evidence that an entity called FedexMeds.com was an occasional referral source of patients, which occasionally transmitted medical records to Respondent. (Gov't Ex. 10 at 73–74; *see generally* Resp't Ex. 12 at 3.)

[41] This testimony is consistent with Ms. Messick's testimony that she or her staff provided medical records to Respondent before he conducted telephone interviews with Internet patients or prescribed medication to them. (Tr. 130.)

direction.[42] (Tr. 36.) Respondent elaborated that other physicians had already performed examinations or tests before the patient came into contact with Respondent, explaining ''That's the whole point.'' (Tr. 36.) Respondent had no affiliation with the physicians whose records he relied on. (Tr. 36.) He admitted to prescribing hydrocodone to thousands of individuals without a face-to-face examination. (Tr. 43; *see* Tr. 53.)

Each day Respondent consulted with approximately thirty customers. (Tr. 26, 51.) He worked five days per week. (Tr. 35; 51–52.) On average, he issued controlled substances prescriptions to 150 patients per week. (Tr. 52.) Respondent worked at least forty weeks per year, usually more. (Tr. 52.) Thus, on approximately 5000 occasions per year or more, Respondent issued controlled substance prescriptions to new or repeat customers. (Tr. 53.)

Many patients came to him pre-diagnosed, and Respondent stated that they had to prove what the diagnosis was. (Tr. 29.) Although Respondent testified that he contacted a patient's primary physician whose medical records he was reviewing ''on occasion'' (Tr. 80) and ''whenever it was necessary'' (Tr. 32), he also testified that he only consulted one or two physicians out of the 150 patients he serviced in a given week, (Tr. 34, 35; *see generally* Gov't Ex. 10 at 30, 78 (''I generally did not have to do that on a regular basis. That was less than once a day. It was when I had specific questions.'')). Respondent testified that it is not a common practice to speak with the medical professional who prepares medical records such as MRIs and radiology reports. (Tr. 32.)

Respondent stated that it would be inappropriate and ''not smart medicine'' (Gov't Ex. 10 at 26) to complete a first-time diagnosis over the phone, but not necessarily a subsequent diagnosis.[43] (Tr. 29–30, 104.) Later, however, he stated that ''I have enough expertise to know whether someone has a respiratory problem at the moment by how they're talking to me over the phone.'' (Tr. 115.)

Respondent conceded that it would be inappropriate to prescribe controlled substances to an individual who had not been diagnosed with having a legitimate medical need for the drugs. (Tr. 30.)

The record also reflects allegations by the Florida Department of Health that Respondent failed to adequately discuss and document treatment options with patients (*see, e.g.,* Gov't Ex. 14 at 3–4), although these allegations were resolved by settlement agreement (Gov't Exs. 15 & 16).

At hearing, Respondent confessed that his evaluation of patients and documentation at UPR ''is not considered adequate,'' and that ''I have a different standard now because I've been educated about it.'' (Tr. 45–46.) ''[T]he happy medium [in fighting controlled substance abuse] is to insist on proper documentation—and try to wean people off it when you can.'' (Tr. 66.) Reflecting on his current practice at Cosmopolitan, Respondent stated that he has been lowering patient dosages and ''getting rid of the people who had abuse potential.'' (Tr. 66.) ''I think I've done a good job where I am of * * * cleaning up the practice.'' (Tr. 66.)

(d) Respondent's Internet Consulting and Prescribing Policies at UPR

Respondent testified to his belief that his patients' primary care physicians had undertaken personal encounters with patients, and therefore patients ''were not placing their whole care in my hands.'' (Tr. 110.) He further testified that in 2002, the Federation of State Medical Boards stated that a face-to-face encounter was not necessary as long as the patient expected that the doctor would take over the treatment plan and review medical documentation. (Tr. 43–44.)

The Federation of State Medical Boards, however, is ''a collection of licensing bodies from all the states.'' (Tr. 44.) Respondent testified that he did not initially know whether it is itself a licensing authority. (Tr. 45.) But he then conceded that ''I realize now that it was a mistake after people with more legal expertise than I have told me'' that statements by the Federation of State Medical Boards do not carry ''legal weight.''[44] (Tr. 45; *see also* Tr. 164.)

Respondent disputed the suggestion that he failed to adequately perform patient evaluations at UPR, testifying that his interaction with patients was adequate according to his understanding of what was required by the Federation of State Medical Boards. (Tr. 43.) He further stated that none of his patients for whom he prescribed over the Internet came to any harm: ''there were no mortalities, no morbidity.''[45] (Tr. 116.) Asked whether any patient suffered an overdose death, Respondent answered that ''I know none of them did while I was prescribing. If it happened since that time, then it happened because someone else was prescribing it. I can't be responsible for what some other doctor did.'' (Tr. 117.) ''I'm sure there would have been a lawsuit if there was one and I never received any.'' (Tr. 123.) He conceded, however, that he has not stayed in touch with all of his UPR Patients since leaving UPR. (Tr. 117.)

(e) Location of Respondent's Customers

Respondent testified that most of the individuals to whom Respondent prescribed controlled substances became Respondent's customers through Internet Web sites. (Tr. 25.) Respondent testified that he issued prescriptions for controlled substances to people located all across the United States. (Tr. 27, 39.) Although he did not remember precisely how many different states, he said the list was ''long.'' (Tr. 39; *see* Resp't Ex. 12 at 3 (''hundreds of patients who lived outside of Florida'').) For instance, in response to questioning by counsel for the Government, Respondent conceded issuing prescriptions for controlled substances to people in Tennessee, California, Illinois and North Carolina. (Tr. 38.) Respondent said that Kentucky and Mississippi were ''off limits,'' but did not actually deny prescribing to individuals in those states. (Tr. 28.)

Respondent admitted that he was not licensed to practice medicine in all fifty states while he worked at UPR. (Tr. 28.) He presently understands that he has an obligation to prescribe or dispense controlled substances in accordance with all applicable state laws, and that prescribing across state lines sometimes includes the application of laws other than the laws of the State of Florida. (Tr. 63.) He concedes that, in hindsight, the prescriptions he issued at UPR to Internet customers ''did not meet the highest standard * * * and I'm sorry.'' (Tr. 63–64.) In his post-hearing brief, Respondent states that he ''now realizes that the prescriptions he issued at [UPR] to Internet patients were not issued in the usual course of professional practice * * * .'' (Resp't Br. at 17.) When asked whether he now knows that his Internet prescribing at UPR was not consistent with the law as it was at that time, Respondent answered ''Absolutely.'' (Tr. 91–92.) Contradicting himself somewhat, Respondent also stated that

[42] As Respondent explained, ''the physical examination has to be done by someone else in the case of telemedicine. [Patients] have to have seen a local doctor that actually saw them and performed the physical examination, and gotten those notes to me, so that I know what was seen and have the information available.'' (Gov't Ex. 10 at 25–26.)

[43] *See also* Gov't Ex. 10 at 12 (''it's certainly not considered appropriate to make new diagnoses in a telemedicine format'').

[44] In any event, Respondent conceded that he personally has not received a license from the Federation of State Medical Boards. (Tr. 45.)

[45] This testimony is consistent with testimony of Ms. Messick, who stated that she was not aware of any injuries or complaints by patients as a result of Respondent's prescribing practices. (Tr. 130.) She conceded, however, that she had not stayed in touch with the thousands of Internet patients with whom Respondent consulted. (Tr. 137.)

at the time he engaged in the prescribing practices that are the subject of the OSC, he wasn't doing anything wrong (Tr. 64–65), explaining that ''if I thought I was doing anything wrong, I wouldn't have done it.'' (Tr. 65.)

Significant testimony addressed the extent of Respondent's reliance on and understanding of the Model Guidelines. Respondent admitted that before accepting employment with UPR, he does not recall whether he read the provision from ''Section Five[:] Guidelines for the Appropriate Use of the Internet in Medical Practice,'' entitled ''Compliance with State and Federal Laws and Web Standards.'' (Tr. 105.) In pertinent part, that provision reads: ''Physicians who treat or prescribe through Internet Web sites are practicing medicine and must possess appropriate licensure in all jurisdictions where patients reside.'' (Resp't Ex. 9 at 9.) Respondent admitted that he failed to comply with that provision. (Tr. 105.)

Asked if he was regretful and remorseful for the role he played at UPR in prescribing controlled substances, Respondent stated: ''Yes, very much. I sincerely wish I had never been duped into being any part of their operation at all.'' (Tr. 92.) Respondent testified that in the future, he would not prescribe for patients in jurisdictions in which he lacks a medical license. (Tr. 111.) Asked by counsel whether he felt remorse for having done so, he said ''Yes. Not only am I remorseful about it, but I feel rather foolish and stupid for doing so in retrospect.'' (Tr. 111.) He also deemphasized his own responsibility, stating ''I was just an hourly employee. I was just a pawn in the machine.'' (Tr. 119.)

(f) Quantity of Prescriptions and Extent of Diversion Avoidance at UPR

On approximately 5000 occasions per year or more during his tenure at UPR, Respondent issued controlled substance prescriptions to new or repeat customers. (Tr. 53; *see also* Tr. 25, 32, 43.)

Most or many of the individuals who contacted Respondent at UPR sought and ultimately received a specific controlled substance. (Tr. 28, 36.) The most common request was for hydrocodone, a Schedule III narcotic. (Tr. 28.) Respondent testified that some patients also sought alprazolam, which he identified as a Schedule IV benzodiazepine trading under the brand name Xanax or Valium.[46] (Tr. 29.) Patients requested these drugs before Respondent consulted with them. (Tr. 29.) Respondent explained that patients ''were just reiterating what their own physician had put them on.'' (Tr. 70.) Respondent testified that on many occasions, he reduced the amount of medications for some patients and suggested alternate treatment methods. (Tr. 79–80.)

In Respondent's professional medical opinion, the abuse of controlled substances is a significant problem. (Tr. 65.) Respondent testified that some people misuse and abuse the kinds of controlled substances that Respondent prescribed at UPR, particularly hydrocodone, alprazolam, oxycodone and methadone. (Tr. 65.) From time to time Respondent encountered patients who abused controlled substances and immediately dismissed them. (Tr. 65.) ''I ferreted it out where I could.'' (Tr. 65.) Respondent, however, could not state how many of his patients were addicted to narcotics while he was prescribing to them. (Tr. 118.) Respondent is familiar with the rising rate of oxycodone overdose deaths, calls it a big problem and ''I do best to make sure that doesn't happen.'' (Tr. 59.) Respondent stated that when physicians prescribe correctly, doctors who prescribe controlled substances to drug abusers do not themselves contribute to the pharmaceutical abuse problem. (Tr. 66.)

(g) The Florida Department of Health Administrative Complaint

Respondent testified that Florida instituted an administrative complaint (Complaint) against him arising out of his Internet prescribing practices at UPR.[47] (Tr. 40; Gov't Ex. 14.) The Complaint alleged, *inter alia,* that in 2004 Respondent repeatedly prescribed hydrocodone to patient [D.P.], a resident of Wyoming who had never had a face-to-face meeting with Respondent. (Gov't Ex. 14 at 2, 3.) It further alleged that Respondent failed to perform an adequate evaluation of [D.P.], including an adequate medical history and an adequate physical examination to justify prescribing controlled substances; that Respondent failed to document discussing the risks and benefits with [D.P.]; that Respondent failed to prepare and document an adequate treatment plan or keep adequate medical records of his treatment of [D.P.]; and that Respondent failed to refer [D.P.] for additional consultations or diagnostic testing. (Gov't Ex. 14 at 4.)

Respondent could not confirm or deny whether he completed the conduct alleged in the Complaint because ''this PA John Protheroe wrote so many prescriptions without my authorization using a stamp of my signature that it may well have been done under—under that process.'' (Tr. 41.) Respondent explained that when he received the Complaint, he had no way of looking into the patient records to determine whether it was Respondent or Mr. Protheroe who wrote the prescriptions in question. (Tr. 41–42.)

Respondent further testified that he did not know the identity of ''[J.N.],'' another patient. (Tr. 42.) The Complaint alleged that [J.N.] was Respondent's patient, located in Idaho, to whom Respondent allegedly prescribed hydrocodone, without conducting a face-to-face meeting or physical examination, discussing the risks and benefits of controlled substances, preparing and documenting an adequate treatment plan, keeping adequate medical records of treatment, or referring [J.N.] for additional consultations or diagnostic testing. (Tr. 42; *see* Gov't Ex. 14 at 4–6.) Respondent explained that when he received the Complaint, he did not have access to the records of patient [J.N.]. (Tr. 73–74.) Nor did Respondent have the opportunity to review the records of [S.J.], another patient listed in the Complaint, because Respondent lacked access to those records, as well. (Tr. 74.)

In short, Respondent does not know whether he issued any of the prescriptions alleged in the Complaint. (Tr. 42, 43.) Respondent conceded, however, that even if he did not personally issue the prescriptions, he did prescribe hydrocodone to thousands of individuals without conducting face-to-face examinations. (Tr. 43.) Respondent explained his belief that the patients for whom he was prescribing already had had a face-to-face meeting with their primary care physicians; Respondent believed he was merely renewing existent prescriptions,

[46] Respondent's testimony that alprazolam is sold under the trade name Valium is incorrect. I take official notice that alprazolam sells under the trade name Xanax and that diazepam sells under the trade name Valium. Under the APA, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' U.S. Dept. of Justice, *Attorney General's Manual on the Administrative Procedure Act* 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA's regulations, Respondent is ''entitled on timely request, to an opportunity to show to the contrary.'' 5 U.S.C. 556(e); 21 CFR 1316.59(e) (2010); *see, e.g., R & M Sales Co.,* 75 FR 78,734, 78,736 n.7 (DEA 2010). Respondent can dispute the facts of which I take official notice by filing a properly supported motion for reconsideration within twenty days of service of this Recommended Decision, which shall begin on the date it is mailed. *See, e.g., Joseph Gaudio, M.D.,* 74 FR 10,083, 10,088 (DEA 2009) (granting respondent opportunity to dispute officially noticed facts within fifteen days of service).

[47] Respondent stated that he never received correspondence from licensing boards in other states complaining of his practice. (Tr. 39.) He did, however, become aware of some such complaints in the context of a previous proceeding against UPS. (Tr. 40.)

continuing the course of care and not initiating the first treatment plan. (Tr. 109.) He conceded, however, that he had treated some patients who had been dropped by their providers, whether for lack of funds or another reason. (Tr. 113, 116.) ''I was continuing the treatment plan that was first set up by their doctor who might no longer have been willing to continue that plan * * * So the patient had nowhere else to go.'' (Tr. 113.)

The Complaint resulted in a settlement agreement, dated October 2, 2007, implemented through a final order dated December 26, 2007. (Tr. 46–48; Gov't Exs. 15 & 16.) Respondent agreed to pay a fine of $12,500, complete continuing medical education courses about prescribing controlled substances (''drug course''), maintaining medical records (''records course'') and laws and rules (''laws and rules course''), perform 100 hours of community service and prepare a paper suitable for publishing in the Journal of the American Osteopathic Association. (Tr. 46; Gov't Ex. 15; *see also* Gov't Ex. 16.)

Respondent's community service was to be completed by December 30, 2009, but Respondent did not complete it until February 9, 2010. (Resp't Ex. 18 at 2; *see also* Tr. 72.) For instance, a February 2, 2010 letter from the Florida Department of Health states that ''Dr. Reppy has not completed any term imposed by the final order and is considered out of compliance at this time.'' (Gov't Exs. 20 & 22.) At hearing, Respondent testified that he had since submitted the paper he was assigned. (Tr. 72.) The paper warns practitioners against the dangers of Internet prescribing, gives case histories and reflects on what happened to Respondent. (Tr. 93.)

Respondent's drug course was to be completed within one year of December 26, 2007, the date of the final order. (Tr. 48; Gov't Ex. 15.) Respondent did not complete the drug course until December 9 through December 11, 2009. (Tr. 48.) He did not complete the records course or the laws and rules course until after September 2010. (Tr. 48.) As of the date of the hearing, however, Respondent had complied with all of his continuing education requirements. (Tr. 71; Resp't Ex. 18 at 2.)

Explaining his failure to meet all the deadlines set by the settlement agreement, Respondent asserted that in 2006 DEA placed on the Internet information related to his reprimand. (Tr. 50.) Thereafter, Respondent ''became essentially unemployable'' at any hospital or large clinic. (Tr. 50.) Consequently, Respondent had no income and was unable to pay the $3000 and $5000 cost of the courses he agreed to take. (Tr. 51.)

Per the settlement agreement, Respondent agreed to pay his $12,500 fine within two years of December 26, 2007. (Gov't Ex. 15; Tr. 49.) Respondent acknowledged that the settlement agreement and final order provided that Respondent would cease professional practice if he did not comply with the two-year deadline for paying the fine set therein. (Tr. 50; *see* Gov't Ex. 15 at 4.) Respondent testified that he has not yet paid the fine in full, but has practiced medicine continuously since the December 26, 2007 final order was issued, in part because he was unable to secure other employment, a problem he attributes partially to the DEA. (Tr. 49, 51.) Respondent testified that ''unless I was ordered by the Department of Health I wasn't going to'' cease practicing medicine, although he had agreed to do so in the October 2, 2007 settlement agreement. (Tr. 50.) The Florida Department of Health ''agreed to the schedule that I'm paying it back on.'' [48] (Tr. 49.) In mitigation, Respondent stated that he reported to a compliance officer who was aware of Respondent's continued practice. (Tr. 70.)

*F. Respondent's Family Practice at Cosmopolitan*

(a) Generally

In July or August of 2010, after leaving UPR, Respondent placed an ad in the local newspaper advertising his new family practice at his current employer, Cosmopolitan Clinic. (Tr. 88; Resp't Ex. 17.) The ad resulted in Respondent acquiring new, non-pain management patients. (Tr. 88.) Respondent has acted to change his practice from a pain management practice to a family practice. (Tr. 88–89.)

Respondent testified as to his documentation practices at Cosmopolitan. (*See* Tr. 80–87; Resp't Ex. 15.) In pertinent part, he testified to using a Consent for Chronic Opioid Therapy, and later using a Controlled Substances Narcotic Agreement. These documents enable Respondent to summarily dismiss any patient who seeks controlled substances from other physicians (Tr. 84), or who fails to notify the clinic in writing upon switching pharmacies, (Tr. 86; Resp't Ex. 15.) Respondent testified that as of the date of the hearing, he understood that he is required to dispense or prescribe controlled substances only for a legitimate medical purpose in the usual course of his professional practice. (Tr. 62.)

At his current practice at Cosmopolitan, Respondent's most frequently prescribed controlled substances are methadone and oxycodone. (Tr. 57.) Respondent prescribes methadone to treat chronic pain conditions unlikely to improve without surgery, and oxycodone for conditions where a short-acting medication is more appropriate. (Tr. 58–59.)

(b) Respondent's Current Patients at Cosmopolitan

[D.C.] has been a patient of Respondent for approximately thirteen to fourteen months for the treatment of degenerative spondylosis. (Resp't Ex. 19 at 9 ¶¶ 1–2.) During this time, Respondent met with [D.C.] approximately ten times. (*Id.* at ¶ 6.) Respondent physically examined [D.C.] at most visits and inquired whether [D.C.] was experiencing any new pain. (*Id.* at ¶ 7.) Respondent always took time with [D.C.] to discuss treatment options and [D.C.] never felt like the visit was rushed. (*Id.* at ¶ 9 & 10.)

[D.C.] believed [D.C.]'s former pain doctor was overmedicating [D.C.]. Respondent happily agreed to reduce the dosage of pain medication that [D.C.]'s former pain doctor was prescribing. (Resp't Ex. 19 at 9 ¶¶ 3–4.) Respondent gradually lowered the dosage over a period of months, ensuring that [D.C.] did not experience any new pain. (*Id.* at ¶ 5.) In fact, the reduction in [D.C.]'s pain has been dramatic. (*Id.* at ¶ 8.) Prior to treatment by Respondent, [D.C.] was taking 30 mg oxycodone five times per day, 10 mg methadone six times per day; and 2 mg Xanax two times per day. (*Id.* at ¶ 11.) Presently, however, [D.C.] considers [D.C.]'s pain to be under control and is taking 5 mg methadone once a day and one teaspoon of liquid oxycodone once a day. (*Id.* at ¶¶ 11 & 12.) The Xanax prescription is no longer needed. (*Id.* at ¶ 12.)

Another patient of Respondent, [C.K.], likes Respondent because he is a ''straight up'' sort of person; [C.K.] feels very comfortable with him. (Resp't Ex. 19 at 12 ¶ 3.) Respondent treats [C.K.] for back and neck pain stemming from an automobile accident, and also pain from a ''bad knee,'' for which surgery has been recommended. (*Id.* at ¶¶ 4, 5 & 6.) Respondent examines [C.K.] on each visit and discusses treatment options. (*Id.* at ¶ 7.) Respondent has worked with [C.K.] to reduce the

[48] Respondent's Exhibit 18, dated October 20, 2010, indicates that Respondent made four periodic payments in February, May, July and September 2010, amounting to a total of $1500 paid out of $12,500 owed. (*See* Resp't Ex. 18 at 2.)

amount of [C.K.]'s pain medication. (*Id.* at ¶ 6.)

(c) Respondent's Current Employees at Cosmopolitan

Respondent's administrative employee Janice Vischio also submitted an affidavit. Although Ms. Vischio is not generally present when Respondent consults with patients, she does witness parts of some conversations. (Resp't Ex. 19. at 2 ¶ 4.) She states that Respondent personally sees patients, takes or reviews patient history and reviews patient office forms. (*Id.* at ¶¶ 5–7.) Moreover, Ms. Vischio has seen Respondent's handwritten notes in patient files. (*Id.* at ¶ 7.)

Conceding that she has not personally seen Respondent examine patients, Ms. Vischio states that she has witnessed him performing exams on occasion and that Respondent documents exams in his files. (*Id.* at ¶ 8.) Respondent takes twenty minutes or more with each new patient, and ten minutes for a follow-up visit, and sometimes exceeds the allotted time limit. (*Id.* at ¶ 9.) Respondent discusses treatment plans with patients, returns their phone calls and discusses their options with them. (*Id.* at ¶ 10.) Ms. Vischio has worked with many physicians in a variety of medical settings, and calls Respondent thorough in his documentation and diligent in his examinations and follow-up. (*Id.* at ¶ 13.)

Ms. Vischio also addressed the new patient intake process. New patients must either obtain a referral for pain management or have a prescription history or list from six months to one year before seeing Respondent. (Resp't Ex. 19 at 3 ¶ 11.) New patients must fill out new patient packet forms, including medical history and treatment. They must also undergo an MRI or have had one within two years. (*Id.* at ¶ 11.) All MRIs are verified by the MRI facility before Respondent sees them. (*Id.* at ¶ 11.)

Ms. Vischio stated that when appropriate, Respondent has reduced the amount of pain medication prescribed; has instructed Ms. Vischio to advise patients of the same; and has heard patients complain that Respondent reduced their pain medication levels. (*Id.* at ¶ 12.)

Ms. Adele Durina, Respondent's office manager and medical assistant, submitted an affidavit stating she enjoys working with Respondent and has worked with him since he began working at Cosmopolitan Clinic because Respondent is considerate of his patients and office staff. (Resp't Ex. 19 at 6 ¶ 3; *see also* Tr. 167.)

When Respondent sees a new patient, he takes twenty to thirty minutes or longer and is very thorough. (Resp't Ex. 19 at 6 ¶ 4.) He conducts a physical examination and records the findings in the patient's chart. (*Id.* at ¶ 5.) Follow-up visits are usually fifteen minutes but can be more. (*Id.* at ¶ 6.) Patients commonly comment that Respondent has taken an exceptional amount of time with them and answered questions and provided information that patients were unable to get from other doctors. (*Id.* at ¶ 7.) Respondent returns patient phone calls with unusual speed, which patients appreciate. (*Id.* at ¶ 8.)

Cosmopolitan Clinic often tests patients to ensure they are not taking medications that Respondent has not prescribed. (Resp't Ex. 19 at 7 ¶ 9; *see also* Tr. 167.) Patients who fail the screen are often dismissed immediately; others are given one, but only one, chance. (*Id.* at ¶ 9.)

## V. The Parties' Contentions

### *A. The Government*

The Government argues that Respondent prescribed controlled substances to thousands of individuals across the United States when he was only licensed to practice medicine in the state of Florida, thereby violating the laws of numerous states,[49] in contravention of 21 CFR 1306.04 (2010). (Gov't Br. at 5; *see* Tr. 11.) Respondent often based his decision to prescribe solely on a review of medical records submitted by individuals who were seeking a controlled substance, usually hydrocodone, a Schedule III narcotic. (Tr. 11–12.) Respondent did not conduct physical examinations on the majority of these individuals. (Tr. 12.)

In addition, the Government argues that Respondent completed the conduct described above while employed by an Internet pharmacy ''whose sole business was to allow people to visit a Web site, ask for a certain drug, get referred to a physician who would consult with them by telephone, look at medical records that had been submitted and then issue the prescribed drug to be filled by that pharmacy.'' (Tr. 12.) The Government urges that Respondent had a legal duty to supervise his PA, Mr. Protheroe, and as a last resort, Respondent should have withdrawn from his employment if Mr. Protheroe failed to comply with Respondent's instructions. (Gov't Br. at 6.) The Government argues that Respondent's failure to do so ''indicates Respondent is willing to permit the misuse of his DEA registration in order to maintain his employment,'' rendering Respondent's registration contrary to the public interest. (*Id.*)

Finally, the Government argues that Respondent's testimony and demeanor at hearing evinced a lack of remorse and an attempt to blame others for his misconduct. ''Had Respondent accepted responsibility and demonstrated remorse for his conduct, his claims that he reformed his prescribing practices might portend a change in conduct.'' (*Id.* at 7.) Instead, the Government argues, registration is improper where ''Respondent blames the legal community, a lawyer who had a financial interest in the pharmacy where Respondent's prescriptions were filled, a physician's assistant, the owner of [UPS], and even DEA for his failure to abide by the law.'' (*Id.*)

### *B. Respondent*

Respondent disputes the quantity of controlled substances that Respondent prescribed. (Tr. 12–13.) Pointing to the practitioner manual distributed by the DEA (*see* Resp't Ex. 6 at 15), Respondent also argues that of the five grounds stated therein upon which a COR may be revoked, the only allegation that the Government has made is that Respondent committed an act that would render the DEA COR inconsistent with the public interest. (Tr. 14.) Noting that 21 U.S.C. § 823 and 824 set forth factors for determining the public interest, Respondent argues that the Florida Board of Osteopathic Medicine has not made a recommendation regarding the issuance of a DEA registration. (Tr. 14; Resp't Br. at 21–22.) Moreover, Respondent argues that Respondent's experience in dispensing controlled substances has not been challenged, and in any event, Respondent has such experience. (Tr. 14; Resp't Br. at 22.) Additionally, Respondent has not been convicted under federal or state laws relating to the manufacture, distribution or dispensing of controlled substances. (Tr. 14; Resp't Br. at 22.)

As for the final factor, ''such other conduct which may threaten the public safety,'' Respondent argues that he is no threat to the public safety. (Tr. 19.) As an initial matter, Respondent argues that he is remorseful, has been rehabilitated and that since discontinuing his Internet prescribing practices, ''no conduct which might threaten the public health and safety has been charged and proved.'' (Resp't Br. at 22.) Respondent also notes that attorney Robert Carr assured Respondent that Respondent's

[49] The Government argues in part that I should give weight to findings in *United Prescription Services, Inc.,* in which ''the Deputy Administrator found that Dr. Reppy violated the laws of California, Tennessee, Indiana and Louisiana * * *.'' (Gov't Br. at 5–6.)

prescribing practices at UPR were within the scope of permitted practice. (Tr. 16; Resp't Exs. 3 & 4.) Additionally, Respondent argues that many of the prescriptions attributed to him were either forged or written by a PA. (Tr. 16; Resp't Br. at 24.) Moreover, Respondent argues that he was acting as a consultant to primary care physicians and was merely extending prescriptions for drugs that had already been prescribed by other physicians. (Tr. 17.)

Respondent further contends that he acquired adequate medical history documentation from Ms. Messick, and that Respondent, ''when necessary, would speak by telephone with either the patient or the patient's primary care physician.'' (Tr. 17–18.)

Respondent also notes that he was compensated on an hourly basis, so the number of prescriptions he wrote was not a factor in his prescribing habits. (Tr. 18.)

In addition, Respondent immediately terminated his Internet prescribing upon being notified that his actions were not in conformity with regulations. (Tr. 16.) He discontinued his prescribing habits far before any notice of these administrative proceedings. (Tr. 18.) He regrets his mistakes and apologizes for them. (Tr. 16, 18.)

In the nearly four years since Respondent engaged in Internet prescribing practices at UPR, Respondent argues that he has conformed his practice to meet all state and federal requirements, including requirements of the Florida Department of Health, Board of Osteopathic Medicine (Tr. 18, 19), and is converting his pain management practice to a family practice treating indigent and low-income patients. (Tr. 18.)

## VI. Discussion and Conclusions

### *A. The Applicable Statutory and Regulatory Provisions*

The Controlled Substances Act (CSA) provides that any person who dispenses (including prescribing) a controlled substance must obtain a registration issued by the DEA in accordance with applicable rules and regulations.[50] ''A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner'' with a corresponding responsibility on the pharmacist who fills the prescription.[51] It is unlawful for any person to possess a controlled substance unless that substance was obtained pursuant to a valid prescription from a practitioner acting in the course of his professional practice.[52] In addition, I conclude that the reference in 21 U.S.C. 823(f)(5) to ''other conduct which may threaten the public health and safety'' would as a matter of statutory interpretation logically encompass the factors listed in § 824(a).[53]

### *B. The Public Interest Standard*

The CSA, at 21 U.S.C. 824(a)(4), provides, insofar as pertinent to this proceeding, that the Deputy Administrator may revoke a COR if she finds that the registrant's continued registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(f). In determining the public interest, the Deputy Administrator is required to consider the following factors:

(1) The recommendation of the appropriate state licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing or conducting research with respect to controlled substances.

(3) The applicant's conviction record under federal or state laws relating to the manufacture, distribution or dispensing of controlled substances.

(4) Compliance with applicable state, federal or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

As a threshold matter, the factors specified in Section 823(f) are to be considered in the disjunctive: the Deputy Administrator may properly rely on any one or a combination of those factors, and give each factor the weight she deems appropriate, in determining whether a registration should be revoked or an application for registration denied. *See David H. Gillis, M.D.,* 58 FR 37,507, 37,508 (DEA 1993); *see also D & S Sales,* 71 FR 37,607, 37,610 (DEA 2006); *Joy's Ideas,* 70 FR 33,195, 33,197 (DEA 2005); *Henry J. Schwarz, Jr., M.D.,* 54 FR 16,422, 16,424 (DEA 1989). Additionally, in an action to revoke a registrant's COR, the DEA has the burden of proving that the requirements for revocation are satisfied.[54] The burden of proof shifts to the registrant once the Government has made its prima facie case.[55]

### *C. The Factors To Be Considered*

Factors 1 and 3: The Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority and Conviction Record Under Federal or State Laws Relating to the Manufacture, Distribution or Dispensing of Controlled Substances

In this case, regarding Factor One, it is undisputed that Respondent currently holds a valid medical license in Florida, but Respondent's medical license has been the subject of state disciplinary action in the past. As discussed in the Evidence and Incorporated Findings of Fact section of this Recommended Decision, the Florida Department of Health instituted an Administrative Complaint against Respondent in May 2007. (Tr. 40; Gov't Ex. 14.) The Complaint alleged, in sum and in substance, that Respondent repeatedly prescribed controlled substances without having face-to-face meetings with patients; without performing adequate patient evaluations, taking adequate medical histories, conducting adequate medical examinations, discussing the risks and benefits of the course of treatment, documenting treatment plans or making appropriate referrals. (*E.g.,* Gov't Ex. 14 at 2–3, 14.)

The Complaint resulted in a settlement agreement, dated October 2, 2007, implemented through a final order dated December 26, 2007. (Tr. 46–48; Gov't Exs. 15 & 16.) Respondent agreed to pay a fine of $12,500, complete continuing medical education courses, perform 100 hours of community service and prepare a paper suitable for publication. (Tr. 46; Gov't Ex. 15; *see also* Gov't Ex. 16.)

Respondent failed to timely complete the deadlines set by the settlement agreement, but as of hearing had completed most of his requirements and was in the process of paying the assessed fine. (*See, e.g.,* Resp't Ex. 18 at 2 & Tr. 72 (community service); Tr. 48 & Gov't Ex. 15 (drug course); Gov't Ex. 15 & Tr. 49, 51 ($12,500 fine).)

The most recent action by the Florida Department of Health reflects a determination that Respondent, notwithstanding findings of unprofessional conduct, can be entrusted with a medical license subject to probationary terms and conditions. While not dispositive,[56] this action by the Florida Department of Health does weigh against a finding that Respondent's continued registration

[50] 21 U.S.C. 822(a)(2); 21 U.S.C. 802(10).

[51] 21 CFR 1306.04(a).

[52] 21 U.S.C. 844(a).

[53] *See Kuen H. Chen, M.D.,* 58 FR 65,401, 65,402 (DEA 1993).

[54] 21 CFR 1301.44(e) (2010).

[55] *Medicine Shoppe—Jonesborough,* 73 FR 364, 380 (DEA 2008); *see also Thomas E. Johnston,* 45 FR 72,311, 72,311 (DEA 1980).

[56] *Mortimer B. Levin, D.O.,* 55 FR 8209, 8210 (DEA 1990) (finding DEA maintains separate oversight responsibility and statutory obligation to make independent determination whether to grant registration).

would be inconsistent with the public interest under Factor One. *Cf. Robert A. Leslie, M.D.,* 68 FR 15,227, 15,230 (DEA 2003) (under Factor One, prior suspension of respondent's state medical license held not dispositive where state license currently under no restrictions).

Regarding Factor Three, there is no evidence that Respondent has ever been convicted under any federal or state law relating to the manufacture, distribution or dispensing of controlled substances. I therefore find that this factor, although not dispositive, *see Leslie,* 68 FR at 15,230, weighs against a finding that Respondent's continued registration would be inconsistent with the public interest.

Factors 2 and 4: Respondent's Experience in Handling Controlled Substances; and Compliance With Applicable State, Federal or Local Laws Relating to Controlled Substances

Respondent argues that his experience in dispensing controlled substances has not been challenged. (Tr. 14; *see* Resp't Br. at 22.)

It has. As summarized above and discussed below, the Government challenges Respondent's supervision of his PA, his unauthorized practice of medicine, the legitimacy of his prescribing practices and his compliance with telemedicine standards, all applied to the dispensing [57] of controlled substances.

(a) Adequacy of Notice of PA Supervision Issue

A threshold matter concerns whether the Government adequately noticed its contention that Respondent violated Florida law relating to the supervision of his PA, Mr. Protheroe.[58] Before the Agency may properly impose a sanction on the basis of a given allegation, Agency precedent requires that a registrant be provided a '''full and fair opportunity' to litigate both the factual and legal bases of the Government's theory.'' *CBS Wholesale Distribs.,* 74 FR 36,746, 36,750 (DEA 2009). As for the factual basis of the Government's theory, I find that the issue of Respondent's relationship with his PA was adequately noticed by the Government's supplemental prehearing statement.[59]

More complicated is whether the Government adequately noticed provisions of Florida law relevant to the supervision of PAs. The OSC alleges in pertinent part that Respondent violated Fla. Stat. Ann. § 458.347 (2008) (''Physician assistants''), which sets forth a regulatory framework for the training, conduct and supervision of PAs.[60] (*See* ALJ 1.) That provision is codified in Chapter 458, entitled ''Medical Practice.'' But Respondent is an osteopathic doctor (Tr. 20; Gov't Ex. 15 at 1), and not an allopathic doctor, so the standards of his practice are governed by Chapter 459 (''Osteopathic Medicine'') and not Chapter 458 (''Medical Practice''). *See* Fla. Stat. Ann. § 458.303 (''The provisions of * * * [the Florida statute noticed in the OSC, Section] 458.347 shall have no application to * * * [o]ther duly licensed health care practitioners * * * .''). As codified in Section 459.022, Chapter 459 contains a PA provision applicable to osteopathic doctors that substantially mirrors the PA provision applicable to allopathic doctors actually noticed by the Government. In fact, a word-by-word comparison of § 458.347 (allopathic doctors) and § 459.022 (osteopathic doctors), as codified during the relevant time period,[61] reveals that the language from each provision governing a physician's duty of care with respect to supervising a PA is textually identical,[62] and the remaining provisions contain no differences relevant to this proceeding.[63]

The OSC also alleges violations of Fla. Admin. Code Ann. r. 64B8–30.008(1)(a) (formulary requirements for PAs). That provision, which falls under the subtitle of regulations applicable to allopathic physicians, provides in pertinent part that PAs are not authorized to prescribe controlled substances. Fla. Admin. Code Ann. r. 64B8–30.008(1)(a). But because subtitle 64B8 of the Florida Administrative Code Annotated governs matters pertinent to the Board of [allopathic] Medicine, and Respondent is a doctor of osteopathy, the relevant Florida administrative provisions governing Respondent's conduct are located under subtitle 64B15 (''Board of Osteopathic Medicine''). As codified in Rule 64B15–6.0038, subtitle 64B15 contains a formulary provision that mirrors the formulary provision applicable to allopathic doctors actually noticed by the Government. A word-by-word comparison of Rule 64B8–30.008(1)(a) (applicable to PAs under allopathic doctors) and Rule 64B15–6.0038 (applicable to PAs under osteopathic doctors) as codified during the relevant time period [64] reveals that the two provisions are textually identical.

As summarized thus far, the OSC in this case notices the Government's intention to litigate issues embracing supervision of Respondent's PA and related formulary provisions of Florida law. Although the provisions actually noticed by the Government pertain to allopathic doctors and not osteopathic doctors, two reasons compel the conclusion that the notice provided in this instance is sufficient to apprise Respondent ''that this allegation would be litigated.'' *See CBS,* 74 FR at 36,749.

First, as discussed above, the pertinent operative sections of the provisions actually noticed in the OSC are literally identical to the duty-of-care provisions applicable to osteopathic doctors. Respondent therefore had not just substantial notice, but truly *actual* notice of the exact legal standards that the Government alleges that Respondent violated.

Second, DEA, to a certain extent, adopts a ''notice pleading'' model with respect to certain matters of law. *Cf.* 21 U.S.C. 823(f)(4) (requiring the DEA to assess a registrant's ''[c]ompliance with

[57] Under the CSA, prescribing is included in the definition of ''dispensing.'' 21 U.S.C. 802(10).

[58] The OSC alleges that Respondent violated Fla. Stat. Ann. § 458.347 (2008) (''Physician assistants''). (ALJ Ex. 1.)

[59] The Government noticed Respondent's testimony: ''regarding his relationship with Physician's Assistant John Protheroe * * * He will testify generally to the manner in which he supervised Mr. Protheroe as well as Mr. Protheroe's responsibilities * * * Mr. Protheroe issued prescriptions for controlled substances using Respondent's DEA registration number * * * with Respondent's consent and under his supervision.'' (Gov't Supp. PHS at 4.)

[60] The version Fla. Stat. Ann. § 458.347 alleged in the OSC is from 2008, but the relevant time period of Respondent's conduct was from 2004 until approximately 2006. (ALJ Ex. 1.) Consequently, the following analysis concerns the 2004 through 2006 versions of that statute.

[61] *See* Gov't Ex. 5 (collecting versions of Fla. Stat. Ann. § 459.022 from 2004–2006); *see also supra* note 60.

[62] *Compare* Fla. Stat. Ann. § 459.022(3) (''Each physician * * * shall be * * * responsible and liable for the performance and the acts and omissions of the physician assistant.''), *with* Fla. Stat. Ann. § 458.347(3) (same). *Compare also* Fla. Stat. Ann. § 459.022(4)(e) (''A supervisory physician may delegate to a fully licensed physician assistant the authority to prescribe or dispense any medication used in the supervisory physician's practice unless such medication is listed on the formulary created pursuant to § 458.347 * * * A physician assistant must clearly identify to the patient that she or he is a physician assistant [and] inform the patient that the patient has the right to see the physician * * *.''), *with* Fla. Stat. Ann. § 458.347(4)(e) (same). The reference in Section 459.022(4)(e) to the location of the formulary of drugs a PA may not prescribe is consistent with the reference in Section 458.347(4)(e) to ''the formulary created pursuant to paragraph (f)'' because the formularies are identical. *See* Fla. Admin. Code Ann. rr. 64B15–6.0038 & 64B8–30.008.

[63] For instance, the addition of the word ''osteopathic'' in the legislative intent headings of Fla. Stat. Ann. § 459.022(1) cannot be considered a material difference from the text found in Section 458.347(1).

[64] *See* Gov't Ex. 3 (collecting Fla. Admin. Code Ann. rr. 64B15–6.0038 (2004), 64B8–30.008 (2005) and 64B15–6.0038 (2006)); *see also supra* note 60.

applicable state, federal or local laws relating to controlled substances''). I find that an otherwise adequate provision of notice of the substantive legal issues to be addressed is not undercut by an erroneous citation, when the text that should have been cited is literally identical to the erroneously cited text and is contained within a neighboring chapter of the same code of state law.

Therefore, although the Government's inaccurate noticing of the provisions of law upon which it intends to seek revocation of a COR could be misleading in some circumstances, I find that under the circumstances of this case Respondent received adequate and timely notice of the legal and factual issues surrounding Respondent's interaction with and supervision of his PA. I therefore conclude that Respondent's interaction with and supervision of his PA may properly be considered as a potential basis for revoking Respondent's COR and denying any pending applications for registration or renewal.

(b) Respondent's Supervision of His PA

An issue under Factors Two and Four of 21 U.S.C. 823(f) is whether Respondent adequately discharged his duty under Florida and federal law to supervise his PA, Mr. Protheroe. I find insofar as is pertinent to this proceeding that Florida law sets forth the duties and obligations of osteopathic physicians vis-à-vis PAs, as set forth below. *See generally* Fla. Stat. Ann. § 459.022; Fla. Admin. Code Ann. r. 64B15–6.0038.

A ''physician assistant'' is ''a person who is a graduate of an approved program or its equivalent or meets standards approved by the boards and is licensed to perform medical services delegated by the supervising physician.'' Fla. Stat. Ann. § 459.022(2)(e). ''Supervision'' means ''responsible supervision and control. Except in cases of emergency, supervision requires the easy availability or physical presence of the licensed physician for consultation and direction of the actions of the physician assistant * * * 'easy availability' includes the ability to communicate by way of telecommunication.'' *Id.* § 459.022(2)(f). A physician ''supervising a licensed physician assistant * * * shall be * * * responsible and liable for the performance and the acts and omissions of the physician assistant.'' *Id.* § 459.022(3). Failing to adequately supervise a PA constitutes grounds for discipline. *Id.* § 459.015(1)(hh). Subject to certain limitations, ''[a] supervisory physician may delegate to a fully licensed physician assistant the authority to prescribe or dispense any medication used in the supervisory physician's practice. * * *'' *id.* § 459.022(4)(e), but, as emphatically stated in the Florida Administrative Code:

> PHYSICIAN ASSISTANTS APPROVED TO PRESCRIBE MEDICINAL DRUGS UNDER THE PROVISIONS OF * * * 459.022(4)(E), F.S., ARE NOT AUTHORIZED TO PRESCRIBE THE FOLLOWING MEDICINAL DRUGS, IN PURE FORM OR COMBINATION: (a) Controlled substances.* * *''

Fla. Admin. Code Ann. r. 64B15–6.0038. In addition, a PA must ''clearly identify to the patient that he or she is a physician assistant * * * [and] must inform the patient that the patient has the right to see the physician prior to any prescription being prescribed or dispensed by the physician assistant.'' *Id.* § 459.022(4)(e)(1).

Federal law also bears upon a physician's supervision of a PA. As an initial matter, 21 U.S.C. 846, a provision noticed by the OSC in the above-captioned case, imposes liability for attempt and conspiracy to violate certain provisions of the CSA.[65] In pertinent part, the following statutory provisions are susceptible to the sweep of § 846. ''Except as authorized by this title, it shall be unlawful for any person knowingly or intentionally * * * to * * * dispense[] a controlled substance.'' 21 U.S.C. 841(a). Moreover, ''[e]very person who dispenses * * * any controlled substance, shall obtain from the Attorney General a registration,''[66] 21 U.S.C. 822(a)(2), with the exception of ''[a]n agent or employee of any registered * * * dispenser of any controlled substance if such agent or employee is acting in the usual course of his business or employment,'' § 822(c)(1). It is illegal ''to use in the course of * * * dispensing of a controlled substance * * * a registration number * * * issued to another person.'' § 843(a)(2).

Read together, I find as a matter of statutory construction that 21 U.S.C. 822, 841, 843 and 846 impose on a practitioner an affirmative duty to supervise his or her PA to ensure that the PA dispenses[67] medication only in accordance with the law, and to prevent the unauthorized use of the practitioner's COR.[68] *See* 21 CFR 1301.22 (2010) (''The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his/her business or employment.''). This conclusion is consistent with Agency precedent holding that a registrant must adequately supervise his or her PA to prevent the unlawful issuance of prescriptions for controlled substances. As the Administrator recently explained, ''a registrant is strictly liable for the misconduct of those persons who he authorizes to act under his registration.'' *Scott C. Bickman, M.D.,* 76 FR 17,694, 17,703 (DEA 2011); *see Robert G. Hallermeier, M.D.,* 62 FR 26,818, 26,820 (DEA 1997) (failure to supervise PA ''permitted the prescribing of controlled substances by an unauthorized individual in violation of numerous provisions of Federal and state laws and regulations, including 21 U.S.C. 829(b) and 841 and 21 CFR 1306.03 and 1306.04(a) (1997) . * * *''); *Jay Wheeler Cranston, M.D.,* 59 FR 36,786, 36,789 (DEA 1994) (''Respondent authorized physician assistants to issue and sign controlled substance prescriptions to patients without direct supervision of a physician in violation of 21 CFR 1306.03 and 1306.05(a) (1994).''). *See generally Dan E. Hale, D.O.,* 69 FR 69,402, 69,406 (DEA 2004) (respondent's grant of permission to PA to ''provide controlled substances to patients prior to the effective date of legislation permitting such activity * * * and unauthorized utilization of a physician assistant to provide controlled substances * * * to drug abusing patients so they would submit to unnecessary medical tests, violated laws relating to controlled substances * * * [and] weighs against registration'').

Turning to the facts of the case at bar, the record reveals that Respondent's supervision of his PA, Mr. Protheroe, was virtually non-existent. Respondent testified that Mr. Protheroe worked under Respondent's license (Tr. 37, 131), giving rise to Respondent's legal duty to supervise him. *See* Fla. Stat. Ann. § 459.022(2)(e). Yet Respondent's testimony shows that Respondent did not supervise Mr. Protheroe. Respondent did not hire him (*see* Tr. 37 (''he was put there by someone else''), did not need him (Tr. 37), complained about him repeatedly to Mr. Bollinger

[65] Under 21 U.S.C. 846, ''[a]ny person who attempts or conspires to commit any offense defined in this title shall be subject to the same penalties as those prescribed for the offense, the commission of which was the object of the attempt or conspiracy.''

[66] *See also* 21 CFR 1301.11 (2010).

[67] Dispensing includes, *inter alia,* prescribing. 21 U.S.C. 802(10).

[68] *See, e.g.,* 21 U.S.C. 820(3) (defining ''agent'' as ''an authorized person who acts on behalf of or at the direction of a * * * dispenser'').

and Ms. Messick (*see, e.g.,* Resp't Ex. 12 at 4; Tr. 131, 138–39), did not control Mr. Protheroe's hours (*see* Tr. 37 (''he was not even present most of the time I was there'')), did not control Mr. Protheroe's work product (*see* Tr. 37 (''He ended up basically exploiting my license behind my back without my permission.''); Tr. 122 (Mr. Protheroe failed to adhere to the criteria by which Respondent rejected patients); *see also* Tr. 131, 138–39) and did not believe he could fire him (Tr. 37 (''I had no power to remove him because I did not pay his salary. I could not tell him to leave.'')).

I find that Respondent failed to exercise ''responsible supervision and control'' over Mr. Protheroe, in violation of Fla. Stat. Ann. § 459.022(2)(f), based in part on the uncontroverted evidence that Mr. Protheroe wrote at least 14,000 unauthorized prescriptions in Respondent's name (Tr. 80; *see generally* Tr. 132; Gov't Ex. 10 at 84–85), many of which while Respondent was away from the office for an extended period of time (Tr. 121–22, 132; Gov't Ex. 10 at 85, 96, 101). Because Respondent testified that he developed concerns regarding Mr. Protheroe's performance before November 2003 (Tr. 121), which was before Respondent went on leave in 2005 (*see* Tr. 121–22, 132), it cannot reasonably be questioned that Respondent is ''responsible and liable for the performance and the acts and omissions of the physician assistant.'' *Id.* § 459.022(3).

Respondent's testimony that Respondent approved a few of Mr. Protheroe's prescriptions each day (Tr. 42) and supervised Mr. Protheroe during the limited times that the latter was in the office (*see* Gov't Ex. 10 at 105) does not satisfy Respondent's duty to supervise Mr. Protheroe, nor is there any evidence that Respondent adequately supervised Mr. Protheroe telephonically as would have been permissible under Fla. Stat. Ann. § 459.022(2)(f). Respondent's failure to adequately supervise Mr. Protheroe constitutes grounds for discipline under Florida law. *Id.* § 459.015(1)(hh).

The evidence further reflects that the majority of prescriptions Mr. Protheroe wrote were for controlled substances. (*E.g.,* Resp't Ex. 12 at 2.) This evidence constitutes a flagrant violation of Florida law that unambiguously prohibits PAs from prescribing controlled substances under any circumstances. Under the Florida Administrative Code, ''physician assistants * * * are not authorized to prescribe * * * [c]ontrolled substances. * * *'' [69] Fla. Admin. Code Ann. r. 64B15–6.0038 (internal formatting omitted). Mr. Protheroe's illegal conduct is chargeable to Respondent because Respondent is ''responsible and liable for the performance and the acts and omissions of the physician assistant.'' Fla. Stat. Ann. § 459.022(3). *Accord cf. Scott C. Bickman, M.D.,* 76 FR at 17,703 (holding registrant strictly liable for misconduct of ''those persons who he authorizes to act under his registration'').

Respondent's testimony that he approved a few of Mr. Protheroe's prescriptions each day (Tr. 42), read together with Respondent's admission that ''[m]ost of the prescriptions written by Mr. Protheroe were for controlled substances'' (Resp't Ex. 12 at 2), suggests Respondent attempted to confer upon Mr. Protheroe in some instances the authority to prescribe controlled substances. But Respondent lacked authority under Florida law to make such an authorization. ''A supervising physician may delegate to a prescribing physician assistant only such authorized medicinal drugs as are * * * not'' controlled substances. Fla. Admin. Code Ann. r. 64B15–6.0038.

To summarize, substantial evidence supports the conclusion that Respondent allowed a PA to use Respondent's COR to issue purported prescriptions of controlled substances to Internet customers, and that Respondent otherwise failed to adequately supervise his PA. Respondent's conduct in this regard violated Fla. Stat. Ann. § 459.022; Fla. Stat. Ann. § 459.015(1)(hh) and Fla. Admin. Code Ann. r. 64B15–6.0038, as well as Respondent's duty under federal law to supervise his PA to ensure that the PA dispenses medication only in accordance with the law, and to prevent the unauthorized or unlawful use of Respondent's COR, *e.g., Robert G. Hallermeier, M.D.,* 62 FR 26,818, 26,820 (DEA 1997); *Jay Wheeler Cranston, M.D.,* 59 FR 36,786, 36,789 (DEA 1994).[70] This finding weighs strongly in favor of a finding under Factors Two and Four of 21 U.S.C. 823(f) that Respondent's continued registration would be inconsistent with the public interest.

(c) Unauthorized Practice of Medicine

Pursuant to 21 CFR 1306.03 (2010), ''[a] prescription for a controlled substance may be issued only by an individual practitioner who is * * * authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession.'' The OSC in the above-captioned case alleges violations of the laws of Mississippi, California and Alabama relating to the unlicensed or long-distance practice of medicine. (*See* ALJ Ex. 1 at 2.)

First at issue is the law of Mississippi. As codified at Miss. Code Ann. § 73–25–34(2), Mississippi has provided without amendment since 1997 that

> no person shall engage in the practice of medicine across state lines (telemedicine) in this state, hold himself out as qualified to do the same, or use any title, word or abbreviation to indicate to or induce others to believe that he is duly licensed to practice medicine across state lines in this state unless he has first obtained a license to do so from the State Board of Medical Licensure. * * *

*See* 1997 Miss. Laws 436.[71]

In this case, the record reflects that Respondent currently holds a medical license from the state of Florida. (Tr. 20.) Respondent was previously licensed in Georgia, California and Hawaii, but has not held medical licenses in any of those states since 1999. (Tr. 21.) Since 2000, Respondent has been licensed to practice medicine solely in Florida. (*See, e.g.,* Tr. 21.)

The record further reflects that during the relevant time period of 2004 to 2006 (ALJ Ex. 1 at 1), most of the individuals to whom Respondent prescribed controlled substances became Respondent's customers through Internet Web sites. (Tr. 25.) Respondent testified that he recalled issuing prescriptions for controlled substances to people located all across the United States. (Tr. 27, 39; *see* Resp't Ex. 12 at 3.) Although he did not remember precisely how many different states his client base represented, he said the list was long. (Tr. 39.) I therefore find that substantial evidence supports the OSC allegation that Respondent issued controlled substances to customers throughout the United States while licensed to practice medicine only in Florida.

This finding, however, does not end the inquiry. Respondent's testimony suggests that he did not issue prescriptions for controlled substances to individuals in Mississippi because that state was ''off limits'' in terms of what his telemedicine contract would permit. (Tr. 28.) The hearing transcript reads:

[69] In this context the term ''controlled substances'' is defined by Fla. Stat. Ann. §§ 893.02 (2004) and 893.03 (2004) and includes hydrocodone and oxycodone, among other drugs. *See* Fla. Stat. Ann. § 893.03(2)(a) (2004).

[70] *See also supra* text at notes 65 to 68.

[71] *See* 1997 MS ALS 436 (on LexisNexis) (historical versions) and MS LEGIS 436 (1997) (Westlaw) (same).

Q: Dr. Reppy, the people that you provided service to when you worked at University, these were people from all over the United States, is that correct?

A: Yes.

Q: And in fact you serviced people in all 50 states, didn't you, during that time?

A: There were some states that were off limits because—like—like Kentucky was one of them and Mississippi was the other one. Those two states had stated that they would—were against any telemedicine-type of contract at all. Now, I was—I was represented by their legal counsel, by—by Mr. Carr that the—that the prescribing pharmacy was licensed in all 50 states and therefore that covered any legal issues with it. That—that wasn't true, but that's what I was told.

(Tr. 27–28.) The record reveals no other information specifically relating to Respondent's Mississippi prescribing practices,[72] and the Government called no witnesses other than Respondent, even though DEA Diversion Investigator Peter Flagg, identified in the Government's supplemental prehearing statement as a witness, was present in the courtroom.[73] (Tr. 2; Gov't Supp. PHS at 1.) Although the second half of Respondent's testimony quoted above lends some support to the Government's allegation that Respondent prescribed to Mississippi residents, the first part of his statement, that Mississippi was off limits, cuts evenly in the other direction, leaving the evidence in equipoise.

''Under the preponderance of the evidence test, the [party with the burden of proof] loses when the evidence is in equipoise because he did not present that slight quantum of evidence necessary to tip the balance from equipoise to his favor.'' *United States* v. *Rodriguez,* 406 F.3d 1261, 1300 (11th Cir. 2005) (Barkett, C.J., dissenting) (citing *Nat'l Lime Ass'n* v. *EPA,* 627 F.2d 416, 453 n.139 (D.C. Cir. 1980) (''The standard of ordinary civil litigation, a preponderance of the evidence, demands only 51% certainty.'') and Black's Law Dictionary 1201 (7th ed. 1999)). I therefore conclude that substantial evidence does not support the conclusion that Respondent violated Miss. Code Ann. § 73–25–34.[74]

Turning to California, the law of that state has provided in pertinent part without amendment since 2002 that

> any person who practices or attempts to practice, or who advertises or holds himself or herself out as practicing, any system or mode of treating the sick or afflicted in this state, or who diagnoses, treats, operates for, or prescribes for any * * * physical or mental condition of any person, without having at the time of so doing a valid, unrevoked, or unsuspended [California medical license] is guilty of a public offense, punishable by fine, imprisonment or both. Cal. Bus. & Prof. Code § 2052(a).

As is true in most contexts, ignorance of the law is no defense. The California Court of Appeal has noted that the ''proscription of the unlicensed practice of medicine is neither an obscure nor an unusual state prohibition of which ignorance can reasonably be claimed, and certainly not by persons * * * who are licensed health care providers. Nor can such persons reasonably claim ignorance of the fact that authorization of a prescription pharmaceutical constitutes the practice of medicine.'' *Hageseth* v. *Superior Court,* 59 Cal. Rptr. 3d 385, 403 (Ct. App. 2007).

Here, Respondent's unrebutted testimony confirms that he issued prescriptions for controlled substances to people in California while he was licensed to practice medicine solely in Florida. (Tr. 21, 28.) Respondent's witness Mr. Carr also testified that ''I know California is one of the states that we were prescribing to—or shipping drugs to.'' (Tr. 158.) I therefore conclude that substantial evidence supports a finding that Respondent violated Cal. Bus. & Prof. Code § 2052(a) (prohibiting the unlicensed practice of medicine).

In addition, Mr. Carr testified that in 2001 or 2002 he researched the law of all fifty states regarding telemedicine (Tr. 144–45) and ''left no stone unturned,'' compiling a file ''well over a foot high of documents I reviewed extensively. * * *'' (Tr. 150), finding that ''the telemedicine * * * realm * * * in 2001 was almost non-existent in any kind of regulations, statutes or anything.'' (Tr. 144.) He concluded that ''the only reference you could really find back—back at that time was neural radiology in pain medicine.'' (Tr. 144.) He could not identify the effective date of California's statute related to Internet prescribing. (Tr. 150, 157.)

Although neither the Government nor Respondent addressed the matter in argument, in light of Mr. Carr's testimony, I find it notable that California in fact adopted an Internet prescribing statute at least as early as 2000. *See* Cal. Bus. & Prof. Code § 2242.1. Pertinent parts of that provision, with 2006 amendments noted,[75] reads:

> No person or entity may prescribe, dispense, or furnish, or cause to be prescribed, dispensed, or furnished, dangerous drugs * * * on the Internet for delivery to any person in this state, without [a good faith] *an appropriate* prior examination and medical indication [therefor], except as authorized by Section 2242.

*Id.* Violators are subject to fines or civil penalties of up to $25,000 per occurrence, *id.* § 2242.1(b) or, ''[i]f the person * * * is not a resident of this state, a violation of this section shall, if applicable, be reported to the person's * * * appropriate professional licensing authority,'' *id.* § 2242.1(e).

In light of the existence of this statute prior to and during the relevant time period (*see* ALJ Ex. 1 (2004 to 2006)), and Mr. Carr's testimony that he shared his research on standards for Internet prescribing practices with Respondent before Respondent began working for UPR, Respondent's testimony that in 2003 ''the legal community was struggling in a gray area to determine what [those standards] would be'' (Tr. 64), at least with respect to California, is not credible. (*Compare* Tr. 60; *see also* Tr. 89–92.) When Respondent issued the prescriptions at issue here, numerous states had already adopted laws or regulations, or had issued policy statements making clear, that Respondent's Internet prescribing practices were illegal.[76] In addition, a 2001 Federal Register notice, offered as Respondent's own exhibit, makes clear that practitioners ''must be licensed to prescribe controlled substances by the State(s) in which they operate.'' [77] (Resp't Ex. 8 at 3.) And the Model Guidelines, offered as Respondent's Exhibit 9, cautions that ''[p]hysicians who treat or prescribe through Internet Web sites are practicing medicine and must possess appropriate licensure in all jurisdictions where *patients* reside.'' (Resp't Ex. 9 at 12 (emphasis supplied).)

Moreover, Respondent's suggestion that a 2002 letter from the DEA (*see* Resp't Ex. 4) gave him permission to prescribe controlled substances to patients in states where he lacked a medical license (Tr. 60; *see also* Tr. 89–

[72] Even the decision in *United Prescription Servs., Inc.,* 72 FR 50,397 (DEA 2007), which the Government withdrew as an exhibit, does not once mention the word ''Mississippi.''

[73] *See supra* note 21 (recounting the Government's withdrawal of its other witnesses).

[74] To summarize: the OSC alleges that Respondent violated Miss. Code Ann. § 73–25–34 (ALJ Ex. 1 at 2), but the Government offered no evidence to support this allegation other than the testimony of Respondent. *See supra* note 21.

[75] Added text is marked by *underlining* and deleted text is marked by [brackets].

[76] *See, e.g.,* Cal. Bus. & Prof. Code § 2242.1(a); Tenn. Comp. R. & Regs. § 0880–2.14(7) (2003) (''Prerequisites to Issuing Prescriptions''); Ohio Admin. Code § 4731–11–09(A) (2003); Oklahoma State Board of Medical Licensure and Supervision, Policy on Internet Prescribing (Ratified 01/25/01).

[77] Although Mr. Carr testified that he interpreted Respondent's Internet prescribing practices as operating in the state of Florida (Tr. 160–61), Respondent offered no such testimony.

92) is misguided. First, the DEA letter addressed the dispensing practices of a pharmacy, not the prescribing practices of a physician. (Tr. 97; *see* Resp't Ex. 4.) Second, the letter cautioned that DEA's general expression of approval of the pharmacy came with a number of caveats: ''Management personnel will verify several elements including * * * professional licensure[,] DEA registration[, l]egitimate patient/prescriber relationship[, p]rescriptions are issued in the usual course of professional practice, and [p]rescriptions are issued for a legitimate medical purpose.'' (Resp't Ex. 4 at 1.) Respondent therefore could not reasonably have relied on the DEA's letter as authorizing him to prescribe controlled substances to patients in states in which he lacked a medical license.

Nor did Respondent reasonably rely on statements by Mr. Carr, given Mr. Carr's obvious financial interest in persuading Respondent to issue prescriptions. (Tr. 151–52.) Indeed, if nothing else, Respondent should have realized from reading a letter signed by, and another letter addressed to, ''Robert Carr/President/United Prescription Services, Inc.'' (Resp't Exs. 3 & 4; Tr. 60, 89–92) that Mr. Carr could not be counted upon to act as a disinterested advisor to Respondent because as president he had a stake in the matter. To be certain, there is substantial evidence that Mr. Carr provided Respondent with incomplete information, and possibly inaccurate information, concerning the state of telemedicine law and the legality of Respondent's prescribing practices at UPR. Even so, ignorance of the law is no excuse, especially where the proscription of the unlicensed practice of medicine is hardly unique to California. *See generally Hageseth,* 59 Cal. Rptr. 3d at 403.

Turning to Alabama, the law of that state has provided since at least 1975 that ''[a]ny person who practices medicine or osteopathy or offers to do so in this state without a[n Alabama medical license] * * * shall be guilty of a Class C felony.'' [78] Ala. Code § 34–24–51. Here, although Respondent admitted to prescribing controlled substances to people located all across the United States (Tr. 27, 39), and volunteered that the list of states in which his customers resided was ''long'' (Tr. 39), there is no testimony or other evidence relating to Respondent's Alabama prescribing practices, if indeed he had any.[79] In fact, the word ''Alabama'' does not appear in the entire hearing transcript.[80] I therefore find that substantial evidence does not support a finding that Respondent violated Ala. Code § 34–24–51.

In its post-hearing brief, the Government identifies legal authority in Tennessee, Illinois and North Carolina that it alleges Respondent violated. (*See* Gov't Br. at 5.) Although Respondent did admit in response to questioning by counsel for the Government that he issued prescriptions for controlled substances to customers in these states while holding a medical license only in Florida (Tr. 38–39), I do not rely on these admissions as a potential basis for recommending imposition of a sanction because the issue of violations of the laws of Tennessee, Illinois and North Carolina was not noticed in the OSC,[81] the Government's prehearing statement [82] or the Government's supplemental prehearing statement. Respondent lacked adequate notice that violations of these states' laws would be at issue where the Government raised the factual basis of its theory for the first time at hearing, and raised the legal basis for the first time in its post-hearing brief. *See CBS Wholesale Distribs.,* 74 FR 36,746, 36,750 (DEA 2009) (finding that Respondent is entitled to a '' 'full and fair opportunity' to litigate both the factual *and legal* bases of the Government's theory'' (emphasis supplied)).

I also decline, for reasons more fully discussed above,[83] the Government's invitation to recommend imposition of a sanction on the basis of ''Respondent's violation of numerous state laws [as] explained in *United Prescription Services, Inc., Revocation of Registration,* 72 FR 50,397 (August 31, 2007).'' (Gov't Br. at 5–6.) The APA, the doctrine of *res judicata* and principles of fair play and substantial justice foreclose the reliance on conclusions as to the legality of Respondent's conduct reached in a prior hearing where Respondent, a non-party in that proceeding, lacked both the motive and the opportunity to fully develop the relevant issues on cross examination and in fact cooperated with the Government.[84] *See* 5 U.S.C. § 551(3) (defining ''party'') and 556(e) (administrative record); *see also Johnson* v. *United States,* 576 F.2d 606, 614 (5th Cir. 1978) (cautioning against the use of offensive collateral estoppel). *Cf., e.g.,* Fed. R. Evid. 804(b)(1) (former testimony hearsay exception).

To summarize, substantial evidence supports the conclusion that Respondent violated the laws of California by issuing prescriptions to customers across the country while licensed to practice medicine solely in the state of Florida, in violation of Cal. Bus. & Prof. Code § 2052(a) and 21 CFR 1306.03 (2010). This finding weighs in favor of a finding under Factors Two and Four of 21 U.S.C. 823(f) that Respondent's continued registration would be inconsistent with the public interest.

(d) Whether Respondent Issued Prescriptions for Controlled Substances Without a Legitimate Medical Purpose and Outside the Usual Course of Professional Practice

Another issue concerns whether Respondent conducted his prescribing practices pursuant to a legitimate medical purpose and within the usual

[78] A 2007 amendment made changes that are not pertinent to this Recommended Decision.

[79] In adversarial proceedings such as this one, ''it is not the ALJ's role but rather that of the parties to develop the record; the ALJ's role is to ensure that the parties do so in accordance with the Agency's rules of procedure. * * *'' *East Main Street Pharmacy,* 75 FR 66,149, 66,150 n.2 (DEA 2010).

[80] In addition, although the opinion in *United Prescription Servs., Inc.,* 72 FR 50,397 (DEA 2007) indicates that a Dr. Wayne Starks issued controlled substances prescriptions to a resident of Alabama in violation of 21 CFR 1306.04(a), *see* 72 FR at 50,408, that conclusion is not binding on Respondent in the above-captioned case, for the reasons discussed above; and in any event, there is no indication that Dr. Starks acted in conjunction with Respondent or at his direction.

[81] The OSC alleges: ''You violated state laws that prohibit the unauthorized practice of medicine, including unlicensed, out-of-state physicians issuing controlled substance prescriptions to state residents. See e.g. Miss. Code Ann. § 73–25–34; Cal. Bus. & Prof. Code § 2052; Ala. Code § 34–24–51.'' (ALJ Ex. 1.) This language is too vague to notice violations of the laws of Tennessee, Illinois and North Carolina because the allegation of violations of ''state laws'' did not reasonably apprise Respondent of *which* other states' laws, if any. To be certain, the three states cited as *exempli gratia* (Mississippi, California and Alabama) could reasonably have apprised Respondent that other states laws might be in contention, too; but nothing in the OSC or other prehearing filings reasonably apprised Respondent of which ones.

[82] While the Government's prehearing statement notices its intent to offer into evidence controlled substances prescriptions to individuals in Illinois and Tennessee (Gov't PHS at 3), the Government withdrew that exhibit (Tr. 6–7). More importantly, the prehearing statement did not allege violations of Illinois, Tennessee or North Carolina law.

[83] *See supra* Part II(A) (finding that the APA and negative implications stemming from the doctrine of offensive collateral estoppel preclude my reliance on conclusions of law regarding Respondent's conduct in a case in which he was not a named party).

[84] Tr. 78; *see* Resp't Br. at 17 (''Respondent's testimony [in the previous UPS proceeding] was beneficial to and supportive of the Government's position, and he also provided an affidavit of assistance to the Government.''); *see also United Prescription Servs., Inc.,* 72 FR 50,397, 50,400 (DEA 2007) (citing affidavit by Dr. Reppy submitted as Government exhibit in prior proceeding).

course of professional practice, consistent with 21 CFR 1306.04(a) and 21 U.S.C. 841(a)(1).[85] To be effective, and lawful, a prescription for a controlled substance ''must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice * * * An order purporting to be a prescription issued not in the usual course of professional treatment * * * is not a prescription * * * and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.'' [86] As the Supreme Court recently explained, ''the prescription requirement * * * ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006) (citing *United States* v. *Moore,* 423 U.S. 122, 135 (1975)).

As an initial matter, ''[a] physician who engages in the unauthorized practice of medicine is not a 'practitioner acting in the usual course of * * * professional practice'' as required by 21 CFR 1306.04(a) (describing requirements for lawful issuance of prescription). *See, e.g., United Prescription Servs., Inc.,* 72 FR 50,397–01, 50,407 (DEA 2007). As noted above, I find that Respondent engaged in the unauthorized practice of medicine by issuing prescriptions for controlled substances to people in California while he was licensed to practice medicine solely in Florida, in violation of Cal. Bus. & Prof. Code § 2052(a). I therefore conclude that Respondent acted outside the usual course of professional practice, in violation of 21 CFR 1306.04(a).

Federal law further provides that revocation of a registration under the public interest standard of 21 U.S.C. 823(f) is not limited to practitioners who intentionally violate the prescription requirement, but also includes a ''practitioner's failure to properly supervise her patients to prevent them from personally abusing controlled substances or selling them to others. * * *'' *Jeri Hassman, M.D.,* 75 FR 8194, 8227 (DEA 2010). A practitioner must also ''have established a bona fide doctor-patient relationship with the individual for whom the prescription is written.'' *Mohammed F. Abdel-Hameed, M.D.,* 66 FR 61,366, 61,369 (DEA 2009). At the time of the events at issue here, the CSA looked to state law to determine whether a physician has established a valid doctor-patient relationship.[87] *United Prescription Servs., Inc.,* 72 FR 50,397, 50,407 (DEA 2007).

Turning to Florida, a state in which Respondent conducted business and has been licensed for at least ten years (*see, e.g.,* Tr. 20–23, 51, 56, 68, 107), the law of that state provided for part of the relevant time period [88] that ''gross or repeated malpractice or the failure to practice osteopathic medicine with that level of care, skill and treatment which is recognized by a reasonable prudent similar osteopathic physician as being accepted under similar conditions and circumstances, constitutes grounds for discipline.'' Fla. Stat. Ann. § 459.015(1)(x) (2001).

In addition, from March 2000 through November 2006,[89] Florida required that ''complete medical history and physical examination must be conducted and documented in the medical record.'' Fla. Admin. Code Ann. r. 64B15–14.005(3)(a) (2000) (''Standards for the Use of Controlled Substances for Treatment of Pain''). Osteopathic physicians have been required continuously since 1997 to ''maintain written legible records on each patient. Such records shall contain * * * (a) Patient histories; (b) Examination results; (c) Test results; (d) Records of drugs prescribed, dispensed or administered; (e) Reports of consultations; and (f) Reports of hospitalizations.'' Fla. Admin. Code Ann. r. 64B15–15.004 (Dec. 22, 1997) (''Written Records; Minimum Content; Retention'').[90] Finally, Florida law has provided continuously since June 19, 2001,[91] that prescribing controlled substances ''inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the physician's professional practice, without regard to his intent.'' Fla. Stat. Ann. § 459.015(1)(t).[92]

The evidence at hearing regarding Respondent's prescribing practices included testimony from Respondent and Ms. Messick. As discussed above in the Evidence and Incorporated Findings of Fact section of this Recommended Decision, Respondent prescribed hydrocodone, a controlled substance, to thousands of patients over a four-year period from 2002 to 2006 (Tr. 21–23, 43, 51, 53) without examining as many as ninety percent of his patients (*see* Tr. 25–26). Despite his claim that his patients ''were not placing their whole care in my hands'' (Tr. 110), Respondent did not consult with the majority of his patients' primary care physicians. (*See, e.g.,* Tr. 34, 35 (one or two physician consultations out of 150 patients serviced in given week); *see also* Gov't Ex. 10 at 30, 37). In fact, Respondent testified that he treated patients who had been discharged by their providers, whether for lack of funding or another reason: ''I was continuing the treatment plan that was first set up by their doctor who might no longer have been willing to continue that plan. * * *'' (Tr. 113; *see also* Tr. 116.) While legitimate reasons might have justified continuing a course of treatment in some instances where the primary care physician refused to do so,[93] Respondent's

[85] The OSC explicitly alleges violations of 21 CFR 1306.04(a) and 21 U.S.C. 841(a)(1). (ALJ Ex. 1.)

[86] 21 CFR 1306.04(a) (2010).

[87] On October 15, 2008, the President signed into law the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Public Law 110–425, 122 Stat. 4820 (2008). Section 2 of the Act prohibits the dispensing of a prescription controlled substance ''by means of the Internet without a valid prescription,'' and defines, in relevant part, ''[t]he term 'valid prescription' [to] mean[ ] a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by * * * a practitioner who has conducted at least 1 in-person medical evaluation of the patient.'' 122 Stat. 4820. Section 2 further defines ''[t]he term 'in-person medical evaluation' [to] mean[ ] a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.'' *Id. See generally* 21 U.S.C. 829 (incorporating amendments). These provisions do not, however, apply to Respondent's conduct, which predated them.

[88] The quoted text that follows was the law in Florida from June 19, 2001, to June 20, 2005. *Compare* 2001 Fla. Sess. Law Serv. Ch. 2001–277 (C.S.S.B. 1558) (West) (2001 amendments enacting language cited), *with* 2005 Fla. Sess. Law Serv. Ch. 2005–266 (C.S.S.B. 940) (West) (substantially altering Fla. Stat. Ann. § 459.015(1)(x)).

[89] *See* Florida Department of State: State Library and Archives of Florida, Florida Administrative Weekly & Florida Administrative Code, *http://www.flrules.org/gateway/RuleNo.asp?title=PRACTICE.* REQUIREMENTs&ID=64B15-14.005.

[90] The foregoing provisions of Florida law are prominently identified in the Florida Administrative Complaint against Respondent (Gov't Ex. 14), which was provided to Respondent as part of the Government's document exchange.

[91] *See* 2001 Fla. Sess. Law Serv. Ch. 2001–277 (C.S.S.B. 1558) (West) (adopting quoted language).

[92] The OSC alleges violations of an identical provision of Florida law applicable to allopathic doctors, Fla. Stat. Ann. § 458.331(q). *See* ALJ. Ex. 1. For reasons discussed above, however, I find the provision applicable to osteopathic doctors was sufficiently noticed.

[93] For instance, read expansively, Respondent's testimony suggests a doctor might legitimately continue a medically sound treatment plan under which the previous provider ceased providing treatment due to a patient's inability to pay. (*See* Gov't Ex. 10 at 19 (testifying that certain pain management patients could not afford monthly office visits costing $150); *see also* Tr. 79.) Respondent, however, did not offer evidence that

Continued

conduct in many instances is inconsistent with a continuing course of treatment.

The evidence reflects Respondent did not consult with the majority of his patients' primary care physicians, and he had limited opportunity, if any, to independently confirm why those physicians stopped treating Respondent's patients. Florida law required Respondent to take and record a complete medical history and medical records, *see* Fla. Admin. Code Ann. r. 64B15–14.005(3)(a) (2000); Fla. Admin. Code Ann. r. 64B15–15.004. But the record is silent as to the steps Respondent took to independently verify most of his patients' histories. (*See* Tr. 32 (''not the common practice'' for Respondent to confer with primary care physicians).) Indeed, Respondent testified that he took no additional steps: ''If you have documentation in front of you that is signed by the primary care doctor * * * that is usually considered sufficient.'' (Tr. 32–33.) He added: ''the error rate in records is not particularly high.'' (Tr. 35.) As for those physicians he did consult, Respondent provided no details as to the contents of the conversations.

Respondent therefore had no way to verify, nor is his testimony consistent with his assertion, that his patients ''were not placing their whole care in [Respondent's] hands.'' (Tr. 110.) The record reflects that other doctors referred no more than approximately 300 patients to Respondent over the course of a four-year period (Tr. 35–36), and that Respondent prescribed hydrocodone to thousands of individuals without a face-to-face interaction or physical examination. (Tr. 43; *see* Tr. 53.) I therefore reject in substantial part Respondent's argument that he merely acted as a consultant to a primary care physician and merely extended prescriptions for drugs that had already been prescribed by another physician. (Tr. 17.) Contrary to Respondent's claim, Respondent had no affiliation with most of the physicians whose records he relied on (Tr. 36) and should have proceeded as if the care of the majority of his patients *was* solely in his own hands because, as Respondent's own testimony shows, in a meaningful number of cases it was. His failure to do so raises the specter of diversion and improper treatment. It also constitutes a ''failure to practice osteopathic medicine with [a reasonable] level of care, skill and treatment,'' which under Florida law from 2001 to 2005 constituted grounds for discipline.[94] *See* Fla. Stat. Ann. § 459.015(1)(x) (2001). His conduct was outside the usual course of professional practice. *See* 21 CFR 1306.04(a); 21 U.S.C. 841(a)(1).

In addition to testifying that he did not perform physical examinations on the majority of his patients (Tr. 25–26), Respondent also conceded that other physicians did not perform examinations of patients at Respondent's direction.[95] (Tr. 36.) And because Respondent acquired his patients' records directly from patients and not from medical professionals (*see* Tr. 34, 79–80), a practice that could lead to fraud (*see generally* Tr. 55–56), Respondent had no way to verify that *anyone* had ever actually conducted physical examinations on many of his patients, or that any such physical examinations were conducted recently enough to warrant a prescription for controlled substances. In light of Respondent's testimony that he had noticed fraudulent alterations in some of his patients' records (Tr. 56), there is insufficient evidence to substantiate Respondent's contention that ''[p]atients did not make [their medical records] up on their own.'' (Tr. 34.) Respondent's conduct does not comply with Florida standards, as follows.

Although there appears to be some ambiguity in Florida law regarding whether a physical examination must be conducted by the prescribing physician, as opposed to a referring physician, there are indications that the prescribing physician must conduct the physical examination himself. A 2002 decision by the State of Florida Division of Administrative Hearings interpreting the state telemedicine rule applicable to osteopathic doctors observed that ''assuming that the physician had complied with the [telemedicine rule, Fla. Admin. Code Ann. r. 64B15–14.008] by conducting a physical examination when the drug was prescribed, the requirement [of a documented patient evaluation, ''including history and physical examination, adequate to establish the diagnosis for which any drug is prescribed''] would already be satisfied.'' *Levy* v. *Dep't of Health,* No. 02–2308RX, at *45, 2002 Fla. Div. Adm. Hear. LEXIS 1443 (Dec. 3, 2002).

Other Florida decisions interpreting Florida's nearly identical telemedicine rule (Fla. Admin. Code Ann. r. 64B8–9.014)[96] applicable to allopathic doctors are consistent with this conclusion. *See, e.g., Dep't of Health* v. *Wise,* No. 06–2014PL, at *20, 26, 2006 Fla. Div. Adm. Hear. LEXIS 530 (Nov. 9, 2006) (''simply relying upon what a patient reports is their blood pressure does not constitute a physical examination'' and concluding ''failure to conduct a physical examination * * * constituted the failure to practice medicine with that level of care, skill, and treatment which is recognized by reasonably prudent physicians as being acceptable under similar condition and circumstances''). I therefore find that Respondent violated applicable Florida rules regarding physical examinations.

Respondent's conduct also does not comply with standards acknowledged by Respondent. Respondent testified that to have a valid doctor-patient relationship, a servicing medical professional must have conducted a physical examination of the patient. (Gov't Ex. 10 at 79–80 (''Someone must have done [a physical examination]).'') For follow-up consultations, Respondent would not require ''a new physical exam with every consult. When it became, in my opinion, too dated, then I would demand another physical exam.'' (Gov't Ex. 10 at 79.) Yet there is substantial evidence, summarized above, that on numerous occasions Respondent failed to ensure that these requirements were met. ''Respondent thus routinely prescribed without any independent assessment and verification of his patients' medical complaints.'' *Ladapo O. Shyngle, M.D.,* 74 FR 6056, 6057, 6058 (DEA 2009) (holding that Florida physician failed to establish bona fide doctor-patient relationship where he ''prescribed on the basis of a telephonic consultation and did not personally conduct a physical exam and take a medical history from the patients'').

Respondent's failure to supervise his PA, John Protheroe, also bears on the reliability of Respondent's medical records. Respondent repeatedly suggested that Respondent was part of a process at UPR over which he lacked control. For instance, Respondent testified that he could not differentiate between prescriptions issued by Mr. Protheroe in Respondent's name and prescriptions that Respondent issued himself.[97] (*E.g.,* Tr. 41–43.) Asked

most or even many of his patients were in this situation.

[94] *See supra* note 88.

[95] As Respondent explained in his testimony in a prior proceeding, ''the physical examination has to be done by someone else in the case of telemedicine. [Patients] have to have seen a local doctor that actually saw them and performed the physical examination, and gotten those notes to me, so that I know what was seen and have the information available.'' (Gov't Ex. 10 at 25–26.)

[96] *See supra* text at notes 99 to 101.

[97] Respondent testified that he did not know the identity of ''[J.N.],'' a patient identified in the Florida Administrative Complaint. (Tr. 42.)

whether Respondent completed the conduct charged in Florida's Administrative Complaint against him, Respondent stated:

> I actually don't know if I did or not, because as I said, this PA John Protheroe wrote so many prescriptions without my authorization using a stamp of my signature that it may well have been done under—under that process.

(Tr. 41.) Yet, in prescribing to his own repeat patients, Respondent's testimony shows he relied on medical records containing previous prescriptions bearing his signature without knowing whether he or Mr. Protheroe issued those prescriptions. Respondent's testimony that he couldn't distinguish whether he or his PA had treated a patient, combined with his willingness to nevertheless issue follow-up prescriptions, is further evidence of Respondent's failure in many instances to establish and maintain a valid doctor-patient relationship.

In addition to the problems noted above, Respondent's verification of patient identity was patently inadequate. Respondent had no face-to-face interactions with as many as ninety percent of his patients. (Tr. 26, 55.) When ascertaining a patient's identity before issuing a controlled substance prescription, therefore, Respondent relied almost exclusively on documents submitted by the patient with no concurrent verification of identity such as comparing a photo identification with the person presenting it.

As for how he verified the identity of patients with whom he never physically interacted, Respondent testified that ''I used the same method of checking their identity as I would if they were present in front of me.'' (Tr. 54.) Yet Respondent conceded that he never saw most of the people to whom he issued prescriptions (Tr. 55), undermining the basis for his claim.

Respondent explained that ''I was rather good at detecting fraud'' by comparing font and language in different parts of patient medical records. (Tr. 56.) Respondent added: ''If the state did not adequately check their identity before issuing them a driver's license * * * I had no way of determining that.'' (Tr. 54.) Respondent's explanation entirely misses the point. The question Respondent should have cared about, but apparently did not, was whether the person receiving treatment was actually the person described in the medical records. A patient referral provides at least some degree of identity verification. But given the low rate at which doctors referred patients to Respondent (Tr. 35–36 (approximately 300 patients over four years)) compared with the total number of Respondent's patients (Tr. 52–53 (150 patients per week, constituting at least 5000 controlled substances prescriptions per year)), verifying that the patient fit the records should have been a great concern for Respondent.

Respondent testified that some people misuse and abuse the kinds of controlled substances that Respondent prescribed at UPR, particularly hydrocodone, alprazolam, oxycodone and methadone. (Tr. 65.) From time to time Respondent encountered patients who abused controlled substances and immediately dismissed them. (Tr. 65.) ''I ferreted it out where I could.'' (Tr. 65.) Respondent, however, could not state how many of his patients were addicted to narcotics while he was prescribing to them. (Tr. 118.)

Without the face-to-face meetings that Respondent conducted in no more than approximately ten percent of consultations (*e.g.,* Tr. 26, 55)), Respondent could not objectively assess whether a person's appearance as recited in photo identification and medical records (to include height, weight, sex, hair color and the like) matched the person presenting as a patient over the telephone. Because patients submitted their own medical records to Respondent's clinic (Tr. 34; 79–80), and thus had both the opportunity and the inclination to fraudulently modify them (*see generally* Tr. 56), Respondent's nearly exclusive reliance on his own ability to detect fraudulent modifications (*see* Tr. 56), even if Respondent was quite skilled in this regard, was unreasonable under the circumstances. Indeed, Respondent conceded that it was possible that a person posing as a patient could take the medical records and identification of a deceased person, and Respondent would have no way of knowing whether the person on the phone was actually the person whose medical records and identification Respondent was reviewing. (Tr. 55–56.) Respondent's testimony suggesting that an unspecified percentage of his patients could not afford traveling to visit Respondent in person (*e.g.,* Tr. 79, 116) does not substantially mitigate the potential for diversion inherent to Respondent's Internet prescribing practices.[98] I find it more likely than not that Respondent failed ''to properly supervise [his] patients to prevent them from personally abusing controlled substances or selling them to others. * * *'' *Jeri Hassman, M.D.,* 75 FR 8194, 8227 (DEA 2010).

In sum, Respondent did not verify that the majority of the individuals to whom he prescribed controlled substances were actually the patients listed in the medical records associated with their files, constituting a departure from the usual course of professional practice. Any quantity of controlled substances Respondent prescribed to these patients was therefore ''inappropriate.'' *See* Fla. Stat. Ann. § 459.015(1)(t). In addition to falling below Florida standards of professional practice, Respondent's identity verification practices also raise the specter of the diversion of controlled substances, given that most or many of the individuals who contacted Respondent at UPR sought and ultimately received controlled substances. (Tr. 28, 36.)

There are further examples in the record indicating significant deviations in Respondent's prescribing practices from the usual course of professional practice, but further elaboration is unnecessary. Respondent ''voluntarily and openly admit[s] that he had issued prescriptions to individuals via the Internet whom he had not examined and who were residents of states other than a state in which Respondent was licensed. * * *'' (Resp't Br. at 23.) Respondent concedes, and I so find by a preponderance of the evidence, that ''the Government has established the fact that the majority of the prescriptions by the Respondent during his work at [UPR] were not valid.'' (Resp't Br. at 23.)

In partial mitigation, Respondent recognizes both that his reliance on Mr. Carr's advice was misplaced and also that Mr. Carr's 2002 correspondence with the DEA does not excuse his prescribing of controlled substances to patients residing in states where he was not licensed. (*Id.*) But even if Respondent's reliance on Mr. Carr's advice were deemed to be reasonable, and I do not so find, such reliance would not outweigh the significant weight properly given to his issuance of thousands of controlled substances prescriptions to patients across the country while he was licensed to practice medicine solely in Florida; his

Respondent does not know whether he issued any of the prescriptions alleged in the Complaint, a situation he attributes to the sheer number of prescriptions his PA wrote without authorization. (Tr. 41–42.)

[98] Moreover, the weight given to Respondent's testimony in this regard is diminished by Respondent's admission that he does not know how much UPR charged. (Tr. 119.)

routine failure to either conduct physical examinations or consult with a patient's primary care physician to ensure that a physical examination was conducted recently enough to sustain a diagnosis justifying controlled substances; his misplaced confidence in his own ability to detect fraud in medical records, which he obtained directly from patients, when he could have required the records be sent directly from other practitioners; and his related failure to acknowledge his failures to sufficiently verify the identity of most patients.

For the foregoing reasons, I find by substantial evidence that Respondent issued a substantial number of prescriptions for other than a legitimate medical purpose or outside the usual course of professional practice and without establishing a bona fide doctor-patient relationship, in violation of Florida law, *see* Fla. Stat. Ann. § 459.015(1)(x) (2001); Fla. Stat. Ann. § 459.015(1)(t) (2001); Fla. Admin. Code Ann. rr. 64B15–14.005(3)(a) and 64B15–15.004, and federal law, *see* 21 CFR 1306.04(a); 21 U.S.C. 841(a)(1); *Mohammed F. Abdel-Hameed, M.D.,* 66 FR 61366, 61369 (DEA 2009) and *Ladapo O. Shyngle, M.D.,* 74 FR 6056, 6057, 6058 (DEA 2009). This finding weighs heavily in favor of a finding under Factors Two and Four of 21 U.S.C. 823(f) that Respondent's continued registration would be inconsistent with the public interest.

(e) Adequacy of Notice of Florida Telemedicine Issue

Next at issue is whether the Government adequately noticed its contention that Respondent violated Florida standards for telemedicine prescribing practice.[99]

Regarding the factual basis of the Government's theory, the Government's prehearing statement calls into issue ''the process by which [Respondent] authorized Internet requests for drugs'' including the information he collected, the basis of his diagnosis, his communication with patients and full disclosure, among other things. (*See* Gov't PHS, Jun. 18, 2010, at 2–3.) Moreover, the Government's prehearing statement also notices its intent to introduce as documentary evidence a copy of Florida Administrative Code Rule 64B8–9.014 (''Standards for Telemedicine Prescribing Practice''), consistent with the OSC. (*Id.* at 3; ALJ Ex. 1.) I therefore find that the factual issue of Respondent's compliance with applicable Florida telemedicine practices was adequately noticed.

More complicated is whether the Government adequately noticed its intent to rely on provisions of Florida law relevant to standards for telemedicine in seeking the revocation of Respondent's COR. As noted above, the Government's prehearing statement noticed the issue of Respondent's compliance with Florida Administrative Code Rule 64B8–9.014. That provision, which falls under the subtitle of regulations applicable to allopathic physicians, sets forth standards for telemedicine prescribing practice in Florida. Fla. Admin. Code Ann. r. 64B8–9.014. But because subtitle 64B8 of the Florida Administrative Code governs matters pertinent to the Board of [allopathic] Medicine, and Respondent is a doctor of osteopathy, the relevant Florida administrative provisions governing Respondent's conduct are located under subtitle 64B15 (''Board of Osteopathic Medicine''). Rule 64B15–14.008 in that subtitle contains a telemedicine provision that mirrors the telemedicine provision applicable to allopathic doctors that was actually noticed by the Government. A word-by-word comparison of Rule 64B8–9.014 (telemedicine standards for allopathic doctors) and Rule 64B15–14.008 (telemedicine standards for osteopathic doctors), as codified during the relevant time period of 2004 through 2006 [100] (*see* ALJ Ex. 1) reveals that the two provisions are substantially identical.[101] Because Respondent thus had actual notice of the legal standards that the Government alleges that Respondent violated, I find that the notice provided in this instance was sufficient to apprise Respondent ''that this allegation would be litigated.'' *See CBS,* 74 FR at 36749.

(f) Respondent's Compliance with Florida Telemedicine Standards

On October 16, 2001, Florida enacted a rule applicable to osteopathic doctors entitled ''Standards for Telemedicine Practice.'' [102] Fla. Admin. Code Ann. r. 64B15–14.008. The spirit of the rule is to prevent physicians from prescribing medications with only minimal diagnosis and documentation. In addition to constituting grounds for disciplinary action under Fla. Stat. Ann. § 459.015(1)(x) and (t),

> [p]rescribing medications based solely on an electronic medical questionnaire constitutes the failure to practice osteopathic medicine with that level of care, skill and treatment which is recognized by reasonably prudent osteopathic physicians as being acceptable. * * *

Fla. Admin. Code Ann. r. 64B15–14.008. Before an osteopathic physician may ''provide treatment recommendations, including issuing a prescription, via electronic or other means,'' the rule requires:

> (1) A documented patient evaluation, including history and physical examination, adequate to establish the diagnosis for which any drug is prescribed.
>
> (2) Sufficient dialogue between the osteopathic physician and the patient regarding treatment options and the risks and benefits of treatment.
>
> (3) Maintenance of contemporaneous medical records meeting the requirements of Rule 64B15–15.004, F.A.C.

*Id.* In addition to an emergency services provision not applicable here, the rule finally states that it ''shall not be construed to prohibit patient care in consultation with another physician who has an ongoing relationship with the patient, and who has agreed to supervise the patient's treatment, including the use of any prescribed medications. * * *'' *Id.*

As discussed supra, Respondent on numerous occasions (Tr. 53 (5000 controlled substances prescriptions per year)) ''provide[d] treatment recommendations, including issuing a prescription, via electronic or other means'' without conducting patient evaluations to include physical examinations or ensuring that such examinations were reliably conducted by other qualified medical professionals (*see, e.g., supra* text at note 95) and without maintaining medical records meeting the requirements of Rule 64B15–15.004 (*see supra* text at notes 93 to 94). Nor did Respondent in more than approximately 300 cases (*see* Tr. 35–36) out of thousands (Tr. 53) ever act in a

[99] The Government's prehearing statement alleges violations of Florida telemedicine standards, as discussed below. Before the Agency may properly impose a sanction on the basis of a given allegation, Agency precedent requires that a registrant be provided a '' 'full and fair opportunity' to litigate both the factual and legal bases of the Government's theory.'' *CBS Wholesale Distribs.,* 74 FR 36746, 36750 (DEA 2009).

[100] *See* Gov't Ex. 4 (collecting versions of Fla. Admin. Code Ann. r. 64B15.4008 from 2004–2006); *see also supra* note 60.

[101] The only notable differences are as follows. First, r. 64B15–14.008 inserts the word ''osteopathic'' at various points to reflect that the actor contemplated is an osteopathic physician and not an allopathic physician. Second, r. 64B8–9.014 explicitly contemplates that PAs may participate in telemedicine practices, whereas r. 64B15–14.008 does not. Finally, r. 64B8–9.014, but not r. 64B15–14.008, explicitly defines ''telemedicine'' as including prescribing via the Internet, telephone or facsimile. *Compare* Fla. Admin. Code Ann. r. 64B8–9.014, *with id.* r. 64B15–14.008.

[102] *See* Florida Department of State: State Library and Archives of Florida, Florida Administrative Weekly & Florida Administrative Code, *https://www.flrules.org/gateway/ruleNo.asp?id=64B15-14.008* (listing enactment date as October 16, 2001, and identifying sole alteration or variance since that time as a variance granted to a Virtual Medical Group, Inc. on May 26, 2006).

consultative capacity ''with another physician who ha[d] an ongoing relationship with the patient, and who ha[d] agreed to supervise the patient's treatment, including the use of any prescribed medications,'' Fla. Admin. Code Ann. r. 64B15–14.008. I therefore find that Respondent failed to comply with Fla. Admin. Code Ann. r. 64B15–14.008 (''Standards for Telemedicine Practice''). This finding weighs in favor of a finding under Factors Two and Four of 21 U.S.C. § 823(f) that Respondent's continued registration would be contrary to the public interest.

Factor 5: Such Other Conduct Which May Threaten the Public Health and Safety

Under Factor Five, the Deputy Administrator is authorized to consider ''other conduct which may threaten the public health and safety.'' 5 U.S.C. 823(f)(5). The Agency has accordingly held that ''where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for his or her actions and demonstrate that he or she will not engage in future misconduct. *Patrick W. Stodola,* 74 FR 20,727, 20,734 (DEA 2009).[103] A ''[r]espondent's lack of candor and inconsistent explanations'' may serve as a basis for denial of a registration. *John Stanford Noell, M.D.,* 59 FR 47,359, 47,361 (DEA 1994). Additionally, ''[c]onsideration of the deterrent effect of a potential sanction is supported by the CSA's purpose of protecting the public interest.'' *Joseph Gaudio, M.D.,* 74 FR 10,083, 10,094 (DEA 2009).

As discussed above, the substance of Respondent's conduct between 2004 and 2006 is relatively uncontroverted. Respondent issued, permitted his PA to issue or failed to prevent his PA from issuing in Respondent's name thousands of controlled substances prescriptions to patients around the country while Respondent was licensed to practice medicine only in Florida. Many of these prescriptions issued without Respondent or a physician acting at Respondent's direction ever conducting a physical examination, let alone seeing the patient. Respondent infrequently consulted with his patients' previous doctors, and routinely accepted medical records sent in by patients, without requiring that records be sent by medical professionals. Moreover, Respondent was aware that some of his patients, or people posing as his patients, fraudulently altered medical files in order to obtain controlled substances. Respondent's actions constituted clear violations of state and federal law.

In light of these essentially uncontroverted facts, a remaining issue in this case is whether Respondent has adequately accepted responsibility for his past misconduct such that his continued registration might nevertheless be consistent with the public interest. *See Patrick W. Stodola,* 74 FR 20,727, 20,734 (DEA 2009). Respondent argues that he has ''expressed considerable regret and remorse for his Internet prescribing and acknowledged its impropriety. * * *'' (Resp't Br. 22.) But across various dimensions, the record reveals that Respondent has not sustained his burden in this regard.

As an initial matter, I reject Respondent's contention that ''no conduct which might threaten the public health and safety has been charged and proved.'' (Resp't Br. at 22.) Indeed, Respondent's failure to verify the identity of the majority of his patients (*see* Tr. 26, 54–56), as detailed above, raises dual specters of diversion and polypharmacy, both of which threaten the public interest. Respondent testified that ''I used the same method of checking [new patients'] identity as I would if they were present in front of me.'' (Tr. 54.) To the contrary, Respondent never saw most of the people to whom he issued approximately 5000 prescriptions for controlled substances per year. (Tr. 52–53, 55.) Moreover, patients submitted their own medical records to Respondent's clinic (Tr. 34; 79–80), and they thus had both the opportunity and the inclination to fraudulently modify them (*see generally* Tr. 56). I find that Respondent's failure to consistently verify patient identities and secure the integrity of patient records weighs in favor of a finding that Respondent's continued registration would be contrary to the public interest.

Respondent has not demonstrated a credible acknowledgment of his inadequate patient identity verification practices, nor has he demonstrated that he will not engage in similar future misconduct. For example, Respondent's sole comment in this regard at hearing offers valuable insight into his outlook: ''If the state did not adequately check [his patients'] identity before issuing them a driver's license * * * I had no way of determining that.'' (Tr. 54.) Respondent's testimony misses the point and offers no support for a finding that he has accepted responsibility for his prior misconduct. To the contrary, Respondent's testimony supports an inference that he would continue the same unreliable and dangerous identity verification practices if permitted to maintain his registration in the future. *See Alra Laboratories, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995) (an ''agency rationally may conclude that past performance is the best predictor of future performance'').

Respondent's flagrant failures to supervise his PA also bear upon a Factor Five analysis. Respondent, who was Medical Director of UPR in 2004 (Resp't Ex. 12 at 2), possessed both actual authority and the legal duty to exercise ''responsible supervision and control'' over Mr. Protheroe. *See, e.g.,* Fla. Stat. Ann. § 459.022(2)(e); *see also, e.g., Dan E. Hale, D.O.,* 69 FR 69,402, 69,406 (DEA 2004); *Robert G. Hallermeier, M.D.,* 62 FR 26,818, 26,820 (DEA 1997); *Jay Wheeler Cranston, M.D.,* 59 FR 36,786, 36,789 (DEA 1994). As chronicled earlier in this Recommended Decision, Respondent failed to exercise this supervisory authority, and at times failed to acknowledge that he had it. He permitted Mr. Protheroe to work under Respondent's license but did not control Mr. Protheroe's hours; he did not control Mr. Protheroe's work product; he did not hire him and did not believe he could fire him. (Tr. 37.) Mr. Protheroe wrote at least 14,000 unauthorized prescriptions in Respondent's name (Tr. 80; *see generally* Tr. 132; Gov't Ex. 10 at 84–85), many of which for controlled substances (*e.g.,* Resp't Ex. 12 at 2), while Respondent was away from the office for an extended period of time (Tr. 121–22, 132; Gov't Ex. 10 at 85, 96, 101), in violation of Fla. Stat. Ann. § 459.022(4)(e) (prohibiting PAs from prescribing controlled substances), as well as other provisions of law.

Respondent fundamentally failed to take responsibility for his failure to supervise Mr. Protheroe. Respondent conceded at hearing that he had an obligation to properly supervise Mr. Protheroe (Tr. 101; *see* Resp't Ex. 9 at 5 (''physicians should * * * [p]roperly supervise physician extenders'')), and stated that he supervised Mr. Protheroe during the limited times ''when he was in the office. * * * '' (Gov't Ex. 10 at 105) and not working from home. Although these statements show that Respondent was aware of his unfulfilled supervision obligation, they reveal no acceptance of responsibility for Respondent's failure to discharge it. To the contrary, Respondent's testimony is consistent with blame-shifting:

Q: And so you had an obligation to properly supervis[e] Mr. Protheroe?

[103] *See also Hoxie* v. *DEA,* 419 F.3d 477, 484 (6th Cir. 2005) (decision to revoke registration ''consistent with the DEA's view of the importance of physician candor and cooperation.'')

A: Yes, sir. I freely admit that he was not adequately supervised. But he was kept away from me and I did not hire or fire him. I supervised him as much as I could to my ability. But, yes, I agree that it wasn't enough. (Tr. 101.)

Respondent testified that he regrets his relationship with Mr. Protheroe. ''[I]t's so soured me on the experience that I've never hired any physician's assistants since and I don't think I ever will.'' (Tr. 108–09.) But even viewed in a light most favorable to Respondent, this statement offers no credible basis to conclude that Respondent acknowledges and accepts responsibility for his failure to supervise, nor is there any basis to conclude that if again confronted with the challenges of supervising a contumacious PA, Respondent would adequately discharge his supervisory obligations.

Respondent's testimony also consistently downplayed any personal role that Respondent played in failing to comply, or that he should have played in complying, with state and federal PA supervision requirements. Even if Respondent felt he couldn't supervise Mr. Protheroe, as a last resort Respondent could have withdrawn from his employment if Mr. Protheroe failed to comply with Respondent's instructions. Respondent's failure to do so indicates Respondent is willing to permit the misuse of his DEA registration in order to maintain his employment, rendering Respondent's registration contrary to the public interest. *See Alra Laboratories,* 54 F.3d at 452.

There are additional areas in which Respondent could have accepted responsibility for his misconduct, but didn't. For instance, rather than admit that, as concluded above, his telemedicine practices were in clear violation of contemporaneous standards (*see, e.g., supra* text at notes 75–76), Respondent at hearing attempted to cast doubt on the clarity of the rules. Commenting on his understanding of the patient evaluation standard of care for Internet prescribing practices in 2002 and 2003, for instance, Respondent opined that today's standard is different, but that previously ''the legal community was struggling in a gray area to determine what those [standards] would be and now they have decided.'' (Tr. 64.) Somewhat contradicting himself, Respondent also testified that he presently understands that he has an obligation to prescribe or dispense controlled substances in accordance with all applicable state laws, and that prescribing across state lines sometimes includes the application of laws other than the laws in the State of Florida. (Tr. 63.) That Respondent eventually chose to discontinue his illegal Internet prescribing practices (Tr. 91; *see also* Resp't Br. at 24) does not, without more, show that Respondent's continued registration would be consistent with the public interest.

Respondent also attempted to shift responsibility for his own professional misconduct to Mr. Carr. As an initial matter, Respondent's claim that he reasonably relied on ''a letter shown me from the DEA giving permission to'' engage in the controversial telemedicine practices here at issue (Tr. 59–60, 110; *see also* Tr. 89–92) is not credible. The reasonableness of Respondent's reliance on the DEA letter is undermined by the fact that the letter concerned the dispensing practices of a pharmacy, not the prescribing practices of a physician. The letter moreover contained caveats that ''[m]anagement personnel will verify several elements including * * * professional licensure[,] DEA registration[, l]egitimate patient/prescriber relationship[, p]rescriptions are issued in the usual course of professional practice, and [p]rescriptions are issued for a legitimate medical purpose.'' (Tr. 97; Resp't Ex. 4 at 1.) Additionally, Respondent's unquestioned reliance on legal advice from Mr. Carr, who Respondent also knew to be president of UPS, undermines the credibility of Respondent's testimony on this issue.

Further defending his reliance on Mr. Carr's advice, Respondent pointed to the Model Guidelines, published by the Federation of State Medical Boards in 2002. (*See* Resp't Ex. 9 at 3, 7.) Paraphrasing a sentence from that document, Respondent stated that ''the physician/patient relationship exists whether or not there has been a personal encounter between the physician and the patient.'' (Tr. 76; *see* Resp't Ex. 9 at 7.) But the Model Guidelines go on to state that ''[p]hysicians who treat or prescribe through Internet Web sites are practicing medicine and must possess appropriate licensure in all jurisdictions where patients reside.'' (Resp't Ex. 9 at 12.) At hearing, Respondent conceded that ''given hindsight * * * I don't think I did fully understand'' the Model Guidelines when he read them. (Tr. 98.) Respondent, however, contradicted his former testimony and stated that he could not confirm that he actually reviewed the Model Guidelines before accepting his position with UPR. (Tr. 100–01.) In any event, Respondent ultimately conceded that he was mistaken, and that statements by the Federation of State Medical Boards do not carry legal weight. (Tr. 45; *see also* Tr. 164.) Respondent ultimately conceded in his testimony that Mr. Carr's assurances were inaccurate. (Tr. 110–11; *see* Resp't Br. at 25.)

But Respondent's acknowledgements are too little; and because many of them precede or follow Respondent's own contradictory testimony, they arrive too late. On the topic of telemedicine standards, for example, even if Respondent's equivocal statements are read to acknowledge that Florida had enacted a telemedicine regulation as early as 2004, Respondent still has not demonstrated that he accepts responsibility for his failures to comport with those standards. For instance, Respondent conceded that in hindsight, the prescriptions he issued at UPR to Internet customers ''did not meet the highest standard * * * and I'm sorry.'' (Tr. 63–64.) Similarly, when his attorney asked him whether he now knows that his Internet prescribing at UPR was not consistent with the law as it was at that time, Respondent answered ''Absolutely.'' (Tr. 91–92.) But Respondent undercut his own display of contrition, elaborating that when he engaged in the prescribing practices that are the subject of the OSC, he wasn't doing anything wrong. (Tr. 64–65.) ''[I]f I thought I was doing anything wrong, I wouldn't have done it.'' (Tr. 65.) Based on Respondent's demeanor while testifying, I find that this statement, along with other similar statements, undermines the sincerity of Respondent's contrition.

Indeed, Respondent's feelings of regret are best characterized not as regret that he acted contrary to the public interest, but regret that his poor choices led to undesirable personal ramifications. Asked if he was regretful and remorseful for the role he played at UPR in prescribing controlled substances, Respondent stated: ''Yes, very much. I sincerely wish I had never been duped into being any part of their operation at all.'' (Tr. 92.) Moving forward, Respondent promised not to prescribe for patients in jurisdictions in which he lacks a medical license. (Tr. 111.) Asked by counsel whether he felt remorse for having done so, he said ''Yes. Not only am I remorseful about it, but I feel rather foolish and stupid for doing so in retrospect.'' (Tr. 111.) This last statement, self-serving though it is, arguably cuts in Respondent's favor. But it is outweighed by Respondent's subsequent de-emphasis of his own responsibility. I give significant weight to Respondent's candid statement that ''I was just an hourly employee. I was just a pawn in the machine.'' (Tr. 119.) This admission belies Respondent's belief that actors other than Respondent

are responsible for Respondent's misconduct. Such a belief is inconsistent with Agency precedent requiring a registrant to accept responsibility for his actions and demonstrate that he will not engage in future misconduct. *See Patrick W. Stodola,* 74 FR 20,727, 20,734 (DEA 2009).

Respondent contends in mitigation that ''no patient for whom Dr. Reppy prescribed over the Internet suffered any damage or harm and there were no mortalities or morbidities, and none of them suffered overdose deaths while he was treating them.'' (Resp't Br. 6 (citing Tr. 117, 118).) Although Respondent has not stayed in touch with all of his patients since he left UPR (Tr. 117), no record evidence contradicts this assertion. Asked whether any patient suffered an overdose death, Respondent answered that ''none of them did while I was prescribing. If it happened since that time, then it happened because someone else was prescribing it. I can't be responsible for what some other doctor did.'' (Tr. 117.) ''I'm sure there would have been a lawsuit if there was one and I never received any.'' (Tr. 123.) Respondent ignores the possibility that his provision of controlled substances to his former Internet patients could lead to adverse health consequences, for which Respondent might ultimately share responsibility.

Respondent also downplays the extent to which he could have known of patient addictions, arguing that ''[t]here is no way to know whether or not patients became addicted'' to controlled substances, suggesting he had only a passive role in the process. (Resp't Br. 6.) Respondent's testimony reflects a misunderstanding of his affirmative responsibility as a prescribing practitioner ''for the proper prescribing and dispensing of controlled substances.'' [104]

In mitigation, more recent conduct does weigh in Respondent's favor. First, substantial evidence supports a finding that a significant period of time has elapsed without incident since the period of time embracing the unlawful conduct at issue here. Two of Respondent's employees and two of his patients affirmed that Respondent: personally sees patients and reviews patient records (Resp't Ex. 19. at 2 ¶¶ 5–7); requires that new patients produce recent prior medical records (Resp't Ex. 19. at 3 ¶ 11); performs physical examinations (*E.g.,* Resp't Ex. 19. at 2 ¶ 8; *id.* at 6 ¶ 3, 5; *id.* at 19 ¶ 7); discusses treatment plans and spends between fifteen and thirty minutes with patients (Resp't Ex. 19. at 2 ¶ 10; *id.* at 6 ¶ 4, 7; *id.* at 9 ¶ 9, 10); reduces patient pain medication levels and suggests alternate treatment methods (Resp't Ex. 19 at 3 ¶ 12; *id.* at 9 ¶¶ 3–4; *see also* Tr. 66, 79–80); and dismisses patients who fail to pass drug screens (Resp't Ex. 19 at 7 ¶ 9.) Insomuch, therefore, as Respondent's current practice is relevant, Respondent has painted a generally positive picture. *See Paul J. Caragine, Jr.,* 63 FR 51,592, 51,601 (DEA 1998) (citing *Norman Alpert, M.D.,* 58 FR 67,420 (DEA 1993)) (''[W]hile passage of time alone is not dispositive it is a consideration in assessing whether Respondent's registration would be inconsistent with the public interest.''). Viewed in isolation, Respondent's medical practice from approximately 2006 to the present weighs somewhat in favor of a finding that Respondent's continued registration would be consistent with the public interest. That said, absent acceptance of responsibility for the misconduct, the passage of time alone precludes the issuance of even a restricted registration. ''DEA has long held that '[t]he paramount issue is not how much time has elapsed since [his] unlawful conduct, but rather, whether during that time * * * Respondent has learned from past mistakes and has demonstrated that he would handle controlled substances properly if entrusted with a' new registration.'' *Robert L. Dougherty, M.D.,* 76 FR 16,823, 16,835 (DEA 2011) (citing *Leonardo* v. *Lopez, M.D.,* 54 FR 36,915, 36,915 (DEA 1989) and *Robert A. Leslie, M.D.,* 68 FR 15,227, 15,227 (DEA 2003)).

To be certain, Respondent's voluntary retreat from a telemedicine pain practice in favor of his current practice provides at least some indication that Respondent will avoid, or limit, the circumstances underlying the misconduct alleged in the instant case. But beyond stating that the prescriptions he issued at UPR to Internet customers ''did not meet the highest standard * * * and I'm sorry'' (Tr. 63–64), Respondent provides limited credible assurance that if given the opportunity he would not simply repeat the same mistakes he made in the past.

In light of the foregoing, Respondent's evidence as a whole fails to sustain his burden to credibly accept responsibility for his misconduct and demonstrate that he will not engage in future misconduct. I find that Factor Five weighs in favor of a finding that Respondent's continued registration would be inconsistent with the public interest.

## VII. Conclusion and Recommendation

After balancing the foregoing public interest factors, I find that the Government has established by substantial evidence a prima facie case in support of revoking Respondent's COR, based on Factors Two, Four and Five of 21 U.S.C. 823(f).

Once DEA has made its prima facie case for revocation or denial, the burden shifts to the respondent to show that, given the totality of the facts and circumstances in the record, revoking or denying the registration would not be appropriate. *See Morall* v. *DEA,* 412 F.3d 165, 174 (D.C. Cir. 2005); *Humphreys* v. *DEA,* 96 F.3d 658, 661 (3d Cir. 1996); *Shatz* v. *United States Dep't of Justice,* 873 F.2d 1089, 1091 (8th Cir. 1989); *Thomas E. Johnston,* 45 FR 72, 311 (DEA 1980).

Additionally, where a registrant has committed acts inconsistent with the public interest, he must accept responsibility for his actions and demonstrate that he will not engage in future misconduct. *See Patrick W. Stodola,* 74 FR 20,727, 20,735 (DEA 2009). Also, ''[c]onsideration of the deterrent effect of a potential sanction is supported by the CSA's purpose of protecting the public interest.'' *Joseph Gaudio, M.D.,* 74 FR 10,083, 10,094 (DEA 2009). An agency's choice of sanction will be upheld unless unwarranted in law or without justification in fact. A sanction must be rationally related to the evidence of record and proportionate to the error committed. *See Morall* v. *DEA,* 412 F.3d 165, 181 (D.C. Cir. 2005). Finally, an ''agency rationally may conclude that past performance is the best predictor of future performance.'' *Alra Laboratories, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995).

I recommend revocation of Respondent's COR BR5287342 and denial of any pending applications for renewal or modification, and any applications for a new COR. I find the evidence as a whole demonstrates that Respondent has not accepted responsibility, and Respondent's continued registration would be inconsistent with the public interest.

Dated: March 31, 2011

**Timothy D. Wing,**

*Administrative Law Judge.*

[FR Doc. 2011–25229 Filed 9–30–11; 8:45 am]

**BILLING CODE 4410–09–P**

[104] 21 CFR 1306.04(a) (2010); *see also* Fla. Admin. Code Ann. r. 64B15–14.005(3)(a) (2000) (''complete medical history and physical examination must be conducted and documented in the medical record.''). *See generally* Fla. Admin. Code Ann. r. 64B15–15.004 (Dec. 22, 1997) (''Written Records; Minimum Content; Retention'').

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Part III

## Department of Energy

Western Area Power Administration

Loveland Area Projects—Western Area Colorado Missouri Balancing Authority—Rate Order No. WAPA–155; Notice; Republication

## DEPARTMENT OF ENERGY

### Western Area Power Administration

### Loveland Area Projects—Western Area Colorado Missouri Balancing Authority—Rate Order No. WAPA–155

*Republication*

**Editorial Note:** FR Doc. 2011–23391 was originally published on pages 56433–56452 in the issue of Tuesday, September 13, 2011. In that publication an incorrect version of this document was published. The corrected document is republished below in its entirety.

**AGENCY:** Western Area Power Administration, DOE.

**ACTION:** Notice of order concerning transmission and ancillary services formula rates.

**SUMMARY:** The Deputy Secretary of Energy has confirmed and approved Rate Order No. WAPA–155 and Rate Schedules L–NT1, L–FPT1, L–NFPT1, L–AS1, L–AS2, L–AS3, L–AS4, L–AS5, L–AS6, L–AS7, L–AS9, and L–UU1, placing Loveland Area Projects (LAP) transmission and Western Area Colorado Missouri (WACM) Balancing Authority ancillary services formula rates into effect on an interim basis. The provisional formula rates will be in effect until the Federal Energy Regulatory Commission (FERC) confirms, approves, and places them into effect on a final basis or until they are replaced by other formula rates. The provisional formula rates will provide sufficient revenue to pay all annual costs, including interest expense, and to repay power investment within the allowable periods.

**DATES:** Rate Schedules L–NT1, L–FPT1, L–NFPT1, L–AS1, L–AS2, L–AS3, L–AS4, L–AS5, L–AS6, L–AS7, L–AS9, and L–UU1 will be placed into effect on an interim basis on the first day of the first full billing period beginning on or after October 1, 2011, and will remain in effect until FERC confirms, approves, and places the rate schedules into effect on a final basis for a 5-year period ending September 30, 2016, or until the rate schedules are superseded.

**FOR FURTHER INFORMATION CONTACT:** Mr. Bradley S. Warren, Regional Manager, Rocky Mountain Customer Service Region, Western Area Power Administration, 5555 East Crossroads Boulevard, Loveland, CO 80538–8986, telephone (970) 461–7201, or Mrs. Sheila D. Cook, Rates Manager, Rocky Mountain Customer Service Region, Western Area Power Administration, 5555 East Crossroads Boulevard, Loveland, CO 80538–8986, telephone (970) 461–7211, e-mail *scook@wapa.gov.*

**SUPPLEMENTARY INFORMATION:** The Deputy Secretary of Energy approved current Rate Schedules L–NT1, L–FPT1, L–NFPT1, L–AS1, L–AS2, L–AS3, L–AS4, L–AS5, L–AS6, and L–AS7 on December 30, 2003 (Rate Order No. WAPA–106, 69 FR 1723, January 12, 2004).[1] These rates became effective on March 1, 2004, with an expiration date of February 28, 2009. The rate schedules, with the exception of Rate Schedule L–AS3, Regulation and Frequency Response, were extended through February 28, 2011, under Rate Order No. WAPA–141.[2] Rate Schedule L–AS3 was revised and approved under Rate Order No. WAPA–118,[3] which became effective on June 1, 2006, with an expiration date of May 31, 2011. Under Rate Order No. WAPA–154,[4] all LAP transmission and WACM ancillary services rate schedules, including L–AS3, were extended through February 28, 2013.

#### LAP Transmission Service

Rate Schedules L–NT1, L–FPT1, and L–NFPT1 for LAP transmission services are based on a revenue requirement that recovers the LAP transmission system costs for facilities associated with providing all transmission services as well as the non-transmission facility costs allocated to transmission services. These firm and non-firm LAP transmission service rates include the costs for scheduling, system control, and dispatch service needed to provide the transmission service.

Rate Schedule L–UU1, Unreserved Use Penalties, is a new rate schedule established in accordance with Western's Open Access Transmission Tariff (Tariff). This rate will recover costs for transmission service that has not been reserved or has been used in excess of the amount reserved. Rate Schedule L–UU1 also provides for a penalty in addition to the base charge for the transmission service used. Previously, a penalty for unauthorized use of transmission was included in the Point-to-Point Transmission Service, Rate Schedules L–FPT1 and L–NFPT1.

Rate Schedule L–AS7, Transmission Losses Service, is designed to recover losses on all real-time and prescheduled transactions on transmission facilities inside WACM.

#### Ancillary Services

Western will provide seven ancillary services pursuant to its Tariff. These are: (1) Scheduling, System Control, and Dispatch Service (L–AS1); (2) Reactive Supply and Voltage Control from Generation or Other Sources Service (L–AS2); (3) Regulation and Frequency Response Service (L–AS3); (4) Energy Imbalance Service (L–AS4); (5) Spinning Reserve Service (L–AS5); (6) Supplemental Reserve Service (L–AS6); and (7) Generator Imbalance Service (L–AS9). Generator Imbalance Service is also a new rate schedule established under the Tariff. Currently, Generator Imbalance Service is provided under Rate Schedule L–AS4, Energy Imbalance Service.

Rates for LAP transmission and ancillary services will be recalculated each year to incorporate the most recent financial, load, and schedule information and will be applicable to all transmission and ancillary services customers.

By Delegation Order No. 00–037.00, effective December 6, 2001, the Secretary of Energy delegated (1) the authority to develop power and transmission rates to the Administrator of Western; (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary of Energy; and (3) the authority to confirm, approve, and place into effect on a final basis, to remand, or to disapprove such rates to FERC. Existing Department of Energy procedures for public participation in power rate adjustments (10 CFR 903) were published on September 18, 1985 (50 FR 37835).

Under Delegation Order Nos. 00–037.00 and 00–001.00C, 10 CFR part 903, and 18 CFR part 300, I hereby confirm, approve, and place Rate Order No. WAPA–155, the proposed LAP transmission and WACM ancillary services formula rates, into effect on an interim basis. By this order, I am placing the rates into effect in less than 30 days to meet contract deadlines, to avoid financial difficulties, and to provide rates for new services. The revised Rate Schedules L–NT1, L–FPT1, L–NFPT1, L–AS1, L–AS2, L–AS3, L–AS4, L–AS5, L–AS6, L–AS7, L–AS9, and L–UU1 will be submitted promptly to FERC for confirmation and approval on a final basis.

[1] WAPA–106 was approved by FERC on a final basis on January 31, 2005, in Docket No. EF2–04–5182–000 (110 FERC ¶ 62,084).

[2] WAPA–141, Extension of Rate Order No. WAPA–106 through February 28, 2011. 73 FR 48382, August 19, 2008.

[3] WAPA–118 was approved by FERC on a final basis on November 17, 2006, in Docket No. EF–06–5182–000 (117 FERC ¶ 62,163).

[4] WAPA–154, Extension of Rate Order Nos. WAPA–106 and WAPA–118 through February 28, 2013. 76 FR 1429, January 10, 2011.

Dated: September 2, 2011.

**Daniel B. Poneman,**

*Deputy Secretary.*

**Order Confirming, Approving, and Placing the Loveland Area Projects Transmission and Western Area Colorado Missouri Balancing Authority Ancillary Services Formula Rates Into Effect on an Interim Basis**

These transmission and ancillary services formula rates are established pursuant to section 302 of the Department of Energy (DOE) Organization Act (42 U.S.C. 7152). This act transferred to and vested in the Secretary of Energy the power marketing functions of the Secretary of the Interior and the Bureau of Reclamation (Reclamation) under the Reclamation Act of 1902 (ch. 1093, 32 Stat. 388), as amended and supplemented by subsequent laws, particularly section 9(c) of the Reclamation Act of 1939 (43 U.S.C. 485h(c)) and section 5 of the Flood Control Act of 1944 (16 U.S.C. 825s), and other acts that specifically apply to the projects involved.

By Delegation Order No. 00–037.00, effective December 6, 2001, the Secretary of Energy delegated: (1) The authority to develop power and transmission rates to the Administrator of Western; (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary of Energy; and (3) the authority to confirm, approve, and place into effect on a final basis, to remand, or to disapprove such rates to the Federal Energy Regulatory Commission (FERC). Existing DOE procedures for public participation in power rate adjustments (10 CFR part 903) were published on September 18, 1985.

**Acronyms/Terms and Definitions**

As used in this Rate Order, the following acronyms/terms and definitions apply:

| Acronym/Term | Definition |
|---|---|
| *$/kW-month:* | Dollars per kilowatt per month. |
| *12-cp:* | Rolling 12-month average of customers' loads in excess of Federal Entitlement, coincident with the Loveland Area Projects (LAP) transmission system peak. |
| *Administrator:* | The Administrator of the Western Area Power Administration. |
| *Area Control Error (ACE):* | The instantaneous difference between a Balancing Authority's net actual and scheduled interchange, taking into account the effects of frequency bias and correction for meter error. |
| *Ancillary Services:* | Those services that are necessary to support the transmission of capacity and energy from resources to loads while maintaining reliable operation of the Transmission Provider's transmission system in accordance with good utility practice. |
| *ATRR:* | Annual transmission revenue requirement. |
| *Automatic Generation Control:* | Equipment that automatically adjusts generation in a Balancing Authority area from a central location to maintain the Balancing Authority's interchange schedule plus frequency bias. |
| *Balancing Authority:* | The responsible entity that integrates resource plans ahead of time, maintains load-interchange-generation balance within a Balancing Authority area, and supports interconnection frequency in real time. |
| *Control Area:* | The term used for a Balancing Authority area in Western's Open Access Transmission Tariff. |
| *CRSP:* | Colorado River Storage Project. |
| *DOE:* | Department of Energy. |
| *Energy Imbalance Service:* | The ancillary service in which the Balancing Authority corrects hourly for the difference between a customer's energy supply and energy usage. |
| *Federal Customers:* | LAP customers taking delivery of long-term firm service under firm electric service contracts, project use, and special use contracts. |
| *Firm Electric Service Contracts:* | Contracts for the sale of long-term firm LAP Federal energy and capacity, pursuant to the Post-1989 General Power Marketing and Allocation Criteria (Marketing Plan). |
| *Firm Point-to-Point Transmission Service:* | The highest priority transmission service offered to customers on a specified path that anticipates no planned interruption. |
| *Federal Entitlements:* | The energy and capacity delivered to Federal Customers under Firm Electric Service Contracts. |
| *FERC:* | Federal Energy Regulatory Commission. |
| *Fry-Ark:* | Fryingpan-Arkansas Project. |
| *FY:* | Fiscal Year, October 1 through September 30. |
| *Generator Imbalance Service:* | The ancillary service in which the Balancing Authority corrects hourly for the difference between a customer's actual generation and scheduled generation. |
| *kW:* | Kilowatt. The electrical unit of capacity equal to 1,000 watts. |
| *kWh:* | Kilowatt-hour. The electrical unit of energy equal to 1 kW produced or delivered for 1 hour. |
| *kW-month:* | Kilowatt-month. The electrical unit of energy equal to 1 kW produced or delivered for 1 month. |
| *LAP:* | Loveland Area Projects. |
| *LAP Transmission System or Service:* | Transmission system operated by, or service provided by, the Loveland Area Projects. |
| *LAP Transmission System Total Load:* | Sum of 12-cp averages for all customer loads for Network Integration Transmission Service, plus 12-month rolling average of monthly entitlements of Federal Customers, plus reserved capacity for all Long-Term Firm Point-to-Point Transmission Service. |
| *Load ratio share:* | Network Transmission Customer's 12-cp load coincident with LAP's monthly transmission system peak, expressed as a ratio. |
| *Load Serving Entity (LSE):* | An entity within the Balancing Authority that secures energy and transmission service (and related interconnected operations services) to serve the electrical demand and energy requirements of its end-use customers. |
| *Long-Term Firm Point-to-Point Transmission Service:* | Firm Point-to-Point Transmission Service reservation for a duration of at least 12 consecutive months. |

| Acronym/Term | Definition |
|---|---|
| *Losses:* | The reduction of power being delivered as it moves across transmission lines or other equipment, due to resistance in the conducting material. |
| *M&I:* | Municipal and Industrial. |
| *Mill:* | Unit of monetary value equal to .001 of a U.S. dollar; i.e., 1/10 of a cent. |
| *Mills/kWh:* | Mills per kilowatt-hour. |
| *Monthly Entitlements:* | Maximum capacity to be delivered each month under Firm Electric Service Contracts. Each monthly entitlement is a percentage of the seasonal contract-rate-of-delivery. |
| *MW:* | Megawatt. The unit of electrical capacity that equals 1,000 kW or 1,000,000 watts. |
| *NERC:* | North American Electric Reliability Corporation. |
| *Network Integration Transmission Service:* | Firm transmission service for the delivery of capacity and energy from designated network resources to designated network loads not using one specific path. |
| *Non-Firm Point-to-Point Transmission Service:* | Point-to-point transmission service reserved on an as-available basis for periods ranging from 1 hour to 1 year. |
| *Open Access Same Time Information System (OASIS):* | An electronic posting system that the Transmission Provider maintains for transmission access data that allows all transmission customers to view the data simultaneously. |
| *Operating Reserve—Spinning Reserve Service:* | Generation capacity needed to serve load immediately in the event of a system contingency. Spinning Reserve Service may be provided by generating units that are on-line and loaded at less than maximum output. |
| *Operating Reserve—Supplemental Reserve Service:* | Generation capacity needed to serve load in the event of a system contingency, which capacity is not available immediately to serve load but rather within a short period of time. Supplemental Reserve Service may be provided by generation units that are on-line but unloaded, by quick start generation, or by interruptible load. |
| *Provisional Formula Rate:* | A formula rate that has been confirmed, approved, and placed into effect on an interim basis by the Deputy Secretary. |
| *P–SMBP:* | Pick-Sloan Missouri Basin Program. |
| *P–SMBP—WD:* | Pick-Sloan Missouri Basin Program—Western Division. |
| *RMR:* | Rocky Mountain Customer Service Region. |
| *Reactive Supply and Voltage Control from Generation or Other Sources Service:* | The ancillary service under which a Balancing Authority operates generation facilities under its control to produce or absorb reactive power to maintain voltages on all transmission facilities within acceptable limits. |
| *Reclamation:* | The United States Bureau of Reclamation. |
| *Regulation and Frequency Response Service:* | The ancillary service under which a Balancing Authority maintains moment-by-moment load-interchange-generation balance with the Balancing Authority area and supports interconnection frequency. |
| *Scheduling, System Control, and Dispatch Service:* | The ancillary service under which a Balancing Authority sets up an arrangement for an energy interchange transaction for delivery and receipt of energy between the two entities involved in the transaction. |
| *Service Agreement:* | The initial agreement and any amendments or supplements entered into by a Transmission Customer and Western for service under the Tariff. |
| *Short-Term Firm Point-to-Point Transmission Service:* | Firm Point-to-Point Transmission Service for a duration of less than 12 consecutive months. |
| *Sub-Balancing Authority:* | An area within a Balancing Authority area which has its own boundary metering scheme and for which an ACE can be measured. |
| *Tariff:* | Western's revised Open Access Transmission Service Tariff, effective December 1, 2009 (Docket NJ10–1–000). |
| *Transmission Customer:* | The RMR customer taking Network Integration Transmission Service or Point-to-Point Transmission Service. |
| *Transmission Losses Service:* | The service provided by the Balancing Authority to supply electrical losses on pre-scheduled and real-time transmission transactions. |
| *Transmission Provider:* | An entity that administers a transmission tariff and provides transmission service to transmission customers under applicable transmission service agreements. |
| *Unreserved Use Penalties:* | The use of transmission capacity that was not reserved, or the use of transmission in excess of reserved capacity. |
| *WACM:* | Western Area Colorado Missouri Balancing Authority. |
| *WECC:* | Western Electricity Coordinating Council. |
| *Western:* | Western Area Power Administration. |

**Effective Date**

The Provisional Formula Rates will take effect on the first day of the first full billing period beginning on or after October 1, 2011, and will remain in effect through September 30, 2016, pending approval by FERC on a final basis.

**Public Notice and Comment**

Western has followed the Procedures for Public Participation in Power and Transmission Rate Adjustments and Extensions, 10 CFR Part 903, in the development of these formula rates and schedules. The steps Western took to involve interested parties in the rate process were:

1. On September 29, 2010, Western held an informal meeting with customers and interested parties to discuss the proposed formula rates for LAP Transmission and WACM Ancillary Services. Western posted all information presented at the informal meeting, as well as responses to questions asked at the meeting, on its Web site at *http://www.wapa.gov/rm/ratesRM/2012/default.htm*.

2. Western published a **Federal Register** notice on January 28, 2011 (76 FR 5148), officially announcing the proposed LAP Transmission and WACM Ancillary Services formula rates adjustment, initiating the public consultation and comment period, announcing the date and location of the public information and public comment

forums, and outlining procedures for public participation.

3. On February 2, 2011, Western sent a letter to all interested parties providing them with a copy of the **Federal Register** notice published on January 28, 2011 (76 FR 5148).

4. On March 9, 2011, Western held its public information forum in Loveland, Colorado, where Western representatives explained the need for the formula rates adjustment in detail and answered questions.

5. On March 9, 2011, following the public information forum, Western held a public comment forum in Loveland, Colorado, to provide an opportunity for customers and other interested parties to comment for the record. At this forum, one individual expressed general support of Western's efforts to communicate with its customers well in advance of implementation of the proposed rates.

6. Western received one written comment during the 90-day consultation and comment period, which ended on April 28, 2011. This comment is addressed below following the ancillary services discussion.

All comments received have been considered in the preparation of this Rate Order.

**Project Descriptions**

The Post-1989 General Power Marketing and Allocation Criteria, published in the **Federal Register** on January 31, 1986 (51 FR 4012), integrated the resources of the P–SMBP—WD and Fry-Ark. This operational and contractual integration, known as LAP, allowed an increase in marketable resources, simplified contract administration, and established a blended rate for LAP power sales. WACM offers Ancillary Services from a combination of all LAP generation resources and some CRSP generation resources.

*P–SMBP—WD*

The P–SMBP was authorized by Congress in section 9 of the Flood Control Act of December 22, 1944 (Pub. L. 534, 58 Stat. 877, 891). This multipurpose program provides flood control, M&I water supply, irrigation, navigation, recreation, preservation and enhancement of fish and wildlife, and hydroelectric power. Multipurpose projects have been developed on the Missouri River and its tributaries in Colorado, Montana, Nebraska, North Dakota, South Dakota, and Wyoming.

In addition to the multipurpose water projects authorized by section 9 of the Flood Control Act of 1944, certain other existing projects have been integrated with the P–SMBP for power marketing, operation, and repayment purposes. The Colorado-Big Thompson, Kendrick, Riverton, and Shoshone Projects were combined with P–SMBP in 1954, followed by the North Platte Project in 1959. These projects are known as the ''Integrated Projects'' of the P–SMBP. The Riverton Project was reauthorized as a unit of the P–SMBP in 1970. Together, the P–SMBP—WD and the Integrated Projects have 19 power plants.

There are six power plants in P–SMBP—WD: Glendo, Kortes, and Fremont Canyon power plants on the North Platte River; Boysen and Pilot Butte power plants on the Wind River; and Yellowtail power plant on the Big Horn River. The Colorado-Big Thompson Project has six power plants: Green Mountain power plant on the Blue River is on the West Slope of the Continental Divide; and Mary's Lake, Estes, Pole Hill, Flatiron, and Big Thompson power plants along the Big Thompson River are on the East Slope of the Continental Divide. The Kendrick Project has two power plants: Alcova and Seminoe power plants on the North Platte River. Power plants in the Shoshone Project are the Shoshone, Buffalo Bill, Heart Mountain, and Spirit Mountain plants on the Shoshone River. The only power plant in the North Platte Project is the Guernsey power plant, also on the North Platte River.

*Fry-Ark*

Fry-Ark is a trans-mountain diversion development in southeastern Colorado authorized by the Act of Congress on August 16, 1962 (Pub. L. 87–590, 76 Stat. 389, as amended by Title XI of the Act of Congress on October 27, 1974 (Pub. L. 93–493, 88 Stat. 1486, 1497)). The Fry-Ark diverts water from the Fryingpan River and other tributaries of the Roaring Fork River in the Colorado River Basin on the West Slope of the Rocky Mountains to the Arkansas River on the East Slope. The water diverted from the West Slope, together with regulated Arkansas River water, provides supplemental irrigation and M&I water supplies and produces hydroelectric power. Flood control, fish and wildlife enhancement, and recreation are other important purposes of Fry-Ark. The only generating facility in Fry-Ark is the Mt. Elbert Pumped-Storage power plant on the East Slope.

*CRSP*

CRSP was authorized by the Colorado River Storage Project Act, ch. 203, 70 Stat. 105, on April 11, 1956. The project provides water-use developments for states in the Upper Basin (Colorado, New Mexico, Utah, and Wyoming) while still maintaining water deliveries to the states of the Lower Basin (Arizona, California, and Nevada) as required by the Colorado River Compact of 1922. CRSP hydroelectric facilities providing ancillary services for WACM are the Aspinall power plant (formerly Curecanti) on the Gunnison River, the Flaming Gorge power plant on the Green River, the Towaoc Power Plant on the Towaoc Canal in southwestern Colorado, and the Glen Canyon power plant on the Colorado River.

**LAP Transmission Service**

Transmission formula rates, including those for Firm and Non-Firm Point-To-Point Transmission Service and Network Integration Transmission Service, are designed to recover the annual costs of the LAP Transmission System. The transmission rates include the cost of Scheduling, System Control, and Dispatch Service. Western will continue to bundle transmission service for delivery of LAP long-term firm Federal power to Federal Customers in the firm electric service rate under existing Firm Electric Service Contracts that expire in 2024.

The penalty for unauthorized use of transmission, currently assessed under the Point-to-Point Transmission rate schedules, will now be assessed as a penalty for unreserved use under a separate rate schedule, L–UU1. Unreserved Use Penalties will include the basic rate for the transmission service used and not reserved, plus a penalty equal to the basic rate.

Transmission losses are assessed for all real-time and prescheduled transactions on transmission facilities inside WACM. The current loss factor, as posted on the RMR OASIS, is 4.5 percent.

**WACM Ancillary Services**

Western will offer seven Ancillary Services pursuant to its Tariff. The seven Ancillary Services are: (1) Scheduling, System Control, and Dispatch Service (SSCD Service); (2) Reactive Supply and Voltage Control from Generation or Other Sources Service (VAR Support Service); (3) Regulation and Frequency Response Service (Regulation Service); (4) Energy Imbalance Service; (5) Spinning Reserve Service; (6) Supplemental Reserve Service; and (7) Generator Imbalance Service. Generator Imbalance Service, currently provided as part of Rate Schedule L–AS4 for Energy Imbalance Service, is a new service under the Tariff. The Ancillary Services formula rates are designed to recover only the

costs incurred for providing the service(s).

**Comparison of Existing and Provisional Formula Rates for Transmission and Ancillary Services**

The following table displays a comparison of existing formula rates and the Provisional Formula Rates for FY 2012. These rates will be recalculated annually based on updated financial, schedule, and load data.

FORMULA RATE COMPARISON TABLE

| Class of Service | Provisional Formula Rates Effective October 1, 2011 (FY 2012) | Existing Formula Rates Effective October 1, 2010 (FY 2011) |
|---|---|---|
| Network Integration Transmission Service | L–NT1<br>Load ratio share of 1/12 of the revenue requirement of $56,775,913. | L–NT1<br>Load ratio share of 1/12 of the revenue requirement of $48,000,660. |
| Firm Point-to-Point Transmission Service | L–FPT1<br>$3.48/kW-month | L–FPT1<br>$3.18/kW-month<br>Unauthorized Use Penalty of 150% of demand charge, with a maximum of monthly service. |
| Non-Firm Point-to-Point Transmission Service | L–NFPT1<br>Maximum of 4.77 mills/kWh | L–NFPT1<br>Maximum of 4.17 mills/kWh<br>Unauthorized Use Penalty of 150% of demand charge, with a maximum of monthly service. |
| Unreserved Use Penalties | L–UU1<br>Penalized 200% of demand charge, with a maximum of monthly service. | Provided Under Rate Schedules L–FPT1 and L–NFPT1 as Unauthorized Use. |
| Transmission Losses Service | L–AS7<br>Transmission losses may be settled either financially or with energy. Insufficient losses supplied will be settled financially by default.<br>All customers will have the option to return the loss obligation for both prescheduled and real-time transactions 7 days later, same profile.<br>Pricing used is WACM weighted average hourly purchase price.<br>Current loss factor as posted is 4.5%. | L–AS7<br>Transmission losses may be settled either financially or with energy. Insufficient losses supplied will be settled financially by default.<br>All customers will have the option to return the loss obligation for both prescheduled and real-time transactions 7 days later, same profile.<br>Pricing used is LAP weighted average hourly real-time purchase price.<br>Current loss factor as posted is 4.5%. |
| Scheduling, System Control, and Dispatch Service | L–AS1<br>$24.22 per schedule per day for non-Federal transmission customers. Not applicable to schedules for delivery of Losses to WACM. | L–AS1<br>$38.30 per tag per day for non-Federal transmission customers. Applicable to all tags. |
| Reactive Supply and Voltage Control from Generation or Other Sources Service | L–AS2<br>$0.305/kW-month | L–AS2<br>$0.180/kW-month |
| Regulation and Frequency Response | L–AS3<br>$0.331/kW-month | L–AS3<br>$0.339/kW-month |
| Energy Imbalance Service | L–AS4<br>—Imbalances less than or equal to 1.5% (minimum 4 MW) of metered load settled using WACM hourly pricing with no penalty.<br>—Imbalances between 1.5% and 7.5% (minimum 4 MW to 10 MW) of metered load settled using WACM hourly pricing with a 10% penalty.<br>—Imbalances greater than 7.5% (minimum 10 MW) of metered load settled using WACM hourly pricing with a 25% penalty.<br>—WACM aggregate imbalance determines pricing in all bands—aggregate surplus dictates sale pricing, aggregate deficit dictates purchase pricing. | L–AS4<br>—Imbalances less than or equal to 5% (minimum 4 MW) of metered load settled using WACM hourly pricing with no penalty.<br>—Imbalances greater than 5% of metered load settled using WACM hourly pricing with a 10% penalty.<br>—WACM aggregate imbalance dictates pricing in no-penalty band. Customer imbalance dictates pricing in penalty band (surpluses indicate sale pricing, deficits indicate purchase pricing).<br>—Intermittent resources not subject to penalties. |
| Operating Reserve Service—Spinning and Supplemental | L–AS5, L–AS6<br>Long-term Reserves are not available from WACM. Reserves may be acquired and provided at pass-through cost, plus an amount for administration. | L–AS5, L–AS6<br>Long-term Reserves are not available from WACM. Reserves may be acquired and provided at pass-through cost, plus an amount for administration. |

FORMULA RATE COMPARISON TABLE—Continued

| Class of Service | Provisional Formula Rates Effective October 1, 2011 (FY 2012) | Existing Formula Rates Effective October 1, 2010 (FY 2011) |
|---|---|---|
| Generator Imbalance Service | L–AS9<br>—Imbalances less than or equal to 1.5% (minimum 4 MW) of metered generation settled using WACM hourly pricing with no penalty.<br>—Imbalances between 1.5% and 7.5% (minimum 4 MW to 10 MW) of metered generation settled using WACM hourly pricing with a 10% penalty.<br>—Imbalances greater than 7.5% (minimum 10 MW) of metered generation settled using WACM hourly pricing with a 25% penalty.<br>—Intermittent resources not subject to 25% penalties.<br>—WACM aggregate imbalance determines pricing in all bands—aggregate surplus dictates sale pricing, aggregate deficit dictates purchase pricing. | Provided under Rate Schedule L–AS4. |

**Certification of Rates**

Western's Administrator certified that the Provisional Formula Rates for LAP Transmission and WACM Ancillary Services under Rate Schedules L–NT1, L–FPT1, L–NFPT1, L–AS1, L–AS2, L–AS3, L–AS4, L–AS5, L–AS6, L–AS7, L–AS9, and L–UU1 are the lowest possible rates consistent with sound business principles. The Provisional Formula Rates were developed following administrative policies and applicable laws.

**LAP Transmission Service Discussion**

*Network Integration Transmission Service*

The monthly charge for Network Integration Transmission Service for the Transmission Customer will be as follows:

$$\text{Monthly Charge} = \text{Customer Load Ratio Share} \times \frac{\text{ATRR}}{12}$$

The customer's load-ratio share is the ratio of its network load to the LAP Transmission System Total Load at the LAP system peak. This is calculated on a rolling 12-month average (12 coincident peak average or 12-cp).

*Firm Point-to-Point Transmission Service*

The formula rate for Firm Point-to-Point Transmission Service is as follows:

$$\text{Firm Point-to-Point Transmission Rate} = \frac{\text{ATRR}}{\text{12-month average of the LAP Transmission System Total Load}}$$

The rates for FY 2012 are as follows:

$$\text{Yearly Delivery: } \$41.80/\text{kW of reserved capacity per year} = \frac{\$56,775,913}{1,358,342\ \text{kW}}$$

Monthly Delivery: $3.48/kW of reserved capacity per month
Weekly Delivery: $0.80/kW of reserved capacity per week
Daily Delivery: $0.11/kW of reserved capacity per day

Discussions of the ATRR and the LAP Transmission System Total Load are located below.

*Non-Firm Point-to-Point Transmission Service*

The maximum Non-Firm Point-to-Point Transmission Service formula rate is the same as the Firm Point-to-Point Transmission Service rate. Non-Firm Point-to-Point Transmission Service is available for periods ranging from 1 hour to 1 year.

Maximum Hourly Non-Firm Rate: 4.77 mills/kW of reserved capacity per hour

*Annual Transmission Revenue Requirement*

The ATRR is applicable to both Network and Point-to-Point Transmission Service. The ATRR is the annual cost of the LAP Transmission System, adjusted for revenue credits, costs that increase the capacity available for transmission, other miscellaneous charges or credits, and the prior year true-up. The formula, with amounts calculated for the FY 2012 rate, is as follows:

| Annual Transmission Revenue Requirement | = | Annual Cost of Transmission System | + | System Augmentation Expense | - | Scheduling and Dispatch Revenue Credits | - | Point-to-Point Transmission Revenue Credits | +/- | Misc Charges/ Credits | +/- | Prior Year True-Up |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Annual Transmission Revenue Requirement | = | $66,533,166 | + | $-0- | - | $694,016 | - | $9,063,237 | - | $-0- | + | $-0- |

| Annual Transmission Revenue Requirement | = | $56,775,913 |
|---|---|---|

The annual cost of the LAP Transmission System is the ratio of gross investment cost for transmission facilities to gross investment cost for all facilities multiplied by the total annual costs for all facilities. Total annual costs include operations and maintenance, interest, and depreciation expenses. The calculation, with amounts for FY 2012, is as follows:

$$\text{Annual Cost of Transmission System} = \frac{\text{Gross Investment Cost for Transmission Facilities}}{\text{Gross Investment Cost for All Facilities}} \times \text{Total Annual Costs for All Facilities}$$

$$\text{Annual Cost of Transmission System} = \frac{\$527,853,417}{\$715,485,652} \times \$90,183,229$$

$$\text{Annual Cost of Transmission System} = \$66,533,166$$

The source for the annual costs is the formalized work plans for FY 2012 and the FY 2010 Results of Operations for P–SMBP—WD, with certain items adjusted for projected asset capitalization or historical trends. See discussion below on ''Change to Forward-Looking Transmission Rates.''

The gross investment cost for transmission facilities is determined by an analysis of the LAP Transmission System. Each LAP facility is classified by function: transmission, sub-transmission, distribution, or generation-related. The facilities identified as performing the function of transmission include all transmission lines that are normally operated in a continuously-looped manner and the associated substations and switchyard facilities. In the LAP Transmission System, these are primarily the 115-kV and the 230-kV transmission lines. In addition, portions of the communication, maintenance, and administration facilities are included in the investment costs for transmission. Only the investment costs of the facilities identified as ''transmission'', including allocated costs for communication, maintenance, and administration facilities, are used in developing the annual cost of the transmission system. The investment costs of facilities identified as ''sub-transmission'' and ''distribution'' are excluded from the ATRR, as the LAP sub-transmission and distribution systems are used primarily for delivery of Federal power to Federal Customers. If a Transmission Customer requires the use of the sub-transmission or distribution systems, an additional facility-use charge will be assessed. All Fry-Ark costs are considered generation-related and, therefore, are excluded from the ATRR.

System augmentation expense includes payments made to others for their systems' augmentation of the LAP Transmission System. Miscellaneous charges and credits will include, but will not be limited to, Unreserved Use Penalties and facility use charges for transmission facility investments included in the revenue requirement. For a description of the prior year true-up, see discussion below on ''Change to Forward-Looking Transmission Rates.''

*Change to Forward-Looking Transmission Rates*

Western has changed the method it uses to calculate the ATRR to recover transmission expenses and investments on a current basis rather than a historical basis. The change allows Western to more accurately match cost recovery with cost incurrence. Western will use projections to estimate transmission costs and load for the upcoming year in the annual rate calculation, rather than using historical information. The method is a change in the manner in which the inputs for the rate are developed, rather than a change to the formula rate itself. When actual cost information for a year becomes available, Western will calculate the actual revenue requirement for that year. Revenue collected in excess of the actual revenue requirement will be included as a credit in the ATRR in a subsequent year. Similarly, any under-collection of the revenue requirement will be included as a charge in the ATRR in a subsequent year. This true-up procedure will ensure that Western recovers no more and no less than the actual transmission costs for any year. For example, as FY 2012 actual financial data becomes available during FY 2013, the under- or over-collection of revenue during FY 2012 can be determined. When the rates are recalculated for FY 2014, the implemented rates will include an adjustment for revenue under- or over-collected in FY 2012.

*Transmission System Total Load for Point-to-Point Service*

The LAP Transmission System Total Load is a 12-month average of the sum of (1) all Network Integration Transmission Service customer loads in excess of deliveries of Federal Entitlements, measured at the monthly LAP Transmission System peak hour, plus (2) the monthly entitlements of Federal Customers, plus (3) the reserved capacity for Long-Term Firm Point-to-Point Transmission Service. This load calculation is prepared once annually and is used to calculate the point-to-point rates for the entire year.

The LAP Transmission System Total Load is calculated as follows, based upon data projected for FY 2012:

| | |
|---|---|
| Federal Customers | 604,639 kW |
| Network Transmission Customers | 743,818 kW |
| Subtotal | 1,348,457 kW |
| Point-to-Point Reserved Capacity | 9,885 kW |
| LAP Transmission System Total Load | 1,358,342 kW |

**Unreserved Use Penalties**

Unreserved use of the transmission system (Unreserved Use) occurs when a Transmission Customer uses transmission service that exceeds its reserved capacity or an eligible customer uses transmission service that it has not reserved. Western will assess Unreserved Use Penalties against a customer that has not secured reserved capacity or exceeds its reserved capacity at any point of receipt or any point of delivery. Unreserved Use may also include a Transmission Customer's failure to curtail transmission when requested.

A customer that engages in Unreserved Use will be assessed a penalty charge of 200 percent of LAP's approved transmission service rate for Firm Point-to-Point Transmission Service as follows:

(1) The Unreserved Use penalty for a single hour of Unreserved Use will be based upon the rate for daily Firm Point-to-Point Service.

(2) The Unreserved Use penalty for more than one assessment for a given duration (e.g., daily) will increase to the next longest duration (e.g., weekly).

(3) The Unreserved Use penalty charge for multiple instances of Unreserved Use (e.g., more than one hour) within a day will be based on the rate for daily Firm Point-to-Point Service. Multiple instances of Unreserved Use isolated to one calendar week will result in a penalty based on the charge for weekly Firm Point-to-Point Service. The penalty charge for multiple instances of Unreserved Use during more than one week during a calendar month will be based on the charge for monthly Firm Point-to-Point Service.

A Transmission Customer that exceeds its firm reserved capacity at any point of receipt or point of delivery or an eligible customer that uses transmission service at a point of receipt or point of delivery that it has not reserved will be required to pay, in addition to the Unreserved Use Penalties, for all applicable Ancillary Services identified in Western's Tariff based on the amount of transmission service it used and did not reserve.

Unreserved Use Penalties collected over and above the base Point-to-Point Transmission Service rate will be included as a credit in the calculation of the ATRR in a subsequent year.

**Transmission Losses Service**

Transmission Losses are assessed for all real-time and prescheduled transactions on transmission facilities inside WACM. In the case of Network Integration Transmission Service Customers, transmission and transformer Losses applicable under customers' respective contracts are calculated as part of the customers' Energy Imbalance Service settlements. Other customers are allowed the option of financial settlement or energy repayment. Energy repayment is either concurrently or 7 days later, to be delivered using the same profile as the related transmission transaction. When a transmission loss energy obligation is not provided (or is under-provided) by a customer for a transmission transaction, the energy still owed for Losses is calculated and a charge is assessed to the customer, based on the WACM weighted average hourly purchase price. The loss factor, currently 4.5 percent, is updated periodically and posted on the RMR OASIS Web site.

**Transmission Service Comments**

RMR received no comments concerning transmission service, Unreserved Use Penalties, or Transmission Losses during the public consultation and comment period.

**Ancillary Services Discussion**

Pursuant to Western's Tariff, WACM will offer seven Ancillary Services. Two of these services, SSCD Service and VAR Support Service, are services that, under Western's Tariff, the Transmission Provider is required to provide (or offer to arrange with the Balancing Authority operator) and the Transmission Customer is required to purchase.

The other five Ancillary Services, Regulation Service, Energy Imbalance Service, Generator Imbalance Service, Operating Reserve—Spinning Reserve Service, and Operating Reserve—Supplemental Reserve Service, are services that the Transmission Provider is required to *offer* to provide to the Transmission Customer. The Transmission Customer is required to acquire these Ancillary Services, either from the Transmission Provider or from a third party, or to self-supply them.

**Scheduling, System Control, and Dispatch Service**

The formula for SSCD Service, with amounts shown for FY 2012, is as follows:

$$\text{Rate per Schedule} = \frac{\text{Annual Cost of Scheduling Personnel and Related Costs}}{\text{Number of Schedules per Year, excluding Schedules for Delivery of Losses to WACM}}$$

$$\text{Rate per Schedule} = \frac{\$3,094,350}{127,778 \text{ Schedules}}$$

$$\text{Rate per Schedule} = \$24.22$$

This rate recovers the annual expenses associated with transmission scheduling. The annual cost of scheduling personnel and related costs is comprised of annual expenses for personnel, facilities, equipment, and software, as well as credits representing fees for agent services and unscheduled flow mitigation services. This revenue requirement is divided by the number of schedules (excluding schedules for delivery of losses to WACM) per year to derive a rate per schedule per day.

Per Schedule 1 of Western's Tariff, ''this service can be provided only by the operator of the Control Area in which the transmission facilities used for transmission service are located.'' In cases in which the Transmission Provider (LAP and/or CRSP) directly provides the service as the Control Area operator, the costs for this service are bundled in the respective Federal transmission rate. In cases in which the Transmission Providers on the schedules are not the operator, WACM indirectly performs this service for those Transmission Providers' transmission systems. Western has historically invoiced the *last* Transmission Provider that is inside WACM on the schedule. Since all non-Federal Transmission Providers are indirectly taking this service from WACM, Western will allocate the cost of each schedule equally among *all* Transmission Providers (Federal and non-Federal) listed on the schedule that are inside WACM. The Federal transmission segments will be exempt from invoicing, as costs for these segments will continue to be included in the Federal (LAP and CRSP) transmission service rates.

Western will not include schedules for delivery of transmission losses to WACM in the calculation of the rate and will not invoice for them, so that entities delivering losses may create individual loss schedules associated with specific transactions without charge. Western will accept any number of schedule changes over the course of a day, without additional charge, so that entities attempting to follow their loads closely may do so without penalty.

**Reactive Supply and Voltage Control from Generation or Other Sources Service**

The formula for VAR Support Service is the following:

$$\text{VAR Support Rate} = \frac{\text{TARRG x \% of Resource}}{\text{Load Requiring VAR Support}}, \text{ where}$$

TARRG = Total Annual Revenue Requirement for Generation
% of Resource = Percentage of Resource Used for VAR Support

The numerator captures the percentage of annual generation plant costs that are used for this service. Most of the LAP generation plant facilities are owned and operated by Reclamation, but Western has some facilities that are considered generation-related. Net generation plant costs are multiplied by a fixed charge rate (FCR) for generation to determine the TARRG, where

$$\text{FCR} = \frac{\text{Annual Operation \& Maintenance Expenses} + \text{Annual Depreciation Expenses}}{\text{Net Total Plant Investment}} + \frac{\text{Annual Interest Expenses}}{\text{Unpaid Balances}}$$

The FCR is a methodology used to assign a portion of total expenses to generation. Applying these formulas to FY 2010 data provides the following results:

$$FCR = \frac{\$42,446,705 + \$739,534}{\$376,063,242} + \frac{\$16,450,805}{\$246,301,546}$$

$$FCR = 17.847\%$$

Applying this percentage to the amount of net generation plant investment results in the TARRG:

TARRG = $334,166,538 × 17.847% = $59,638,020

The percentage of the TARRG that is included in the revenue requirement is based on the nameplate capability of the generating units with regard to reactive and real power production. The TARRG is multiplied by the complement of the weighted average power factor rating for generating units. The weighted average power factor rating for the LAP generating units is 94.77 percent, so the revenue requirement for this rate includes 5.23 percent of the TARRG. The portion of the revenue requirement contributed by LAP plant costs is as follows:

LAP Plant Costs = $59,638,020 × 5.2284% = $3,118,089

Plant costs for CRSP plants providing VAR Support Service are calculated using identical methodology. The contribution to the revenue requirement from CRSP plants is $1,539,255. The total revenue requirement, after adjusting for a small amount of VAR Support Service revenue on point-to-point transmission transactions not in the rate design, is as follows:

| | |
|---|---|
| LAP Plant Costs | $3,118,089 |
| CRSP Plant Costs | $1,539,255 |
| PTP Revenue | $(53,525) |
| Revenue Requirement | $4,603,819 |

The load taking this service totals 1,258,524 kW, resulting in a proposed rate for FY 2012 of:

$$\text{VAR Support Rate} = \frac{\$4,603,819}{1,258,524\ \text{kW}}$$

$$\text{VAR Support Rate} = \$3.658 / \text{kW-year}$$

$$\text{VAR Support Rate} = \$0.305 / \text{kW-month}$$

The rate is applicable to all transmission transactions inside WACM in excess of any Federal Entitlements. For Federal Entitlements, the cost for this service will be included in the firm electric service rates. Customers with generators providing WACM with VAR Support Service may be excluded from the application of this rate. Any such exclusion must be documented in the customer's Service Agreement.

**Regulation and Frequency Response Service**

The formula rate for Regulation Service has two different applications:

1. *Load-based Assessment.* The formula for the Load-based Assessment is as follows:

$$\text{Regulation Service Rate} = \frac{\text{Total Annual Revenue Requirement for Regulation Service}}{\text{Load in WACM Requiring Regulation Service Plus the Installed Nameplate Capacity of Intermittent Generators Serving Load Inside WACM}}$$

The rate applies to all entities' auxiliary load (total metered load less Federal Entitlements) and also to the installed nameplate capacity of intermittent generators serving load inside WACM.

The revenue requirement will include costs such as plant costs, purchases of a regulation product, purchases of power in support of the generating units' ability to regulate, purchases of transmission for regulating units that are trapped geographically inside another balancing authority, purchases of transmission required to relocate energy due to regulation/load following issues, and lost sales opportunities resulting from the requirement to generate at night to permit units to have ''down'' regulating capability.

The methodology for determining annual plant costs is as follows. First, the annual costs for plants used to regulate is calculated by multiplying the net plant costs by the FCR for generation.

Annual Costs = 17.847% × $159,716,812

Annual Costs = $28,504,334

Then, the annual cost per unit of capacity for regulating plants is calculated by dividing the annual costs for regulating plants by the capacity of those plants:

$$\text{Annual Cost per Unit of Capacity} = \frac{\$28,504,334}{472,550\ \text{kW}}$$

$$\text{Annual Cost per Unit of Capacity} = \$60.32 / \text{kW}$$

Next, the portion of the total annual plant costs to be recovered in the Regulation Service rate is calculated by multiplying the annual unit cost by the amount of capacity required for regulation. The capacity required for regulation is subject to re-evaluation every year. Current analyses indicate that 75 MW of capacity will be required for WACM Regulation Service for FY 2012. Of this total, 55 MW will be supplied by LAP plants and 20 MW will be supplied by CRSP plants.

Regulating Plant Costs (LAP) = $60.32 × 55,000 kW

Regulating Plant Costs (LAP) = $3,317,614

CRSP regulating plant costs are calculated in a similar manner. Inserting this and other financial data for FY 2010 into the formula results in the following Revenue Requirement:

| | |
|---|---|
| LAP Plant Costs | $3,317,614 |
| Purchase Power Costs in Support of Regulation | 5,049,193 |
| Lost Sales Opportunities from having to generate in off-peak hours | 1,320,110 |
| Transmission Costs for Trapped Regulating Units | 1,042,800 |
| Purchases of Transmission | 52,598 |
| CRSP Plant Costs | 590,429 |
| Annual Revenue Requirement | 11,372,744 |

The load inside WACM requiring Regulation Service and the installed nameplate capacity of intermittent resources serving load inside WACM are 2,791,390 kW and 73,220 kW, respectively.

$$\text{Rate for Load-based Assessment} = \frac{\$11,372,744}{2,864,610\ \text{kW}}$$

$$\text{Rate for Load-based Assessment} = \$\ 3.970 / \text{kW-year}$$

$$\text{Rate for Load-based Assessment} = \$\ 0.331 / \text{kW-month}$$

2. *Self-Provision Assessment.* Western allows entities with AGC to self-provide for all or a portion of their loads. Entities with AGC are known as Sub-Balancing Authorities (SBA) and must meet all of the following criteria:

a. Have a well-defined boundary, with WACM-approved revenue-quality metering, accurate as defined by NERC, to include MW flow data availability at 6-second or smaller intervals;

b. Have AGC capability; and

c. Have demonstrated Regulation Service capability.

Self-provision will be measured by use of the entity's 1-minute average ACE to determine the amount of self-provision. The ACE will be used to calculate Regulation Service charges every hour as follows:

a. If the entity's 1-minute average ACE for the hour is less than or equal to 0.5 percent of its hourly average load, no Regulation Service charges will be assessed by WACM.

b. If the entity's 1-minute average ACE for the hour is greater than or equal to 1.5 percent of its hourly average load, WACM will assess full Regulation Service charges using the Load-based Assessment applied to the entity's 12-cp load for that month.

c. If the entity's 1-minute average ACE for the hour is greater than 0.5 percent of its hourly average load, but less than 1.5 percent of its hourly average load, WACM will assess Regulation Service charges based on linear interpolation of zero charge and full charge, using the Load-based Assessment applied to the entity's 12-cp load for that month.

d. Western will monitor the entity's self-provision on a regular basis. If Western determines that the entity has not been attempting to self-regulate, Western will, upon notification, employ the full Load-based Assessment described above.

*Alternative Arrangements*

1. *Exporting Intermittent Resource Requirement:* An entity that exports the output from an intermittent generator to another Balancing Authority will be required to dynamically meter or dynamically schedule that resource out of WACM to another Balancing Authority unless arrangements, satisfactory to Western, are made for that entity to acquire this service from a third party or self-supply (as outlined below). An intermittent generator is one that is volatile and variable due to factors beyond direct operational control and, therefore, is not dispatchable.

2. *Self- or Third-party supply:* Western may allow an entity to supply some or all of its required regulation, or contract with a third party to do so, even without well-defined boundary metering. This entity must have revenue quality metering at every load and generation point, accurate as defined by NERC, to include MW flow data availability at 6-second or smaller intervals. WACM will evaluate the entity's metering, telecommunications and regulating resource, as well as the

required level of regulation, and determine whether the entity qualifies to self-supply under this provision. If approved, the entity will be required to enter into a separate agreement with Western, which will specify the terms of the self-supply application.

**Energy Imbalance Service**

WACM provides Energy Imbalance Service using a penalty and bandwidth structure with three deviation bands as follows. The term ''metered load'' is defined to be ''metered load adjusted for losses.''

1. An imbalance of less than or equal to 1.5 percent of metered load (or 4 MW, whichever is greater) for any hour will be settled financially at 100 percent of the WACM weighted average hourly price. Each hour will stand on its own—there will be no monthly netting.

2. An imbalance between 1.5 percent and 7.5 percent of metered load (or 4 to 10 MW, whichever is greater) for any hour will be settled financially at 90 percent of WACM weighted average hourly price when net energy scheduled exceeds metered load or 110 percent of the WACM weighted average hourly price when net energy scheduled is less than metered load.

3. An imbalance greater than 7.5 percent of metered load (or 10 MW, whichever is greater) for any hour will be settled financially at 75 percent of the WACM weighted average hourly price when net energy scheduled exceeds metered load or 125 percent of the WACM weighted average hourly price when net energy scheduled is less than metered load.

*Aggregate Imbalance, Pricing, and Settlement*

All Energy Imbalance Service provided by WACM will be accounted for hourly and settled financially after the end of each month. The WACM aggregate imbalance will determine the pricing used in all settlements, including those subject to a penalty. For each hour, the gross energy imbalance for all entities inside WACM will be totaled/netted to determine an aggregate energy imbalance for WACM. The sign of the aggregate energy imbalance will determine whether WACM sale or purchase pricing will be used for settling imbalances in that hour. A calculated surplus will dictate the use of sale pricing; a calculated deficit will dictate the use of purchase pricing.

When there are no real-time sales or purchases within an hour, pricing defaults will be applied in the following order:

1. Weighted average sale or purchase pricing for the day (on- and off-peak).

2. Weighted average sale or purchase pricing for the current month (on- and off-peak).

3. Weighted average sale or purchase pricing for the prior month (on- and off-peak).

4. Weighted average sale or purchase pricing for the month immediately prior to the prior month (and continuing in this manner until sale or purchase pricing is located) (on- and off-peak).

*Expansion of the Bandwidth*

Expansion of the bandwidth may be done to accommodate the following: (1) Response to physical resource loss; (2) transition of large thermal resources. Details are as follows:

1. Western will expand the bandwidth during an event established by a Western-recognized reserve-sharing group, such as the Rocky Mountain Reserve Group. A response made by a member of the reserve group will be accounted for by an after-the-fact schedule. Normally, these events are 1–2 hours in duration. Since the after-the-fact schedule replaces lost generation, no expansion will be necessary for the entity receiving the response. The expanded bandwidth will apply to the customer that increased generation in response to the event and will be based on the magnitude of that customer's generation response.

2. During transition of large base-load thermal resources (capacity greater than 200 MW) between off-line and on-line following a reserve sharing group response, Western may expand the bandwidth to eliminate all penalties during hours in which the unit generates less than the predetermined minimum scheduling level. Western may not have access to information necessary to determine these hours for some generators and will not have access to information on events for reserve sharing groups outside RMR. Customers should request bandwidth expansion in hours in which they believe it to be warranted. Western may request additional information for its decision as to whether to grant the request. Bandwidth will not be expanded when ramping services have been acquired by another entity.

*Balancing Authority Operating Constraints*

Western reserves the right to offer no credit for Energy Imbalance Service over-deliveries during times of WACM operating constraints, such as ''must-run'' hydrologic conditions, or times when WACM cannot dispose of surplus energy. Due to the unpredictable nature of hour-to-hour energy imbalances and the very short notice for disposition of over-deliveries, WACM may experience some hours of zero-value sales and may eliminate credits in these hours.

If WACM is unable to dispose of the entire net over-delivery and operating criteria for the Balancing Authority are not met, there may be financial sanctions to Western from reliability oversight agencies, such as NERC or WECC. In these cases, credits to customers will be eliminated and customers over-delivering may share in the cost of the sanction. Also, there may be conditions under which customers who under-deliver may share in any sanctions imposed on Western by reliability oversight agencies.

**Generator Imbalance Service**

WACM will provide Generator Imbalance Service to the following customers:

1. Jointly-owned generators whose output is shared by several entities. At the written request of all entities who jointly own the generator's output, WACM will accept allocations of the generation among the participants. In this situation, a participant's share of actual generation will be included in its separate Energy Imbalance calculation.

2. Intermittent generators. At the written request of the customer, WACM will include the intermittent generator(s) in the customer's Energy Imbalance calculation. The customer makes this choice with the understanding that the intermittent generator will be subject to 3rd band (25 percent) penalties (see formula rate details below).

3. Non-intermittent generators serving load only outside WACM.

An entity's solely-owned non-intermittent generator serving load inside WACM will be included in its Energy Imbalance Service calculation.

WACM will provide Generator Imbalance Service using a penalty and bandwidth structure with three deviation bands as follows:

1. An imbalance of less than or equal to 1.5 percent of metered generation (or 4 MW, whichever is greater) for any hour is settled financially at 100 percent of the WACM weighted average hourly price.

2. An imbalance between 1.5 percent and 7.5 percent of metered generation (or 4 to 10 MW, whichever is greater) for any hour is settled financially at 90 percent of the WACM weighted average hourly price when actual generation exceeds scheduled generation or 110 percent of the WACM weighted average hourly price when actual generation is less than scheduled generation.

3. An imbalance greater than 7.5 percent of metered generation (or 10

MW, whichever is greater) for any hour is settled financially at 75 percent of the WACM weighted average hourly price when actual generation exceeds scheduled generation or 125 percent of the WACM weighted average hourly price when actual generation is less than scheduled generation.

Intermittent generators will be exempt from the 25 percent penalty band. All imbalances greater than 1.5 percent of metered generation for an intermittent generator will be subject only to a 10 percent penalty.

The features of Energy Imbalance Service described above under Aggregate Imbalance, Pricing, and Settlement, Expansion of the Bandwidth, and Balancing Authority Operating Constraints, also apply to Generator Imbalance Service.

*Penalty Elimination*

In any hour, Western will charge a customer a penalty for either Generator Imbalance Service or Energy Imbalance Service, but not both, unless the imbalances aggravate rather than offset each other. In an hour in which penalties on offsetting imbalances would exist based on the separate imbalance calculations, Western will remove the penalty from the Generator Imbalance calculation. There will be no penalty elimination for jointly-owned generators whose participants have a separate Energy Imbalance calculation.

*Administrative Charge*

In the Notice of Proposed Rates (76 FR 5148), Western proposed to assess an administrative charge on each monthly settlement under both Energy Imbalance and Generator Imbalance Services. After further analysis and customer input, Western has decided not to implement an administrative charge under either service.

**Operating Reserve—Spinning and Supplemental**

WACM has no long-term Reserves available for sale. At a customer's request, WACM will purchase and pass through the cost of Reserves and any activation energy, plus a fee for administration. For all Reserves purchased, the customer will be responsible for providing the transmission to deliver the Reserves.

**Ancillary Services Comments**

Western received one written comment concerning the Ancillary Services during the public consultation and comment period. This comment has been paraphrased where appropriate, without compromising the meaning of the comment.

*Comment:* The customer requested that, for Regulation Service, rather than requiring an intermittent generator that exports its output to dynamically meter or dynamically schedule the generation out of WACM, Western open communications to pursue other options to avoid this requirement. The customer expressed concern about the cost of implementing this requirement and the effects the unexpected costs will have on member municipalities and their customers. The customer also noted that these additional costs were not known at the inception of its existing projects when cost analyses were being performed.

*Response:* Western thanks the customer for its comment. As noted above under Regulation and Frequency Response Service (Alternative Arrangements), Western has included as a part of the Regulation Service rate schedule, a condition under which an exporting intermittent generator will not have to be dynamically removed from WACM. Under this condition, the entity must make arrangements, satisfactory to Western, to acquire Regulation and Frequency Response Service from a third party or self-supply it. Western believes that this is a reasonable requirement that will not place an undue burden on existing or potential customers who will export intermittent generation from WACM, but will support the concept in Western's Tariff that WACM is required to provide Ancillary Services only for Load-Serving Entities.

**Availability of Information**

All brochures, studies, comments, letters, memorandums, or other documents that Western used to develop the Provisional Formula Rates are available for inspection and copying at the Rocky Mountain Regional Office, located at 5555 East Crossroads Boulevard, Loveland, Colorado. Many of these documents and supporting information are also available on Western's Web site under the ''2012 Rate Adjustment—Transmission and Ancillary Services'' section located at *http://www.wapa.gov/rm/ratesRM/2012/default.htm.*

**Ratemaking Procedure Requirements**

*Environmental Compliance*

In compliance with the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 et seq.), Council on Environmental Quality Regulations (40 CFR parts 1500–1508), and DOE NEPA Regulations (10 CFR part 1021), Western has determined that this action is categorically excluded from preparing an environmental assessment or an environmental impact statement.

*Determination Under Executive Order 12866*

Western has an exemption from centralized regulatory review under Executive Order 12866; accordingly, no clearance of this notice by the Office of Management and Budget is required.

*Submission to the Federal Energy Regulatory Commission*

The formula rates herein confirmed, approved, and placed into effect on an interim basis, together with supporting documents, will be submitted to FERC for confirmation and final approval.

**Order**

In view of the foregoing, and under the authority delegated to me, I confirm and approve on an interim basis, effective on the first full billing period on or after October 1, 2011, formula rates for Loveland Area Projects Transmission and Western Area Colorado Missouri Balancing Authority Ancillary Services under Rate Schedules L–NT1, L–FPT1, L–NFPT1, L–AS1, L–AS2, L–AS3, L–AS4, L–AS5, L–AS6, L–AS7, L–AS9, and L–UU1. By this order, I am placing the rates into effect in less than 30 days to meet contract deadlines, to avoid financial difficulties, and to provide rates for new services. These rate schedules shall remain in effect on an interim basis, pending FERC's confirmation and approval of them or substitute formula rates on a final basis through September 30, 2016.

Dated: September 2, 2011.

Daniel B. Poneman,

*Deputy Secretary.*

**Rate Schedule L–AS1**

**Schedule 1 to Tariff**

**October 1, 2011**

**United States Department of Energy**

**Western Area Power Administration**

**Rocky Mountain Region**

**Western Area Colorado Missouri Balancing Authority**

**Scheduling, System Control, and Dispatch Service**

*Applicable*

Scheduling, System Control, and Dispatch Service is required to schedule the movement of power into, out of, inside, or through the Western Area Colorado Missouri Balancing Authority (WACM). This service must be purchased from the WACM operator. The rate will be applied to all

schedules, except those for the delivery of transmission losses to WACM.

Unless other arrangements are made with Western, the rate will be divided equally among the transmission providers displayed in the schedule that are inside WACM. The charges applicable to non-Federal transmission will be assessed to those transmission providers. The charges applicable to Federal transmission will be included in the Federal transmission service rates.

WACM will accept any number of scheduling changes over the course of the day without any additional charge.

*Effective*

The first day of the first full billing period beginning on or after October 1, 2011, through September 30, 2016.

*Formula Rate*

$$\text{Rate per Schedule} = \frac{\text{Annual Cost of Scheduling Personnel and Related Costs}}{\text{Number of Schedules per Year, excluding schedules for Delivery of Losses to WACM}}$$

*Rate*

The rate to be in effect October 1, 2011, through September 30, 2012, is $24.22 per schedule per day. A revised rate will go into effect October 1 of each year of the effective rate period based on the formula above and updated financial and schedule data. Western will notify the Customer annually of the revised rate before October 1.

Any change to the rate for Scheduling, System Control, and Dispatch Service will be listed in a revision to this rate schedule issued under applicable Federal laws, regulations, and policies and made part of the applicable service agreement.

**Rate Schedule L–AS2**

**Schedule 2 to Tariff**

**October 1, 2011**

**United States Department of Energy**

**Western Area Power Administration**

**Rocky Mountain Region**

**Western Area Colorado Missouri Balancing Authority**

**Reactive Supply and Voltage Control from Generation or Other Sources Service**

*Applicable*

To maintain transmission voltages on all transmission facilities within acceptable limits, generation facilities under the control of the Western Area Colorado Missouri Balancing Authority (WACM) are operated to produce or absorb reactive power. Thus, Reactive Supply and Voltage Control from Generation or Other Sources Service (VAR Support Service) is provided for each transaction on the transmission facilities. The amount of VAR Support Service supplied to the Customer's (Federal Transmission Customers and customers on others' transmission systems inside WACM) transactions will be based on the VAR Support Service necessary to maintain transmission voltages within limits that are generally accepted in the region and consistently adhered to by WACM. The Customer must purchase this service from the WACM operator.

Customers with generators providing WACM with VAR Support Service may be excluded from the application of this rate. Any such exclusion must be documented in the Customer's service agreement.

*Effective*

The first day of the first full billing period beginning on or after October 1, 2011, through September 30, 2016.

*Formula Rate*

Total Annual Revenue Requirement for Generation = TARRG

Percentage of Resource Capacity Used for VAR Support Service = % of Resource

$$\text{VAR Support Rate} = \frac{\text{TARRG x \% of Resource}}{\text{Load in WACM Requiring VAR Support Service}}$$

*Rate*

The rate to be in effect October 1, 2011, through September 30, 2012, is:

| | |
|---|---|
| Monthly | $0.305/kW-month |
| Weekly | $0.070/kW-week |
| Daily | $0.010/kW-day |
| Hourly | $0.000418/kWh |

A revised rate will go into effect October 1 of each year of the effective rate period based on the formula above and updated financial and load data. Western will notify the Customer annually of the revised rate before October 1.

Any change to the rate for VAR Support Service will be listed in a revision to this rate schedule issued under applicable Federal laws, regulations, and policies and made part of the applicable service agreement.

**Rate Schedule L–AS3**

**Schedule 3 to Tariff**

**October 1, 2011**

**United States Department of Energy**

**Western Area Power Administration**

**Rocky Mountain Region**

**Western Area Colorado Missouri Balancing Authority**

**Regulation and Frequency Response Service**

*Applicable*

Regulation and Frequency Response Service (Regulation Service) is necessary to provide for the continuous balancing of resources with obligations, and for maintaining scheduled interconnection frequency at sixty cycles per second (60 Hz). Regulation Service is accomplished by committing on-line generation whose output is raised or lowered as necessary, predominantly through the use of automatic generation control (AGC) equipment, to follow the moment-by-moment changes in load. The obligation to maintain this balance between resources and load lies with the Western Area Colorado Missouri Balancing Authority (WACM) operator. Customers (Federal Transmission Customers and customers on others' transmission systems inside WACM) must purchase this service from WACM or make alternative comparable arrangements to satisfy their Regulation Service obligations.

*Types*

There are two different applications of this Formula Rate:

1. *Load-based Assessment:* The rate for the load-based assessment is reflected in the Formula Rate section and is applied to entities that take Regulation Service from WACM. This load-based rate is assessed on an entity's auxiliary load (total metered load less Federal entitlements) and is also applied to the installed nameplate capacity of all intermittent generators serving load inside WACM.

2. *Self-provision Assessment:* Western allows entities with AGC to self-provide for all or a portion of their loads. Entities with AGC are known as Sub-Balancing Authorities (SBA) and must meet all of the following criteria:

a. Have a well-defined boundary, with WACM-approved revenue-quality metering, accurate as defined by the North American Electric Reliability Corporation (NERC), to include MW flow data availability at 6-second or smaller intervals;

b. Have AGC capability;

c. Demonstrate Regulation Service capability; and

d. Execute a contract with WACM:

i. Provide all requested data to WACM.

ii. Meet SBA error criteria as described under section 2.1 below.

2.1. Self-provision is measured by use of the entity's 1-minute average Area Control Error (ACE) to determine the amount of self-provision. The ACE is used to calculate the Regulation Service charges every hour as follows:

a. If the entity's 1-minute average ACE for the hour is less than or equal to 0.5 percent of its hourly average load, no Regulation Service charge is assessed by WACM for that hour.

b. If the entity's 1-minute average ACE for the hour is greater than or equal to 1.5 percent of its hourly average load, WACM assesses Regulation Service charges to the entity's entire auxiliary load, using the hourly Load-based Assessment applied to the entity's auxiliary 12-cp load for that month.

c. If the entity's 1-minute average ACE for the hour is greater than 0.5 percent of its hourly average load, but less than 1.5 percent of its hourly average load, WACM assesses Regulation Service charges based on linear interpolation of zero charge and full charge, using the hourly Load-based Assessment applied to the entity's auxiliary 12-cp load for that month.

d. Western monitors the entity's Self-provision on a regular basis. If Western determines that the entity has not been attempting to self-regulate, WACM will, upon notification, employ the Load-based Assessment described in No. 1, above.

*Alternative Arrangements*

Exporting Intermittent Resource Requirement: An entity that exports the output from an intermittent generator to another balancing authority will be required to dynamically meter or dynamically schedule that resource out of WACM to another balancing authority unless arrangements, satisfactory to Western, are made for that entity to acquire this service from a third party or self-supply (as outlined below). An intermittent generator is one that is volatile and variable due to factors beyond direct operational control and, therefore, is not dispatchable.

Self- or Third-party supply: Western may allow an entity to supply some or all of its required regulation, or contract with a third party to do so, even without well-defined boundary metering. This entity must have revenue quality metering at every load and generation point, accurate as defined by NERC, to include MW flow data availability at 6-second or smaller intervals. Western will evaluate the entity's metering, telecommunications and regulating resource, as well as the required level of regulation, and determine whether the entity qualifies to self-supply under this provision. If approved, the entity is required to enter into a separate agreement with Western which will specify the terms of the self-supply application.

*Customer Accommodation*

For entities unwilling to take Regulation Service, self-provide it as described above, or acquire the service from a third party, Western will assist the entity in dynamically metering its loads/resources to another balancing authority. Until such time as that meter configuration is accomplished, the entity will be responsible for charges assessed by WACM under the rate in effect.

*Effective*

The first day of the first full billing period beginning on or after October 1, 2011, through September 30, 2016.

*Formula Rate*

$$\text{Regulation Service Rate} = \frac{\text{Total Annual Revenue Requirement for Regulation Service}}{\text{Load inside WACM Requiring Regulation Service Plus the Installed Nameplate Capacity of Intermittent Generators Serving Load Inside WACM}}$$

*Rate*

The rate to be in effect October 1, 2011, through September 30, 2012, for Nos. 1 and 2, as described above in the ''Types'' section of this rate schedule, is:

| | |
|---|---|
| Monthly | $0.331/kW-month |
| Weekly | $0.076/kW-week |
| Daily | $0.011/kW-day |
| Hourly | $0.000458/kWh |

A revised rate will go into effect October 1 of each year of the effective rate period based on the formula above and updated financial and load data. Western will notify the Customer annually of the revised rate before October 1.

Any change to the rate for Regulation Service will be listed in a revision to this rate schedule issued under applicable Federal laws, regulations, and policies and made part of the applicable service agreement.

**Rate Schedule L–AS4**

**Schedule 4 to Tariff**

**October 1, 2011**

**United States Department of Energy**

**Western Area Power Administration**

**Rocky Mountain Region**

**Western Area Colorado Missouri Balancing Authority**

**Energy Imbalance Service**

*Applicable*

The Western Area Colorado Missouri Balancing Authority (WACM) provides Energy Imbalance Service when there is a difference between a Customer's (Federal Transmission Customers and customers on others' transmission systems inside WACM) resources and obligations. Energy Imbalance is calculated as resources minus obligations (adjusted for transmission and transformer losses) for any combination of generation, scheduled transfers, transactions, or actual load integrated over each hour. Customers inside WACM must either obtain this service from WACM or make alternative comparable arrangements to satisfy their Energy Imbalance Service obligation. This rate applies to all customers with load inside WACM.

*Effective*

The first day of the first full billing period beginning on or after October 1, 2011, through September 30, 2016.

*Formula Rate*

Imbalances are calculated in three deviation bands as follows. The term ''metered load'' is defined to be ''metered load adjusted for losses.''

1. An imbalance of less than or equal to 1.5 percent of metered load (or 4 MW, whichever is greater) for any hour is settled financially at 100 percent of the WACM weighted average hourly price.

2. An imbalance between 1.5 percent and 7.5 percent of metered load (or 4 to 10 MW, whichever is greater) for any hour is settled financially at 90 percent of the WACM weighted average hourly price when net energy scheduled exceeds metered load or 110 percent of the WACM weighted average hourly price when net energy scheduled is less than metered load.

3. An imbalance greater than 7.5 percent of metered load (or 10 MW, whichever is greater) for any hour is settled financially at 75 percent of the WACM weighted average hourly price when net energy scheduled exceeds metered load or 125 percent of the WACM weighted average hourly price when net energy scheduled is less than metered load.

All Energy Imbalance Service provided by WACM is accounted for hourly and settled financially. The WACM aggregate imbalance determines the pricing used in all deviation bands. A surplus dictates the use of sale pricing; a deficit dictates the use of purchase pricing. When no hourly data is available, the pricing defaults for sales and purchase pricing are applied in the following order:

1. Weighted average sale or purchase pricing for the day (on- and off-peak).

2. Weighted average sale or purchase pricing for the month (on- and off-peak).

3. Weighted average sale or purchase pricing for the prior month (on- and off-peak).

4. Weighted average sale or purchase pricing for the month prior to the prior month (and continuing until sale or purchase pricing is located) (on- and off-peak).

Expansion of the bandwidth may be allowed during the following instances:

- Response to the loss of a physical resource.
- During transition of large base-load thermal resources (capacity greater than 200 MW) between off-line and on-line following a reserve sharing group response, when the unit generates less than the predetermined minimum scheduling level.

During periods of balancing authority operating constraints, Western reserves the right to eliminate credits for over-deliveries. The cost to Western of any penalty assessed by a regulatory authority due to a violation of operating standards resulting from under- or over-delivery of energy may be passed through to Energy Imbalance Service customers.

*Rate*

The bandwidths, penalties, and pricing described above are in effect October 1, 2011, through September 30, 2012.

Any change to the rate for Energy Imbalance Service will be listed in a revision to this rate schedule issued under applicable Federal laws, regulations, and policies and made part of the applicable service agreement.

**Rate Schedule L–AS5**

**Schedule 5 to Tariff**

**October 1, 2011**

**United States Department of Energy**

**Western Area Power Administration**

**Rocky Mountain Region**

**Western Area Colorado Missouri Balancing Authority**

**Operating Reserve—Spinning Reserve Service**

*Applicable*

Spinning Reserve Service (Reserves) is needed to serve load immediately in the event of a system contingency. Reserves may be provided by generating units that are on-line and loaded at less than maximum output. The Customers (Federal Transmission Customers and customers on others' transmission system inside Western Area Colorado Missouri Balancing Authority (WACM)) must either purchase this service from WACM or make alternative comparable arrangements to satisfy their Reserves obligation.

*Effective*

The first day of the first full billing period beginning on or after October 1, 2011, through September 30, 2016.

*Formula Rate*

WACM has no long-term Reserves available for sale. At a Customer's request, WACM will purchase Reserves and pass through the cost of Reserves and any activation energy, plus a fee for administration. The Customer will be responsible for providing the transmission to deliver the Reserves.

**Rate Schedule L–AS6**

**Schedule 6 to Tariff**

**October 1, 2011**

**United States Department of Energy**

**Western Area Power Administration**

**Rocky Mountain Region**

**Western Area Colorado Missouri Balancing Authority**

**Operating Reserve—Supplemental Reserve Service**

*Applicable*

Supplemental Reserve Service (Reserves) is needed to serve load in the event of a system contingency; however, it is not available immediately to serve load but rather within a short period of time. Reserves may be provided by generating units that are on-line but unloaded, by quick-start generation, or by interruptible load. The Customers (Federal Transmission Customers and customers on others' transmission system inside Western Area Colorado Missouri Balancing Authority (WACM)) must either purchase this service from WACM or make alternative comparable arrangements to satisfy their Reserves obligation.

*Effective*

The first day of the first full billing period beginning on or after October 1, 2011, through September 30, 2016.

*Formula Rate*

WACM has no long-term Reserves available for sale. At a Customer's request, WACM will purchase Reserves and pass through the cost of Reserves and any activation energy, plus a fee for administration. The Customer will be responsible for providing the transmission to deliver the Reserves.

**Rate Schedule L–AS7**

**October 1, 2011**

**United States Department of Energy**

**Western Area Power Administration**

**Rocky Mountain Region**

**Western Area Colorado Missouri Balancing Authority**

**Transmission Losses Service**

*Applicable*

The Western Area Colorado Missouri Balancing Authority (WACM) provides Transmission Losses Service to all Transmission Service Providers who market transmission inside WACM. The loss factor currently in effect is posted on the Rocky Mountain Region (RMR) Open Access Same-Time Information System (OASIS) Web site.

*Effective*

The first day of the first full billing period beginning on or after October 1, 2011, through September 30, 2016.

*Formula Rate*

Transmission Losses are assessed for all real-time and prescheduled transactions on transmission facilities inside WACM. The Customer is allowed the option of energy repayment or financial repayment. Energy repayment may be either concurrently or seven days later, to be delivered using the same profile as the related transmission transaction. Customers must declare annually their preferred methodology of energy payback.

When a transmission loss energy obligation is not provided (or is under-provided) by a Customer for a transmission transaction, the energy still owed for Transmission Losses is calculated and a charge is assessed to the Customer, based on the WACM weighted average hourly purchase price.

Pricing for loss energy due 7 days later, and not received by WACM, will be priced at the 7-day-later-price based on the WACM weighted average hourly purchase price.

There will be no financial compensation or energy return to Customers for over-delivery of Transmission Losses, as there should be no condition beyond the control of the Customer that results in overpayment.

*Rate*

This loss factor, as posted on the RMR OASIS, is in effect October 1, 2011, through September 30, 2012. Customers may settle financially or with energy. The pricing for this service will be the WACM weighted average hourly purchase price. When no hourly data is available, pricing defaults will be applied in the following order:

1. Weighted average purchase pricing for the day (on- and off-peak).

2. Weighted average purchase pricing for the current month (on- and off-peak).

3. Weighted average purchase pricing for the prior month (on- and off-peak).

4. Weighted average purchase pricing for the month prior to the prior month (and continuing until or purchase pricing is located) (on- and off-peak).

Any change to the rate for Transmission Losses Service will be listed in a revision to this rate schedule issued under applicable Federal laws, regulations, and policies and made part of the applicable service agreement.

**Rate Schedule L–FPT1**

**Schedule 7 to Tariff**

**October 1, 2011**

**United States Department of Energy**

**Western Area Power Administration**

**Rocky Mountain Region**

**Loveland Area Projects**

**Long-Term Firm and Short-Term Firm Point-To-Point Transmission Service**

*Applicable*

The Transmission Customer shall compensate the Loveland Area Projects (LAP) each month for Reserved Capacity under the applicable Firm Point-to-Point Transmission Service Agreement and the rate outlined herein.

*Discounts*

Three principal requirements apply to discounts for transmission service as follows: (1) Any offer of a discount made by LAP must be announced to all eligible customers solely by posting on the Rocky Mountain Region's Open Access Same-Time Information System web site (OASIS); (2) any customer-initiated requests for discounts, including requests for use by the LAP merchant, must occur solely by posting on the OASIS; and (3) once a discount is negotiated, details must be immediately posted on the OASIS. For any discount agreed upon for service on a path, from Point(s) of Receipt to Point(s) of Delivery, LAP must offer the same discounted transmission service rate for the same time period to all eligible customers on all unconstrained transmission paths that go to the same point(s) of delivery on the transmission system.

*Effective*

The first day of the first full billing period beginning on or after October 1, 2011, through September 30, 2016.

*Formula Rate*

$$\text{Firm Point-to-Point Transmission Rate} = \frac{\text{Annual Transmission Revenue Requirement}}{\text{LAP Transmission System Total Load}}$$

*Rate*

The rate to be in effect October 1, 2011, through September 30, 2012, is:

| | Maximum of |
|---|---|
| Yearly | $41.80/kW of reserved capacity per year |
| Monthly | $3.48/kW of reserved capacity per month |
| Weekly | $0.80/kW of reserved capacity per week |
| Daily | $0.11/kW of reserved capacity per day |

A revised rate will go into effect October 1 of each year of the effective rate period based on the formula above, updated financial and load projections, and the true-up of previous projections. Western will notify the Transmission Customer annually of the revised rate before October 1.

Any change to the rate for Long-Term Firm and Short-Term Firm Transmission Service will be listed in a revision to this rate schedule issued under applicable Federal laws, regulations, and policies and made part of the applicable service agreement.

**Rate Schedule L–NFPT1**

**Schedule 8 to Tariff**

**October 1, 2011**

**United States Department of Energy**

**Western Area Power Administration**

**Rocky Mountain Region**

**Loveland Area Projects**

**Non-Firm Point-To-Point Transmission Service**

*Applicable*

The Transmission Customer will compensate Loveland Area Projects (LAP) for Non-Firm Point-to-Point Transmission Service under the applicable Non-Firm Point-to-Point Transmission Service Agreement and the rate outlined herein.

*Discounts*

Three principal requirements apply to discounts for transmission service as follows: (1) Any offer of a discount made by LAP must be announced to all eligible customers solely by posting on Rocky Mountain Region's Open Access Same-Time Information System web site (OASIS); (2) any customer-initiated requests for discounts, including requests for use by the LAP merchant, must occur solely by posting on the OASIS; and (3) once a discount is negotiated, details must be immediately posted on the OASIS. For any discount agreed upon for service on a path, from Point(s) of Receipt to Point(s) of Delivery, LAP must offer the same discounted transmission service rate for the same time period to all eligible customers on all unconstrained transmission paths that go to the same point(s) of delivery on the transmission system.

*Effective*

The first day of the first full billing period beginning on or after October 1, 2011, through September 30, 2016.

*Formula Rate*

$$\text{Maximum Non-Firm Point-to-Point Transmission Rate} = \text{Firm Point-to-Point Transmission Rate}$$

*Rate*

The rate to be in effect October 1, 2011, through September 30, 2012, is:

| | Maximum of |
|---|---|
| Yearly | $41.80/kW of reserved capacity per year |
| Monthly | $3.48/kW of reserved capacity per month |
| Weekly | $0.80/kW of reserved capacity per week |
| Daily | $0.11/kW of reserved capacity per day |
| Hourly | 4.77 mills/kWh |

A revised rate will go into effect October 1 of each year of the effective rate period based on the formula above, updated financial and load projections, and the true-up of previous projections. Western will notify the Transmission Customer annually of the revised rate before October 1.

Any change to the rate for Non-Firm Point-to-Point Transmission Service will be listed in a revision to this rate schedule issued under applicable Federal laws, regulations, and policies and made part of the applicable service agreement.

**Rate Schedule L–NT1**

**Schedule H to Tariff**

**October 1, 2011**

**United States Department of Energy**

**Western Area Power Administration**

**Rocky Mountain Region**

**Loveland Area Projects**

**Annual Transmission Revenue Requirement for Network Integration Transmission Service**

*Applicable*

Transmission Customers will compensate the Loveland Area Projects each month for Network Integration Transmission Service under the applicable Network Integration Transmission Service Agreement and the Annual Transmission Revenue Requirement described herein.

*Effective*

The first day of the first full billing period beginning on or after October 1, 2011, through September 30, 2016.

*Formula Rate*

$$\text{Monthly Charge} = \text{Transmission Customer's Load-Ratio Share} \times \frac{\text{Annual Transmission Revenue Requirement}}{12}$$

*Rate*

The Annual Transmission Revenue Requirement in effect October 1, 2011, through September 30, 2012, is $56,775,913.

A revised Annual Transmission Revenue Requirement will go into effect October 1 of each year of the effective rate period based on updated financial projections and the true-up of previous projections. Western will notify the Transmission Customer annually of the revised Annual Transmission Revenue Requirement before October 1.

Any change to the rate for Network Integration Transmission Service will be listed in a revision to this rate schedule issued under applicable Federal laws, regulations, and policies and made part of the applicable service agreement.

**Rate Schedule L–AS9**

**Schedule 9 to Tariff**

**October 1, 2011**

**United States Department of Energy**

**Western Area Power Administration**

**Rocky Mountain Region**

**Western Area Colorado Missouri Balancing Authority**

**Generator Imbalance Service**

*Applicable*

The Western Area Colorado Missouri (WACM) Balancing Authority provides Generator Imbalance Service when there is a difference between a Customer's (Federal Transmission Customers and customers on others' transmission systems inside WACM) resources and obligations. Generator Imbalance is calculated as actual generation minus scheduled generation for each hour. Customers inside WACM must either obtain this service from WACM or make alternative comparable arrangements to satisfy their Generator Imbalance Service obligation. This rate applies to all jointly-owned generators (unless arrangements are made to allocate actual generation to each individual owner), intermittent generators (unless arrangements are made to assess the intermittent generator under Rate Schedule L–AS4), and any non-intermittent generators serving load only outside WACM.

*Effective*

The first day of the first full billing period beginning on or after October 1, 2011, through September 30, 2016.

*Formula Rate*

Imbalances are calculated in three deviation bands as follows:

1. An imbalance of less than or equal to 1.5 percent of metered generation (or 4 MW, whichever is greater) for any hour is settled financially at 100 percent of the WACM weighted average hourly price.

2. An imbalance between 1.5 percent and 7.5 percent of metered generation (or 4 to 10 MW, whichever is greater) for any hour is settled financially at 90 percent of the WACM weighted average hourly price when actual generation exceeds scheduled generation or 110 percent of the WACM weighted average hourly price when actual generation is less than scheduled generation.

3. An imbalance greater than 7.5 percent of metered generation (or 10 MW, whichever is greater) for any hour is settled financially at 75 percent of the WACM weighted average hourly price when actual generation exceeds scheduled generation or 125 percent of the WACM weighted average hourly price when actual generation is less than scheduled generation.

Intermittent generators are exempt from 25 percent penalties. All imbalances greater than 1.5 percent of metered generation are subject only to a 10 percent penalty.

All Generator Imbalance Service provided by WACM is accounted for hourly and settled financially. The WACM aggregate imbalance determines the pricing used in all deviation bands. A surplus dictates the use of sale pricing; a deficit dictates the use of purchase pricing. When no hourly data is available, the pricing defaults for sales and purchase pricing are applied in the following order:

1. Weighted average sale or purchase pricing for the day (on- and off-peak).

2. Weighted average sale or purchase pricing for the current month (on- and off-peak).

3. Weighted average sale or purchase pricing for the prior month (on- and off-peak).

4. Weighted average sale or purchase pricing for the month prior to the prior month (and continuing until sale or purchase pricing is located) (on- and off-peak).

Expansion of the bandwidth may be allowed during the following instances:

- Response to the loss of a physical resource.
- During transition of large base-load thermal resources (capacity greater than 200 MW) between off-line and on-line following a reserve sharing group response, when the unit generates less than the predetermined minimum scheduling level.

During periods of balancing authority operating constraints, Western reserves the right to eliminate credits for over-deliveries. The cost to Western of any penalty assessed by a regulatory authority due to a violation of operating standards resulting from under- or over-delivery of energy may be passed through to Generator Imbalance Service customers.

*Rate*

The bandwidths, penalties, and pricing described above are in effect October 1, 2011, through September 30, 2012.

Any change to the rate for Generator Imbalance Service will be listed in a revision to this rate schedule issued under applicable Federal laws, regulations, and policies and made part of the applicable service agreement.

**Rate Schedule L–UU1**

**Schedule 10 to Tariff**

**October 1, 2011**

**United States Department of Energy**

**Western Area Power Administration**

**Rocky Mountain Region**

**Loveland Area Projects**

**Unreserved Use Penalties**

*Applicable*

The Transmission Customer shall compensate the Loveland Area Projects (LAP) each month for any unreserved use of the transmission system (Unreserved Use) under the applicable transmission service rates as outlined herein. Unreserved Use occurs when an eligible customer uses transmission service that it has not reserved or a Transmission Customer uses transmission service in excess of its reserved capacity. Unreserved Use may also include a Customer's failure to curtail transmission when requested.

*Penalty Rate*

The penalty rate for a Transmission Customer that engages in Unreserved Use is 200 percent of LAP's approved rate for firm point-to-point transmission service assessed as follows: the Unreserved Use Penalty for a single hour of Unreserved Use is based upon the rate for daily firm point-to-point service. The Unreserved Use Penalty for more than one assessment for a given duration (e.g., daily) increases to the next longest duration (e.g., weekly). The Unreserved Use Penalty for multiple instances of Unreserved Use (e.g., more than one hour) within a day is based on the rate for daily firm point-to-point service. The Unreserved Use Penalty for multiple instances of Unreserved Use isolated to one calendar week is based on the rate for weekly firm point-to-point service. The Unreserved Use Penalty for multiple instances of Unreserved Use during more than one week in a calendar month is based on the rate for monthly firm point-to-point service.

A Transmission Customer that exceeds its firm reserved capacity at any point of receipt or point of delivery, or an eligible customer that uses transmission service at a point of receipt or point of delivery that it has not reserved, is required to pay for all ancillary services that were provided by the Western Area Colorado Missouri Balancing Authority and associated with the Unreserved Use. The Customer will pay for ancillary services based on the amount of transmission service it used and did not reserve.

*Effective*

The first day of the first full billing period beginning on or after October 1, 2011, through September 30, 2016.

*Rate*

The rate for Unreserved Use Penalties is 200 percent of LAP's approved rate for firm point-to-point transmission service assessed as described above.

Any change to the rate for Unreserved Use Penalties will be listed in a revision to this rate schedule issued under applicable Federal laws, regulations, and policies and made part of the applicable service agreement.

[FR Doc. 2011–23391 Filed 9–12–11; 8:45 am]

**Editorial Note:** FR Doc. 2011–23391 which was originally published on pages 56433–56452 in the issue of Tuesday, September 13, 2011 is being republished in its entirety in the issue of Monday, October 3, 2011 because of editing errors.

[FR Doc. R1–2011–23391 Filed 9–30–11; 8:45 am]

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# FEDERAL REGISTER

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Part IV

## Department of Health and Human Services

42 CFR Part 73
Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review; Proposed Rule

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

**[Docket No. CDC–2011–0012]**

**42 CFR Part 73**

**RIN 0920–AA34**

## Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Proposed rule.

**SUMMARY:** In accordance with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Response Act), the Centers for Disease Control and Prevention (CDC) located within the Department of Health and Human Services (HHS) has reviewed the list of biological agents and toxins that have the potential to pose a severe threat to public health and safety and is proposing to amend and republish the list as required by the Bioterrorism Response Act. Further, on July 2, 2010, the President signed Executive Order 13546, ''Optimizing the Security of Biological Select Agents and Toxins in the United States'' that directed the Secretaries of HHS and Agriculture (USDA) to designate a subset of the select agents and toxins list (Tier 1) that presents the greatest risk of deliberate misuse with the most significant potential for mass casualties or devastating effects to the economy, critical infrastructure; or public confidence; explore options for graded protection for these Tier 1 agents and toxins to permit tailored risk management practices based upon relevant contextual factors; and consider reducing the overall number of agents and toxins on the select agents and toxins list. E.O. 13546 also established the Federal Experts Security Advisory Panel (FESAP) to advise the HHS and USDA Secretaries on the designation of Tier 1 agents and toxins, reduction in the number of agents on the Select Agent List, establishment of suitability standards for those having access to Tier 1 select agents and toxins, and establishment of physical security and information security standards for Tier 1 select agents and toxins. The tiering of the select agents and toxins list will allow the application of more optimized security measures for those select agents or toxins which pose a higher risk to public health and safety should they be stolen or otherwise misused.

In addition to addressing the FESAP recommendations in this Notice of Proposed Rulemaking (NPRM), we are also proposing to add two agents, Lujo and Chapare viruses to the list; adding definitions; and clarifying language concerning security, training, biosafety, and incident response. These changes will increase the usability of the select agents and toxins regulations as well as providing for enhanced program oversight.

**DATES:** Comments should be received on or before December 2, 2011.

**ADDRESSES:** You may submit comments, identified by Regulatory Information Number (RIN), 0920–AA34 in the heading of this document by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Centers for Disease Control and Prevention, Select Agent Program, 1600 Clifton Road, NE., Mailstop A–46, Atlanta, Georgia 30333, *Attn:* RIN 0920–AA34.

*Instructions:* All submissions received must include the agency name and RIN for this rulemaking. All relevant comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

*Docket Access:* For access to the docket to read background documents or comments received or to download an electronic version of the NPRM, go to *http://www.regulations.gov.* Comments will be available for public inspection Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m. at 1600 Clifton Road, NE., Atlanta, GA 30333. Please call ahead to 1–866–694–4867 and ask for a representative in the Division of Select Agents and Toxins to schedule your visit. Our general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet as they are received and without change.

**FOR FURTHER INFORMATION CONTACT:** Robbin Weyant, Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mailstop A–46, Atlanta, Georgia 30333. *Telephone:* (404) 718–2000.

**SUPPLEMENTARY INFORMATION:** The Preamble to this notice of proposed rulemaking is organized as follows:

I. Background
II. Proposed Changes to 42 CFR Part 73, Including Responses to Comments to the ANPRM
A. Modifications to the List of HHS Select Agents and Toxins
B. Modifications to the List of Overlap Select Agents and Toxins
C. Tiering
D. Responses to Other Comments and Other Proposed Changes
i. Exclusions
ii. Security
iii. Select Agent Inventory
iv. Definitions
v. Recombinant/Synthetic Nucleic Acids
vi. Toxins
vii. Responsible Official
viii. Access to Select Agents and Toxins
ix. Security Plan
x. Biosafety Plans
xi. Restricted Experiments
xii. Incident Response
xiii. Training
xiv. Transfers
xv. Records
xvi. Administrative Review
xvii. Guidance Documents
III. Required Regulatory Analyses
A. Executive Order 12866 and 13563
B. Regulatory Flexibility Act
C. Paperwork Reduction Act
D. Executive Order 12988: Civil Justice Reform
E. Executive Order 13132: Federalism
F. Plain Writing Act of 2010
IV. References

### I. Background

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Subtitle A (Department of Health and Human Services) of Title II (Enhancing Controls on Dangerous Biological Agents and Toxins) of Public Law 107–188 (June 12, 2002) (42 U.S.C. 262a) (the Bioterrorism Response Act), requires the HHS Secretary to establish by regulation a list of each biological agent and each toxin that has the potential to pose a severe threat to public health and safety. In determining whether to include an agent or toxin on the list, the HHS Secretary considers the effect on human health of exposure to an agent or toxin; the degree of contagiousness of the agent and the methods by which the agent or toxin is transferred to humans; the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent illnesses resulting from an agent or toxin; the potential for an agent or toxin to be used as a biological weapon; and the needs of children and other vulnerable populations. The current list of HHS select agents and toxins can be found at 42 CFR 73.3 (HHS select agents and toxins) and 42 CFR 73.4 (Overlap select agents and toxins). The list of HHS and Overlap select agents and toxins is available at: *http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html.* The Bioterrorism Response Act requires that the HHS Secretary review and republish the list of select

agents and toxins on at least a biennial basis. See 42 U.S.C. 262a(a)(2).

The HHS Secretary last republished the HHS select agents and toxins list in the **Federal Register** on October 16, 2008 (73 FR 61363). The HHS select agents and toxins list is divided into two sections. The select agents and toxins listed in § 73.3 (HHS select agents and toxins) are those regulated only by HHS under the authority of the Bioterrorism Response Act. The select agents and toxins listed in § 73.4 (Overlap select agents and toxins) are those regulated by HHS under the authority of the Bioterrorism Response Act and regulated by the USDA under the authority of the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. 8401).

To fulfill this statutory mandate, the Center for Disease Control and Prevention's (CDC) Division of Select Agents and Toxins (DSAT) initiated its biennial review process, which included consultation with CDC's Intragovernmental Select Agents and Toxins Technical Advisory Committee (ISATTAC) and other subject matter experts. The ISATTAC is comprised of Federal government employees from the CDC, the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the USDA/Animal and Plant Health Inspection Service (APHIS), USDA/Agricultural Research Service (ARS), USDA/CVB (Center for Veterinary Biologics), the Department of Homeland Security (DHS), the Department of Defense (DOD), and the Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response in HHS.

CDC also published an ANPRM in the **Federal Register** (75 FR 42363) (July 21, 2010 ANPRM) inviting comments concerning potential changes to part 73 of Title 42 of the Code of Federal Regulations (the select agent regulations). We solicited comments regarding (1) the appropriateness of the current HHS list of select agents and toxins; (2) whether there are other biological agents or toxins that should be added to the HHS list; (3) whether biological agents or toxins currently on the HHS list should be deleted from the list; (4) whether the HHS select agents and toxins list should be tiered based on the relative bioterrorism risk of each biological agent or toxin; and (5) whether the security requirements for select agents or toxins in the highest tier should be further stratified based on type of use or other factors. We requested recommendations regarding the criteria to use to designate high risk select agents and toxins and those recommendations were included in the interagency working group discussions on the matter. Relevant issues raised by the comments are discussed below in ''II. Proposed Changes to 42 CFR part 73.''

On July 2, 2010, President Obama signed Executive Order (E.O.) 13546: ''Optimizing the Security of Biological Select Agents and Toxins in the United States'' that directed the Secretaries of HHS and USDA to (1) designate a subset of the select agents and toxins list (Tier 1) that presents the greatest risk of deliberate misuse with the most significant potential for mass casualties or devastating effects to the economy, critical infrastructure; or public confidence; (2) explore options for graded protection of Tier 1 agents and toxins to permit tailored risk management practices based upon relevant contextual factors; and (3) consider reducing the overall number of agents and toxins on the select agents and toxins list. E.O. 13546 also established the FESAP to advise the HHS and USDA Secretaries on the designation of Tier 1 agents and toxins, reduction in the number of agents on the Select Agent List, establishment of personnel reliability standards for those having access to Tier 1 select agents and toxins, and establishment of physical security and information security standards for Tier 1 select agents and toxins. E.O. 13546 is available at: *http://edocket.access.gpo.gov/2010/pdf/2010-16864.pdf.* The FESAP provided its recommendations to the HHS and USDA Secretaries on November 2, 2010. The FESAP recommendations addressed the reduction of the list of select agents and toxins, the identification of a subset of the list that includes those that presents the greatest risk of deliberate misuse with the most significant potential for mass casualties or devastating effects to the economy, critical infrastructure; or public confidence; and the optimization of security programs at registered entities. In drafting its recommendations to modify and stratify the list of select agents and toxins, the FESAP utilized expert knowledge of the agents, combined with information from the DHS's Material Threat Determinations of biological agents and toxins. Care was used to balance risks identified with the Congressional mandate to ensure the availability of select agents and toxins for research and educational activities.

Other sources of input that we have considered in the drafting of this Proposed Rule include the following: The National Science Advisory Board for Biosecurity, the National Academies, and comments received from professional societies and the public in response to the CDC ANPRM published on July 21, 2010.

The purpose of this notice of proposed rulemaking is to seek public comment on (1) the appropriateness of the current HHS and Overlap list of select agents and toxins including whether there are other agents or toxins that should be added to the HHS or Overlap list or whether agents or toxins currently on the HHS or Overlap list should be deleted from the list; (2) the appropriateness of the proposed tiering of the select agents and toxins list; (3) whether minimum standards for personnel reliability, physical and cyber security should be prescribed for identified Tier 1 agents; and (4) any other aspect of the proposed amendments to the select agent regulations.

## II. Proposed Changes to 42 CFR Part 73

PROPOSED CHANGES TO 42 CFR PART 73

| Section No. | Current | Change |
|---|---|---|
| 73.0 | Applicability and related requirements | No change. |
| 73.1 | Definitions | Definitions added: Adjudicated as a mental defective; alien; committed to any mental institution; controlled substance; crime punishable by imprisonment for a term exceeding 1 year; indictment; information security; lawfully admitted for permanent residence; mental institution; occupational exposure; recombinant and synthetic nucleic acids; restricted person; unlawful use of any controlled substance. |
| 73.2 | Purpose and scope | No change. |
| 73.3 | HHS select agents and toxins | Designates Tier 1 select agents and toxins; adds select agents and toxins; clarifies language; deletes from the HHS list. |

PROPOSED CHANGES TO 42 CFR PART 73—Continued

| Section No. | Current | Change |
|---|---|---|
| 73.4 | Overlap select agents and toxins | Designates Tier 1 select agents and toxins; adds select agents and toxins; clarifies language; deletes from the overlap list. |
| 73.5 | Exemptions for HHS select agents and toxins. | Amends the immediate notification list to Tier 1 agents. |
| 73.6 | Exemptions for overlap select agents and toxins. | Amends the immediate notification list to Tier 1 agents. |
| 73.7 | Registration and related security risk assessments. | No change. |
| 73.8 | Denial, revocation, or suspension of registration. | Clarifies language. |
| 73.9 | Responsible Official | Redesignates paragraphs; adds new paragraphs (a)(3), (a)(6). |
| 73.10 | Restricting access to select agents and toxins; security risk assessments. | Redesignates paragraphs; adds new paragraph (e); adds clarifying language. |
| 73.11 | Security | Revises regulatory text—paragraph (b), (c)(2). Redesignates paragraphs; adds new paragraphs (c)(8), (c)(9), (c)(10), (e). |
| 73.12 | Biosafety | Revises paragraphs (a) and (c)(1); replaces ''url'' in paragraph (c)(3); redesignates paragraph (d); adds new paragraph (d). |
| 73.13 | Restricted experiments | Clarifies language. |
| 73.14 | Incident response | Redesignates paragraphs; adds new paragraphs (d) and (e). |
| 73.15 | Training | Revises paragraph (a); redesignates paragraphs; adds new paragraph (b). |
| 73.16 | Transfers | Redesignates paragraphs; adds new paragraphs (f), (h), (l). |
| 73.17 | Records | Revises paragraph (a)(1); redesignates paragraphs; adds new paragraph (a)(2). |
| 73.18 | Inspections | No changes. |
| 73.19 | Notification of theft, loss, or release | No changes. |
| 73.20 | Administrative review | Revises paragraphs. |
| 73.21 | Civil money penalties | No changes. |

*A. Modifications to the List of HHS Select Agents and Toxins*

The following changes to the list of HHS select agents and toxins are proposed based on comments received in response to the July 21, 2010 ANPRM, recommendations from the FESAP and ISATTAC, and our review of current scientific data regarding select agents and toxins. As we discuss below, we are proposing to remove 6 select agents, add 2 select agents, and identify 11 select agents and toxins as ''Tier 1'' agents to the HHS list of select agents and toxins.

Proposed Addition of Lujo and Chapare Viruses

On August 19, 2009 (74 FR 41829), we proposed the addition of Chapare virus to the HHS list of select agents and toxins; we did not receive any comments regarding that proposal. Based on scientific data and risks associated with this virus, the ISATTAC recommended the addition of Chapare virus to the HHS list of select agents and toxins. The determination to add Chapare virus to the HHS list of select agents and toxins was based on the following scientific information. The HHS list currently includes members of the *arenaviridae* family (Junin, Machupo, Sabia, Flexal, Guanarito, and Lassa). Arenaviruses are rodent-borne viruses, some of which can be associated with large hemorrhagic fever outbreaks, and untreated case fatalities can be in excess of 30 percent. Chapare virus is a recently described New World arenavirus that is associated with fatal hemorrhagic fever syndrome and is most closely related to Sabia virus, an HHS select agent (Ref 1). Based on the ISATTAC recommendation and our examination of the current scientific data and risks associated with this virus, we are proposing to add Chapare to the HHS list.

The ISATTAC also recommended the addition of Lujo virus to the HHS list of select agents and toxins. Based on this recommendation and our examination of the current scientific data and risks associated with this virus, we are also proposing to add Lujo virus. The scientific determination was based on the fact that the Lujo virus caused a fatal outbreak of hemorrhagic fever, has an unprecedented high case fatality rate of 80 percent, has been phylogenetically identified as an arenavirus and is related to those members of the Old World *arenaviridae* family (Junin, Machupo, Sabia, Flexal, Guanarito, and Lassa) listed as HHS select agents that cause hemorrhagic fever and pose a significant risk to public health and safety (Ref 2).

Proposed Removal of Cercopithecine Herpesvirus 1 (Herpes B Virus)

Commenters acknowledged in response to the July 21, 2010 ANPRM that (1) the Herpes B virus naturally infects many species of macaques; and (2) can produce a serious, often fatal, infection in humans when not treated. However, the commenters argued that Herpes B virus should not be included as a select agent based on the following assertions:

- The inclusion of the virus on the list will produce no significant improvements in safety for the American public.
- Given the high prevalence of infection in non-human primates and the relatively few human infections that have been recorded, it suggests that the virus is not easily transmitted to humans.
- The virus is capable of being treated with several available licensed antiviral compounds.
- The virus does not present a sufficient risk of infection by the aerosol route.
- The virus is a highly unlikely candidate for a bioterrorism agent due to its environmental instability and the need for direct contact for infection. The argument is further enhanced by the absence of the virus listed on the NIH's National Institute of Allergy and Infectious Diseases lists of Category A, B & C Priority Pathogens or the CDC's Category A, B & C Bioterrorism Agents lists.
- The virus is widely available in nature.

The ISATTAC and the FESAP also recommended the removal of Cercopithecine herpesvirus 1 (Herpes B virus) from the HHS list of select agents and toxins. We agreed with the

commenters, ISATTAC, and FESAP and propose to remove Cercopithecine herpesvirus 1 (Herpes B virus) from the HHS list of select agents and toxins. Our rationale for this proposal is based on the facts that this virus is not easily transmitted to humans, the person-to-person transmission risk is small, the numbers of recorded human infections are low, and multiple licensed antiviral treatments for Herpes B infections are available.

Proposed Removal of *Coccidioides posadasii/Coccidioides immitis*

Commenters to our July 21, 2010 ANPRM argued that *Coccidioides posadasii/Coccidioides immitis* should not be included as a select agent based on the following reasons:

- The characteristics of *Coccidioides* species do not provide convincing properties of an effective agent of bioterrorism.
- The fungi are endemic in the southwestern United States, but do not cause large epidemics even with high prevalence in the air during wind storms.
- Infections caused by the fungi are easily treatable by licensed antifungal medicines, especially early in disease.
- The difficulty to use *Coccidioides* species as a bioweapon, and hence the need for strict regulation under the select agent regulations, is exemplified by their non-communicability, lack of history of use or development as successful biological weapons, and a relatively low incidence of symptomatic disease following natural infection.
- *Coccidioides* species would not be an effective bioterrorism weapon because the percentage of deaths and hospitalizations are low considering the number of people infected.

The FESAP also recommended removal of *Coccidioides posadasii/Coccidioides* immitis from the HHS list of select agents and toxins. We agreed with the commenters and FESAP and propose to remove *Coccidioides posadasii/Coccidioides* immitis from the HHS list of select agents and toxins. The scientific determination was based on the availability of licensed treatments for *Coccidioides* infection and a lowering of our assessment of the impact of *Coccidioides* infection on human health, as indicated by the high proportion of subclinical cases observed in endemic areas (Ref 3).

Proposed Retention of *Coxiella burnetii*

Commenters to the July 21, 2010 ANPRM argued that *Coxiella burnetii* (Q fever) should be removed from the select agents and toxins list based on the following assertions:

- Q fever is not contagious and is effectively treated with licensed antibiotics.
- It is generally a self-limiting infection with potential control by licensed vaccination.
- The ubiquitous nature of *Coxiella burnetii* means that it can be easily acquired from environmental sources and calls into question the effectiveness and procedures for maintaining inventories of select agents.
- Person-to-person transmission of the disease is rare and is fatal less than one percent of the time.
- A vaccine is available for this agent internationally, but not domestically.
- The agent is commonly found in animal populations within the United States.

However, FESAP and ISATTAC did not recommend removing this bacterium from the HHS list of select agents and toxins. We agreed with the FESAP and ISATTAC recommendations and propose to retain *Coxiella burnetii* on the HHS select agents and toxins list. The determinations to retain this agent on the HHS list are its robust environmental stability, ease of transmission to humans, extremely low infectious dose, and prior association of this agent with offensive programs. CDC invites comments regarding retaining this agent on the HHS list of select agents and toxins.

Proposed Removal of South American Genotypes of Eastern Equine Encephalitis Virus (EEEV)

Commenters on the July 21, 2010 ANPRM regarding the proposed inclusion of EEEV on the list of select agents and toxins argued that EEEV should not be included as a select agent based on the following reasons:

- The virus occurs naturally in the environment.
- Direct person-to-person transmission does not occur.
- Local and State health departments and mosquito control agencies routinely release information regarding the location of arboviral activity in the community, so upholding strict biosecurity measures in a laboratory has little or no impact on reducing a terrorist's ability to acquire this agent.
- Only North American strains of EEEV should be regulated because transmission patterns limit the distribution and epidemic potential of South American strains, which are less pathogenic.

We examined the current scientific data and noted that strains of EEEV can be categorized into two distinct genotypes primarily based upon geographic distribution: North American genotype (NA EEE) and South American genotype (SA EEE). The NA EEE genotype consists of strains obtained from North America and the Caribbean while SA EEE genotype viruses originate in Central and South America. Viruses in the two genotypes are distinctly different in their genetics, epidemiology, and pathogenicity. NA EEE, which are the strains responsible for human and equine disease, are all genetically very similar to each other (less than 3% divergence at the nucleotide level) and can be easily distinguished from SA EEE genotype strains by sequencing. NA EEE genotype strains differ from SA EEE viruses by greater than 20% at the nucleotide level and approximately 10% at the amino acid level. Since FESAP agreed with our scientific assessment that SA EEE genotypes should be removed from the HHS list of select agents and toxins, we are proposing to remove SA EEE genotypes from the HHS list of select agents and toxins (Ref 4).

Proposed Removal of Flexal Virus

Commenters that responded to the July 21, 2010 ANPRM felt that Flexal virus should be removed from the HHS list of select agents and toxins based on the lack of severity of disease and the lack of significant outbreaks of disease associated with infection with this virus in humans. FESAP also recommended that Flexal virus be removed from the list. Since our research found a lack of significant outbreaks of disease associated with Flexal virus in humans and that this virus would be a highly unlikely candidate for a bioterrorism agent, we are proposing to remove Flexal virus from the HHS list of select agents and toxins.

Proposed Retention of Monkeypox Virus

Commenters to the July 21, 2010 ANPRM recommended that Monkeypox virus should not be included as a select agent based on the following assertions:

- An effective licensed vaccine is available.
- Promising antivirals are in advanced stages of development.
- The virus is inefficiently transmitted from person-to-person.

We examined the current scientific data and noted that there is an increased incidence of Monkeypox virus in humans as well as studies identifying the virus being easily transmitted in Gambian rats. A recent study on an outbreak in Sudan indicates there is much strain variation in level of infectivity and severity of disease. Concern over the detection of new lineages with increased pathogenesis has been expressed. Another recent

outbreak of Monkeypox virus in the United States suggested numerous animals could become infected complicating the understanding of zoonotic maintenance of the virus (Ref 29–33).

While there has been documented cross protection against Monkeypox virus by Vaccinia virus vaccine, the decrease in the number of individuals with any immunity to the virus is drastically declining (since smallpox vaccination no longer occurs). Further, even though there is a stockpile of Vaccinia virus vaccine available, the vaccine has numerous undesirable side-effects that make it less than optimal for mass vaccination. There are also several antiviral treatments for Monkeypox in advanced stages of development, but they are not currently available. Thus, there is currently no specific treatment (Ref 29–33).

FESAP recommended keeping Monkeypox virus on the HHS list of select agents and toxins.

Based on the scientific determination outlined above, we are proposing to retain Monkeypox virus on the HHS list of select agents and toxins. We will continue to monitor progress in the development of antivirals and other means of prevention and control of Monkeypox virus infections and invite comments on removing a certain clade of Monkeypox virus (i.e., West African clade of Monkeypox virus) from the HHS list of select agents and toxins.

Proposed Reorganization of Tick-Borne Encephalitis Complex Viruses (TBEV)

Even though we received no comments to the July 21, 2010 ANPRM regarding the removal of these viruses from the HHS list of select agents and toxins, we are proposing the removal of TBEV Central European subtype from the HHS list of select agents and toxins for the following scientific reasons:

- The TBEV Central European Tick-borne subtype has been shown to be less virulent in humans than the Far Eastern subtype (Ref 5).
- No TBEV vaccines are licensed or available in the United States; however two safe, effective inactivated TBEV vaccines are available internationally.

FESAP also recommended the removal of the TBEV Central European subtype from the HHS list of select agents and toxins.

In addition to removing the TBEV Central European subtype from the HHS list of select agents and toxins, we propose to reorganize the listing of the TBEV to reflect the current nomenclature given by the International Committee on Taxonomy of Viruses. For TBEV proper, there are now just three recognized subtypes: Central European, Far Eastern, and Siberian. The Russian Spring and Summer encephalitis designation is no longer recognized (Ref 6). Two other viruses on the HHS list of select agents and toxins, Kyasanur Forest disease virus and Omsk Hemorrhagic fever virus, are no longer classified as TBEV. In recognition of these taxonomic changes, we are proposing to include these viruses on the HHS list of select agents and toxins as follows:

Tick-borne encephalitis virus
  Far Eastern subtype
  Siberian subtype
Kyasanur Forest disease virus
Omsk Hemorrhagic fever virus

Proposed Retention of *Rickettsia prowazekii* and *Rickettsia Rickettsii*

Commenters that responded to the July 21, 2010 ANPRM argued that *Rickettsia prowazekii* and *Rickettsia rickettsii* should be removed from the HHS list of select agents and toxins based on the following assertions:

- Mimicking transmission by arthropod vectors in an effort to disperse these pathogens with the intent to disrupt society would be challenging and technologically unlikely to be successful.
- Common and readily available licensed antibiotics are highly effective, and contagion is not a threat because spread is determined by contact with the vectors, not through person-to-person contact.
- Although *Rickettsia prowazekii* may be a pathogen of military significance, *Rickettsia rickettsii* is not. According to the commenter, propagation of the pathogens requires growth in cultured host cells and natural infection occurs by parenteral inoculation through a tick vector, so mass exposure by aerosolization or contamination of food sources is unlikely to result in disease.
- The potential to use this agent as a platform to construct a genetically engineered new pathogen would be extremely difficult.
- The primary disease associated with *Rickettsia rickettsii* is Rocky Mountain Spotted Fever, and the symptoms are recognizable and marketed diagnostics and treatment are readily available.
- *Rickettsia rickettsii* should be removed because generation of even moderate amounts of infectious material is exceedingly difficult and requires specialized equipment.
- Rickettsiae are not spread directly from person-to-person, would not survive if dispersed into the environment, and are susceptible to a number of readily available licensed antibiotics. In addition, there is no possibility of eliminating their presence in the environment.
- Potential benefits of lessening restriction on research include improved diagnostic capabilities and better potential for vaccine development.

The FESAP and ISATTAC recommended keeping *Rickettsia prowazekii* and *Rickettsia rickettsii* on the HHS list of select agents and toxins. Since we agreed with these expert panels, we are proposing to retain *Rickettsia prowazekii* and *Rickettsia rickettsii* on the HHS select agents and toxins list based on our scientific determination regarding the environmental stability, low infectious dose, aerosol transmission, and clinical significance of infection with these organisms.

Proposed Retention of *Yersinia pestis*

Commenters that responded to the July 21, 2010 ANPRM argued that *Yersinia pestis* should not be included as a select agent based on the following assertions:

- *Yersinia pestis* is naturally occurring and does not survive for long outside of its rodent host because of susceptibility to heat and sunlight.
- Decontamination of surfaces is highly effective in limiting its spread.
- Licensed treatments are readily available for those who may become exposed.

The FESAP and ISATTAC recommended that *Yersinia pestis* remain on the HHS list of select agents and toxins.

We agree with the FESAP and ISATTAC, and are proposing to keep *Yersinia pestis* on the HHS select agents and toxins list based on our scientific conclusion regarding the bacterium's high mortality rate, ease of dissemination and production, and person-to-person transmission of *Yersinia pestis* infections.

Proposed Reorganization of Staphylococcal Enterotoxins

Commenters to the July 21, 2010 ANPRM suggested that the regulations needed a clear statement concerning staphylococcal enterotoxins (SEs) and staphylococcal enterotoxin-like toxins (SEls). Commenters stated that SEs and SEls have been distinguished from each other on the basis of emetic activity (Ref 12). Commenters were confused regarding whether the intent of the select agent regulations is to acknowledge this difference and not regulate SEls or to regulate both SEs and SEls.

ISATTAC recommended that we amend the HHS list of select agents and toxins to specifically include Staphylococcal enterotoxins A, B, C, D, and E in the HHS list of select agents and toxins. We agree with the commenters and the ISATTAC recommendation, and propose to amend the select agents and toxins list from ''Staphylococcal enterotoxins'' to specifically include ''Staphylococcal enterotoxins A, B, C, D, and E'' in the HHS list of select agents and toxins (Ref 7–14). Serotypes G, H, and I should not added to the HHS list of select agents and toxins because serotypes G, H, and I are at least 10 fold less of a risk than SEE and SEA (Ref 15–16.) According to the International Nomenclature Committee for Staphylococcal Superantigens, emesis in a primate model within five hours post-feeding must be observed to classify an exotoxin as an enterotoxin (Ref 12). If emesis is not observed in this period of time, the exotoxin should be classified as enterotoxin-like rather than enterotoxin. Based on this internationally accepted standard, we are proposing serotypes J, K, L, M, N, O, P, Q, T, U, U2 and V should be designated staphylococcal enterotoxin-like rather than enterotoxin because these serotypes have been shown to either not cause emesis in a primate model or have not been tested for emesis (Ref 17–26). Therefore, we are proposing serotypes J, K, L, M, N, O, P, Q, T, U, U2 and V should not added to the HHS list of select agents and toxins.

*B. Modifications to the List of Overlap Select Agents and Toxins*

The following changes to the list of Overlap select agents and toxins are proposed based on comments received to the July 21, 2010 ANPRM, recommendations from the FESAP and ISATTAC, and our review of current scientific data regarding select agents and toxins.

Proposed Retention of *Bacillus anthracis* (Pasteur Strain)

A commenter to the July 21, 2010 ANPRM stated that the Pasteur strain of *Bacillus anthracis* should not be considered a select agent because the strain is attenuated and used for quality control testing in Laboratory Response Network (LRN) laboratories. The commenter argued that changing the status of the Pasteur strain would alleviate the burden of recordkeeping for quality control and proficiency testing activities.

We made no changes based on this comment. It should be noted that we excluded *Bacillus anthracis* Sterne strain in 2003 because the attenuated strain was determined to not pose a severe threat to public health and safety, animal health, or animal products. We have not excluded the plasmid-negative Pasteur variant in order to prevent the combination of plasmids from Sterne and Pasteur-types of strains to create a wild type phenotype.

Proposed Retention of *Brucella abortus, Brucella melitensis,* and *Brucella suis*

Commenters to the July 21, 2010 ANPRM recommended that *Brucella abortus, Brucella melitensis,* and *Brucella suis* be removed from the Overlap list of select agents and toxins for the following reasons:

- The benefits of removal far exceed any risk mitigated by continuing the listing. In the years since the organism was first listed, research and development has been greatly diminished.
- As currently regulated, existing BSL–3 facilities do not have the capacity to conduct brucellosis research with sufficient numbers of animals to generate statistically valid research results, and it is too expensive to construct and maintain enough high capacity BSL–3 facilities to conduct the necessary research. The commenter contended that any risk currently mitigated by the listing is fully manageable without such listing.
- *Brucella abortus* and *Brucella suis* should be removed because the organisms are adversely affected by environmental conditions and can be diagnosed and controlled in animals and readily treated in humans. The classification of these bacteria as select agents has hampered research that could result in vaccines that would protect susceptible animal populations. Although brucellosis will remain a disease of agricultural significance, *Brucella abortus* and *Brucella suis* are not ideal biological weapons. The commenter suggested, however, that *Brucella melitensis* remain on the list because it is a foreign animal disease and the most infectious of all the species.
- *Brucella* species should have their listed status reconsidered because human infection is rarely fatal, acute brucellosis can be readily treated with available antibiotics, human-to-human transmission is extremely rare, and wildlife carriers in the United States often come into contact with humans without significant transmission.
- Naturally occurring substances such as *Brucella* should be removed because infections regularly occur from natural exposures.
- The primary mode of transmission for *Brucella* abortus is through contact with contaminated fluids/tissues, its pathogenicity is moderate, and infections are routinely treated with antibiotics that do an effective job. The commenter recommended removal of *Brucella abortus* strain 1119–3 because the strain is identical using conventional typing tests to strain 19 and is used as an antigen strain in diagnostic tests. Strain 19 and RB51 have been excluded as licensed vaccine products, but other research strains have not been excluded.
- Another commenter supported downgrading the risk assessment for vaccine strains of *Brucella.* The commenter was concerned that the only criterion the ISATTAC accepts for exclusion is licensed drug status, but such a high standard is disadvantageous to research on this pathogen.

The FESAP and ISATTAC recommended that *Brucella abortus, Brucella melitensis,* and *Brucella suis* remain on the Overlap list of select agents and toxins. We made no changes based on these comments because we agreed with these expert panels that *Brucella abortus, Brucella melitensis,* and *Brucella suis* remain on the Overlap list of select agents and toxins based on the bacteria's ease of production, high infectivity via the aerosol route, low infectious dose, and no brucellosis vaccines are currently available for humans in the United States.

Proposed Retention of *Burkholderia mallei* and *Burkholderia pseudomallei*

Commenters to the July 21, 2010 ANPRM contended that *Burkholderia mallei* and *Burkholderia pseudomallei* should not be included as select agents based on the following reasons:

- The agents do not rise to the same level of public health threat or feasibility for weaponization that the other agents on the list do.
- *Burkholderia mallei* and *Burkholderia pseudomallei* are endemic in a number of areas of the world.
- Disease resulting from *Burkholderia mallei* and *Burkholderia pseudomallei* is treatable with low mortality.
- It is questionable how they would be used as bioweapons.

The FESAP and ISATTAC recommended that *Burkholderia mallei and Burkholderia pseudomallei* remain on the Overlap list of select agents and toxins. We made no changes based on these comments because we agreed with these expert panels that *Burkholderia mallei and Burkholderia pseudomallei* should remain on the Overlap list of select agents and toxins based on our scientific determination that the bacteria

can be produced in large quantity; transmitted via aerosol; and *Burkholderia pseudomallei* is highly stable in the environment. The mortality rate for untreated cases of both melioidosis and glanders is high, and given the rarity of these diseases in the United States, experience in their diagnosis and treatment is limited.

Proposed Reorganization of Venezuelan Equine Encephalitis Virus (VEEV)

Commenters to the July 21, 2010 ANPRM contended that VEEV subtypes ID and IE should not be included as select agents based on the following reasons:

- Inclusion of VEEV subtypes as select agents should be based solely on their ability to cause an epidemic or epizootic following a bioterrorism event. This would require inclusion of only varieties 1AB and 1C VEEV which have been shown to have epidemic/epizootic potential.
- The reasons for excluding 1D and 1E VEEVs from the select agent list are: (1) No subtype 1D or 1E VEEV have ever caused large equine epizootics; (2) Inclusion of 1D viruses because they might be precursors to 1C viruses is not sufficient for making 1D viruses select agents. Essentially all of this evidence is laboratory based. The possibility of a 1D virus mutating to a 1C virus following a bioterrorism event is unlikely because 1D viruses are unlikely to establish epidemic or epizootic transmission cycles in the US. Natural transmission cycles would likely be needed for any evolution from 1D to 1C to occur in nature; (3) Emergency vaccination of equines with currently approved equine vaccines or humans with IND vaccines (e.g. TC–83) would interdict or greatly dampen a 1D or a 1E epizootic, based on antigenic cross-reactivities of subtype 1 viruses; and (4) The currently available humanized or human anti-VEEV monoclonal antibodies that could be produced for emergency use would also have prophylactic, and possibly therapeutic efficacy for all VEEV subtype 1 infections with which they cross react (includes 1D and 1E viruses).

The FESAP and ISATTAC recommended removal of certain subtypes of Venezuelan equine encephalitis virus from the Overlap list of select agents and toxins. Since we agreed with commenters and expert panels recommendations, we are proposing to clarify that only VEEV subtypes IAB and IC should remain on the Overlap list of select agents and toxins because these subtypes contain the only recognized strains of Venezuelan equine encephalitis that have demonstrated the ability to cause epidemics or epizootics. The remaining subtypes, ID and IE, are strains prevalent among the existing animal populations and do not represent the same type of risk. Other viruses within the Venezuelan equine encephalitis complex (subtypes IF and II through IV) are separate viruses and are not included in the HHS and USDA overlap list of select agents and toxins.

*C. Tiering*

E.O. 13546 specifies that a subset of the Select Agent List be categorized as ''Tier 1'' because these agents and toxins present the greatest risk of deliberate misuse with the most significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence. All but one of the commenters to the July 21, 2010 ANPRM who addressed the idea of a tiering system based on the relative bioterrorism risk of each agent or toxin favored the use of tiers. Several commenters mentioned specific criteria for tiering. A few commenters expressed the concern that tiering could create confusion, especially for facilities with multiple Biological Select Agents and Toxins (BSAT) and had concerns about additional requirements that would be placed on some laboratories. Some commenters identified specific Tier 1 candidates from the BSAT listed in 42 CFR 73.3 and § 73.4. Most of these commenters included Variola major virus and Variola minor virus, as well as Reconstructed 1918 Influenza virus, Ebola viruses, and Marburg virus in their Tier 1 list. Two commenters also suggested *Bacillus anthracis* and Lassa fever virus. Other commenters suggested *Francisella tularensis,* South America hemorrhagic fever viruses, *Brucella* species, *Coxiella burnettii,* Botulinum neurotoxin, and Ricin as candidates for Tier 1.

Based on E.O. 13546, a FESAP recommendation and our agreement with the comments received, we are proposing to amend the select agent regulations to establish a number of select agents and toxins as Tier 1 select agents and toxins within the lists of HHS and Overlap select agents and toxins. All select agents and toxins were scored against 20 criteria by over 60 Subject Matter Experts representing the Federal life sciences, public health, law enforcement, security, and intelligence communities, which included:

- The relative ease with which a particular select agent or toxin might be disseminated or transmitted from one human to another or into the environment where it could produce a deleterious effect upon human health;
- The potential for a high mortality rate;
- The potential for a major human health impact;
- Select agents or toxins whose misuse might result in public panic or other social or economic disruption; and
- Select agents or toxins whose use might require Federal, State, and/or local officials to take special action in planning for major human health disasters.

The select agents that we propose will be designated as Tier 1 are the following:

HHS

- Ebola virus
- *Francisella tularensis*
- Marburg virus
- Variola major virus
- Variola minor virus
- *Yersinia pestis*
- Botulinum neurotoxin
- Toxin-producing strains of *Clostridium botulinum*

OVERLAP

- *Bacillus anthracis*
- *Burkholderia mallei*
- *Burkholderia pseudomallei*

Regarding the Reconstructed 1918 Influenza virus, recent studies have increased our understanding of the public health risks associated with this agent. Current reports indicate that 60 percent of the population in the United States is immune to the 1918 Influenza virus and that antiviral treatments exist (Ref 27–28). Based on this information we propose to retain the Reconstructed 1918 Influenza virus on the HHS list of select agents and toxins, but not to include it in Tier 1 of this list.

Based on the information currently available, we conclude that the adoption of the Tier 1 designation would not result in significant economic effects to the regulated community. However, we are asking for any additional data or comments on the potential effects of designating the above agents as Tier 1.

*D. Responses to Other Comments and Other Proposed Changes*

With respect to the remainder of the sections outlined below, we are proposing the following changes based on comments received in response to the July 21, 2010 ANPRM and recommendations from the FESAP. We are proposing to update the Web address throughout the document as all information concerning the Federal Select Agent Program is now centralized on the National Select Agent Registry Web site at *http://www.selectagents.gov/*. We also are proposing non-substantive changes throughout the

regulations for purposes of clarity. In addition, HHS/CDC and USDA/APHIS made the language similar to ensure consistency between the regulations.

Exclusions

In order to update the regulations to accurately reflect the way in which we handle the listing of exclusions, we are proposing to remove the language stating that exclusions will be published in the **Federal Register**. This change is necessary because, while we anticipated publication of exclusions both in the **Federal Register** and on the Internet at the time the regulations were initially created, we have found that publication on the select agent Web site only has served to provide the most up-to-date information to the regulated community.

Security

Commenters that responded to the July 21, 2010 ANPRM suggested security requirements include laboratory handling only by certified, trained individuals; physical security systems; restricted access; and security risk assessments. Commenters also identified some criteria for stratifying, such as making the requirements risk-based, considering the type of work done at the facility, acknowledging that many threats are from disgruntled insiders, requiring review of the stratification by subject matter experts, and taking into account the needs of the researchers at the facility.

Based on our agreement with the comments received, and input from the FESAP and stakeholder groups, we are proposing more specific minimum security standards for Tier 1 select agents or toxins. These additional requirements would be added as section 73.11(e). We believe these proposed minimum security standards for Tier 1 select agents would serve to further mitigate the potential for deliberate misuse of these select agents and toxins that could result in mass casualties or devastating effects to the economy, critical infrastructure, or public confidence.

These proposed changes are based on established security industry standards with respect to securing high risk material and developed in accordance with the experience and expertise of the Federal Select Agent Program and in consultation with DOD, FBI, and DHS security experts. They are necessary in order to further ensure the safety and security of those select agents and toxins that are proposed to be deemed Tier 1 agents. The requirements for working with all other select agents and toxins would remain unchanged with the exception of certain miscellaneous changes that are detailed below.

Security of Variola Major Virus and Variola Minor Virus

In recognition of the special public health risks associated with Variola major virus and Variola minor virus, we are also proposing to require additional physical security measures over and above those proposed for Tier 1. These additional requirements would be added as section 73.11(e)(5) (Security). We believe this change is necessary because Variola major virus and Variola minor virus were determined to pose a significantly higher public health risk than the other agents and toxins that were proposed for the Tier 1 select agents and toxins list. We also believe that it would not be appropriate to require that the special security procedures appropriate for Variola major virus and Variola minor virus be made applicable to other agents or toxins on a Tier 1 list.

Select Agent Inventory

Many commenters to the July 21, 2010 ANPRM pointed out that the requirement to account for individual vials of each pathogen is inappropriate for replicating biological agents. Commenters stated that this is a costly and burdensome responsibility for laboratories and their staff and that this requirement should be abolished except for Tier 1 agents.

We are not proposing any changes to the select agent regulations based on these comments. Currently, the select agent regulations state that an accurate, current inventory for each select agent (including viral genetic elements, recombinant nucleic acids, and recombinant organisms) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials) must be maintained. The requirement to account for individual vials of each pathogen in long term storage is necessary to ensure the biosecurity of select agents and toxins. Further guidance on this requirement can be found at *http://www.selectagents.gov.*

Definitions

In order to improve the clarity of the HHS Select Agent Regulations, we are proposing to add the following definitions to 42 CFR 73.1, to clarify the terms related to the identification of a *Restricted person: Adjudicated as a mental defective, Alien, Crime punishable by imprisonment for a term exceeding 1 year, Committed to any mental institution, Controlled substance, Indictment, Information security; Lawfully admitted for permanent residence, Mental institution,* and *Unlawful user of any controlled substance.* We believe that these definitions will assist Responsible Officials as well as those seeking approval to access select agents and toxins to better understand what status or activities, past or present, might prohibit such access.

Although these terms were undefined in the Bioterrorism Response Act, it is evident that Congress modeled many of them after the disqualifiers that are used by the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF) when enforcing the Gun Control Act of 1968. Because the purpose of the Select Agent Program differs from ATF's enforcement actions under the Gun Control Act, we do not believe that these terms must be defined exactly the same. The Gun Control Act regulates access to firearms, while the Bioterrorism Response Act regulates access to biological agents and toxins that the government has recognized as having the potential to be used as weapons of mass destruction by the wrong hands.

Nevertheless, we looked at the statutory and regulatory definitions of these terms under the Gun Control Act when drafting our definitions. With the exception of the term ''crime punishable by imprisonment for a term exceeding 1 year,'' we decided to adopt the applicable definitions used by ATF.

We are proposing to define a ''crime punishable by imprisonment for a term exceeding 1 year'' as ''any Federal, State, or foreign offense for which the maximum penalty, whether or not imposed, is capital punishment or imprisonment in excess of 1 year. What constitutes a conviction of such a crime shall be determined in accordance with the law of the jurisdiction in which the proceedings were held. Any conviction that has been set aside or nullified as a matter of law or for which a person has been pardoned shall not be considered a conviction for purposes of this part.'' Contrary to definition of this term used under the Gun Control Act, we have decided that foreign offenses should be considered a disqualifier. In doing so we are aware of the Supreme Court's decision in *Small* v. *United States,* 544 U.S. 385 (2005) in which the court, interpreting the provisions of 18 U.S.C. 922(g)(1), held that phrase ''convicted in any court'' refers only to U.S. courts, not to foreign courts. In its opinion interpreting the Gun Control Act, the court stated that ''the statute itself and its history offer only congressional silence'' as to whether Congress considered whether the statutory

language included foreign convictions. In the case of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism and Response Act), we believe Congress spoke clearly about their desire to limit or deny access to select agents and toxins for those who have committed serious crimes regardless of where committed.

We believe that in light of the threat of bioterrorism attacks, Congress would not want to exclude an individual convicted of a U.S. offense from having access to BSAT, but still allow access to an individual convicted in a foreign court of a similar offense.

As a part of the safeguard and security section of the Bioterrorism Response Act, Congress not only put select agents and toxins off limits to a ''restricted person,'' as that term is defined by 18 U.S.C. 175b, but to those who are ''reasonably suspected by any Federal law enforcement or intelligence agency of'' (1) committing a ''Federal crime of terrorism'' transcending national boundaries (18 U.S.C. 2332b), (2) the knowing involvement with an organization that engages in domestic or international terrorism or with any other organization that engages in international crimes of violence; or (3) being an agent of a foreign power. We believe it would be an inconsistent reading of statutory authority to allow the Secretary to limit or deny access to select agents and toxins to someone identified by the Attorney General as being reasonably suspected of committing a Federal crime of terrorism transcending national boundaries but to be powerless in cases where a person had actually been convicted of a serious crime in a foreign country. We also believe that the instances of regulation can be distinguished in that with regard to the Gun Control Act of 1968, the government is regulating access to guns while with respect to the Bioterrorism Response Act, the government is regulating access to biological agents and toxins that the government has recognized as having the potential to be used in the wrong hands as weapons of mass destruction.

We specifically request comments on the use of a foreign conviction as a predicate for denying access to select agents and toxins. We recognize that there can be significant differences between foreign convictions and domestic convictions. For example, foreign legal systems may not provide the same due process safeguards afforded to citizens of the United States, including impartial tribunals and jury trials. Additionally, foreign countries may punish conduct that is permitted under domestic law or may require more severe penalties than under domestic law. We note that in the past, courts have applied the criteria set forth in Section 482 of the Restatement (third) of Foreign Relations Law of the United States (1986) in determining whether a foreign judgment should be recognized in the United States. That Section provides that a court in the United States may not recognize a judgment of the court of a foreign state if the judgment was rendered under a judicial system that does not provide impartial tribunals or procedures compatible with due process of law or the court that rendered the judgment did not have jurisdiction over the defendant in accordance with the law of the rendering state. It further provides that a court in the United States need not recognize a judgment of the court of a foreign state if the court that rendered the judgment did not have jurisdiction of the subject matter of the action, the defendant did not receive notice of the proceedings in sufficient time to enable him to defend, the judgment was obtained by fraud, the cause of action on which the judgment was based, or the judgment itself, is repugnant to the public policy of the United States or of the State where recognition is sought, the judgment conflicts with another final judgment that is entitled to recognition, or the proceeding in the foreign court was contrary to an agreement between the parties to submit the controversy on which the judgment is based to another forum. We are seeking comment on whether these criteria should be applied in considering whether access to select agents and toxins should be denied based on a foreign conviction or whether other criteria or factors would be appropriate to consider.

Also, contrary to the definition used by ATF, we are proposing that a state offense classified by the laws of that state as a misdemeanor, but which has a term of imprisonment exceeding one year, should be considered a disqualifier—even though an individual convicted of the same offense would not be disqualified under the Gun Control Act. Finally, we are proposing to permit access to BSAT to individuals who have been convicted of a disqualifying offense if their convictions have been set aside or nullified as a matter of law or they have been pardoned. Although such language was not specifically included in the Bioterrorism Response Act, we believe that we should take into account certain post-conviction actions when determining whether we should deny an individual access to BSAT.

We are proposing to add a definition for *Occupational exposure* based on the definition used in the Occupational Safety and Health Administration (OSHA) regulations found in 29 CFR 1910.1030. In addition, we are proposing to add the definitions for *Recombinant and Synthetic Nucleic Acids* to clarify the existing regulations, as the term ''recombinant nucleic acids'' is employed but not defined, and synthetic nucleic acids are not currently addressed in the HHS Select Agent Regulations.

Recombinant/Synthetic Nucleic Acids

In addition to adding the proposed definition for *Recombinant and Synthetic Nucleic Acids,* we are also proposing to add the phrase ''and/or synthetic'' after the word ''Recombinant'' throughout 73.3 (c) and 73.4 (c). Current regulations regarding recombinant nucleic acids and recombinant organisms focus solely on the use of recombinant technology in the generation of these genetic elements. Since synthetic DNA technology may also be used to generate such genetic elements, we are proposing to expand the category of genetic elements to include recombinant and/or synthetic DNA.

Toxins

Sections in §§ 73.3 and 73.4 of 42 CFR contain provisions for toxins regulated by HHS under part 73. In 42 CFR 73.3(e) and 73.4(e), we are proposing to clarify that the ''inactive form of a select toxin'' may be excluded from regulation since the current term, ''attenuated strain of toxin'' is scientifically inaccurate. ''Attenuated'' is a term that is applied to living organisms and toxins are not living organisms. Since ''Inactive form of a select toxin'' is a more accurate term, we are proposing to amend the regulations to include the correct terminology.

Section 42 CFR 73.3(d)(3) specifies the permissible select toxin amounts under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor that are excluded from the requirements of the select agent regulations. We are proposing to require that the person transferring toxins in amounts which would otherwise be excluded from the provisions of the select agent regulations would be excluded only if the transferor: (1) Can show that the transferor used due diligence (i.e., reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose) to assure that the recipient has a legitimate need to handle

or use such toxins; and (2) reports to CDC if they detect a known or suspected violation of Federal law or become aware of suspicious activity related to the toxin. The HHS Secretary would also retain the authority to, without prior notification, inspect and copy or request the submission of the due diligence documentation. It should be noted that this proposed requirement would not apply to toxins exempted under Section 42 CFR 73.5(c).

We are proposing to add 42 CFR 73.3(d)(4) which would state, ''Notwithstanding section (i) above, an animal inoculated with or exposed to an HHS select toxin.'' The current regulations consider that an animal injected with or exposed to (e.g., by inhalation, dermal absorption, or ingestion) a select toxin is a ''select toxin'' itself and would need to be housed in a registered space. This change would allow animals injected with or exposed to a select toxin to not be considered a ''select toxin.'' Therefore, the animals would not need to be housed in a registered space. This change will eliminate an unnecessary burden on a registered entity because recovering the toxin from within an animal subject is highly difficult and such removal is unlikely to produce a reasonable yield of recovery. In addition, there is uncertainty as to whether the toxin would remain active when recovered from the animal. For these reasons, it is highly unlikely that once introduced into an animal, sufficient toxin would be able to be recovered to pose a significant hazard to public health.

Exemptions

The regulations found in 42 CFR 73.5 and 73.6 requires identified select agents listed on the CDC's Category A Bioterrorism Agents list (i.e., agents that pose a risk to national security because they can be easily disseminated or transmitted from person to person; result in high mortality rates and have the potential for major public health impact; might cause public panic and social disruption; and require special action for public health preparedness) contained in a specimen presented for diagnosis or verification to be immediately reported to APHIS or CDC by telephone, facsimile, or e-mail.

We are proposing to amend this immediate notification to only those select agents and toxins identified as Tier 1 agents because these agents and toxins present the greatest risk of deliberate misuse with the most significant potential for mass casualties.

Responsible Official

The regulations found in 42 CFR 73.9 set out requirements for entities requesting to work with select agents and toxins to designate a Responsible Official, who ensures that the entity meets the requirements of the regulations.

We are proposing to add a specific requirement that all Responsible Officials possess the appropriate training or expertise to execute their required duties. We are also proposing to add a requirement that the Responsible Official's regular place of employment or principal duty station must be collocated in close proximity with the physical location of the registered entity entered in section 1A of APHIS/CDC Form 1 (Application for Registration for Possession, Use, and Transfer of Select Agents and Toxins OMB Control No. 0579–0213, OMB Control No. 0920–0576, Expiration Date 12/31/2011). We believe that the Responsible Official should have a physical (and not merely a telephonic or audio/visual) presence at the entity to ensure that the entity is in compliance with the select agent regulations and be able to quickly respond to on-site incidents involving select agents and toxins.

We are also proposing to clarify the role of Alternate Responsible Official in order to definitively establish that the Alternate Responsible Official must have the knowledge and authority to act for the Responsible Official in his/her absence.

Access to Select Agents and Toxins

We are proposing to amend the regulations in 42 CFR 73.10. These regulations establish parameters for restricting access to select agents and toxins and the process by which individuals may be approved by HHS/CDC or USDA/APHIS for access to select agents and toxins after the completion of a security risk assessment by the Attorney General. Specifically, we are proposing to add new provisions by which individuals may have access to select agents and toxins at entities other than the individual's ''home'' entity.

We are also proposing to decrease the maximum length of time in which a security risk assessment will be valid from five years to three years in order to more expeditiously identify individuals who may have fallen into one of the prohibited or restricted categories.

Security Plan

The regulations in 42 CFR 73.11 establish the requirements for developing and implementing a security plan sufficient to safeguard select agents or toxins against unauthorized access, theft, loss, or release. The regulations currently require that the security plan must be submitted by all regulated entities upon request. We are proposing to amend § 73.11 to require that the security plan be submitted for initial registration and renewals of registration.

Since we believe animals and plants exposed to or infected with a select agent should be handled as a select agent and safeguarded in the same manner as a select agent, we are proposing to require that the security plan include provisions to address safeguarding of animals or plants intentionally or exposed to or infected with select agents against unauthorized access, theft, loss or release. We are not requiring this plan to address procedures concerning animals exposed to toxins because, as discussed above, it is highly unlikely that once introduced into an animal, sufficient toxin can be recovered to pose a significant hazard to public health and safety. We are additionally proposing to add a requirement that the security plan include procedures for the Responsible Official to immediately notify the Federal Bureau of Investigation (FBI) of suspicious activity that may be criminal in nature and related to the entity, its personnel, or its select agents or toxins. We believe that any criminal activity of this kind should be immediately and directly reported to the FBI so they can initiate an investigation or other appropriate response.

We are proposing that the security plans of entities with select agents and toxins must include provisions for information security. These information security provisions would include network connectivity monitoring, restriction of user permissions so that only mission-specific files and applications may be accessed, measures to prevent network infiltration by malicious code, configuration management including regular patching and system and software updates, and backup security measures in the event that access control systems and/or surveillance devices are rendered inoperable. We believe that information security enhancements are important because the security of records or information systems that could allow an individual to gain access to the select agents or toxins should be safeguarded to prevent unauthorized access, theft, loss, or release of these materials.

We are proposing to codify current practices for shipping, receiving, and storage of select agents and toxins to ensure that the entity has documented

processes for securing and monitoring the shipment, receipt, and storage of these items. These changes would serve to decrease the chance that such materials would be made available to an unauthorized individual or an individual without a legitimate use for the material.

We are also proposing to remove the reference in 73.11(e), ''Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents'' in Morbidity and Mortality Weekly Report (December 6, 2002) because we posted a security information guidance document in March 2007 that supersedes this reference.

Biosafety Plan

We are proposing to amend the regulations in 42 CFR 73.12 to require that a regulated entity's biosafety plan address procedures concerning animals or plants accidentally or intentionally exposed to or infected with a select agent. We are not requiring this plan to address procedures concerning animals exposed to toxins. As stated previously, this is because it is highly unlikely that once introduced into an animal, sufficient toxin can be recovered to pose a significant hazard to public health, agriculture or agriculture products.

We are also proposing that the biosafety plan must include provisions for the implementation of an occupational health program for individuals with access to Tier 1 select agents and toxins. We believe aspects of an individual's health may be relevant to their suitability to access biological select agents and toxins; identification of potential health problems and review of medication or treatment that may affect security and safety is paramount; and, occupational health programs should inform scientists of the types of medications and treatments that might have a potential deleterious effect on working safely and securely with select agents and toxins.

Restricted Experiments

The regulations in 42 CFR 73.13 concern restricted experiments that may not be performed unless approved by the HHS Secretary. We are proposing to add language in order to expand the current ''restricted experiment'' approval requirement to include all experiments involving the creation of drug resistant select agents that are not known to acquire the resistance naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture and not just those involving recombinant DNA. The regulations in 42 CFR 73.13 concern restricted experiments which may not be performed unless approved by the HHS Secretary. Furthermore, we are proposing to state that, in addition to the existing prohibition on conducting restricted experiments without express approval, entities may not possess the products (i.e., creation of drug resistant select agents that are not known to acquire the resistance naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture, or recombinant and or synthetic DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight resulting from restricted experiments) resulting from restricted experiments without the express approval of the HHS Secretary. We are also proposing to remove recombinant technology as the only determining factor for a restricted experiment. Current regulations regarding restricted experiments focus solely on the use of recombinant technology in the generation of drug resistant select agents or biosynthesis of toxins lethal to vertebrates. Since synthetic DNA technology or selection in sublethal exposures may also be used to generate such products, we are proposing to expand the category of restricted experiments to include passive selection, recombinant and/or synthetic DNA.

Incident Response

The regulations in 42 CFR 73.14 contain requirements for development of incident response plans. We are proposing to specify that each entity's incident response plan be based upon a site-specific risk assessment. We believe this change would further ensure the specificity and quality of the plan. In addition, we are proposing that the incident response procedures contain specific provisions concerning animals or plants accidentally or intentionally exposed to or infected with a select agent. We are not requiring this plan to address procedures concerning animals exposed to toxins. As stated previously, this is because it is highly unlikely that once introduced into an animal, sufficient toxin can be recovered to pose a significant hazard to public health, agriculture or agriculture products.

Training

We are proposing to amend the regulations in 42 CFR 73.15 that contain provisions of mandatory training for staff and visitors who work in or visit areas where select agents or toxins are handled or stored to provide security awareness and incident response training. We believe these additional training initiatives are needed to ensure that (1) personnel will be better trained to safeguard select agents and toxins from thefts, losses, intentional releases, or unauthorized access and (2) personnel will be better trained to ensure that select agents and toxins are safeguarded during exigent circumstances that include natural and man-made disasters. We are also proposing to clarify the language regarding the level of training that staff and visitors would be required to receive in order to establish that training for escorted personnel based on the risk associated with accessing areas where select agents and toxins are used and/or stored. Currently, refresher training is required to be provided once a year. We are proposing to require that such training also be provided if a registered entity's security, incident response, or biosafety plans are substantively altered. Finally, we are proposing to specify that the Responsible Official ensure maintenance of training records. Currently, there is no particular person designated as the entity's required record keeper, only that a training record must be kept.

Transfers

The transportation in commerce of hazardous materials, including select agents and toxins, is governed by the United States Department of Transportation's Hazardous Material Regulations found in Title 49 of the Code of Federal Regulations, parts 100–185. The regulations in 42 CFR 73.16 do not impose requirements on the transportation in commerce of select agents or toxins. We are proposing to clarify when ''transportation in commerce'' begins and ends to better allow registered individuals and entities to adequately address those situations when a select agent or toxin is (1) ready to be packaged for transportation, (2) packaged for shipment, or (3) received and handled by a person with approval to access select agents and toxins. In addition, we are proposing language to codify policies and practices into a standard for shipping, receiving, and storage of select agents and toxins to ensure that the entity has documented processes for securing and monitoring the shipment, receipt, and storage of select agents and toxins that make it extremely unlikely that such materials would be made available to an unauthorized individual or an individual without a legitimate use for the material. We note the concerns identified in two HHS Office of Inspector General (OIG) audits regarding

vulnerabilities that may occur during the shipment of select agents and toxins. HHS/CDC reviewed how entities ship select agents and toxins and evaluated ways to improve this process to ensure they are not only safeguarded against unauthorized access, but also against theft, loss, or release. We believe that the proposed amendments will help address OIG's concerns.

Records

The regulations in 42 CFR 73.17 address recordkeeping requirements for regulated entities as those records that relate to select agents and toxins. We are proposing to clarify the current language that an accurate, current inventory needs to be maintained for each select agent that the entity possesses including synthetic select agent organisms and any animals or plants intentionally or unintentionally exposed to or infected with a select agent (including number and species, location and appropriate disposition). We believe this clarification is needed to ensure that accurate, current records are maintained for all select agents that the entity possesses. We are currently soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. Please send written comments to Daniel Holcomb, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*. Please state that your comments refer to Possession, Use, and Transfer of Select Agents and Toxins (OMB Control No. 0920–0576).

As previously stated, we are not proposing to require regulated entities to keep records regarding animals exposed to toxins because it is highly unlikely that once introduced into an animal, sufficient toxin can be recovered to pose a significant hazard to public health, agriculture or agriculture products.

Administrative Review

We are proposing to amend the regulations in 42 CFR 73.20 that addresses the administrative review of an individual or entity's denial, revocation, or suspension of registration and access approval. Specifically, we are proposing to modify the current regulations in order to allow individuals more time to gather the necessary components of their appeal following the denial, limitation, or revocation of access approval. Currently, this process must be initiated in 30 calendar days. We are proposing to extend the deadline to 180 calendar days. We believe this change would provide individuals with sufficient time to gather all documents necessary to support an appeal. Finally, we are proposing to remove the provision ''Where the denial, revocation, or suspension of an individual's access approval is based upon identification by the Attorney General, the request for review will be forwarded to the Attorney General'' to provide clarification that the decision regarding the appeal is determined by the HHS Secretary.

Guidance Documents

We are specifically requesting comments from the regulated community and any other interested persons on the development of one or more guidance documents that would serve to provide assistance in the interpretation of the select agent regulations.

The areas where guidance documents may be developed in relation to the select agent regulations include, but are not limited to:

1. Aspects of the required security plan. These may include, but are not limited to:

- Standards for information security;
- Development of suitability or personnel reliability practices, including pre-access and ongoing assessment processes of persons who will have access to Tier 1 select agents or toxins;
- Procedures for the method by which an entity's Responsible Official will coordinate his or her efforts with the entity's safety and security professionals to ensure security of Tier 1 select agents or toxins and have access to relevant information from all professionals dealing with biological select agents and toxins safety and security;
- Development of a self- and peer-reporting program to track incidents or conditions that could affect an individual's ability to safely access or work with Tier 1 select agents and toxins; and
- Layered physical security protection of assets for entities housing Tier 1 select agents and toxins.

2. Aspects of the required biosafety plan, e.g., components of an occupational health program for individuals with access to Tier 1 select agents and toxins; and

3. Aspects of the required training, e.g., best practices for development of a security awareness training program.

We welcome public comment on the use of Web sites, articles, or other sources that may be used to develop such documents, in addition to suggestions as to what elements should be included as useful examples. These documents would serve as a resource to the regulated community as a whole.

## III. Required Regulatory Analyses

*a. Executive Orders 12866 and 13563*

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

Under E.O. 12866 HHS must determine whether a regulatory action is ''significant.'' A ''significant regulatory action'' under E.O. 12866 is defined as (1) an action that is likely to result in a rule that may have an annual effect on the economy of $100 million or more, or adversely and materially affects a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (or an economically significant action); (2) creates a serious inconsistency or otherwise interferes with an action taken or planned by another agency; (3) materially alters the budgetary impact of entitlements, grants, user fees or loan programs or the rights and obligations of recipients; or (4) raises novel legal or policy issues. Because this rulemaking proposes changes to how a subset of select agents and toxins are protected, this rule is has been determined to be ''significant'' under E.O. 12866 and, therefore, has been reviewed by the Office of Management and Budget (OMB).

We have prepared an economic analysis for this rule. The economic analysis provides a cost-benefit analysis, as required by E.O. 12866, and an initial regulatory flexibility analysis (See III.b.) that examines the potential economic effects of this proposed rule on small entities, as required by the Regulatory Flexibility Act. The economic analysis is summarized below. Copies of the full analysis are available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT** or on the Federal Select Agent Program Web site at: *http://www.selectagents.gov/* or on the public docket at *http://www.regulations.gov.*

Summary of the Regulatory Impact Analysis

Certain pathogens or biological toxins that are released intentionally or accidentally can result in disease, wide-ranging and devastating impacts on the economy, disruption to society, diminished confidence in public and private institutions, and large-scale loss of life. People or livestock can be exposed to these agents from inhalation, through the skin, or by the ingestion of contaminated food, feed, or water. Similarly, crops can be exposed to biological pathogens in several ways—at the seed stage, in the field, or after harvest.

The *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (Pub. L. 107–188) (the Act) provides for the regulation of certain biological agents and toxins that have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products. APHIS and CDC have the primary responsibility for implementing the provisions of the Act within USDA and HHS, respectively. Within APHIS, Veterinary Services (VS) select agents and toxins are those that have been determined to have the potential to pose a severe threat to animal health or animal products, and Plant Protection and Quarantine (PPQ) select agents and toxins are those that have been determined to have the potential to pose a severe threat to plant health or plant products. HHS select agents and toxins are those that have been determined to have the potential to pose a severe threat to human health. APHIS and CDC coordinate regulatory activities for overlap select agents and toxins that have been determined to pose a severe threat to human and to animal health or animal products.

Sections 201 and 212(a)(2) of the Act requires a biennial review and republication of the select agent and toxin list, with revisions as appropriate in accordance with this law. See 42 U.S.C. 262a(a)(2) and 7 U.S.C. 8401(a)(2), respectively. This rule would implement the recommendations of the third biennial review of the list. Furthermore, revision of these regulations would incorporate the recommendations developed as a result of E.O. 13546, ''Optimizing the Security of Biological Select Agents and Toxins in the United States,'' which requires that the HHS and USDA Secretaries publish proposed regulations to establish risk-based tiering of the select agent list, and revise the regulations, rules, and guidance to accommodate a tiered select agent list no later than October 2011.

In addition, we are proposing several amendments to the regulations, including the addition of definitions and clarification of language concerning security, training, biosafety/biocontainment, and incident response. These changes would increase the applicability and effectiveness of the select agent regulations and provide for enhanced program oversight. This rule would update the USDA, HHS, and overlap select agent and toxin lists. The regulation of select agents and toxins is intended to prevent their misuse and thereby reduce the potential for those pathogens to harm humans, animals, animal products, plants or plant products in the United States. Should any select agent or toxin be intentionally or unintentionally released into the environment, the consequences would be significant. Consequences could include disruption of markets, difficulties in sustaining an adequate food and fiber supply, and the potential spread of disease infestations over large areas. The entities most likely to be affected by this rule would be those laboratories and other institutions conducting research and related activities that involve the use of the newly categorized Tier 1 select agents and toxins. The impact of the changes to the regulations is expected to be minimal. Based on information obtained through site-specific inspections, we believe that very few entities would incur significant costs for compliance. Many of the proposed changes to the regulations would impose an added time cost to measures already required for compliance, with respect to security, biocontainment/biosafety, and incident response plans, information security, and ongoing background checks. While the total cost of the proposed regulations is estimated to range between $4.9 million and $6.4 million, we believe many of these costs are currently incurred by affected entities as generally recognized practices. Costs actually incurred would depend upon the number of computers and facility systems that require the proposed enhanced security. The expected benefits of strengthened safeguards against the unintentional or deliberate release of a select agent or toxin exceed the estimated costs of the proposed measures. Based on the information we have, there is no reason to conclude that adoption of this proposed rule would result in any significant economic effect on a substantial number of small entities. The entities are those laboratories and other institutions conducting research and related activities entities in possession of Tier 1 select agents or toxins, and, to a somewhat lesser extent, those entities possessing the newly added select agents and toxins. The economic analysis presents categories and information from the Department of Commerce and the Small Business Administration for those entities we have identified as most likely to be affected by this rule. While we believe affected entities are contained within these categories, we are seeking further information regarding how many entities fall specifically into each category, and are therefore, inviting comments on potential effects. In particular, we are interested in determining the number and kind of small entities that may incur benefits or costs from the implementation of this proposed rule.

This proposed rule would update the APHIS, CDC, and overlap select agent and toxin lists. The regulation of select agents and toxins is intended to prevent their misuse and thereby reduce the potential for those pathogens to harm humans, animals, animal products, plants or plant products in the United States. Should any select agent or toxin be intentionally or unintentionally released into the environment, the consequences would be significant. Consequences could include disruption of markets, difficulties in sustaining an adequate food and fiber supply, and the potential spread of disease infestations over large areas. The entities most likely to be affected by this rule would be those laboratories and other institutions conducting research and related activities that involve the use of the newly categorized Tier 1 select agents and toxins. The impact of the changes to the regulations is expected to be minimal, however. Based on information obtained through site-specific inspections, indications are that very few entities would incur significant costs for compliance. Many of the proposed changes to the regulations would impose an added cost of the time spent on documenting measures already required for compliance, with respect to security, biocontainment/biosafety, and incident response plans, information security, and ongoing background checks. While the total costs imposed by the proposed regulations are estimated to range between $5.30 million and $6.95 million, including costs to government, we believe many of these costs are incurred through observance of generally recognized industry standards. Costs actually incurred would depend upon the extent to which current facility

practices will need to be enhanced based on the proposed requirements. The expected benefits of strengthened safeguards against the costs associated with unintentional or deliberate release of select agents or toxins would greatly exceed the estimated costs of the proposed measures. The cost associated with a single outbreak have been known to exceed $100 million as outlined in the Regulatory Impact Analysis. Deliberate introduction greatly increases the probability of a select agent or toxin becoming established and causing wide-ranging and devastating impacts on an economy, loss of market access for consumer goods and services, disruption to society, and diminished confidence in public and private institutions.

This analysis reviews expected benefits and costs of the proposed rule in accordance with Executive Orders 12866 and 13563. Possible impacts for small entities are also considered as required by the Regulatory Flexibility Act, which requires agencies to prepare and make available for public comment an initial regulatory flexibility analysis that describes expected impacts of a proposed rule on small businesses, small organizations and small governmental jurisdictions.

Based on the information we have, there is no reason to conclude that adoption of this proposed rule would result in any significant economic effect on a substantial number of small entities. However, we do not currently have all of the data necessary for a comprehensive analysis of the effects of this proposed rule on small entities. Therefore, we are inviting comments on potential effects. In particular, we are interested in determining the number and kind of small entities that may incur benefits or costs from the implementation of this proposed rule.

*b. Regulatory Flexibility Act*

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) requires an agency to consider the potential impact of its regulations on small entities, including small businesses, small governmental units, and small not-for-profit organizations. We certify that this rule will not have a significant economic impact on a substantial number of small entities within the meaning of the RFA. Therefore, a regulatory flexibility analysis as provided for under the RFA is not required.

*c. Paperwork Reduction Act of 1995*

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket Nos. APHIS–2009–0070 and CDC–2011–0012. Please send a copy of your comments to: (1) Docket Nos. APHIS–APHIS–2009–0070 and CDC–2011–0012, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238, and (2) Clearance Officer, OCIO, USDA, room 404–W, 14th Street and Independence Avenue, SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

The Bioterrorism Preparedness Act is designed to prevent, prepare for and respond to bioterrorism and other public health emergencies. The law requires individuals possessing agents or toxins deemed a severe threat to human, animal, or plant health, or to animal or plant products, to be registered with the Secretary of Agriculture or the Secretary of Health and Human Services, unless they have been specifically exempted.

This proposed rule entails the use of a number of separate forms designed to obtain critical information concerning individuals or entities in possession of certain agents or toxins, as well as the specific characteristics of the agents or toxins—including name, strain, and genetic information. This data is needed, in part, to allow APHIS and CDC to determine the biosafety level of an entity as well as the entity's biosecurity situation. This, in turn, helps APHIS and CDC ensure that appropriate safeguard, containment, and disposal requirements commensurate with the risk of the agent or toxin are present at the entity, thus preventing access to such agents and toxins for use in domestic or international terrorism. Facilities containing select agents will be required to maintain records on animals and plants, and revise their Biosafety/Biocontainment Plan and Incident Response Plan for review by APHIS and CDC upon request.

Information to determine that individuals seeking to register have a lawful purpose to possess, use, or transfer agents or toxins will also be requested as part of the registration process. In addition, we will be requesting submission of their Security Plan for our review.

APHIS and CDC are asking OMB to approve, for 3 years, the use of these information collections, associated with its efforts to more closely regulate select agents or toxins that could be used to commit acts of domestic or international terrorism. We are soliciting comments from the public (as well as affected agencies) concerning this information collection activity. APHIS and CDC need this outside input to help accomplish the following:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as 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).

*Estimate of burden:* Public reporting burden for this collection of information is estimated to average 2.3187883 hours per response.

*Respondents:* Researchers, universities, research and development organizations, commercial manufacturers, non-profit institutions, diagnostic laboratories and other interested parties who possess, use, or transfer agents or toxins deemed a severe threat to human, animal or plant health, or to animal or plant products.

*Estimated annual number of respondents:* 386.

*Estimated annual number of responses per respondent:* 12.230569.

*Estimated annual number of responses:* 4,721.

*Estimated total annual burden on respondents:* 10,947 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

| Section | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden hours |
|---|---|---|---|---|---|
| 9 CFR 121.5 and 6, 7 CFR 331.5, 43 CFR 73.5 and 6. | Report of Identification of a Select Agent or Toxin. | 161 | 3 | 1 | 299 |
| § 121.7, § 331.7, § 73.7 | Application for Registration | 7 | 1 | 5 | 35 |
| § 121.7, § 331.7, § 73.7 | Amendment to a Certificate of Registration. | 380 | 7 | 1 | 1,955 |
| § 121.11, § 331.11, § 73.11 | Security Plan | 380 | 1 | 5 | 1,900 |
| § 121.12, § 331.12, § 73.12 | Biosafety/Biocontainment Plan | 380 | 1 | 8 | 3,040 |
| § 121.13, § 331.13, § 73.13 | Request Regarding a Restricted Experiment. | 160 | 1 | 2 | 320 |
| § 121.14, § 331.14, § 73.14 | Incident Response Plan | 380 | 1 | 5 | 1,900 |
| § 121.15, § 331.15, § 73.15 | Training | 380 | 1 | 1 | 380 |
| § 121.16, § 331.16, § 73.16 | Request to Transfer Select Agents and Toxins. | 290 | 1 | 2 | 580 |
| § 121.17, § 331.17, § 73.17 | Records | 295 | 1 | 0.5 | 148 |
| § 121.19, § 331.19, § 73.19 | Notification of Theft, Loss, or Release. | 195 | 1 | 2 | 390 |

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851–2908.

*d. Executive Order 12988: Civil Justice Reform*

This proposed rule has been reviewed under E.O. 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

*e. Executive Order 13132: Federalism*

This rule has been reviewed under E.O. 13132, Federalism. The rule does not impose any regulation that would preempt State, local, and Indian Tribe requirements, or that would have any substantial direct effects on the States, or on the distribution of power and responsibilities among the various levels of government.

*f. Plain Writing Act of 2010*

Under Public Law 111–274 (October 24, 2010), executive branch Departments and Agencies are required to use plain language in documents that explain to the public how to comply with a requirement the Federal Government administers or enforces. HHS has attempted to use plain language in promulgating the proposed rule consistent with the Federal Plain Writing Act guidelines.

## IV. References


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**List of Subjects in 42 CFR Part 73**

Biologics, Incorporation by reference, Packaging and containers, Penalties, Reporting and recordkeeping requirements, Transportation.

For the reasons stated in the preamble, the Centers for Disease Control and Prevention, United States Department of Health and Human Services, proposes to amend 42 CFR part 73 as follows:

## PART 73—SELECT AGENTS AND TOXINS

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

**Authority:** 42 U.S.C. 262a; sections 201–204, 221 and 231 of Title II of Public Law 107–188, 116 Stat 637 (42 U.S.C. 262a).

2. Section 73.1 is amended by adding, in alphabetical order, definitions of *Adjudicated as a mental defective, Alien, Committed to any mental institution, Controlled substance, Crime punishable by imprisonment for a term exceeding 1 year, Indictment, Information security, Lawfully admitted for permanent residence, Mental institution, Occupational exposure, Recombinant and synthetic nucleic acids, Restricted person,* and *Unlawful user of any controlled substance* to read as set forth below.

**§ 73.1 Definitions.**

* * * * *

*Adjudicated as a mental defective.* A determination by a court, board, commission, or other lawful authority that a person, as a result of marked subnormal intelligence, or mental illness, incompetency, condition, or disease is a danger to himself/herself or to others or lacks the mental capacity to contract or manage his/her own affairs. The term includes a finding of insanity by a court in a criminal case and those persons found incompetent to stand trial or found not guilty by reason of lack of mental responsibility pursuant to articles 50a and 72b of the Uniform Code of Military Justice, 10 U.S.C. 850a, 876b.

*Alien.* Any person not a citizen or national of the United States.

* * * * *

*Committed to any mental institution.* A formal commitment of a person to any mental institution by a court, board, commission, or other lawful authority. The term includes a commitment to a mental institution involuntarily. The term includes commitment for mental defectiveness or mental illness. It also includes commitments for other reasons, such as for drug use. The term does not include a person in a mental institution for observation or a voluntary admission to a mental institution.

*Controlled substance.* A drug or other substance, or immediate precursor, as defined in section 102 of the Controlled Substances Act, 21 U.S.C. 802. The term includes, but is not limited to, marijuana and scheduled depressants, stimulants, and narcotic drugs. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in Subtitle E of the Internal Revenue Code of 1986, as amended.

*Crime punishable by imprisonment for a term exceeding 1 year.* Any Federal, State, or foreign offense for which the maximum penalty, whether or not imposed, is capital punishment or imprisonment in excess of 1 year. What constitutes a conviction of such a crime shall be determined in accordance with the law of the jurisdiction in which the proceedings were held. Any conviction that has been set aside or nullified as a matter of law or for which a person has been pardoned shall not be considered a conviction for purposes of this part.

* * * * *

*Indictment.* A formal written accusation originating with a prosecutor and issued by a grand jury against a party charged with a crime. For the purpose of these regulations the term indictment includes any ''information'' that is a formal accusation of a crime, differing only in that it is being presented by a competent public officer on his oath of office, instead of a grand jury.

*Information security.* Protecting information and information systems from unauthorized access, use, disclosure, disruption, modification, or destruction in order to provide—

(1) *Integrity,* which means guarding against improper information modification or destruction, and includes ensuring information nonrepudiation and authenticity;

(2) *Confidentiality,* which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and

(3) *Availability,* which means ensuring timely and reliable access to and use of information.

* * * * *

*Lawfully admitted for permanent residence.* The status of having been lawfully accorded the privilege of residing permanently in the United States as an immigrant in accordance with the immigration laws, such status not having changed.

*Mental institution.* Includes mental health facilities, mental hospitals, sanitariums, psychiatric facilities, and other facilities that provide diagnoses by licensed professionals of mental retardation or mental illness, including a psychiatric ward in a general hospital.

* * * * *

*Occupational exposure.* Any reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials or toxins that may result from the performance of an employee's duties.

* * * * *

*Recombinant and synthetic nucleic acids.*

(1) Recombinant nucleic acid molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell;

(2) Synthetic nucleic acid molecules that are chemically, or by other means, synthesized or amplified nucleic acid molecules that may wholly or partially contain functional equivalents of nucleotides; or

(3) Molecules that result from the replication of those described in paragraphs (1) or (2) of this definition.

* * * * *

*Restricted person.* An individual who:

(1) Is under indictment for a crime punishable by imprisonment for a term exceeding 1 year;

(2) Has been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year;

(3) Is a fugitive from justice;

(4) Is an unlawful user of any controlled substance (as ''controlled substance'' is defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

(5) Is an alien illegally or unlawfully in the United States;

(6) Has been adjudicated as a mental defective or has been committed to any mental institution;

(7) Is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country as to which the Secretary of State, pursuant to section 6(j) of the Export Administration Act of 1979 (50 U.S.C. App. 2405(j)), section 620A of chapter 1 of part M of the Foreign Assistance Act of 1961 (22 U.S.C. 2371), or section 40(d) of chapter 3 of the Arms Export Control Act (22 U.S.C. 2780d), has made a determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism; or

(8) Has been discharged from the Armed Services of the United States under dishonorable conditions.

* * * * *

*Unlawful user of any controlled substance.* For purposes of this part, a person who uses a controlled substance and has lost the power of self-control with reference to the use of that controlled substance; and any person who is a current user of a controlled substance in a manner other than as prescribed by a licensed physician. Such use is not limited to the use of drugs on a particular day, or within a matter of days or weeks before, but rather that the unlawful use has occurred recently enough to indicate that the individual is actively engaged in such conduct. A person may be an unlawful current user of a controlled substance even though the substance is not being used at the precise time the person seeks to have access to a select agent or toxin. An inference of current use may be drawn from evidence of a recent use or possession of a controlled substance or a pattern of use or possession that reasonably covers the present time, e.g., a conviction for use or possession of a controlled substance within the past year; multiple arrests for such offenses within the past 5 years if the most recent arrest occurred within the past year, or persons found through a drug test to use a controlled substance unlawfully, provided that the test was administered within the past year. For a current or former member of the Armed Forces, an inference of current use may be drawn from recent disciplinary or other administrative action based on confirmed drug use, e.g., court-martial conviction, nonjudicial punishment, or an administrative discharge based on drug use or drug rehabilitation failure.

* * * * *

3. Section 73.3 is amended as follows:

a. By adding a sentence to the end of paragraph (a) to read as set forth below.

b. By revising paragraph (b) to read as set forth below.

c. In paragraph (c), in the introductory text, by adding the phrase ''and/or Synthetic'' after the word ''Recombinant'' each time it appears.

d. In paragraph (c)(2) introductory text, by adding the phrase ''and/or synthetic'' after the word ''Recombinant''.

e. By revising paragraph (d)(3) to read as set forth below.

f. By adding a new paragraph (d)(4) to read as set forth below.

g. By revising paragraph (e) to read as set forth below.

h. In paragraph (f)(3)(i), by removing the words ''Lassa fever virus, South American Haemorrhagic Fever virus (Junin, Machupo, Sabia, Flexal, Guanarito)'' and by adding the words ''Botulinum neurotoxin producing species of Clostridium.''

**§ 73.3 HHS select agents and toxins.**

(a) * * * The select agents and toxins marked with an asterisk (*) are designated as Tier 1 select agents and toxins and are subject to additional requirements as listed in this part.

(b) HHS select agents and toxins: [1]

Abrin
Botulinum neurotoxins*
Botulinum neurotoxin producing species of Clostridium*
Chapare
*Clostridium perfringens* epsilon toxin
Conotoxins
*Coxiella burnetii*
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Eastern Equine Encephalitis virus (North American genotypes)
Ebola virus*
*Francisella tularensis**
Lassa fever virus
Lujo
Marburg virus*
Monkeypox virus

Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)

Ricin
*Rickettsia prowazekii*
*Rickettsia rickettsii*
Saxitoxin
Shiga-like ribosome inactivating proteins
Shigatoxin
South American Haemorrhagic Fever viruses
Guanarito
Junin
Machupo
Sabia
Staphylococcal enterotoxins (SE) A–E (SEA, SEB, SEC, SED, SEE)
T–2 toxin
Tetrodotoxin
Tick-borne encephalitis virus
Far Eastern subtype
Siberian subtype
Kyasanur Forest disease virus
Omsk hemorrhagic fever virus
Variola major virus (Smallpox virus)*
Variola minor virus (Alastrim)*
*Yersinia pestis**

* * * * *

(d) * * *

(3) Except as required in § 73.16(l), HHS toxins under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor, if:

(i) The aggregate amount does not, at any time, exceed the following amounts: 100 mg of Abrin; 0.5 mg of Botulinum neurotoxins; 100 mg of *Clostridium*

[1] Including all toxin derivatives, both naturally occurring and synthetic, that retain function.

*perfringens* epsilon toxin; 100 mg of Conotoxins; 1,000 mg of Diacetoxyscirpenol; 100 mg of Ricin; 100 mg of Saxitoxin; 100 mg of Shiga-like ribosome inactivating proteins; 100 mg of Shigatoxin; 5 mg of Staphylococcal enterotoxins; 1,000 mg of T–2 toxin; or 100 mg of Tetrodotoxin.

(ii) Amounts of toxins equal to or less than the amounts identified in paragraph (d)(3)(i) of this section are transferred only after the transferor uses due diligence and documents that the recipient has a legitimate need (i.e. reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose) to handle or use such toxins. Notwithstanding the provisions of paragraph (d) of this section, the HHS Secretary retains the authority to, without prior notification, inspect and copy or request the submission of the due diligence documentation to the CDC.

(iii) The transfer of amounts of toxins equal to or less than the amounts identified in paragraph (d)(3)(i) of this section reports to CDC if they detect a known or suspected violation of Federal law or become aware of suspicious activity related to a toxin listed in section of this part.

(4) Notwithstanding paragraph (d)(3)(i) of this section, an animal inoculated with or exposed to an HHS select toxin.

(e) An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of this part based upon a determination by the HHS Secretary that the attenuated strain or inactivated toxin does not pose a severe threat to public health and safety.

(1) To apply for exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification to the applicant. Exclusions will be listed on the National Select Agent Registry Web site at *http://www.selectagents.gov/.*

(2) If an excluded attenuated strain or inactivated toxin is subjected to any manipulation that restores or enhances its virulence or toxic activity, the resulting select agent or toxin will be subject to the requirements of this part.

* * * * *

4. Section 73.4 is amended as follows:

a. By adding a sentence to the end of paragraph (a) to read as set forth below.

b. By revising paragraph (b) to read as set forth below.

c. In paragraph (c), in the introductory text, by adding the phrase ''and/or synthetic'' after the word ''Recombinant'' each time it appears.

d. In paragraph (c)(2), by adding the phrase ''and/or synthetic'' after the word ''Recombinant''.

e. By revising paragraph (e) to read as set forth below.

f. In paragraph (f)(3)(i), by removing the words ''*Brucella melitensis,* Hendra virus, Nipah virus, Rift Valley fever virus, and Venezuelan equine encephalitis virus'' and adding the words ''*Burkholderia mallei* and *Burkholderia pseudomallei''* in their place.

**§ 73.4 Overlap select agents and toxins.**

(a) * * * The select agents and toxins marked with an asterisk (*) are designated as Tier 1 select agents and toxins and are subject to additional requirements as listed in this part.

(b) Overlap select agents and toxins:

*Bacillus anthracis;**
*Brucella abortus;*
*Brucella melitensis;*
*Brucella suis;*
*Burkholderia mallei;**
*Burkholderia pseudomallei;**
Hendra virus;
Nipah virus;
Rift Valley fever virus;
Venezuelan equine encephalitis virus: Epizootic Subtypes IAB, IC.

* * * * *

(e) An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of this part based upon a determination by the HHS Secretary or Administrator that the attenuated strain or inactivated toxin does not pose a severe threat to public health and safety, to animal health or to animal products.

(1) To apply for exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification to the applicant. Exclusions will be listed on the National Select Agent Registry Web site at *http://www.selectagents.gov/.*

(2) If an excluded attenuated strain or inactivated toxin is subjected to any manipulation that restores or enhances its virulence or toxic activity, the resulting select agent or toxin will be subject to the requirements of this part.

* * * * *

**§ 73.5 [Amended]**

5. Section 73.5(a)(3)(i) is amended by removing the words ''Lassa fever virus, South American Haemorrhagic Fever virus (Junin, Machupo, Sabia, Flexal, Guanarito)'' and by adding the words ''Botulinum neurotoxin producing species of *Clostridium''* in their place.

**§ 73.6 [Amended]**

6. Section 73.6(a)(3)(i) is amended by removing the words ''Brucella melitensis, Hendra virus, Nipah virus, Rift Valley fever virus, and Venezuelan equine encephalitis virus'' and adding the words ''*Burkholderia mallei* and *Burkholderia pseudomallei*'' in their place.

**§ 73.8 [Amended]**

7. Section 73.8 (a)(1) is amended by removing the words ''within any of the categories described in 18 U.S.C. 175b'' and adding the words ''a restricted person'' in their place.

* * * * *

8. Section 73.9 is amended as follows:

a. By redesignating paragraphs (a)(3) through (a)(5) as paragraphs (a)(4) through (a)(6) respectively.

b. By adding a new paragraph (a)(3) to read as set forth below.

c. In newly redesignated paragraph (a)(5), by removing the word ''and''.

d. By further redesignating newly redesignated paragraph (a)(6) as paragraph (a)(7).

e. By adding a new paragraph (a)(6) to read as set forth below.

f. By revising the first sentence of paragraph (b) to read as set forth below.

g. In paragraph (c)(1), by removing the words ''Bacillus anthracis, Botulinum neurotoxins, Brucella melitensis, Francisella tularensis, Ebola viruses, Hendra virus, Marburg virus, Lassa fever virus, Nipah virus, Rift Valley fever virus, South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito), Variola major virus (Smallpox virus), Variola minor (Alastrim), Venezuelan equine encephalitis virus and Yersina pestis'' and adding the words ''*Bacillus anthracis, Botulinum neurotoxins, Botulinum neurotoxin producing species of Clostridium, Burkholderia mallei, Burkholderia pseudomallei, Francisella tularensis, Ebola viruses, Marburg virus, Variola major virus (Smallpox virus), Variola minor (Alastrim), and Yersinia pestis*'' in their place.

(a) * * *

(3) Have the appropriate training and expertise to competently implement and manage the requirements of this part;

* * * * *

(6) Have their principal duty station at the physical location of the entity; and

* * * * *

(b) An entity may designate one or more individuals to serve as an alternate Responsible Official, who acts for the Responsible Official in his/her absence.

* * *

* * * * *

9. Section 73.10 is amended as follows:

a. By redesignating paragraphs (e) through (j) as paragraphs (f) through (k) respectively.

b. By adding a new paragraph (e) to read as set forth below.

c. In newly redesignated paragraph (g), by removing the words ''within any of the categories described in 18 U.S.C. 175b'' and adding the words ''a restricted person'' in their place.

d. In newly redesignated paragraph (j), by removing the word ''five'' and adding the word ''three'' in its place.

**§ 73.10 Restricting access to select agents and toxins; security risk assessments.**

* * * * *

(e) A person who has a valid approval from the HHS Secretary or Administrator for access to a select agent or toxin may request the HHS Secretary or Administrator to provide the person's approval status to another registered individual or entity for a specified period of time.

* * * * *

10. Section 73.11 is amended as follows:

a. By revising paragraph (b) to read as set forth below.

b. By revising paragraph (c)(2) to read as set forth below.

c. By adding new paragraphs (c)(8), (c)(9), and (c)(10) to read as set forth below.

d. By redesignating paragraphs (e) and (f) as paragraphs (f) and (g), respectively and by revising redesignated paragraph (f) to read as set forth below.

e. By adding a new paragraph (e) to read as set forth below.

**§ 73.11 Security.**

* * * * *

(b) The security plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use. A current security plan must be submitted for initial registration, renewal of registration, or when requested.

(c) * * *

(2) Contain provisions for the control of access to select agents and toxins, including the safeguarding of animals or plants intentionally or accidentally exposed to or infected with a select agent, against unauthorized access, theft, loss or release.

* * * * *

(8) Describe procedures for how the Responsible Official will be informed of suspicious activity that may be criminal in nature and related to the entity, its personnel, or its select agents or toxins; and how the Responsible Official will notify the Federal Bureau of Investigation (FBI) of such activity,

(9) Contain provisions for information security that:

(i) Ensure that all external connections to systems which control security of the facility are isolated or have controls that permit and monitor for only authorized and authenticated user access;

(ii) Ensure that authorized and authenticated users are only granted access to select agent and toxin related information, files, equipment (e.g., servers or mass storage devices) and applications as necessary to fulfill their roles and responsibilities, and that access is modified when the user's roles and responsibilities change or when their access to select agent and toxin is suspended or revoked;

(iii) Ensure that controls are in place that are designed to prevent malicious code (such as, but not limited to, computer virus, worms, spyware) from compromising the confidentiality, integrity, or availability of information systems;

(iv) Establish a robust configuration management practice for information systems to include regular patching and updates made to operating systems and individual applications; and

(v) Establish procedures that provide backup security measures in the event that access control systems and/or surveillance devices are rendered inoperable.

(10) Contain provisions and policies for shipping, receiving, and storage of select agents and toxins, including documented procedures for receiving, monitoring, and shipping of all select agents and toxins. These provisions must provide that an entity will properly secure containers on site and have a written contingency plan for unexpected shipments.

* * * * *

(e) In addition to the requirements contained in paragraphs (c) and (d) of this section, the security plan for an individual or entity possessing a Tier 1 select agent or toxin must also:

(1) Describe procedures for conducting a pre-access suitability assessment of persons who will have access to a Tier 1 select agent or toxin;

(2) Describe procedures for how an entity's Responsible Official will coordinate their efforts with the entity's safety and security professionals to ensure security of Tier 1 select agents and toxins and share, as appropriate, relevant information; and

(3) Describe procedures for the ongoing assessment of the suitability of personnel with access to a Tier 1 select agent or toxin. The procedures must include:

(i) Self- and peer-reporting of incidents or conditions that could affect an individual's ability to safely have access to or work with select agents and toxins, or to safeguard select agents and toxins from theft, loss, or release;

(ii) The training of all entity employees on entity policies and procedures for reporting, evaluation, and corrective actions concerning the assessment of personnel suitability to access Tier 1 agents and toxins; and

(iii) The ongoing suitability monitoring of individuals with access to Tier 1 select agents and toxins.

(4) Entities with Tier 1 select agents and toxins must prescribe and/or implement the following security enhancements:

(i) Procedures that will limit access to registered space only to those approved by the HHS Secretary or the Administrator and meet the criteria of the entity's program that will ensure individuals with access approval to select agents and toxins are trustworthy and behaving in a manner that upholds public health and safety, security, and the integrity of the scientific enterprise.

(ii) Procedures that limit access to laboratory and storage facilities outside of normal business hours to only those specifically approved by the Responsible Official or designee;

(iii) Procedures for allowing visitors, their property, and vehicles at the entry and exit points to the registered space, or at other designated points of entry to the building, facility, or compound based on the entity's site-specific risk assessment;

(iv) A minimum of three barriers where each subsequent barrier is different and adds to the delay in reaching secured areas where select agents and toxins are used or stored. Barriers must be monitored in such a way as to detect and assess intentional and unintentional circumventing of established access control measures under all conditions (day/night, severe weather, etc.);

(v) All registered space or areas that reasonably afford access to the registered space must be protected by an intrusion detection system (IDS) unless physically occupied;

(vi) Personnel monitoring the IDS must be capable of evaluating and interpreting the alarm and alerting the designated security response force or law enforcement;

(vii) Provide backup power and energy sources to power information security networks and integrated access

controls and related systems during emergencies;

(viii) Response time for security forces or local police must not exceed 15 minutes from the time of an intrusion alarm or report of a security incident;

(ix) Entities must conduct complete inventory audits of all Tier 1 select agents and toxins in long-term storage when any of the following occur:

(A) Upon the physical relocation of a collection or inventory of select agents or toxins for those Tier 1 select agents or toxins in the collection or inventory;

(B) Upon the departure or arrival of a principal investigator for those Tier 1 select agents and toxins under the control of that principal investigator; or

(C) In the event of a theft or loss of a Tier 1 select agent or toxin.

(5) Entities that possess Variola major virus and Variola minor virus must have the following additional security requirements:

(i) Require personnel with access to Variola major or Variola minor virus to have a Top Secret security clearance,

(ii) Require Variola major or Variola minor virus storage locations be under the surveillance of closed circuit television that is monitored,

(iii) After hours access procedures for Variola major or Variola minor virus must require notification of the entity's security staff prior to entry into the Variola laboratory and upon exit,

(iv) Require that observation zones be maintained in outdoor areas adjacent to the physical barrier at the perimeter of the entity and be large enough to permit observation of the activities of people at that barrier in the event of its penetration,

(v) Provide for a minimum of four barriers for the protection of the Variola major or Variola minor virus, one of which must be a perimeter fence,

(vi) Require a numbered picture badge identification subsystem to be used for all individuals who are authorized to access Variola major or Variola minor without escort,

(vii) Require the use, at all times, of properly trained, and equipped security force personnel able to interdict threats identified in the site specific risk assessment,

(viii) Identify security force personnel designated to strengthen onsite response capabilities, and that will be onsite and available at all times to carry out their assigned response duties,

(ix) Provide for security patrols to periodically check external areas of the registered areas to include physical barriers and building entrances,

(x) Require that all on-duty security force personnel shall be capable of maintaining continuous communication with support and response assets by way of security operations center,

(xi) Require that Variola major and Variola minor material in long term storage be stored in tamper-indicating containers,

(xii) Require that all spaces containing working or permanent Variola major or Variola minor stocks be locked and protected by an intrusion alarm system that will alarm upon the unauthorized entry of a person anywhere into the area,

(xiii) Require that alarms required pursuant to this section annunciate in a continuously manned security operations center located within the facility,

(xiv) Require that the security operations center shall be located within a building so that the interior is not visible from the perimeter of the protected area.

(f) In developing a security plan, an individual or entity should consider the documents entitled, ''Select Agents and Toxins Security Information Document'' and ''Select Agents and Toxins Security Plan Template.'' These documents are available on the Internet at *http://www.selectagents.gov/.*

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11. Section 73.12 is amended as follows:

a. By revising paragraph (a) to read as set forth below.

b. By revising paragraph (c)(1) to read as set forth below.

c. In paragraph (c)(3), by removing the URL ''*http://www.cdc.gov/*'' and adding in its place ''*http://www.selectagents.gov*''.

d. By redesignating paragraph (d) as paragraph (e).

e. By adding a new paragraph (d) to read as set forth below.

**§ 73.12 Biosafety.**

* * * * *

(a) An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals or plants intentionally or accidentally exposed to or infected with a select agent.

* * * * *

(c) * * *

(1) The CDC/NIH publication, ''Biosafety in Microbiological and Biomedical Laboratories.'' This document is available on the Internet at *http://www.selectagents.gov.*

* * * * *

(d) The biosafety plan must include an occupational health program for individuals with access to Tier 1 select agents and toxins, and those individuals must be enrolled in the occupational health program. The occupational health program may also be made available to individuals without access to Tier 1 select agents and toxins.

* * * * *

**§ 73.13 [Amended]**

12. Section 73.13 is amended as follows:

a. In paragraph (a), in the introductory text, by adding the phrase '', or possess products (i.e. select agents that are not known to acquire the resistance naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture, or recombinant and or synthetic DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight) resulting from,'' after the word ''conduct'' both times it appears.

b. In paragraph (b)(1), by removing the words ''Experiments utilizing recombinant DNA that involve the deliberate transfer of'' and replacing them with the words ''Experiments that involve the deliberate transfer of, or selection for,''.

c. In paragraph (b)(2), by adding the words ''synthetic or'' before the word ''recombinant.''

13. Section 73.14 is amended as follows:

a. By revising paragraph (a) to read as set forth below.

b. By revising paragraph (b) to read as set forth below.

c. By redesignating paragraph (c) and (d) as paragraphs (d) and (f) respectively.

d. By adding a new paragraph (c) to read as set forth below.

e. By adding a new paragraph (e) to read as set forth below.

**§ 73.14 Incident response.**

(a) An individual or entity required to register under this part must develop and implement a written incident response plan based upon a site specific risk assessment.[2] The incident response plan must be coordinated with any entity-wide plans, kept in the

[2] Nothing in this section is meant to supersede or preempt incident response requirements imposed by other statutes or regulations.

workplace, and available to employees for review.

(b) The incident response plan must fully describe the entity's response procedures for the theft, loss, or release of a select agent or toxin; inventory discrepancies; security breaches (including information systems); severe weather and other natural disasters; workplace violence; bomb threats and suspicious packages; and emergencies such as fire, gas leak, explosion, power outage, etc.

(c) The response procedures must account for hazards associated with the select agent or toxin and appropriate actions to contain such select agent or toxin, including any animals or plants intentionally or accidentally exposed to or infected with a select agent.

* * * * *

(e) Entities with Tier 1 select agents and toxins must have the following additional incident response policies or procedures:

(1) The incident response plan must fully describe the entity's response procedures for failure of intrusion detection or alarm system; and

(2) The incident response plan must describe notification procedures for the FBI in the event of a theft or suspicious activity that may be criminal in nature involving a Tier 1 select agent or toxin.

* * * * *

14. Section 73.15 is revised to read as follows:

**§ 73.15 Training.**

(a) An individual or entity required to register under this part must provide information and training on biosafety, security (including security awareness) and incident response:

(1) To each individual with access approval from the HHS Secretary or Administrator before that individual has such access to select agents and toxins. The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins.

(2) To each individual not approved for access to select agents and toxins by the HHS Secretary or Administrator before that individual enters areas where select agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.). Training for escorted personnel must be based on the risk associated with accessing areas where select agents and toxins are used and/or stored.

(b) Entities with Tier 1 select agents and toxins must conduct annual insider threat awareness briefings on how to identify and report suspicious behaviors.

(c) Refresher training must be provided annually or at such time as the registered individual or entity significantly amends its security, incident response, or biosafety plans.

(d) The Responsible Official must ensure a record of the training provided to each individual with access to select agents and each escorted individual (e.g., laboratory workers, visitors, etc.) is maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training.

15. Section 73.16 is amended as follows:

a. By redesignating paragraph (f), (g), (h), and (i) as paragraphs (i), (j), (k), and (g) respectively.

b. In redesignated paragraph (g), by removing the words ''packaging and''.

c. By adding a new paragraph (f) to read as set forth below.

d. By adding a new paragraph (h) to read as set forth below.

e. By adding a new paragraph (l) to read as set forth below.

**§ 73.16 Transfers.**

* * * * *

(f) After authorization is provided by APHIS or CDC, the select agent(s) and toxin(s) are packaged for shipment in compliance with all applicable laws concerning packaging by an individual approved by the HHS Secretary or Administrator to have access to select agents and toxins, following a security risk assessment by the Attorney General.

* * * * *

(h) Transportation in commerce starts when the select agent(s) or toxin(s) are packaged for shipment and ready for receipt by a courier transporting select agent(s) or toxin(s) and ends when the package is received by the intended recipient who is an individual approved by the HHS Secretary or Administrator to have access to select agents and toxins, following a security risk assessment by the Attorney General.

* * * * *

(l) A registered individual or entity transferring an amount of a HHS toxin otherwise excluded under the provisions of § 73.3(d) of this part must:

(1) Transfer the HHS toxin only after using due diligence and documenting that the recipient has a legitimate need (reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose) to handle or use such toxins. The HHS Secretary retains the authority to, without prior notification, inspect and copy or request the submission of the due diligence documentation to the CDC.

(2) Report to CDC any known or suspected violation of Federal law or suspicious activity related to the toxin.

16. Section 73.17 is amended as follows:

a. By revising paragraph (a)(1) introductory text to read as set forth below.

b. By redesignating paragraphs (a)(2) through (a)(6) as paragraphs (a)(3) through (a)(7) respectively.

c. By adding a new paragraph (a)(2) to read as set forth below.

**§ 73.17 Records.**

(a) * * *

(1) An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and recombinant and/or synthetic organisms) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials), including:

* * * * *

(2) An accurate, current inventory of any animals or plants intentionally or accidentally exposed to or infected with a select agent (including number and species, location, and appropriate disposition);

* * * * *

17. Section 73.20 is revised to read as set forth below.

**§ 73.20 Administrative review.**

(a) An individual or entity may appeal a denial, revocation, or suspension of registration under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the HHS Secretary within 30 calendar days of the decision.

(b) An individual may appeal a denial, limitation, or revocation of access approval under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the HHS Secretary within 180 calendar days of the decision.

(c) The HHS Secretary's decision constitutes final agency action.

Dated: September 21, 2011.

**Kathleen Sebelius,**

*Secretary.*

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Part V

## Department of Agriculture

Animal and Plant Health Inspection Service

7 CFR Part 331

9 CFR Part 121

Agricultural Bioterrorism Protection Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List; Amendments to the Select Agent and Toxin Regulations; Proposed Rule

**DEPARTMENT OF AGRICULTURE**

**Animal and Plant Health Inspection Service**

**7 CFR Part 331**

**9 CFR Part 121**

**[Docket No. APHIS–2009–0070]**

**RIN 0579–AD09**

## Agricultural Bioterrorism Protection Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List; Amendments to the Select Agent and Toxin Regulations

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Proposed rule.

**SUMMARY:** In accordance with the Agricultural Bioterrorism Protection Act of 2002, we are proposing to amend and republish the list of select agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant products. The Act requires the biennial review and republication of the list of select agents and toxins and the revision of the list as necessary. This action would implement the findings of the third biennial review of the list. In addition, we are proposing to reorganize the list of select agents and toxins based on the relative potential of each select agent or toxin to be misused to adversely affect human, plant, or animal health. Such tiering of the list would allow for the optimization of security measures for those select agents or toxins that present the greatest risk of deliberate misuse with the most significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence. We are also proposing a number of amendments to the regulations, including the addition of definitions and clarification of language concerning security, training, biosafety, biocontainment, and incident response. These changes would increase the usability of the select agent regulations as well as provide for enhanced program oversight.

**DATES:** We will consider all comments that we receive on or before December 2, 2011.

**ADDRESSES:** You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!documentDetail;D=APHIS-2009-0070-0001.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2009–0070, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2009-0070* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

**FOR FURTHER INFORMATION CONTACT:** Mr. Charles L. Divan, Branch Chief, APHIS Agriculture Select Agent Program, APHIS, 4700 River Road Unit 2, Riverdale, MD 20737–1231; (301) 734–5960.

**SUPPLEMENTARY INFORMATION:**

### Background

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (referred to below as the Bioterrorism Response Act) provides for the regulation of certain biological agents that have the potential to pose a severe threat to both human and animal health, to animal health, to plant health, or to animal and plant products. The Animal and Plant Health Inspection Service (APHIS) has the primary responsibility for implementing the provisions of the Act within the Department of Agriculture (USDA). Veterinary Services (VS) select agents and toxins are those that have been determined to have the potential to pose a severe threat to animal health or animal products. Plant Protection and Quarantine (PPQ) select agents and toxins are those that have the potential to pose a severe threat to plant health or plant products. Overlap select agents and toxins are those that have been determined to pose a severe threat to both human and animal health or animal products. Overlap select agents are subject to regulation by both APHIS and the Centers for Disease Control and Prevention (CDC), which has the primary responsibility for implementing the provisions of the Act for the Department of Health and Human Services (HHS).

Subtitle B (which is cited as the ''Agricultural Bioterrorism Protection Act of 2002'' and referred to below as the Act), section 212(a), provides, in part, that the Secretary of Agriculture (the Secretary) must establish by regulation a list of each biological agent and each toxin that the Secretary determines has the potential to pose a severe threat to animal or plant health, or to animal or plant products. Paragraph (a)(2) of section 212 requires the Secretary to review and republish the list every 2 years and to revise the list as necessary. In this document, we are proposing to amend and republish the list of select agents and toxins based on the findings of our third biennial review of the list.

In determining whether to include an agent or toxin on the list, the Act requires that the following criteria be considered:

- The effect of exposure to the agent or the toxin on animal and plant health, and on the production and marketability of animal or plant products;
- The pathogenicity of the agent or the toxin and the methods by which the agent or toxin is transferred to animals or plants;
- The availability and effectiveness of pharmacotherapies and prophylaxis to treat and prevent any illness caused by the agent or toxin; and
- Any other criteria that the Secretary considers appropriate to protect animal or plant health, or animal or plant products.

We use the term ''select agents and toxins'' throughout the preamble of this proposed rule. Unless otherwise specified, the term ''select agents and toxins'' will refer to all agents or toxins listed by APHIS. When it is necessary to specify the type of select agent or toxin, we will use the following terms: ''PPQ select agents and toxins'' (for the plant agents and toxins listed in 7 CFR 331.3), ''VS select agents and toxins'' (for the animal agents and toxins listed in 9 CFR 121.3), or ''overlap select agents and toxins'' (for the agents and toxins listed in both 9 CFR 121.4 and 42 CFR 73.4).

On July 29, 2010, we published in the **Federal Register** (75 FR 44724–44725, Docket No. APHIS–2009–0070) an advance notice of proposed rulemaking and request for comments (ANPR) [1] in order to announce our intention to review and reorganize the select agent list. We solicited comments regarding potential additions and deletions from the list of select agents and toxins as well as comments on reorganization of the list based on the relative potential of each select agent or toxin to be misused to adversely affect human, plant, or animal health. We requested recommendations as to what criteria should be utilized to designate high risk select agents and toxins and incorporated those recommendations

[1] To view the ANPR and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2009-0070.*

into the interagency working group discussions on the matter. We solicited comments for 30 days ending August 30, 2010. We received 30 comments by that date. They were from scientists, scientific organizations, private individuals, and industry groups. Suggestions in these comments were used in order to inform our discussions on the content of the select agent list and our determination regarding reorganization of the list.

**PPQ Select Agents and Toxins**

APHIS's PPQ program convened an interagency working group to review the list of PPQ select agents and toxins and develop recommendations regarding possible changes to that list. Using the four criteria for listing found in the Act, economic crop data, current Federal quarantine notices, and new scientific information, the working group revisited the currently listed PPQ select agents and toxins and evaluated a number of new plant pathogens for inclusion on the list. Based on this review, APHIS is proposing to amend the list of PPQ select agents and toxins listed in 7 CFR 331.3 by removing *Xylella fastidiosa,* citrus variegated chlorosis (CVC) strain, from the list as it no longer meets the criteria for use as an agroterrorism agent. Since CVC was first included on the list, extensive research on this select agent has been completed. New scientific information has led to creation of detection methods that provide for better early response and control methods. These new technologies can be applied regardless of how the agent might be introduced, including purposeful introduction for harmful purposes. Furthermore, the use of geostatistical analysis in citrus production areas using geographic information systems is now well-developed with relation to monitoring and facilitating a response to any purposeful introduction. As a result of this new research, as well as the development of new regulatory systems for CVC, the likelihood that someone would use CVC as an agent of bioterrorism is reduced, and our ability to manage an introduction is increased.

**VS Select Agents and Toxins**

APHIS's VS program also convened an interagency working group to review the list of VS select agents and toxins and the list of overlap select agents and toxins in 9 CFR part 121 in order to update and revise the lists as necessary.

We are proposing to remove nine VS select agents and toxins from the list set out in § 121.3(b). Specifically, we are proposing to remove the following: Akabane virus; Bluetongue virus (exotic), Bovine spongiform encephalopathy agent; Camel pox virus; *Ehrlichia ruminantium* (Heartwater); Japanese encephalitis virus; Malignant catarrhal fever virus (Alcelaphine herpesvirus type 1); Menangle virus; and Vesicular stomatitis virus (exotic): Indiana subtypes VSV–IN2, VSV–IN3.

The interagency working group considered each of the VS select agents and toxins with respect to the four criteria for listing found in the Act and based on the group's analysis, APHIS has determined that the nine VS select agents and toxins listed above should be removed from the list. These agents were judged not to pose a significant threat to animal health, either because the disease risk is not significant (*e.g.,* low mortality rate in the event of infection), they affect only minor (*i.e.,* not economically significant) species, or they are not likely to be used as an agroterrorism agent (*e.g.,* difficulty of transmission from animal to animal).

For example, Japanese encephalitis virus primarily affects horses and pigs and is transmitted via a mosquito bite. It is not directly contagious between animals. Horses represent a dead-end host for the disease; mosquitoes biting an infected horse will not pick up virus to transmit to any new animals. Pigs represent an amplifying host, but modern pig husbandry practices in the U.S. minimize exposure of the herd to mosquitoes and make it difficult to establish and sustain a natural transmission cycle.

Likewise, a sustained transmission cycle of malignant catarrhal fever virus (Alcelaphine herpesevirus type 1) requires the presence of the reservoir host (African wildlife) in close physical association with the susceptible domestic species (cattle and bison).

With respect to the remaining agents:

- Camel pox only affects camels, which are a minor species in the US;
- Akabane virus, bluetongue virus (exotic), Ehrlichia ruminantium (Heartwater), and vesicular stomatitis virus (exotic): Indiana subtypes VSV–IN2, VSV–IN3 all utilize insect vectors as a mode of transmission and are not usually spread by direct contact between animals;
- Menangle virus transmission is associated with certain species of fruit bats, which are native only to Australia and Southeast Asia; and
- Bovine spongiform encephalopathy agent is only known to be transmitted through the ingestion of infected tissues.

All of these circumstances make transmission from animal-to-animal difficult, which greatly lessens the chance of an outbreak either accidental or intentional. Consequently, the extent to which Federal, State, and/or local officials need to take special action in planning for a major animal health disaster as a result of any of these organisms is decreased in light of these factors. Therefore, in considering these reasons as well as recommendations provided in previous reports such as ''The Report of the Working Group on Strengthening the Biosecurity of the United States'' [2] and the ''Federal Experts Security Advisory Panel: Recommendations Concerning the Select Agent Program'' [3] as well as comments received on the ANPR, APHIS has determined those pathogens listed here are not likely to be used as agroterrorism agents and no longer need to be designated as VS select agents.

**Overlap Select Agents and Toxins**

We are also proposing to modify the listing for one of the overlap select agents by removing certain subtypes of Venezuelan equine encephalitis virus from the list of overlap select agents and toxins set out in 9 CFR 121.4(b), and to clarify that only Venezuelan equine encephalitis subtypes IAB and IC would remain on the list. These subtypes contain the only recognized strains of Venezuelan equine encephalitis that can suddenly affect a large number of animals over a large area (*i.e.,* epizootic). The remaining subtypes, ID and IE, are strains prevalent among existing animal populations (*i.e.,* enzootic) and do not represent the same type of risk. Other viruses within the Venezuelan equine encephalitis complex (subtypes IF and II through IV) are separate viruses and are not included in the list of overlap select agents and toxins. Accordingly, CDC will also be proposing a parallel change to its overlap select agent regulations.

**Reorganization of the Current List of Select Agents and Toxins**

We are proposing to establish a number of select agents and toxins as ''Tier 1'' select agents and toxins within the lists of VS and overlap select agents and toxins. We are not including PPQ select agents and toxins in this proposed reorganization because none of the proposed Tier 1 select agents and toxins are from the plant list. All other select agents and toxins would continue to be subject to the current requirements concerning select agents and toxins. All select agents and toxins were scored against 20 criteria by over 60 subject

[2] Available on the Internet at *http://www.phe.gov/Preparedness/legal/boards/biosecurity/Documents/biosecreportfinal102309.pdf.*

[3] Available on the Internet at *http://www.phe.gov/Preparedness/legal/boards/fesap/Documents/fesap-recommendations-101102.pdf.*

matter experts representing the Federal life sciences, public health, law enforcement, security, and intelligence communities. These criteria included:

- The relative ease with which a particular select agent or toxin might be disseminated or transmitted from one animal to another or into the environment where it could produce a deleterious effect upon animal or plant health;
- The potential for high animal or plant mortality rates;
- The potential for a major animal or plant health impact;
- Select agents or toxins whose misuse might result in public panic or other social or economic disruption; and
- Select agents or toxins whose use might require Federal, State, and/or local officials to take special action in planning for major animal or plant health disasters.

APHIS and CDC determined that two VS select agents and three overlap select agents should be given Tier 1 status. Based on the criteria listed above, we are proposing to list foot-and-mouth disease virus and rinderpest virus as Tier 1 VS select agents and toxins and *Bacillus anthracis, Burkholderia mallei,* and *Burkholderia pseudomallei* as Tier 1 overlap select agents and toxins. We are also proposing to amend the list of overlap select agents and toxins whose seizure by any Federal law enforcement agency requires reporting to APHIS or CDC within 24 hours (located in 9 CFR 121.4(f)(3)(i)) to include only those overlap agents designated as Tier 1. The current list, which is comprised of *Bacillus anthracis, Brucella melitensis,* Hendra virus, Nipah virus, Rift Valley fever virus, and Venezuelan equine encephalitis virus was initially adapted from a different system of threat assessment categorization. The proposed changes would bring the list in line with the listing of Tier 1 agents, which was developed as a result of the experience and expertise of the select agent program. These changes, in tandem with the enhanced practices for physical and information security detailed below, would serve to further mitigate the potential for deliberate misuse of these select agents and toxins that could result in devastating effects to the economy, critical infrastructure, or public confidence.

Accordingly, we are also proposing additions to the VS regulations that would allow for the optimization of security measures for those select agents or toxins that present the greatest risk of deliberate misuse with the most significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence, *i.e.,* Tier 1 select agents and toxins. These requirements would include:

- Additions regarding the assessment of persons who will have access to Tier 1 select agents and toxins that would be made to the security plan currently required to be developed by all entities seeking approval for the possession, use, and transfer of select agents and toxins; ongoing oversight of those persons with access to Tier 1 select agents and toxins; and the role of the entity's responsible official in coordinating and assuring the security of Tier 1 select agents and toxins;
- Security enhancements that include provisions for security barriers, intrusion detection and monitoring, delay/response force, access control, and information security;
- Additions to the biosafety plan currently required to be developed by all entities seeking approval for the possession, use, and transfer of select agents and toxins that would describe implementation of an occupational health program for individuals with access to Tier 1 select agents and toxins;
- Development of security policies and procedures describing the entity's response to a failure of an intrusion detection or alarm system and notification procedures for the Federal Bureau of Investigation (FBI) in the event of theft or suspicious activity that may be criminal in nature involving a Tier 1 select agent or toxin. These policies and procedures would be required as part of the entity's incident response plan; and
- Required annual insider threat awareness briefings focused on how to identify and report suspicious behaviors.

These changes would serve to further mitigate the potential for deliberate misuse of these select agents and toxins that could result in devastating effects to the economy, critical infrastructure, or public confidence.

We are also proposing to add required physical security measures in addition to the proposed general Tier 1 required security measures for those entities working with foot-and-mouth disease virus and rinderpest virus due to the particular dangers posed by these two viruses.

Foot-and-mouth disease is an extremely contagious viral disease of domesticated cloven-hoofed animals (*e.g.,* cattle, sheep, goats, and pigs) and many wild animals. It is easily transmissible from infected animals to susceptible animals through contact with contaminated objects, consumption of contaminated meat products or ingestion of contaminated milk, artificial insemination, and inhalation of infectious aerosols. It is not found in the United States and the U.S. domestic animal population is therefore considered highly susceptible. Foot-and-mouth disease virus can cause infection and disease in close to 100 percent of susceptible animals. The potential exists for severe economic impacts through loss of animal production and products and trade restrictions. Because of these factors, this select agent is considered to have a high potential as a weapon of bioterrorism and we are therefore proposing to require that it be handled only in high containment facilities which provide enhanced biosafety and biosecurity features in order to safeguard its distribution.

Rinderpest is a contagious viral disease of cattle, buffalo, and some wild species of cloven-hoofed animals, such as giraffe and wildebeest. Like foot-and-mouth disease virus, it is not native to the United States and can cause 100 percent illness if susceptible animals come in contact with infected animals or contaminated surfaces. As the result of an extensive international campaign consisting of vaccinations, clinical disease research, serological surveillance sampling, contingency planning, and laboratory support in affected regions, the World Organization for Animal Health declared rinderpest to be globally eradicated in May 2011. Post-eradication efforts will include surveillance of all international laboratories with existing stocks of the virus, consensus regarding laboratories authorized to retain the agent and the type of laboratory work which will continue, and destruction of all other inventoried stocks. Also, conditions for laboratory storage will be developed in order to ensure biosafety and security of the agent. The proposed enhanced security measures are necessary in order to ensure that the United States will be able to maintain inventories of rinderpest virus under secure and safe conditions.

All of these proposed changes are based on established Government and security industry standards with respect to securing high risk material and developed in accordance with the experience and expertise of the Select Agent Program. They are necessary in order to further ensure the safety and security of those select agents and toxins that pose the most potential harm to the animal and human environment. As stated previously, the requirements for working with all other select agents and toxins would remain unchanged with the exception of certain

miscellaneous changes, which are detailed below.

**Miscellaneous Changes**

We are proposing to make several smaller-scale changes to the regulations, including the addition of definitions and clarification of language concerning security, training, biosafety, biocontainment, and incident response. These changes, which are described in detail below, would increase the usability of the select agent regulations as well as provide for enhanced program oversight.

In 7 CFR 331.1 and 9 CFR 121.1, we are proposing to add definitions for *adjudicated as a mental defective, alien, committed to any mental institution, controlled substance, crime punishable by imprisonment for a term exceeding 1 year, indictment, lawfully admitted for permanent residence, mental institution, restricted person,* and *unlawful user of any controlled substance.* We believe that these definitions would assist regulated entities as well as those seeking approval to access select agents and toxins to better understand what status or activities, past or present, might prohibit such access.

Although these terms were undefined in the Bioterrorism Response Act, it is evident that Congress modeled many of them after the disqualifiers that are used by the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF) when enforcing the Gun Control Act of 1968. Because the purpose of the Select Agent Program differs from ATF's enforcement actions under the Gun Control Act, we do not believe that these terms must be defined exactly the same. The Gun Control Act regulates access to firearms, while the Bioterrorism Response Act regulates access to biological agents and toxins that the government has recognized as having the potential to be used as weapons of mass destruction by the wrong hands.

Nevertheless, we looked at the statutory and regulatory definitions of these terms under the Gun Control Act when drafting our definitions. With the exception of the term ''crime punishable by imprisonment for a term exceeding 1 year,'' we decided to adopt the applicable definitions used by ATF.

The definition of *crime punishable by imprisonment for a term exceeding 1 year* would be established as ''any Federal, State, or foreign offense for which the maximum penalty, whether or not imposed, is capital punishment or imprisonment in excess of 1 year. What constitutes a conviction of such a crime shall be determined in accordance with the law of the jurisdiction in which the proceedings were held. Any conviction which has been set aside or nullified as a matter of law or for which a person has been pardoned shall not be considered a conviction for purposes of this part.'' Contrary to definition of this term used under the Gun Control Act, we have decided that foreign offenses should be considered a disqualifier. In doing so we are aware of the Supreme Court's decision in *Small* v. *United States,* 544 US 385 (2005) in which the court, interpreting the provisions of 18 U.S.C. 922(g)(1), held that the phrase ''convicted in any court'' refers only to U.S. courts, not to foreign courts. In its opinion interpreting the Gun Control Act, the court stated that ''the statute itself and its history offer only congressional silence'' as to whether Congress considered whether the statutory language included foreign convictions. In the case of the Bioterrorism Response Act, we believe Congress spoke clearly about their desire to limit or deny access to select agents and toxins for those who have committed serious crimes regardless of where those crimes were committed. As a part of the safeguard and security section of the Bioterrorism Response Act, Congress not only put select agents and toxins off limits to a ''restricted person,'' as that term is defined by 18 U.S.C. 175b, but to the those who are ''reasonably suspected by any Federal law enforcement or intelligence agency of'' (1) Committing a ''Federal crime of terrorism'' transcending national boundaries (18 U.S.C. 2332b); (2) the knowing involvement with an organization that engages in domestic or international terrorism or with any other organization that engages in international crimes of violence; or (3) being an agent of a foreign power. We believe it would be an inconsistent reading of statutory authority to allow the Secretary to limit or deny access to select agents and toxins to someone identified by the Attorney General as being only reasonably suspected of committing a Federal crime of terrorism transcending national boundaries but to be powerless in cases where a person had actually been convicted of a serious crime in a foreign country. We believe that in light of the threat of bioterrorism attacks, Congress would not want to exclude an individual convicted of a U.S. offense from having access to select agents and toxins, but still allow access to an individual convicted in a foreign court of a similar offense. We also believe that the instances of regulation can be distinguished in that with regard to the Gun Control Act the government is regulating access to guns while, with respect to the Bioterrorism Response Act, the government is regulating access to biological agents and toxins which the government has recognized as having the potential to be used in the wrong hands as weapons of mass destruction.

We are specifically requesting comments on the use of a foreign conviction as a predicate for denying access to select agents and toxins. We recognize that there can be significant differences between foreign convictions and domestic convictions. For example, foreign legal systems may not provide the same due process safeguards afforded to citizens of the United States, including impartial tribunals and jury trials. Additionally, foreign countries may punish conduct that is permitted under domestic law or may require more severe penalties than under domestic law. We note that in the past, courts have applied the criteria set forth in Section 482 of the Restatement (third) of Foreign Relations Law of the United States (1986) in determining whether a foreign judgment should be recognized in the United States. That Section provides that a court in the United States may not recognize a judgment of the court of a foreign state if the judgment was rendered under a judicial system that does not provide impartial tribunals or procedures compatible with due process of law or the court that rendered the judgment did not have jurisdiction over the defendant in accordance with the law of the rendering state. It further provides that a court in the United States need not recognize a judgment of the court of a foreign state if the court that rendered the judgment did not have jurisdiction of the subject matter of the action, the defendant did not receive notice of the proceedings in sufficient time to enable him to defend, the judgment was obtained by fraud, the cause of action on which the judgment was based, or the judgment itself, is repugnant to the public policy of the United States or of the State where recognition is sought, the judgment conflicts with another final judgment that is entitled to recognition, or the proceeding in the foreign court was contrary to an agreement between the parties to submit the controversy on which the judgment is based to another forum. We are seeking comment on whether these criteria should be applied in considering whether access to select agents and toxins should be denied based on a foreign conviction or whether other criteria or factors would be appropriate to consider.

We are also proposing to add a definition for *information security* to the

regulations in 7 CFR 331.1 and 9 CFR 121.1 as it is used but not defined. This definition would be identical to that used in the ''Information Security'' subchapter of the U.S. Code (44 U.S.C. 3542).

We are also proposing to add a definition for *occupational exposure* to the VS regulations in 9 CFR 121.1 as it is used in the regulations but not defined. This definition is based on that used in the Occupational Safety and Health Administration regulations in 29 CFR 1910.1030. We are not proposing to add a corresponding definition to the PPQ regulations in 7 CFR 331.1 since PPQ select agents and toxins do not pose a severe threat to human health and, therefore, it is unnecessary to address personnel safety and health.

Finally, we are proposing to add a definition for *recombinant and synthetic nucleic acids.* This addition is necessary, as the term ''synthetic nucleic acids'' is employed in the proposed changes to the select agent regulations. We are proposing to include synthetic nucleic acids in the regulations because, while synthetic nucleic acids have the same potential for harm as recombinant nucleic acids, the process of production is different.

We are proposing to amend 7 CFR 331.3(e), 9 CFR 121.3(e) and 9 CFR 121.4(e). These paragraphs specify that attenuated strains of select agents or toxins may be excluded from the requirements of the select agent regulations subject to an official request and supporting scientific information. We are proposing to state that the ''inactive form of a select toxin'' may be excluded from regulation under each respective part subject to the application procedure. This change is necessary because the current term, ''attenuated strain of toxin,'' is scientifically inaccurate. Attenuated is a term that is applied to living organisms, and toxins are not living organisms. ''Inactive form of a select toxin'' is a more accurate term and we are therefore proposing to amend the regulations to include the correct terminology. We are also proposing to update the Web site address in paragraph (e)(1) of each section as all information concerning the Select Agent Program is now centralized on the National Select Agent Registry Web site at *http://www.selectagents.gov/*. Finally, we are proposing to remove the language stating that exclusions will be published in the **Federal Register**. This change is necessary because, while we anticipated publication of exclusions both in the **Federal Register** and on the Internet at the time the regulations were initially created, we have found that publication on the select agent Web site only has served to provide the most up-to-date information to the regulated community. We are therefore proposing to update the regulations to accurately reflect the way in which we handle the listing of exclusions.

The regulations in 7 CFR 331.9 and 9 CFR 121.9 set out requirements for entities requesting to work with select agents and toxins to designate a responsible official, who ensures that the entity continues to meet the requirements of the regulations. We are proposing to explicitly require that all designated responsible officials possess the appropriate training or expertise to execute their required duties. We are also proposing to clarify the role of alternate responsible official in order to definitively establish that the alternate responsible official must have the knowledge and authority to act for the responsible official in his/her absence. Finally, we are proposing to add a requirement that the responsible official's principal duty station be the physical location of the registered entity. These changes would clarify the requirements that a person must meet in order to serve as a responsible official or alternate responsible official.

We are proposing to amend the regulations in 7 CFR 331.10 and 9 CFR 121.10. These regulations establish parameters for restricting access to select agents and toxins and the process by which individuals may be approved for access to select agents and toxins after the completion of a security risk assessment by the Attorney General. Specifically, we are proposing to add new provisions by which individuals may have access to select agents at entities other than the individual's ''home'' entity. We are also proposing to decrease the maximum length of time for which a security risk assessment will be valid from 5 years to 3 years in order to more expeditiously identify individuals who may have fallen into one of the prohibited or restricted categories.

The regulations require registered entities to develop and implement a number of plans in order to ensure the safety and security of the select agents they handle. These are:

- A security plan, as described by the regulations in 7 CFR 331.11 and 9 CFR 121.11, that provides for measures sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release;
- A biocontainment plan, in the case of PPQ select agents, or a biosafety plan, in the case of VS select agents, as described in the regulations in 7 CFR 331.12 and 9 CFR 121.12, that provides for measures sufficient to contain the select agent or toxin (*e.g.,* physical structure and features of the entity, and operational and procedural safeguards); and
- An incident response plan, as described in the regulations in 7 CFR 331.14 and 9 CFR 121.14, that provides for measures that the registered entity will implement in the event of theft, loss, or release of a select agent or toxin; inventory discrepancies; security breaches (including information systems); severe weather and other natural disasters; workplace violence; bomb threats and suspicious packages; and emergencies such as fire, gas leak, explosion, power outage, etc. The response procedures must account for hazards associated with the select agent or toxin and appropriate actions to contain such agent or toxin.

Details of the changes we are proposing to each plan individually may be found below. Generally, we are proposing to require that the security plan, biocontainment/biosafety plan, and incident response plan include provisions to address the safeguarding of animals or plants that have been intentionally or accidentally exposed to or infected with select agents against unauthorized access, theft, loss or release. This would enhance the comprehensiveness of the regulations as well as provide necessary guidance regarding handling of animals and plants inoculated with select agents. We would not require the plan to address animals and plants exposed to select toxins, however. Recovering the toxin from within an animal or plant subject is highly difficult and such removal does not produce a reasonable yield of recovery. In addition, there is uncertainty as to whether or not the toxin would remain active when recovered from the animal or plant. For these reasons it is highly unlikely that once introduced into an animal or plant, a sufficient amount of toxin could be recovered to pose a significant hazard to public health, agriculture or agriculture products.

Currently, the security plan described in 7 CFR 331.11 and 9 CFR 121.11 must be developed by all regulated entities and submitted for review only upon request. We are now proposing to require that the security plan be submitted for initial registration and renewals of registration as well as at any other time upon request. We are also proposing to add a requirement that the security plan include procedures that require the responsible official to immediately notify the FBI in order to initiate a threat assessment process in the event that he or she becomes aware

of suspicious activity which is criminal in nature, related to the facility, its personnel, or select agents. This addition would provide for added security and establish a framework for communication between regulated entities and the FBI. We are also proposing to add provisions for information security, including the need for backup measures if the entity relies on information systems for security. These provisions would include network connectivity monitoring, restriction of user permissions so that only mission-specific files and applications may be accessed, measures to prevent network infiltration by malicious code, and configuration management including regular patching and system and software updates. We believe these additions are necessary in order to establish requirements for a more comprehensive security plan. We are also proposing to codify current practices for shipping, receiving, and storage of select agents and toxins to ensure that the entity has documented processes for securing and monitoring the shipment, receipt, and storage of these items. These changes would serve to decrease the chance that such materials would be made available to an unauthorized individual or an individual without a legitimate use for the material. Finally, we are proposing to amend paragraph (e) in 7 CFR 331.11 and 9 CFR 121.11, which currently directs individuals creating a security plan to guidance for developing such documents contained in the ''Morbidity and Mortality Weekly Report'' from December 2002. Applicants would instead be directed to the ''Security Information Document'' and the ''Security Plan Template'' on the select agents Web site.

We are proposing to update the specific Web site address references to various CDC and National Institutes of Health guidance publications found in 9 CFR 331.12(c)(1) and (c)(3). The regulations in 7 CFR 331.13 and 9 CFR 121.13 concern restricted experiments, which are those experiments that may not be performed by regulated entities without the approval of the Administrator. We are proposing to state that, in addition to the existing prohibition on conducting restricted experiments, entities may not possess the products of restricted experiments without the approval of the Administrator. We are also proposing to remove recombinant technology as a determining factor for a restricted experiment. This is because the current regulations regarding restricted experiments focus solely on the use of recombinant technology in the generation of drug resistant select agents or biosynthesis of toxins lethal to vertebrates. Since synthetic DNA or other methods (*e.g.,* selection in sublethal exposures) may also be used to generate such products, we are proposing to expand the category of restricted experiments to include passive selection, recombinant, and synthetic DNA. Finally, we are proposing to add language in order to clarify the requirement that all experiments involving the creation of drug resistant select agents must be submitted to the Select Agent Program for approval.

Additionally, we are proposing to specify in 7 CFR 331.14 and 9 CFR 121.14 that each entity's incident response plan be based upon a site-specific risk assessment. This change would further ensure the specificity and quality of the plan. In addition, we are proposing that the incident response procedures contain stipulations concerning animals and plants accidentally or intentionally exposed to or infected with a select agent. This change would provide specific guidance and further elaborate our requirements for incident response plans.

We are proposing to amend the regulations in 7 CFR 331.15 and 9 CFR 121.15, which concern provision of mandatory training for staff and visitors who work in or visit areas where select agents or toxins are handled or stored. We are proposing to require all registered entities to provide security awareness and incident response training. This is in addition to the existing training requirements, which are concerned with biocontainment and security practices in the case of PPQ select agents, and biosafety and security practices in the case of VS select agents. We are also proposing to establish that training for escorted personnel would be based on the risk associated with accessing areas where select agents and toxins are used and/or stored. Currently, refresher training is required to be provided once a year. We are proposing to require that such training also be provided if a registered entity's security, incident response, biosafety, or biocontainment plans are substantively altered. Finally, we are proposing to specify that the responsible official ensure maintenance of training records. Currently there is no particular person designated as the entity's required record keeper, only that a training record must be kept. The above changes are necessary in order to provide clarity and ease of use to the regulations.

We are proposing to amend the regulations in 7 CFR 331.16 and 9 CFR 121.16, which concern the transfer of select agents and toxins from one registered entity to another. The proposed additions would serve to codify practices for shipping, receiving, and storage of select agents and toxins and ensure that all registered entities have documented processes for securing and monitoring the shipment, receipt, and storage of select agents and toxins that make it extremely unlikely that such materials would be made available to an unauthorized individual.

The regulations in 7 CFR 331.17 and 9 CFR 121.17 concern required recordkeeping procedures for regulated entities as those records relate to select agents and toxins. We are proposing to add language to address synthetic select agent organisms and animals and plants inoculated with select agents. This change would improve oversight of the select agent program as it relates to synthetic select agent organisms. We are also proposing to add recordkeeping requirements whereby regulated entities maintain an accurate, current inventory of any animals or plants intentionally or accidentally exposed to or infected with a select agent (including number and species, location, and appropriate disposition). As previously stated, we are not proposing to require regulated entities to keep records regarding animals or plants exposed to select toxins.

We are proposing to amend the regulations in 7 CFR 331.19, which concern requirements for notification of theft, loss, or release of select agents. Specifically, we are proposing to remove paragraph (b)(1)(vi), which states that an individual entity must report certain information to APHIS or CDC immediately upon discovery of a release of a select agent or toxin outside of the primary barriers of the biocontainment area. Currently we require that the number of individuals potentially exposed at the entity be reported. We are proposing to remove this requirement as PPQ select agents and toxins do not pose a severe threat to human health and, therefore, it is unnecessary to address personnel safety and health in the same manner as they are addressed in the VS regulations. The notification requirements in 9 CFR 121.19 would remain unchanged.

The regulations in 7 CFR 331.20 and 9 CFR 121.20 concern the guidelines for administrative review of an individual's or entity's denial, revocation, or suspension of registration and access approval. We are proposing to modify the current regulations in order to allow individuals more time to gather the necessary components of their appeal following the denial, limitation, or

revocation of access approval. Currently, this process must be completed in 30 calendar days. We are proposing to extend the deadline to 180 calendar days. This change is necessary because, thus far, all appeal requests from individuals regarding their access approval have been received after the 30-day deadline has passed. Because of specific program procedures, these individuals receive no advance notice of a denial, limitation, or revocation of their access approval. Given this situation and the requirements for submitting a formal appeal, we believe it is appropriate to extend the deadline in order to allow individuals to gather the necessary background data for their appeals. We are not proposing to grant a similar extension for entities which have had their registration denied, revoked, or suspended, as these entities typically have had advance notice of such a determination and are thus able to document and prepare their appeals within the existing 30-day timeframe.

Given that we are reorganizing 7 CFR 331.20 and 9 CFR 121.20 in order to more clearly spell out the way in which an individual or an entity may appeal the denial, revocation, or suspension of registration and access approval, we are also proposing to remove footnote 9 from the regulations in 7 CFR 331.20 and corresponding footnote 15 in 9 CFR 121.20. This proposed change is necessary because these footnotes would offer redundant information concerning the appeals process in light of both sections' reorganization. Finally, we are proposing to remove the provision stating that a request for review of a denial, limitation, or revocation of access approval will be forwarded to the Attorney General by the Administrator for further review. Forwarding a request for review to the Attorney General describes an internal process. This proposed change is necessary because the current language implies a level of decisionmaking on the part of the Attorney General that does not exist and the change would more clearly establish that the decision to grant access approval rests solely with the Administrator.

**Guidance Documents**

We are specifically requesting comment from the regulated community and any other interested persons on the need for and desirability of guidance documents that would serve to assist regulated entities in preparation of the elements that comprise various aspects of the select agent regulations.

The areas where such guidance documents may be useful include, but are not limited to:

1. Aspects of the required security plan. These may include, but are not limited to:

- Provisions for information security;
- Development of suitability or personnel reliability practices, including pre-access and ongoing assessment of persons who will have access to Tier 1 select agents or toxins;
- Procedures for the method by which an entity's responsible official will coordinate his or her efforts with the entity's safety and security professionals to ensure security of Tier 1 select agents or toxins;
- Development of a self- and peer-reporting program to track incidents or conditions that could affect an individual's ability to safely access or work with Tier 1 select agents and toxins; and
- Layered protection of assets for entities housing Tier 1 select agents and toxins.

2. Aspects of the required biosafety plan, *e.g.,* components of an occupational health program for individuals with access to Tier 1 select agents and toxins; and

3. Aspects of the required training, *e.g.,* best practices for development of a security awareness training program.

We welcome public comment on Web sites, articles, or other sources that may be used to develop such guidance documents, in addition to suggestions as to what elements should be included as useful examples. These documents would serve as a resource to the regulated community as a whole.

**Executive Orders 12866 and 13563 and Regulatory Flexibility Act**

This proposed rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

We have prepared an economic analysis for this rule. The economic analysis provides a cost-benefit analysis, as required by Executive Orders 12866 and 13563, and an initial regulatory flexibility analysis that examines the potential economic effects of this proposed rule on small entities, as required by the Regulatory Flexibility Act. The economic analysis is summarized below. Copies of the full analysis are available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT** or on the Regulations.gov Web site (see **ADDRESSES** above for instructions for accessing Regulations.gov).

Based on the information we have, there is no reason to conclude that adoption of this proposed rule would result in any significant economic effect on a substantial number of small entities. The entities are those laboratories and other institutions conducting research and related activities entities in possession of Tier 1 select agents or toxins, and, to a somewhat lesser extent, those entities possessing the newly added select agents and toxins. The economic analysis presents categories and information from the Department of Commerce and the Small Business Administration for those entities we have identified as most likely to be affected by this rule. While we believe affected entities are contained within these categories, we are seeking further information regarding how many entities fall specifically into each category, and are therefore, inviting comments on potential effects. In particular, we are interested in determining the number and kind of small entities that may incur benefits or costs from the implementation of this proposed rule.

This proposed rule would update the APHIS, CDC, and overlap select agent and toxin lists. The regulation of select agents and toxins is intended to prevent their misuse and thereby reduce the potential for those pathogens to harm humans, animals, animal products, plants or plant products in the United States. Should any select agent or toxin be intentionally or unintentionally released into the environment, the consequences would be significant. Consequences could include disruption of markets, difficulties in sustaining an adequate food and fiber supply, and the potential spread of disease infestations over large areas. The entities most likely to be affected by this rule would be those laboratories and other institutions conducting research and related activities that involve the use of the newly categorized Tier 1 select agents and toxins. The impact of the changes to the regulations is expected to be minimal, however. Based on information obtained through site-specific inspections, indications are that very few entities would incur significant costs for compliance. Many of the proposed changes to the regulations would impose an added cost of the time spent on documenting measures already required for compliance, with respect to security, biocontainment/biosafety, and incident response plans, information security, and ongoing background checks. While the total costs imposed by the proposed regulations are estimated to range between $5.30 million and $6.95 million, including costs to government, we believe many of these costs are incurred through observance of

generally recognized industry standards. Costs actually incurred would depend upon the extent to which current facility practices will need to be enhanced based on the proposed requirements. The expected benefits of strengthened safeguards against the costs associated with unintentional or deliberate release of select agents or toxins would greatly exceed the estimated costs of the proposed measures. The cost associated with a single outbreak have been known to exceed $100 million as outlined in the Regulatory Impact Analysis. Deliberate introduction greatly increases the probability of a select agent or toxin becoming established and causing wide-ranging and devastating impacts on an economy, loss of market access for consumer goods and services, disruption to society, and diminished confidence in public and private institutions.

**Executive Order 12372**

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

**Executive Order 12988**

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

**Paperwork Reduction Act**

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket Nos. APHIS–2009–0070 and CDC–2011–0012. Please send a copy of your comments to: (1) Docket Nos. APHIS–APHIS–2009–0070 and CDC–2011–0012, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238, and (2) Clearance Officer, OCIO, USDA, room 404–W, 14th Street and Independence Avenue, SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

The Bioterrorism Preparedness Act is designed to prevent, prepare for and respond to bioterrorism and other public health emergencies. The law requires individuals possessing agents or toxins deemed a severe threat to human, animal, or plant health, or to animal or plant products, to be registered with the Secretary of Agriculture or the Secretary of Health and Human Services, unless they have been specifically exempted.

This proposed rule entails the use of a number of separate forms designed to obtain critical information concerning individuals or entities in possession of certain agents or toxins, as well as the specific characteristics of the agents or toxins—including name, strain, and genetic information. This data is needed, in part, to allow APHIS and CDC to determine the biosafety level of an entity as well as the entity's biosecurity situation. This, in turn, helps APHIS and CDC ensure that appropriate safeguard, containment, and disposal requirements commensurate with the risk of the agent or toxin are present at the entity, thus preventing access to such agents and toxins for use in domestic or international terrorism. Facilities containing select agents will be required to maintain records on animals and plants, and revise their Biosafety/Biocontainment Plan and Incident Response Plan for review by APHIS and CDC upon request.

Information to determine that individuals seeking to register have a lawful purpose to possess, use, or transfer agents or toxins will also be requested as part of the registration process. In addition, we will be requesting submission of their Security Plan for our review.

APHIS and CDC are asking OMB to approve, for 3 years, the use of these information collections, associated with its efforts to more closely regulate select agents or toxins that could be used to commit acts of domestic or international terrorism. We are soliciting comments from the public (as well as affected agencies) concerning this information collection activity. APHIS and CDC need this outside input to help accomplish the following:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as 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).

*Estimate of burden:* Public reporting burden for this collection of information is estimated to average 2.3187883 hours per response.

*Respondents:* Researchers, universities, research and development organizations, commercial manufacturers, non-profit institutions, diagnostic laboratories and other interested parties who possess, use, or transfer agents or toxins deemed a severe threat to human, animal or plant health, or to animal or plant products.

*Estimated annual number of respondents:* 386.

*Estimated annual number of responses per respondent:* 12.230569.

*Estimated annual number of responses:* 4,721.

*Estimated total annual burden on respondents:* 10,947 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

| Section | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden hours |
|---|---|---|---|---|---|
| 9 CFR 121.5 and 6, 7 CFR 331.5, 43 CFR 73.5 and 6. | Report of Identification of a Select Agent or Toxin. | 161 | 3 | 1 | 299 |
| § 121.7, § 331.7, § 73.7 | Application for Registration | 7 | 1 | 5 | 35 |
| § 121.7, § 331.7, § 73.7 | Amendment to a Certificate of Registration. | 380 | 7 | 1 | 1,955 |

| Section | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden hours |
|---|---|---|---|---|---|
| § 121.11, § 331.11, § 73.11 | Security Plan | 380 | 1 | 5 | 1,900 |
| § 121.12, § 331.12, § 73.12 | Biosafety/Biocontainment Plan | 380 | 1 | 8 | 3,040 |
| § 121.13, § 331.13, § 73.13 | Request Regarding a Restricted Experiment. | 160 | 1 | 2 | 320 |
| § 121.14, § 331.14, § 73.14 | Incident Response Plan | 380 | 1 | 5 | 1,900 |
| § 121.15, § 331.15, § 73.15 | Training | 380 | 1 | 1 | 380 |
| § 121.16, § 331.16, § 73.16 | Request to Transfer Select Agents and Toxins. | 290 | 1 | 2 | 580 |
| § 121.17, § 331.17, § 73.17 | Records | 295 | 1 | 0.5 | 148 |
| § 121.19, § 331.19, § 73.19 | Notification of Theft, Loss, or Release. | 195 | 1 | 2 | 390 |

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851–2908.

**E-Government Act Compliance**

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this proposed rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851–2908.

**List of Subjects**

*7 CFR Part 331*

Agricultural research, Laboratories, Plant diseases and pests, Reporting and recordkeeping requirements.

*9 CFR Part 121*

Agricultural research, Animal diseases, Laboratories, Medical research, Reporting and recordkeeping requirements.

Accordingly, we propose to amend 7 CFR part 331 and 9 CFR part 121 as follows:

**TITLE 7—[AMENDED]**

## PART 331—POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS

1. The authority citation for part 331 continues to read as follows:

**Authority:** 7 U.S.C. 8401; 7 CFR 2.22, 2.80, and 371.3.

2. Section 331.1 is amended by adding, in alphabetical order, definitions of *adjudicated as a mental defective, alien, committed to any mental institution, controlled substance, crime punishable by imprisonment for a term exceeding 1 year, indictment, information security, lawfully admitted for permanent residence, mental institution, recombinant and synthetic nucleic acids, restricted person,* and *unlawful user of any controlled substance* to read as follows:

**§ 331.1 Definitions.**

*Adjudicated as a mental defective.* A determination by a court, board, commission, or other lawful authority that a person, as a result of marked subnormal intelligence, or mental illness, incompetency, condition, or disease is a danger to himself/herself or to others or lacks the mental capacity to contract or manage his/her own affairs. The term includes a finding of insanity by a court in a criminal case and those persons found incompetent to stand trial or found not guilty by reason of lack of mental responsibility pursuant to articles 50a and 72b of the Uniform Code of Military Justice, 10 U.S.C. 850a, 876b.

* * * * *

*Alien.* Any person not a citizen or national of the United States.

* * * * *

*Committed to any mental institution.* A formal commitment of a person to any mental institution by a court, board, commission, or other lawful authority. The term includes a commitment to a mental institution involuntarily. The term includes commitment for mental defectiveness or mental illness. It also includes commitments for other reasons, such as for drug use. The term does not include a person in a mental institution for observation or a voluntary admission to a mental institution.

*Controlled substance.* A drug or other substance, or immediate precursor, as ''controlled substance'' is defined in section 102 of the Controlled Substances Act, 21 U.S.C. 802. The term includes, but is not limited to, marijuana and scheduled depressants, stimulants, and narcotic drugs. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in Subtitle E of the Internal Revenue Code of 1986, as amended.

*Crime punishable by imprisonment for a term exceeding 1 year.* Any Federal, State, or foreign offense for which the maximum penalty, whether or not imposed, is capital punishment or imprisonment in excess of 1 year. What constitutes a conviction of such a crime shall be determined in accordance with the law of the jurisdiction in which the proceedings were held. Any conviction which has been set aside or nullified as a matter of law or for which a person has been pardoned shall not be considered a conviction for the purposes of this part.

* * * * *

*Indictment.* A formal written accusation originating with a prosecutor and issued by a grand jury against a party charged with a crime. For the purpose of these regulations the term indictment includes an ''information,'' which is a formal accusation of a crime, differing only in that it is being presented by a competent public officer on his oath of office, instead of a grand jury.

*Information security.* Protecting information and information systems from unauthorized access, use, disclosure, disruption, modification, or destruction in order to provide:

(1) Integrity, which means guarding against improper information modification or destruction, and includes ensuring information nonrepudiation and authenticity;

(2) Confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and

(3) Availability, which means ensuring timely and reliable access to and use of information.

* * * * *

*Lawfully admitted for permanent residence.* The status of having been lawfully accorded the privilege of residing permanently in the United States as an immigrant in accordance with the immigration laws, such status not having changed.

*Mental institution.* Includes mental health facilities, mental hospitals, sanitariums, psychiatric facilities, and other facilities that provide diagnoses by licensed professionals of mental retardation or mental illness, including a psychiatric ward in a general hospital.

* * * * *

*Recombinant and synthetic nucleic acids.* (1) Recombinant nucleic acid molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell;

(2) Synthetic nucleic acid molecules that are chemically, or by other means, synthesized or amplified nucleic acid molecules that may wholly or partially contain functional equivalents of nucleotides; or

(3) Molecules that result from the replication of those described in paragraph (1) or (2) of this definition.

* * * * *

*Restricted person.* An individual who:

(1) Is under indictment for a crime punishable by imprisonment for a term exceeding 1 year;

(2) Has been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year;

(3) Is a fugitive from justice;

(4) Is an unlawful user of any controlled substance (as ''controlled substance'' is defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

(5) Is an alien illegally or unlawfully in the United States;

(6) Has been adjudicated as a mental defective or has been committed to any mental institution;

(7) Is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country as to which the Secretary of State, pursuant to section 6(j) of the Export Administration Act of 1979 (50 U.S.C. App. 2405(j)), section 620A of chapter 1 of part M of the Foreign Assistance Act of 1961 (22 U.S.C. 2371), or section 40(d) of chapter 3 of the Arms Export Control Act (22 U.S.C. 2780(d)), has made a determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism; or

(8) Has been discharged from the Armed Services of the United States under dishonorable conditions.

* * * * *

*Unlawful user of any controlled substance.* For purposes of this regulation, a person who uses a controlled substance and has lost the power of self-control with reference to the use of that controlled substance; and any person who is a current user of a controlled substance in a manner other than as prescribed by a licensed physician. Such use is not limited to the use of drugs on a particular day, or within a matter of days or weeks before, but rather that the unlawful use has occurred recently enough to indicate that the individual is actively engaged in such conduct. A person may be an unlawful current user of a controlled substance even though the substance is not being used at the precise time the person seeks to have access to a select agent or toxin. An inference of current use may be drawn from evidence of a recent use or possession of a controlled substance or a pattern of use or possession that reasonably covers the present time, *e.g.,* a conviction for use or possession of a controlled substance within the past year; multiple arrests for such offenses within the past 5 years if the most recent arrest occurred within the past year, or persons found through a drug test to use a controlled substance unlawfully, provided that the test was administered within the past year. For a current or former member of the Armed Forces, an inference of current use may be drawn from recent disciplinary or other administrative action based on confirmed drug use, *e.g.,* court-martial conviction, nonjudicial punishment, or an administrative discharge based on drug use or drug rehabilitation failure.

* * * * *

3. Section 331.3 is amended as follows:

a. By revising paragraph (b) to read as set forth below.

b. In paragraph (c) introductory text, by adding the words ''and/or synthetic'' after the word ''recombinant'' each time it appears.

c. In paragraph (c)(2) introductory text, by adding the words ''and/or synthetic'' after the word ''Recombinant''.

d. By revising paragraph (e) to read as set forth below.

**§ 331.3 PPQ select agents and toxins.**

* * * * *

(b) PPQ select agents and toxins:

*Peronosclerospora philippinensis* (*Peronosclerospora sacchari*);

*Phoma glycinicola* (formerly *Pyrenochaeta glycines*);

*Ralstonia solanacearum,* race 3, biovar 2;

*Rathayibacter toxicus;*

*Sclerophthora rayssiae* var. *zeae;*

*Synchytrium endobioticum;*

*Xanthomonas oryzae.*

* * * * *

(e) An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of this part based upon a determination that the attenuated strain or inactivated toxin does not pose a severe threat to plant health or plant products.

(1) To apply for exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification to the applicant. Exclusions will be listed on the National Select Agent Registry Web site at *http://www.selectagents.gov/.*

(2) If an excluded attenuated strain or inactivated toxin is subjected to any manipulation that restores or enhances its virulence or toxic activity, the resulting select agent or toxin will be subject to the requirements of this part.

* * * * *

**§ 331.8 [Amended]**

4. In § 331.8, paragraph (a)(1) is amended by removing the words ''within any of the categories described in 18 U.S.C. 175b'' and adding the words ''a restricted person'' in their place.

5. Section 331.9 is amended as follows:

a. By redesignating paragraphs (a)(3) through (a)(5) as paragraphs (a)(4), (a)(5), and (a)(7) respectively.

b. By adding a new paragraph (a)(3) to read as set forth below.

c. In newly redesignated paragraph (a)(5), by removing the word ''and''.

d. By adding a new paragraph (a)(6) to read as set forth below.

e. By revising the first sentence of paragraph (b) to read as set forth below.

**§ 331.9 Responsible official.**

(a) * * *

(3) Have the appropriate training or expertise to competently implement and manage the requirements of this part;

* * * * *

(6) Have their principal duty station at the physical location of the entity; and

* * * * *

(b) An entity may designate one or more individuals to serve as an alternate responsible official who acts for the responsible official in his/her absence.

* * *

* * * * *

6. Section 331.10 is amended as follows:

a. By redesignating paragraphs (e) through (i) as paragraphs (f) through (j) respectively.

b. By adding a new paragraph (e) to read as set forth below.

c. In newly redesignated paragraph (g)(1), by removing the words ''within any of the categories described in 18 U.S.C. 175b'' and adding the words ''a restricted person'' in their place.

d. In newly redesignated paragraph (i), by removing the number ''5'' and adding the number ''3'' in its place.

**§ 331.10 Restricting access to select agents and toxins; security risk assessments.**

* * * * *

(e) A person who has a valid approval from the HHS Secretary or Administrator for access to a select agent or toxin may request the HHS Secretary or Administrator to provide the person's approval status to another registered individual or entity for a specified period of time.

* * * * *

7. Section 331.11 is amended as follows:

a. By revising paragraph (b) to read as set forth below.

b. By revising paragraph (c)(2) to read as set forth below.

c. In paragraph (c)(6), by removing the word ''and''.

d. In paragraph (c)(7), by removing the period and adding a semicolon in its place.

e. By adding new paragraphs (c)(8), (c)(9), and (c)(10) to read as set forth below.

f. By revising paragraph (e) to read as set forth below.

**§ 331.11 Security.**

* * * * *

(b) The security plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use. A current security plan must be submitted for initial registration, renewal of registration, or when requested.

(c) * * *

(2) Contain provisions for the control of access to select agents and toxins, including the safeguarding of animals or plants intentionally or accidentally exposed to or infected with a select agent, against unauthorized access, theft, loss or release.

* * * * *

(8) Describe procedures for how the responsible official will be informed of suspicious activity that may be criminal in nature and related to the entity, its personnel, or its select agents or toxins; and how the responsible official will notify the Federal Bureau of Investigation (FBI) of such activity;

(9) Contain provisions for information security that:

(i) Ensure that all external connections to systems which control security of the facility are isolated or have controls that permit and monitor for only authorized and authenticated user access;

(ii) Ensure that authorized and authenticated users are only granted access to select agent and toxin related information, files, equipment (*e.g.,* servers or mass storage devices) and applications as necessary to fulfill their roles and responsibilities, and that access is modified when the user's roles and responsibilities change or when their access to select agent and toxin is suspended or revoked;

(iii) Ensure that controls are in place that are designed to prevent malicious code (such as, but not limited to, computer viruses, worms, and spyware) from compromising the confidentiality, integrity, or availability of information systems;

(iv) Establish a robust configuration management practice for information systems to include regular patching and updates made to operating systems and individual applications; and

(v) Establish procedures that provide backup security measures in the event that access control systems and/or surveillance devices are rendered inoperable.

(10) Contain provisions and policies for shipping, receiving, and storage of select agents and toxins, including documented procedures for receiving, monitoring, and shipping of all select agents and toxins. These provisions must provide that an entity will properly secure containers on site and have a written contingency plan for unexpected shipments.

* * * * *

(e) In developing a security plan, an individual or entity should consider the documents entitled, ''Select Agents and Toxins Security Information Document'' and ''Select Agents and Toxins Security Plan Template.'' These documents are available on the Internet at *http://www.selectagents.gov/.*

* * * * *

8. Section 331.12 is amended by revising paragraph (a) to read as follows:

**§ 331.12 Biocontainment.**

(a) An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use.[4] The biocontainment plan must contain sufficient information and documentation to describe the containment procedures for the select agent or toxin, including any animals or plants intentionally or accidentally exposed to or infected with a select agent.

* * * * *

**§ 331.13 [Amended]**

9. Section 331.13 is amended as follows:

a. By removing footnote 5.

b. In paragraph (a) introductory text, by adding the words '', or possess products (*i.e.,* select agents that are not known to acquire the resistance naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture, or recombinant and or synthetic DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight) resulting from,'' after the word ''conduct''.

c. In paragraph (a)(1), by removing the words ''Experiments utilizing recombinant DNA that involve the deliberate transfer of'' and replacing them with the words ''Experiments that involve the deliberate transfer of, or selection for,''.

d. In paragraph (a)(2), by adding the words ''synthetic or'' before the word ''recombinant''.

10. Section 331.14 is amended as follows:

a. By redesignating footnote 6 as footnote 5.

b. By revising the first sentence in paragraph (a) to read as set forth below.

c. By redesignating footnote 7 as footnote 6.

d. By revising paragraph (b) to read as set forth below.

e. By redesignating paragraphs (c) and (d) as paragraphs (d) and (e), respectively.

f. By adding a new paragraph (c) to read as set forth below.

**§ 331.14 Incident response.[5]**

(a) An individual or entity required to register under this part must develop and implement a written incident response plan[6] based upon a site specific risk assessment. * * *

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[4] Technical assistance and guidance may be obtained by contacting APHIS.

[5] Nothing in this section is meant to supersede or preempt incident response requirements imposed by other statutes or regulations.

[6] Technical assistance and guidance may be obtained by contacting APHIS.

(b) The incident response plan must fully describe the entity's response procedures for the theft, loss, or release of a select agent or toxin; inventory discrepancies; security breaches (including information systems); severe weather and other natural disasters; workplace violence; bomb threats and suspicious packages; and emergencies such as fire, gas leak, explosion, power outage, etc.

(c) The response procedures must account for hazards associated with the select agent or toxin and appropriate actions to contain such select agent or toxin, including any animals or plants intentionally or accidentally exposed to or infected with a select agent.

* * * * *

11. Section 331.15 is revised to read as follows:

**§ 331.15 Training.**

(a) An individual or entity required to register under this part must provide information and training on biocontainment, security (including security awareness), and incident response to:

(1) Each individual with access approval from the HHS Secretary or Administrator before that individual has such access to select agents and toxins. The training must address the particular needs of the individuals, the work they will do, and the risks posed by the select agents or toxins; and

(2) Each individual not approved for access to select agents and toxins by the HHS Secretary or Administrator before that individual enters areas where select agents or toxins are handled or stored (*e.g.,* laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.). Training for escorted personnel must be based on the risk associated with accessing areas where select agents and toxins are used and/or stored.

(b) Refresher training must be provided annually or at such time as the registered individual or entity significantly amends its security, incident response, or biocontainment plans.

(c) The responsible official must ensure a record of the training provided to each individual with access to select agents and each escorted individual (*e.g.,* laboratory workers, visitors, etc.) is maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training.

12. Section 331.16 is amended as follows:

a. By redesignating footnote 8 as footnote 7.

b. By redesignating paragraphs (e) through (h) as paragraphs (h), (i), (j), and (f) respectively.

c. By adding a new paragraph (e) to read as set forth below.

d. In newly redesignated paragraph (f), by removing the words ''packaging and''.

e. By adding a new paragraph (g) to read as set forth below.

**§ 331.16 Transfers.**

* * * * *

(e) After authorization is provided by APHIS or CDC, the select agent(s) or toxin(s) are packaged for shipment in compliance with all applicable laws concerning packaging by an individual approved by the HHS Secretary or Administrator to have access to select agents and toxins, following a security risk assessment by the Attorney General.

* * * * *

(g) Transportation in commerce starts when the select agent(s) or toxin(s) are packaged for shipment and ready for receipt by a courier transporting select agent(s) or toxin(s) and ends when the package is received by the intended recipient who is an individual approved by the HHS Secretary or Administrator to have access to select agents and toxins, following a security risk assessment by the Attorney General.

* * * * *

13. Section 331.17 is amended as follows:

a. By revising paragraph (a)(1) introductory text to read as set forth below.

b. By redesignating paragraphs (a)(2) through (a)(6) as paragraphs (a)(3) through (a)(7), respectively.

c. By adding a new paragraph (a)(2) to read as set forth below.

**§ 331.17 Records.**

(a) * * *

(1) An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and recombinant and/or synthetic organisms) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials), including:

* * * * *

(2) An accurate, current inventory of any animals or plants intentionally or accidentally exposed to or infected with a select agent (including number and species, location, and appropriate disposition);

* * * * *

**§ 331.19 [Amended]**

14. Section 331.19 is amended as follows:

a. By removing paragraph (b)(1)(iv).

b. By redesignating paragraphs (b)(1)(v) through (b)(1)(viii) as paragraphs (b)(1)(iv) through (b)(1)(vii), respectively.

15. Section 331.20 is revised to read as follows:

**§ 331.20 Administrative review.**

(a) An individual or entity may appeal a denial, revocation, or suspension of registration under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the Administrator within 30 calendar days of the decision.

(b) An individual may appeal a denial, limitation, or revocation of access approval under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the Administrator within 180 calendar days of the decision.

(c) The Administrator's decision constitutes final agency action.

**TITLE 9—[AMENDED]**

**PART 121—POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS**

16. The authority citation for part 121 continues to read as follows:

**Authority:** 7 U.S.C. 8401; 7 CFR 2.22, 2.80, and 371.4.

17. Section 121.1 is amended by adding, in alphabetical order, definitions of *adjudicated as a mental defective, alien, committed to any mental institution, controlled substance, crime punishable by imprisonment for a term exceeding 1 year, indictment, information security, lawfully admitted for permanent residence, mental institution, occupational exposure, recombinant and synthetic nucleic acids, restricted person,* and *unlawful user of any controlled substance* to read as follows:

**§ 121.1 Definitions.**

*Adjudicated as a mental defective.* A determination by a court, board, commission, or other lawful authority that a person, as a result of marked subnormal intelligence, or mental illness, incompetency, condition, or disease is a danger to himself/herself or to others or lacks the mental capacity to contract or manage his/her own affairs. The term includes a finding of insanity by a court in a criminal case and those persons found incompetent to stand trial or found not guilty by reason of lack of mental responsibility pursuant to

articles 50a and 72b of the Uniform Code of Military Justice, 10 U.S.C. 850a, 876b.

* * * * *

*Alien.* Any person not a citizen or national of the United States.

* * * * *

*Committed to any mental institution.* A formal commitment of a person to any mental institution by a court, board, commission, or other lawful authority. The term includes a commitment to a mental institution involuntarily. The term includes commitment for mental defectiveness or mental illness. It also includes commitments for other reasons, such as for drug use. The term does not include a person in a mental institution for observation or a voluntary admission to a mental institution.

*Controlled substance.* A drug or other substance, or immediate precursor, as defined in section 102 of the Controlled Substances Act, 21 U.S.C. 802. The term includes, but is not limited to, marijuana and scheduled depressants, stimulants, and narcotic drugs. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in Subtitle E of the Internal Revenue Code of 1986, as amended.

*Crime punishable by imprisonment for a term exceeding 1 year.* Any Federal, State, or foreign offense for which the maximum penalty, whether or not imposed, is capital punishment or imprisonment in excess of 1 year. What constitutes a conviction of such a crime shall be determined in accordance with the law of the jurisdiction in which the proceedings were held. Any conviction which has been set aside or nullified as a matter of law or for which a person has been pardoned shall not be considered a conviction for the purposes of this part.

* * * * *

*Indictment.* A formal written accusation originating with a prosecutor and issued by a grand jury against a party charged with a crime. For the purpose of these regulations the term indictment includes an ''information,'' which is a formal accusation of a crime, differing only in that it is being presented by a competent public officer on his oath of office, instead of a grand jury.

*Information security.* Protecting information and information systems from unauthorized access, use, disclosure, disruption, modification, or destruction in order to provide:

(1) Integrity, which means guarding against improper information modification or destruction, and includes ensuring information nonrepudiation and authenticity;

(2) Confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and

(3) Availability, which means ensuring timely and reliable access to and use of information.

* * * * *

*Lawfully admitted for permanent residence.* The status of having been lawfully accorded the privilege of residing permanently in the United States as an immigrant in accordance with the immigration laws, such status not having changed.

*Mental institution.* Includes mental health facilities, mental hospitals, sanitariums, psychiatric facilities, and other facilities that provide diagnoses by licensed professionals of mental retardation or mental illness, including a psychiatric ward in a general hospital.

*Occupational exposure.* Any reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials or toxins that may result from the performance of an employee's duties.

* * * * *

*Recombinant and synthetic nucleic acids.* (1) Recombinant nucleic acid molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell;

(2) Synthetic nucleic acid molecules that are chemically, or by other means, synthesized or amplified nucleic acid molecules that may wholly or partially contain functional equivalents of nucleotides; or

(3) Molecules that result from the replication of those described in paragraph (1) or (2) of this definition.

* * * * *

*Restricted person.* An individual who:

(1) Is under indictment for a crime punishable by imprisonment for a term exceeding 1 year;

(2) Has been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year;

(3) Is a fugitive from justice;

(4) Is an unlawful user of any controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

(5) Is an alien illegally or unlawfully in the United States;

(6) Has been adjudicated as a mental defective or has been committed to any mental institution;

(7) Is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country as to which the Secretary of State, pursuant to section 6(j) of the Export Administration Act of 1979 (50 U.S.C. App. 2405(j)), section 620A of chapter 1 of part M of the Foreign Assistance Act of 1961 (22 U.S.C. 2371), or section 40(d) of chapter 3 of the Arms Export Control Act (22 U.S.C. 2780(d)), has made a determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism; or

(8) Has been discharged from the Armed Services of the United States under dishonorable conditions.

* * * * *

*Unlawful user of any controlled substance.* For purposes of this regulation, a person who uses a controlled substance and has lost the power of self-control with reference to the use of that controlled substance; and any person who is a current user of a controlled substance in a manner other than as prescribed by a licensed physician. Such use is not limited to the use of drugs on a particular day, or within a matter of days or weeks before, but rather that the unlawful use has occurred recently enough to indicate that the individual is actively engaged in such conduct. A person may be an unlawful current user of a controlled substance even though the substance is not being used at the precise time the person seeks to have access to a select agent or toxin. An inference of current use may be drawn from evidence of a recent use or possession of a controlled substance or a pattern of use or possession that reasonably covers the present time, *e.g.,* a conviction for use or possession of a controlled substance within the past year; multiple arrests for such offenses within the past 5 years if the most recent arrest occurred within the past year, or persons found through a drug test to use a controlled substance unlawfully, provided that the test was administered within the past year. For a current or former member of the Armed Forces, an inference of current use may be drawn from recent disciplinary or other administrative action based on confirmed drug use, *e.g.,* court-martial conviction, nonjudicial punishment, or an administrative discharge based on drug use or drug rehabilitation failure.

* * * * *

18. Section 121.3 is amended as follows:

a. By adding a new sentence at the end of paragraph (a) to read as set forth below.

b. By revising paragraph (b) to read as set forth below.

c. In paragraph (c) introductory text, by adding the words ''and/or synthetic'' after the word ''recombinant'' each time it appears.

d. In paragraph (c)(2), by adding the words ''and/or synthetic'' after the word ''Recombinant''.

e. By revising paragraph (e) to read as set forth below.

f. In paragraph (f)(3)(i), by removing the words ''Newcastle disease virus (velogenic)'' and adding the words ''virulent Newcastle disease virus'' in their place.

**§ 121.3 VS select agents and toxins.**

(a) * * * The select agents and toxins marked with an asterisk (*) are designated as Tier 1 select agents and toxins and are subject to additional requirements as listed in this part.

(b) VS select agents and toxins:

African horse sickness virus;
African swine fever virus;
Avian influenza virus (highly pathogenic);
Classical swine fever virus;
* Foot-and-mouth disease virus;
Goat pox virus;
Lumpy skin disease virus;
*Mycoplasma capricolum* subspecies *capripneumoniae* (contagious caprine pleuropneumonia);
*Mycoplasma mycoides* subspecies *mycoides* small colony (*Mmm* SC) (contagious bovine pleuropneumonia);
Peste des petits ruminants virus;
* Rinderpest virus;
Sheep pox virus;
Swine vesicular disease virus;
Virulent Newcastle disease virus.[1]

* * * * *

* * * * *

(e) An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of this part based upon a determination by the Administrator that the attenuated strain or inactivated toxin does not pose a severe threat to animal health or to animal products.

(1) To apply for exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification to the applicant. Exclusions will be listed on the National Select Agent Registry Web site at *http://www.selectagents.gov/.*

(2) If an excluded attenuated strain or inactivated toxin is subjected to any manipulation that restores or enhances its virulence or toxic activity, the resulting select agent or toxin will be subject to the requirements of this part.

* * * * *

19. Section 121.4 is amended as follows:

a. By adding a new sentence at the end of paragraph (a) to read as set forth below.

b. By revising paragraph (b) to read as set forth below.

c. In paragraph (c) introductory text, by adding the words ''and/or synthetic'' after the word ''recombinant'' each time it appears.

d. In paragraph (c)(2) introductory text, by adding the phrase ''and/or synthetic'' after the word ''Recombinant''.

e. By revising paragraph (e) to read as set forth below.

f. In paragraph (f)(3)(i), by removing the words ''*Brucella melitensis,* Hendra virus, Nipah virus, Rift Valley fever virus, and Venezuelan equine encephalitis virus'' and adding the words ''*Burkholderia mallei,* and *Burkholderia pseudomallei''* in their place.

**§ 121.4 Overlap select agents and toxins.**

(a) * * * The select agents and toxins marked with an asterisk (*) are designated as Tier 1 select agents and toxins and are subject to additional requirements as listed in this part.

(b) Overlap select agents and toxins:

* *Bacillus anthracis;*
*Brucella abortus;*
*Brucella melitensis;*
*Brucella suis;*
* *Burkholderia mallei;*
**Burkholderia pseudomallei;*
Hendra virus;
Nipah virus;
Rift Valley fever virus;
Venezuelan equine encephalitis virus: Epizootic Subtypes IAB, IC.

* * * * *

(e) An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of this part based upon a determination by the HHS Secretary or Administrator that the attenuated strain or inactivated toxin does not pose a severe threat to public health and safety, to animal health or to animal products.

(1) To apply for exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification to the applicant. Exclusions will be listed on the National Select Agent Registry Web site at *http://www.selectagents.gov/.*

(2) If an excluded attenuated strain or inactivated toxin is subjected to any manipulation that restores or enhances its virulence or toxic activity, the resulting select agent or toxin will be subject to the requirements of this part.

* * * * *

**§ 121.5 [Amended]**

20. In § 121.5, paragraph (a)(3)(i) is amended by removing the words ''bovine spongiform encephalopathy agent,''.

**§ 121.6 [Amended]**

21. In § 121.6, paragraph (a)(3)(i) is amended by removing the words ''Hendra virus, Nipah virus, Rift Valley fever virus, and Venezuelan equine encephalitis virus'' and adding the words ''*Burkholderia mallei,* and *Burkholderia pseudomallei''* in their place.

**§ 121.8 [Amended]**

22. In section 121.8, paragraph (a)(1) is amended by removing the words ''within any of the categories described in 18 U.S.C. 175b'' and adding the words ''a restricted person'' in their place.

23. Section 121.9 is amended as follows:

a. By redesignating paragraphs (a)(3) through (a)(5) as paragraphs (a)(4), (a)(5), and (a)(7) respectively.

b. By adding a new paragraph (a)(3) to read as set forth below.

c. In newly redesignated paragraph (a)(5), by removing the word ''and''.

d. By adding a new paragraph (a)(6) to read as set forth below.

e. By revising the first sentence of paragraph (b) to read as set forth below.

f. By revising the first sentence of paragraph (c)(1) to read as set forth below.

**§ 121.9 Responsible official.**

(a) * * *

(3) Have the appropriate training and expertise to competently implement and manage the requirements of this part;

* * * * *

(6) Have their principal duty station at the physical location of the entity; and

* * * * *

(b) An entity may designate one or more individuals to serve as an alternate responsible official who acts for the responsible official in his/her absence.

* * *

[1] A virulent Newcastle disease virus (avian paramyxovirus serotype 1) has an intracerebral pathogenicity index in day-old chicks (*Gallus gallus*) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.

(c) * * *

(1) The identification of any of the following select agents or toxins must be immediately reported by telephone, facsimile, or e-mail: African horse sickness virus, African swine fever virus, avian influenza virus (highly pathogenic), *Bacillus anthracis, Brucella melitensis, Burkholderia mallei, Burkholderia pseudomallei,* classical swine fever virus, foot-and-mouth disease virus, virulent Newcastle disease virus, rinderpest virus, and swine vesicular disease virus. * * *

* * * * *

24. Section 121.10 is amended as follows:

a. By redesignating paragraphs (e) through (j) as paragraphs (f) through (k), respectively.

b. By adding a new paragraph (e) to read as set forth below.

c. In newly redesignated paragraph (g)(1), by removing the words ''within any of the categories described in 18 U.S.C. 175b'' and adding the words ''a restricted person'' in their place.

d. In newly redesignated paragraph (j), by removing the number ''5'' and adding the number ''3'' in its place.

**§ 121.10 Restricting access to select agents and toxins; security risk assessments.**

* * * * *

(e) A person who has a valid approval from the HHS Secretary or Administrator for access to a select agent or toxin may request the HHS Secretary or Administrator to provide the person's approval status to another registered individual or entity for a specified period of time.

* * * * *

25. Section 121.11 is amended as follows:

a. By revising paragraph (b) to read as set forth below.

b. By revising paragraph (c)(2) to read as set forth below.

c. In paragraph (c)(6), by removing the word ''and''.

d. By adding new paragraphs (c)(8), (c)(9), and (c)(10) to read as set forth below.

e. By redesignating paragraphs (e) and (f) as paragraphs (f) and (g), respectively.

f. By adding a new paragraph (e) to read as set forth below.

g. By revising newly redesignated paragraph (f) to read as set forth below.

**§ 121.11 Security.**

* * * * *

(b) The security plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use. A current security plan must be submitted for initial registration, renewal of registration, or when requested.

(c) * * *

(2) Contain provisions for the control of access to select agents and toxins, including the safeguarding of animals or plants intentionally or accidentally exposed to or infected with a select agent, against unauthorized access, theft, loss or release.

* * * * *

(8) Describe procedures for how the responsible official will be informed of suspicious activity that may be criminal in nature and related to the entity, its personnel, or its select agents or toxins; and how the responsible official will notify the Federal Bureau of Investigation (FBI) of such activity;

(9) Contain provisions for information security that:

(i) Ensure that all external connections to systems which control security of the facility are isolated or have controls that permit and monitor for only authorized and authenticated user access;

(ii) Ensure that authorized and authenticated users are only granted access to select agent and toxin related information, files, equipment (*e.g.,* servers or mass storage devices) and applications as necessary to fulfill their roles and responsibilities, and that access is modified when the user's roles and responsibilities change or when their access to select agent and toxin is suspended or revoked;

(iii) Ensure that controls are in place that are designed to prevent malicious code (such as, but not limited to, computer viruses, worms, and spyware) from compromising the confidentiality, integrity, or availability of critical information systems;

(iv) Establish a robust configuration management practice for information systems to include regular patching and updates made to operating systems and individual applications; and

(v) Establish procedures that provide backup security measures in the event that access control systems and/or surveillance devices are rendered inoperable.

(10) Contain provisions and policies for shipping, receiving, and storage of select agents and toxins, including documented procedures for receiving, monitoring, and shipping of all select agents and toxins. These provisions must provide that an entity will properly secure containers on site and have a written contingency plan for unexpected shipments.

* * * * *

(e) In addition to the requirements contained in paragraphs (c) and (d) of this section, the security plan for an individual or entity possessing a Tier 1 select agent or toxin must also:

(1) Describe procedures for conducting a pre-access suitability assessment of persons who will have access to a Tier 1 select agent or toxin;

(2) Describe procedures for how an entity's responsible official will coordinate their efforts with the entity's safety and security professionals to ensure security of Tier 1 select agents and toxins and share, as appropriate, relevant information; and

(3) Describe procedures for the ongoing assessment of the suitability of personnel with access to a Tier 1 select agent or toxin. The procedures must include:

(i) Self- and peer-reporting of incidents or conditions that could affect an individual's ability to safely have access to or work with select agents and toxins, or to safeguard select agents and toxins from theft, loss, or release;

(ii) The training of all entity employees on entity policies and procedures for reporting, evaluation, and corrective actions concerning the assessment of personnel suitability to access Tier 1 agents and toxins; and

(iii) The ongoing suitability monitoring of individuals with access to Tier 1 select agents and toxins.

(4) Entities with Tier 1 select agents and toxins must prescribe and/or implement the following security enhancements:

(i) Procedures that limit access to registered space only to those approved by the HHS Secretary or the Administrator and meet the criteria of the entity's program that will ensure individuals with access approval to select agents and toxins are trustworthy and behaving in a manner that upholds public health and safety, the protection of animal or plant health and animal or plant products, security, and the integrity of the scientific enterprise. In developing these procedures, an individual or entity may consider the guidance documents available on the Internet at *http://www.selectagents.gov/.;*

(ii) Procedures that limit access to laboratory and storage facilities outside of normal business hours to only those specifically approved by the responsible official or designee;

(iii) Procedures for allowing visitors, their property, and vehicles at the entry and exit points to the registered space, or at other designated points of entry to the building, facility, or compound

based on the entity's site-specific risk assessment;

(iv) A minimum of three barriers where each subsequent barrier is different and adds to the delay in reaching secured areas where select agents and toxins are used or stored. Barriers must be monitored in such a way as to detect and assess intentional and unintentional circumventing of established access control measures under all conditions (day/night, severe weather, etc.);

(v) All registered space or areas that reasonably afford access to the registered space must be protected by an intrusion detection system (IDS) unless physically occupied;

(vi) Personnel monitoring the IDS must be capable of evaluating and interpreting the alarm and alerting the designated security response force or law enforcement;

(vii) Provide backup power and energy sources to power information security networks and integrated access controls and related systems during emergencies;

(viii) Response time for security forces or local police must not exceed 15 minutes from the time of an intrusion alarm or report of a security incident;

(ix) Entities must conduct complete inventory audits of all Tier 1 select agents and toxins in long-term storage when any of the following occur:

(A) Upon the physical relocation of a collection or inventory of select agents or toxins for those Tier 1 select agents or toxins in the collection or inventory;

(B) Upon the departure or arrival of a principal investigator for those Tier 1 select agents or toxins under the control of that principal investigator; or

(C) In the event of a theft or loss of a Tier 1 select agent or toxin.

(5) Entities that possess foot-and-mouth disease virus and rinderpest virus must have the following additional security requirements:

(i) A minimum of four barriers, one of which must be a perimeter security fence or equivalent which is monitored 24 hours a day, 7 days a week (24/7) to detect the presence of unauthorized persons, vehicles, materials, or unauthorized activities;

(ii) Onsite 24/7 armed security response force with roving patrol. Response time must not exceed 5 minutes from the time of an intrusion alarm or report of a security incident;

(iii) CCTV surveillance with 24/7 monitoring and recording; and

(iv) Transport vehicle with GPS tracking designed to serve as a containment vehicle.

(f) In developing a security plan, an individual or entity should consider the documents entitled ''Select Agents and Toxins Security Information Document'' and ''Select Agents and Toxins Security Plan Template.'' These documents are available on the Internet at *http://www.selectagents.gov/.*

* * * * *

26. Section 121.12 is amended as follows:

a. By revising paragraph (a) to read as set forth below.

b. By revising paragraph (c)(1) to read as set forth below.

c. In paragraph (c)(3), by removing the address ''*http://www.aphis.usda.gov./programs/ag_selectagent/index.html*'' and replacing it with the address ''*http://www.selectagents.gov/*''.

d. By redesignating paragraph (d) as paragraph (e).

e. By adding a new paragraph (d) to read as set forth below.

**§ 121.12 Biosafety.**

(a) An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use.[9] The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals or plants intentionally or accidentally exposed to or infected with a select agent.

* * * * *

(c) * * *

(1) The CDC/NIH publication, ''Biosafety in Microbiological and Biomedical Laboratories.'' This document is available on the Internet at *http://www.selectagents.gov/.*

* * * * *

(d) The biosafety plan must include an occupational health program for individuals with access to Tier 1 select agents and toxins, and those individuals must be enrolled in the occupational health program. The occupational health program may also be made available to individuals without access to Tier 1 select agents and toxins.

* * * * *

**§ 121.13 [Amended]**

27. Section 121.13 is amended as follows:

a. In the section heading, by removing footnote 10.

b. In paragraph (a), by adding the words '', or possess products (*i.e.,* select agents that are not known to acquire the resistance naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture, or recombinant and or synthetic DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight) resulting from,'' after the word ''conduct'' both times it appears.

c. In paragraph (b)(1), by removing the words ''Experiments utilizing recombinant DNA that involve the deliberate transfer of'' and adding the words ''Experiments that involve the deliberate transfer of, or selection for,'' in their place.

d. In paragraph (b)(2), by adding the words ''synthetic or'' before the word ''recombinant''.

28. Section 121.14 is amended as follows:

a. In the section heading, by redesignating footnote 11 as footnote 10.

b. In paragraph (a), by redesignating footnote 12 as footnote 11 and revising the first sentence to read as set forth below.

c. By revising paragraph (b) to read as set forth below.

d. By redesignating paragraphs (c) and (d) as paragraphs (d) and (f), respectively.

e. By adding a new paragraph (c) to read as set forth below.

f. By adding a new paragraph (e) to read as set forth below.

**§ 121.14 Incident response.[10]**

(a) An individual or entity required to register under this part must develop and implement a written incident response plan [11] based upon a site specific risk assessment. * * *

(b) The incident response plan must fully describe the entity's response procedures for the theft, loss, or release of a select agent or toxin; inventory discrepancies; security breaches (including information systems); severe weather and other natural disasters; workplace violence; bomb threats and suspicious packages; and emergencies such as fire, gas leak, explosion, power outage, etc.

(c) The response procedures must account for hazards associated with the select agent or toxin and appropriate actions to contain such select agent or toxin, including any animals or plants intentionally or accidentally exposed to or infected with a select agent.

* * * * *

(e) Entities with Tier 1 select agents and toxins must have the following

[9] Technical assistance and guidance may be obtained by contacting APHIS.

[10] Nothing in this section is meant to supersede or preempt incident response requirements imposed by other statutes or regulations.

[11] Technical assistance and guidance may be obtained by contacting APHIS.

additional incident response policies or procedures:

(1) The incident response plan must fully describe the entity's response procedures for failure of intrusion detection or alarm system; and

(2) The incident response plan must describe notification procedures for the FBI in the event of a theft or suspicious activity that may be criminal in nature involving a Tier 1 select agent or toxin.

* * * * *

29. Section 121.15 is revised to read as follows:

**§ 121.15 Training.**

(a) An individual or entity required to register under this part must provide information and training on biosafety, security (including security awareness), and incident response to:

(1) Each individual with access approval from the HHS Secretary or Administrator before that individual has such access to select agents and toxins. The training must address the particular needs of the individuals, the work they will do, and the risks posed by the select agents or toxins; and

(2) Each individual not approved for access to select agents and toxins by the HHS Secretary or Administrator before that individual works in or otherwise enters areas where select agents or toxins are handled or stored (*e.g.,* laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.). Training for escorted personnel must be based on the risk associated with accessing areas where select agents and toxins are used and/or stored.

(b) Entities with Tier 1 select agents and toxins must conduct annual insider threat awareness briefings on how to identify and report suspicious behaviors.

(c) Refresher training must be provided annually or at such time as the registered individual or entity significantly amends its security, incident response, or biosafety plans.

(d) The responsible official must ensure a record of the training provided to each individual with access to select agents and each escorted individual (*e.g.,* laboratory workers, visitors, etc.) is maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training.

30. Section 121.16 is amended as follows:

a. By redesignating footnote 14 as footnote 12.

b. By redesignating paragraphs (f) through (i) as paragraphs (i), (k), and (g), respectively.

c. By adding a new paragraph (f) to read as set forth below.

d. In newly redesignated paragraph (g), by removing the words ''packaging and''.

e. By adding a new paragraph (h) to read as set forth below.

**§ 121.16 Transfers.**

* * * * *

(f) After authorization is provided by APHIS or CDC, the select agent(s) and toxin(s) are packaged for shipment in compliance with all applicable laws concerning packaging by an individual approved by the HHS Secretary or Administrator to have access to select agents and toxins, following a security risk assessment by the Attorney General.

* * * * *

(h) Transportation in commerce starts when the select agent(s) or toxin(s) are packaged for shipment and ready for receipt by a courier transporting select agent(s) or toxin(s) and ends when the package is received by the intended recipient who is an individual approved by the HHS Secretary or Administrator to have access to select agents and toxins, following a security risk assessment by the Attorney General.

* * * * *

31. Section 121.17 is amended as follows:

a. By revising paragraph (a)(1) introductory text to read as set forth below.

b. By redesignating paragraphs (a)(2) through (a)(6) as paragraphs (a)(3) through (a)(7), respectively.

c. By adding a new paragraph (a)(2) to read as set forth below.

**§ 121.17 Records.**

(a) * * *

(1) An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and recombinant and/or synthetic organisms) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials), including:

* * * * *

(2) An accurate, current inventory of any animals or plants intentionally or accidentally exposed to or infected with a select agent (including number and species, location, and appropriate disposition);

* * * * *

32. Section 121.20 is revised to read as follows:

**§ 121.20 Administrative review.**

(a) An individual or entity may appeal a denial, revocation, or suspension of registration under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the Administrator within 30 calendar days of the decision.

(b) An individual may appeal a denial, limitation, or revocation of access approval under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the Administrator within 180 calendar days of the decision.

(c) The Administrator's decision constitutes final agency action.

Done in Washington, DC, this 29th day of September 2011.

**Gregory L. Parham,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 2011–25520 Filed 9–30–11; 8:45 am]

**BILLING CODE 3410–34–P**

# FEDERAL REGISTER

Vol. 76 Monday,
No. 191 October 3, 2011

Part VI

## The President

Memorandum of September 28, 2011—Provision of Aviation Insurance Coverage for Commercial Air Carrier Service in Domestic and International Operations

Federal Register
Vol. 76, No. 191
Monday, October 3, 2011

# Presidential Documents

**Title 3—**

## The President

**Memorandum of September 28, 2011**

## Provision of Aviation Insurance Coverage for Commercial Air Carrier Service in Domestic and International Operations

**Memorandum for the Secretary of Transportation**

By the authority vested in me as President by the Constitution and the laws of the United States, including 49 U.S.C. 44301–44310, I hereby:

1. Determine that the continuation of U.S. commercial air transportation is necessary in the interest of air commerce, national security, and the foreign policy of the United States.

2. Approve the provision by the Secretary of Transportation of insurance or reinsurance to U.S. air carriers against loss or damage arising out of any risk from the operation of an aircraft in the manner and to the extent provided in chapter 443 of title 49 of the U.S. Code until September 30, 2012, when he determines such insurance or reinsurance cannot be obtained on reasonable terms and conditions from any company authorized to conduct an insurance business in a State of the United States.

You are directed to bring this determination immediately to the attention of all air carriers, as defined in 49 U.S.C. 40102(a)(2), and to arrange for its publication in the *Federal Register.*

THE WHITE HOUSE,
*Washington, September 28, 2011*

[FR Doc. 2011–25649
Filed 9–30–11; 11:15 am]
Billing code 4910–9–P

# Reader Aids

**Federal Register**

Vol. 76, No. 191

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## CFR PARTS AFFECTED DURING OCTOBER

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

## LIST OF PUBLIC LAWS

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**S. 846/P.L. 112–31**
To designate the United States courthouse located at 80 Lafayette Street in Jefferson City, Missouri, as the Christopher S. Bond United States Courthouse. (Sept. 23, 2011; 125 Stat. 360)
**Last List September 20, 2011**

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